DOI: 10.1111/dme.13930

Research: Educational and Psychological Aspects

Assessing patient-reported outcomes for automated insulin delivery systems: the psychometric properties of the INSPIRE measures

J. Weissberg-Benchell[1], J. B. Shapiro[2], K. Hood[3], L. M. Laffel[4], D. Naranjo[3], K. Miller[5] and K. Barnard[6]

[1]Department of Psychiatry and Behavioral Sciences, Ann and Robert H., Lurie Children's Hospital of Chicago, Northwestern University, Feinberg School of Medicine, [2]Department of Psychology, Loyola University, Chicago, IL, [3]Departments of Pediatrics, Psychiatry& Behavioral Sciences, Stanford University School of Medicine, Stanford, CA, [4]Joslin Diabetes Center, Harvard Medical School, Boston, MA, [5]Jaeb Center for Health Research, Tampa, Florida, USA and [6]Bournemouth University, Bournemouth, UK

Accepted 12 February 2019

Abstract

Aim Participants in clinical trials assessing automated insulin delivery systems report perceived benefits and burdens that reflect their experiences and may predict their likelihood of uptake and continued use of this novel technology. Despite the importance of understanding their perspectives, there are no available validated and reliable measures assessing the psychosocial aspects of automated insulin delivery systems. The present study assesses the initial psychometric properties of the INSPIRE measures, which were developed for youth and adults with Type 1 diabetes, as well as parents and partners.

Methods Data from 292 youth, 159 adults, 150 parents of youth and 149 partners of individuals recruited from the Type 1 Diabetes Exchange Registry were analysed. Participants completed INSPIRE questionnaires and measures of quality of life, fear of hypoglycaemia, diabetes distress, glucose monitoring satisfaction. Exploratory factor analysis assessed factor structures. Associations between INSPIRE scores and other measures, HbA_{1c}, and technology use assessed concurrent and discriminant validity.

Results Youth, adult, parent and partner measures assess positive expectancies of automated insulin delivery systems. Measures range from 17 to 22 items and are reliable (α = 0.95–0.97). Youth, adult and parent measures are unidimensional; the partner measure has a two-factor structure (perceptions of impact on partners versus the person with diabetes). Measures showed concurrent and discriminant validity.

Conclusions INSPIRE measures assessing the positive expectancies of automated insulin delivery systems for youth, adults, parents and partners have meaningful factor structures and are internally consistent. The developmentally sensitive INSPIRE measures offer added value as clinical trials test newer systems, systems become commercially available and clinicians initiate using these systems.

Diabet. Med. 36: 644–652 (2019)

Introduction

Automated insulin delivery systems are associated with improved glycaemic outcomes, including reduced HbA_{1c}, increased time spent within glucose targets and reduced hypoglycaemia [1,2]. Multiple clinical trials assessing the feasibility and safety of different systems are underway, and the duration of the studies has increased [3,4], with some following participant outcomes for as long as 6 months in free-living, home settings [5]. These systems differ from other diabetes technologies in that they are programmed to respond to glucose values and to deliver insulin according to the individual needs of the user. People with diabetes and their loved ones must trust in the accuracy and safety of this technology as they give over greater control to an automated system although the user must continue engaging in many

Correspondence to: Jill Weissberg-Benchell.
E-mail: jwbenchell@luriechildrens.org

What's new?

- Participants in clinical trials of automated insulin delivery systems report perceived benefits and burdens of these systems. It is not yet known if these perceptions predict their likelihood of uptake and continued use.
- Currently, there are no available validated and reliable measures assessing the psychosocial aspects of automated insulin delivery systems.
- This study adds to the current science by providing an essential ingredient in the ongoing assessment of automated insulin delivery systems. Specifically, it offers information regarding the initial psychometric properties of the INSPIRE measures, a developmentally sensitive suite of measures for youth, adults, parents and partners.
- The measures assess the positive expectancies of users. The measures can support clinical practice by providing important insights into the onboarding and support needs of persons transitioning to these novel systems.

self-care tasks, such as maintaining the insulin pump, infusion sites and continuous glucose monitoring (CGM).

In clinical trials assessing users' perspectives, participants report mixed views. Benefits include improved daytime [6] and night-time [6,7] glycaemic control, and psychosocial benefits of reduced worry [6] and burden [8,9], decreased fear of hypoglycaemia [9], decreased diabetes distress [8], improved sleep [6], increased treatment satisfaction [8], improved well-being [7], and trust in the system [5,8]. Concerns such as delays in responding to out of range numbers [8,9], algorithms that were too conservative [5], challenges around exercise [5–8,10], technical difficulties [6,8,10] such as inaccurate sensors or connectivity challenges [10], intrusive alarms [5,6,10] and concerns regarding the size of the devices [6–8], and the need to carry multiple devices [5,9] were all raised.

Although these findings inform future research and clinical decision-making, validated and reliable measures specifically assessing the psychosocial aspects of this novel technology are required. These systems are fundamentally different from any other diabetes technology in that they effectively take on substantial aspects of glycaemic management rather than only supporting individuals in their self-management. Thus, assessing perceptions regarding system safety, efficacy, reliability and adaptability to real-life demands (e.g. eating schedules, exercise, illness, work stresses) without increasing the burden of diabetes self-management is vital, as more devices are moving toward commercialization. Therefore, it is important to gain a greater understanding of the potential benefits and burdens of automated insulin delivery systems on users and the trade-offs that people are willing to make to realize the full potential of the systems in their everyday lives [11].

Reliable and valid measures are crucial to assess the psychosocial aspects of these systems. Russell and Beck [12] have recommended that efficacy, safety and psychosocial well-being are all key outcomes of any trial of automated insulin delivery systems, highlighting the fact that the degree to which individuals use the systems depends on their perceptions of benefits, both medical and psychosocial. To meet this need, we conducted a review of the literature, focus groups, individual interviews and cognitive debriefing in developing the INSPIRE measures (Insulin delivery Systems: Perceptions, Ideas, Reflections and Expectations) with children/youth and adults with Type 1 diabetes, parents of young persons with Type 1 diabetes and partners of adults with Type 1 diabetes. We previously reported qualitative findings from the focus groups and interviews [13]. Here, we report the initial psychometric properties of these measures, highlighting their reliability and validity, and offering a glimpse of the expectations and hopes for using automated insulin delivery systems as perceived by many stakeholders. Psychometrically sound measures can support clinical practice, helping clinicians understand the facilitators and barriers to uptake and continued use.

Research design and methods

Participants

In total, 750 participants, recruited from the Type 1 Diabetes Exchange Registry, were included in the psychometric study to validate the INSPIRE questionnaires. The sample included 292 youth with Type 1 diabetes aged 8–17 years, 159 adults with Type 1 diabetes aged 18–86 years, 150 parents of youth aged 3–17 years, and 149 partners of adults with Type 1 diabetes (adults with Type 1 diabetes aged 18–86 years). Recruitment strategies included e-mail fielding of the surveys up to three times to each eligible participant. The Institutional Review Board at the Jaeb Center for Health Research approved the study protocol before any survey fielding and electronic informed consent/assent was obtained. Inclusion criteria for the study included the following: (i) child with Type 1 diabetes aged 8–17 years, adult with Type 1 diabetes aged $\geq$ 18 years, parent of child with Type 1 diabetes age $<$ 18 years, partner of adult with Type 1 diabetes age $\geq$ 18 years; (ii) Type 1 diabetes duration $\geq$ 6 months for the child or adult with Type 1 diabetes; and (iii) a HbA_{1c} value collected through the Type 1 Diabetes Exchange Clinic Registry within the previous 6 months for the child or adult with Type 1 diabetes. Adults with Type 1 diabetes were asked to forward the e-mail to their significant others if they were willing, which included a separate link to the partner survey. Parents of children with Type 1 diabetes were sent an e-mail that included links to both the parent and child/

Table 1 Demographic characteristics of each participant group (N = 750)

	Youth (n = 292)	Parents (n = 150)	Adults (n = 159)	Partners (n = 149)
Age*	12.49 (2.76)	11.68 (2.87)	39.26 (16.91)	35.71 (14.66)
Duration of diabetes*	6.97 (3.21)	6.81 (3.42)	23.34 (14.05)	20.66 (11.81)
HbA_{1c}*	8.53 (1.54)	8.39 (1.33)	7.72 (1.35)	7.64 (1.47)
Sex				
Female	127 (43.5)	68 (45.3)	102 (64.2)	94 (63.1)
Male	165 (56.6)	82 (54.7)	57 (35.8)	55 (36.9)
Race/ethnicity				
White/Non-Hispanic	224 (76.7)	115 (76.7)	145 (91.2)	132 (88.6)
Black/Non-Hispanic	14 (4.8)	6 (4.0)	2 (1.3)	1 (0.7)
Hispanic/Latino	30 (10.3)	16 (10.7)	5 (3.1)	7 (4.7)
Other	24 (8.2)	13 (8.7)	7 (4.4)	9 (6.0)
Use insulin pump	205 (70.2)	109 (73.2)	112 (70.4)	107 (72.3)
Use CGM	93 (31.8)	50 (35.2)	63 (40.6)	54 (37.5)
Health insurance				
Private	190 (65.1)	101 (72.1)	128 (81.0)	123 (83.1)
Public aid	84 (28.8)	36 (25.7)	30 (19.0)	25 (16.9)
None	3 (1.0)	3 (2.1)	0 (0.0)	0 (0.0)
Annual income ($)				
< 50 000	80 (27.4)	41 (31.8)	39 (32.5)	35 (31.3)
50 000–75 000	42 (14.4)	23 (17.8)	20 (16.7)	22 (19.6)
75 000	114 (39.0)	65 (50.4)	61 (50.8)	55 (49.1)

Values are given as n (%) except *mean (SD).
Age, gender, racial identity, health insurance coverage and annual income refer to the person with diabetes and not necessarily to the respondent.
CGM, continuous glucose monitoring.

adolescent surveys. Surveys were e-mailed to 1949 adults and their partners, and to 4866 parents and their children. Once each group reached 150 respondents, enrolment was closed. For each questionnaire, respondents could not skip answers, as they needed to respond to each question before going on the next question.

Demographic data are presented in Table 1. Samples were fairly split between male and female respondents, and the majority of respondents were white, non-Hispanic. There was a significant difference in HbA_{1c} values between adults with Type 1 diabetes (M = 61 mmol/mol; 7.72% ± 1.35%), children aged 8–12 years with Type 1 diabetes (M = 69 mmol/mol; 8.45% ± 1.35%), and teenagers aged 13–18 years with Type 1 diabetes (M = 71 mmol/mol; 8.64% ± 1.74%), $F(3,437) = 15.82$, $P < 0.001$, such that adults had significantly lower HbA_{1c} values than children ($P < 0.001$) and adolescents ($P < 0.001$), but child and adolescent HbA_{1c} values did not significantly differ from each other (P = 0.835).

Study procedures

The INSPIRE questionnaires were developed by an initial review of the literature for relevant patient-reported perceptions from clinical trials that then informed the semi-structured questions used in the focus groups and individual interviews with 284 participants [13]. Participants were children, teens and adults with Type 1 diabetes, parents of youth and partners of adults. These data informed the initial development of respondent-specific measures (youth with Type 1 diabetes, adults with Type 1 diabetes, parents and partners). Items for these measures were then refined via a process of cognitive debriefing interviews with each group of stakeholders [14,15] with questions on item content, format and understandability [16,17]. After each participant independently completed the questionnaire, an interviewer probed for specific information on any difficulties respondents experienced, and their basis for their response for each item. Such probes elicited information regarding the clarity and rationale of the instructions, the meaning of the individual items, topics that were missing, the appropriateness of the response choices, and any overall comments on the relevance and complexity of the questionnaire [18].

Cognitive interviews were conducted by the research teams at three research sites: Ann & Robert H. Lurie Children's Hospital of Chicago, Stanford University, and Joslin Diabetes Center. Interviews were completed either in-person at the clinical site or via Health Insurance Portability and Accountability Act (HIPAA)-compliant video conferencing. Both methods were kept as similar as possible. Each site completed interviews of 5–10 individuals in each participant group. A senior researcher listened to all audio-recorded interviews and summarized feedback into key themes: items that were hard to understand, items that were irrelevant, items that were redundant, items that were confusing as to meaning, and items that should have been included but were missing.

A summary of the feedback for each participant group was created and discussed among senior researchers until consensus was reached on questionnaire revisions. Following cognitive interviewing, and prior to fielding of the questionnaires to assess the psychometric properties, the youth measure was reduced to 27 items, the adult measure was 31 items, the parent measure was 30 items and the partner measure was 31 items. Response options included a scale of 0 (Strongly disagree) to 4 (Strongly agree). Participants also completed measures of health- and diabetes-specific psychosocial constructs to assess concurrent and discriminant validity.

Measures to determine psychometric properties

Quality of life

Youth completed the 23-item Pediatric Quality of Life Inventory Version 4.0 Generic Core Module (PedsQL) [19] to assess health-related quality of life over the past month. There were different versions for children aged 8–12 years and adolescents aged 13–18 years. Items are rated on a five-point scale with item ratings of 0 = Never, 25 = Almost never, 50 = Sometimes, 75 = Often and 100 = Almost always. Internal consistency was strong (child version, Cronbach's α = 0.94; adolescent version, α = 0.92).

Adults, parents and partners completed the five-item WHO-5 Well-Being Questionnaire [20] to assess quality of life over the past two weeks. Each item is rated on a scale of 0 (At no time) to 5 (All of the time) and a percentage score is calculated by multiplying the raw summed score by 4 for a total score ranging from 0 to 100, with higher scores indicating better quality of life. Internal consistency was high for adults with diabetes, parents of youth, and partners (α = 0.90).

Glucose monitoring satisfaction

Adolescents aged 13–18 years, adults, parents and partners completed the 15-item Glucose Monitoring System Satisfaction Survey (GMSS) [21] to assess satisfaction with their current glucose monitoring device. GMSS is rated on a five-point scale from 1 (Strongly disagree) to 5 (Strongly agree). Eleven of the items are reverse-scored and a mean score was calculated with higher scores indicating greater glucose monitoring device satisfaction. Internal consistency was good for adolescent, adult, parent and partner samples (α = 0.88–0.90).

Fear of hypoglycaemia

The Hypoglycemia Fear Survey [22,23] assesses fear of hypoglycaemia with versions for youth, parents and adults. Youth and parents completed the 15-item worry subscale, whereas adults completed the 18-item worry subscale. Items were rated from 1 (Never) to 5 (Almost always) with higher summed total scores indicating greater worries about hypoglycaemia. Internal consistency was strong for youth, parents and adults (α = 0.92–0.94).

Affect specific to blood glucose monitoring

Participants completed the eight-item Blood Glucose Monitoring Communication (BGMC) questionnaire [24] which measures negative affect related to blood glucose monitoring over the past week. Items are rated from 1 (Almost never) to 3 (Almost always) with higher scores indicating greater negative affect specific to blood glucose monitoring. Internal consistency was good for youth, adults, parents and partners (α = 0.80–0.86).

Diabetes distress

The Problem Areas in Diabetes (PAID) assesses diabetes-specific emotional distress in children, teenagers and parents of youth with Type 1 diabetes. There are different versions for each group. Children aged 8–12 years completed the 17-item child version (PAID-C) [25], adolescents aged 13–17 completed a 20-item teen version (PAID-T) [26], and parents completed the 18-item parent revised version (PAID-PR) [27]. For youth questionnaires, items were rated from 1 (Not a problem) to 6 (Big problem), with higher scores indicating greater diabetes distress over the past month. For parents, items were rated from 0 (Disagree) to 4 (Agree). Internal consistency was strong for children, adolescents and parents (α = 0.92–0.96).

The Diabetes Distress Scale (DDS) assesses diabetes-specific emotional distress over the past month for adults and partners. Adults completed the 28-item DDS for Adults with Type 1 Diabetes (T1-DDS) [28]. Items were rated from 1 (Not a problem) to 6 (A very serious problem). Partners completed the 21-item DDS for Partners of Adults with Type 1 Diabetes (Partner-DDS) [29]. Items were rated from 0 (Not at all) to 4 (A great deal). Mean scores were calculated for both measures with higher scores indicating greater diabetes distress. Internal consistency was strong for adults and partners (α = 0.94).

Demographic and biomedical data HbA_{1c}

HbA_{1c} and demographic and clinical characteristics were extracted from the most recent data update in the Type 1 Diabetes Exchange Registry database. The HbA_{1c} with the date closest to the date of survey completion was reported.

Data analytic plan

Total scores on the INSPIRE questionnaires were calculated by obtaining a mean score across items, then multiplying the mean score by 25 to scale total INSPIRE measure scores from 0 to 100, with higher scores indicating greater positive expectations for automated insulin delivery systems. Reliability was assessed using Cronbach's α. Construct validity was assessed via exploratory factor analysis (EFA) to determine if there were meaningful factor structures. Moreover, concurrent and discriminant validity was assessed by examining associations between the INSPIRE measures and

key psychosocial constructs associated with the continued use of insulin pump and continuous glucose monitoring technologies [18,30–32].

EFA with maximum likelihood extraction, direct oblimin rotation, and pairwise case exclusion in SPSS version 23 identified the factor structure of each INSPIRE measure. Oblique rotation was used to allow for correlation between factors. Items were removed if they had extreme skewness or kurtosis, if 50% or more participants responded 'Not applicable', 'Strongly agree' or 'Strongly disagree', or if item-to-total correlations were < 0.3. The number of factors was identified using parallel analysis [31]. Additional items were removed one at a time if communalities were < 0.3.

Correlations between each INSPIRE measure total score and other measures were examined to investigate concurrent and discriminant validity, including measures of quality of life, glucose monitoring satisfaction, fear of hypoglycaemia worry subscale, negative affect related to blood glucose monitoring, diabetes-specific distress and HbA_{1c}. Concurrent validity was determined by assessing relations between current technology use and positive expectancies of automated insulin delivery systems. Discriminant validity was determined by assessing relations between INSPIRE measures and other measures designed to assess different psychosocial constructs that we would expect to have no or small associations with INSPIRE questionnaires. Associations between demographic variables including age, sex, self-reported race/ethnicity, type of insurance coverage of the person with diabetes, duration of diabetes, HbA_{1c}, insulin pump use, CGM use, education level (parent education level used for youth surveys), family annual income, and each INSPIRE scale were also examined, using correlations, one-way analysis of variance (ANOVA), and independent sample *t*-tests as appropriate.

Results

INSPIRE: youth

EFA was used to analyse the factor structure of the 27-item youth INSPIRE measure. Two items were removed because more than 50% of participants answered 'Strongly agree' (It is important to me that the automated insulin delivery system is waterproof; It is important to me that the automated insulin delivery system fits comfortably in the clothes I wear). No items were extremely skewed or kurtotic. Six additional items were removed due to item to total correlations < 0.3. Kaiser–Meyer–Olkin (KMO) = 0.94 and Bartlett's test of sphericity, χ^2 (171) = 3763.94, $P < 0.001$, indicated an analysable correlation matrix. Parallel analysis suggested one factor. Two more items were removed due to communalities < 0.3. See Table 2 for all deleted items. One factor explained 56.46% of the variance and factor loadings ranged from 0.61 to 0.83 (see Table 3). The final 17-item measure showed high internal consistency ($\alpha = 0.95$; $M = 77.70 \pm 16.44$; 25th percentile, $M = 68.01$; 75th percentile, $M = 92.28$).

As shown in Table 4, the youth measure was correlated significantly with HbA_{1c} and negative affect related to blood glucose monitoring, such that greater positive expectancies towards automated insulin delivery systems were associated with higher HbA_{1c} and greater negative affect. The youth measure was not correlated significantly with other psychosocial measures. The only significant demographic associations were pump use, $t(281) = -3.48$, $P = 0.001$, and CGM use, $t(278) = -2.66$, $P = 0.008$; with use of technology being associated with higher INSPIRE scores (pump use, Cohen's $d = 0.44$; CGM use, $d = 0.30$). There were no differences based on sex, $t(286) = 1.11$, $P = 0.269$, race/ethnicity, $F(3,284) = 0.61$, $P = 0.606$, parent education, $F(3,274) = 0.70$, $P = 0.552$, family income, $F(2,231) = 0.17$, $P = 0.841$, or type of insurance coverage, $F(2,270) = 0.09$, $P = 0.913$.

INSPIRE: parents

Similarly, EFA was used on the 30-item parent version. No items were removed due to ceiling or floor effects, or extreme skewness or kurtosis. Eight items were removed due to item to total correlations < 0.3. KMO = 0.92 and Bartlett's test, $\chi^2(231) = 1686.62$, $P < 0.001$, indicated an analysable correlation matrix. Parallel analysis suggested one factor. One more item was removed due to communalities < 0.3. See Table 2 for all deleted items. One factor explained 56.06% of the variance and factor loadings ranged from 0.58 to 0.87 (see Table 3). The final 21-item measure showed high internal consistency ($\alpha = 0.97$; $M = 76.13 \pm 15.05$; 25th percentile, $M = 67.50$; 75th percentile, $M = 85.71$).

The parent measure was not associated significantly with any of the psychosocial measures (see Table 4). There were no significant differences based on youth pump use, $t(144) = -1.24$, $P = 0.217$, youth CGM use, $t(137) = -1.70$, $P = 0.091$, youth sex, $t(145) = -0.48$, $P = 0.634$, youth racial identity, $F(3,143) = 2.13$, $P = 0.099$, parent education, $F(3,141) = 0.97$, $P = 0.408$, family income, $F(2,123) = 1.52$, $P = 0.222$, or youth insurance coverage, $F(2,135) = 1.56$, $P = 0.213$.

INSPIRE: adults

EFA was used to analyse the factor structure of the 28-item adult INSPIRE measure. One item was removed prior to EFA because more than 50% of participants answered 'Strongly agree' (It is important to me that an automated insulin delivery system fits comfortably in the clothes I wear). No items were extremely skewed or kurtotic. Six additional items were removed due to item to total correlations < 0.3. KMO = 0.90 and Bartlett's test, χ^2 (276) = 1516.47, $P < 0.001$, indicated an analysable correlation matrix. Parallel analysis suggested one factor. Two more items were

Table 2 Items deleted from each INSPIRE measure due to ceiling effects, item-to-total correlations < 0.3 or communalities < 0.3

Youth	Parent	Adult	Partner
It is important to me that it is waterproof.*	It is important to me that it is waterproof.†	It is important to me that it is waterproof.‡	It is important to me that it is waterproof.‡
It is important to me that it fits comfortably in the clothes I wear.*	It is important to me that it fits comfortably in the clothes my child wears.‡	It is important to me that it fits comfortably in the clothes I wear.0	It is important to me that it fits comfortably in the clothes my partner wears.‡
I worry that I will pay such close attention to it that I won't be able to relax.†	I worry that I will pay such close attention to it that I won't be able to relax.†	I worry that I will pay such close attention to it that I won't be able to relax.†	I worry that I will pay such close attention to it that I won't be able to relax.†
I am concerned that it will fail.†	I am concerned that it will fail.†	I am concerned that it will fail.†	I am concerned it will fail.†
I worry that the tape will cause rashes or skin reactions.†	I worry that the tape will cause rashes or skin reactions.†	I worry that the tape will cause rashes or skin reactions.†	I worry that the tape will cause rashes or skin reactions.†
I worry that it will bring attention to my diabetes.†	I worry that it will bring attention to diabetes.†	I worry that it will bring attention to my diabetes.†	I worry that it will bring attention to diabetes.†
I worry the high costs of the system will be a financial barrier to using the system.†	I worry the high costs of the system will be a financial barrier to using the system.†	I worry the high costs of the system will be a financial barrier to using the system.‡	I worry the high costs of the system will be a financial barrier to using the system.†
It is important to me that it is tubeless.†	It is important to me that it is tubeless.†	It is important to me that it is tubeless.†	It is important to me that it is tubeless.†
It is important to me that the parts of the system are contained in one device.‡	It is important to me that the parts of the system are contained in one device.†	It is important to me that the parts of the system are contained in one device.†	It is important to me that the parts of the system are contained in one device.‡
The automatic insulin delivery system will make managing diabetes easy when driving (for those who drive) or when traveling.‡			

*Removed due to ceiling effect. †Removed due to item to total correlation < 0.3. ‡Removed due to communality <0.3.

removed due to communalities < 0.3. See Table 2 for all deleted items. One factor explained 53.92% of the variance and factor loadings ranged from 0.57 to 0.84 (see Table 3). The final 22-item measure showed high internal consistency ($\alpha = 0.97$; $M = 74.51 \pm 16.57$; 25th percentile, $M = 63.40$; 75th percentile, $M = 87.50$).

The adult measure was significantly correlated with age, diabetes duration and the WHO-5 scale. Greater positive expectancies towards automated insulin delivery systems were associated with younger age, shorter duration of diabetes and higher quality of life (see Table 4). The INSPIRE score was significantly associated with pump use, $t(151) = -2.62$, $P = 0.010$, with pump use being higher than multiple daily injections ($d = 0.47$). There were no differences based on education level (college graduate versus non-college graduate), $t(150) = 1.40$, $P = 0.163$, CGM use, $t(148) = 0.72$, $P = 0.472$, sex, $t(151) = -0.92$, $P = 0.358$, race/ethnicity, $F(3,149) = 0.21$, $P = 0.886$, family income, $F(2,114) = 0.92$, $P = 0.400$, or insurance coverage, $F(1,150) = 1.29$, $P = 0.257$.

INSPIRE: partners

EFA was used to analyse the factor structure of the 31-item partner INSPIRE measure. No items were removed due to ceiling or floor effects, or extreme skewness or kurtosis. Six items were removed due to item to total correlations < 0.3. KMO = 0.90 and Bartlett's test, χ^2 (300) = 2213.88, $P<0.001$, indicated an analysable correlation matrix. Parallel analysis suggested two factors, with one factor representing partner-specific items and one factor representing items about the person with diabetes. Three more items were removed due to communalities < 0.3. See Table 2 for all deleted items. Two factors explained 61.67% of the variance. Factor loadings for partner-specific items ranged from 0.44 to 0.95 and loadings for the factor about the individual with diabetes ranged from 0.60 to 0.89 (see Table 3). The final 22-item measure showed high internal consistency ($\alpha = 0.97$; $M = 72.98 \pm 16.83$; 25th percentile, $M = 64.77$; 75th percentile, $M = 82.95$).

The partner measure was correlated significantly with the HbA_{1c} of the person with diabetes; no significant correlations were observed with other psychosocial measures (see Table 4). The only demographic association was pump use for the person with diabetes, $t(141) = -2.60$, $P = 0.010$, with automated insulin delivery expectations more positive when the adult with diabetes used pump therapy vs. multiple daily injections ($d = 0.45$). There were no significant differences based on CGM use, $t(137) = -1.14$, $P = 0.258$, sex, $t(142) = -0.57$, $P = 0.568$, race/ethnicity, $F(3,140) = 0.80$, $P = 0.497$, education of the person with diabetes, $F(3,138) = 0.96$, $P = 0.415$, family income, $F(2,107) = 0.93$, $P = 0.399$, or insurance type of the person with diabetes, $F(1,141) = 0.07$, $P = 0.786$.

Table 3 Factor loadings for each INSPIRE automated insulin delivery system measure

Item	Youth Factor 1	Parent Factor 1	Adult Factor 1	Partner	
				Factor 1	Factor 2
More hopeful about future	0.67	0.75	0.73	0.76	–
Worry less	0.79	0.69	0.74	0.69	–
Reduce family concerns	0.66	0.74	0.77	0.63	–
Easier to do what I want	0.79	0.75	0.82	0.60	–
Decrease lows	0.74	0.76	0.72	0.81	–
Decrease highs	0.75	0.80	0.75	0.87	–
Stay in target range	0.81	0.82	0.77	0.81	–
Improve A1c	0.81	0.79	0.68	0.75	–
Easy to eat	0.77	0.64	0.67	0.67	–
Easy to exercise	0.77	0.67	0.69	0.75	–
Manage diabetes easier at work/school	0.83	0.86	0.84	0.85	–
Manage diabetes easier when driving/travelling	–	0.87	0.83	0.89	–
Manage diabetes easier with social life	0.79	0.74	0.80	0.78	–
Manage diabetes with sex life	–	–	0.63	0.69	–
Manage diabetes with alcohol	–	0.58	0.68	0.69	–
Help manage sick days	0.73	0.76	0.75	0.72	–
Help if pregnant	–	0.76	0.69	0.79	–
Reduce risk of complications	–	0.82	0.79	0.76	–
Sleep better	0.62	0.67	0.57	0.30	−0.44
Fewer lows at night	0.73	0.80	0.66	0.66	–
Improve quality of life	0.78	0.71	0.79	–	−0.95
Improve family quality of life	0.71	0.69	0.73	–	−0.92

–, item was not included as part of the final INSPIRE measure for that respondent group.

Discussion

Results indicate that the INSPIRE questionnaires are reliable and valid measures of perceptions of positive expectancies regarding automated insulin delivery by various stakeholders. The developmentally sensitive measures are brief, ranging from 17 to 22 items, making them feasible for individuals to complete in busy diabetes clinic settings or in a clinical trial. In short, the INSPIRE questionnaires measure positive expectancies of what an automated insulin delivery system can do to improve overall diabetes-specific well-being. They offer added value as clinicians are able to initiate use of such systems and as newer systems are tested in clinical trials.

The initial assessment of the psychometric properties of these measures suggest that the INSPIRE questionnaires are reliable (α = 0.95-0.97). Negatively worded items dropped out during the psychometric analyses, and the same items dropped out across respondents. Measures for youth, adults and parents were consistently unidimensional, and the measure for partners showed a two-factor structure, with one factor focused on the perceived impact of system use on the partner and the other related to the perceived impact on the person with diabetes. Moreover, similar items among the respondents were removed from the measures because the items did not capture enough variability in responses. These items, in which more than 50% reported 'Strongly agree', included wanting the system to be waterproof and wanting the system to fit comfortably in clothing. These system features would appear important and developers may want to consider this in their design. The consistency of our findings across respondents support the construct validity of the measures.

Table 4 Bivariate correlations of each form of the INSPIRE measures with demographic and other validated psychosocial measures

INSPIRE	Youth	Parents	Adults	Partners
Age	0.023	−0.112	−0.232*	−0.092
Diabetes Duration	−0.002	0.047	−0.178*	−0.029
HbA_{1c}	0.185*	0.009	0.039	0.194*
PedsQL - Child	0.013	–	–	–
PedsQL - Teen	0.062	–	–	–
WHO-5	–	0.007	0.175*	0.055
GMSS	0.017†	0.010	0.070	−0.022
BGMC	0.137*	0.144	0.146	0.027
HFS (worry subscale)	0.022	0.129	0.144	–
PAID - Child	0.153	–	–	–
PAID – Teen	0.068	–	–	–
PAID – Parent Revised	–	0.099	–	–
DDS	–	–	0.072	0.059

*$P<0.05$.†Measure was only completed by teens aged 13–17 years and not by children under 13 years.
–, measure not completed by respondent; therefore, no correlation could be calculated.
PedsQL, Pediatric Quality of Life Inventory; WHO-5, WHO-5 Well-Being Questionnaire; GMSS, Glucose Monitoring System Satisfaction Survey; BGMC, Blood Glucose Monitoring Communication (BGMC) Questionnaire; HFS, Hypoglycemia Fear Survey; PAID, Problem Areas in Diabetes Survey; DDS, Diabetes Distress Scale. Duration of diabetes and HbA_{1c} correlations for parents refer to youth duration/HbA_{1c} and for partners, they refer to the adult partner with diabetes.

During concurrent validity analyses, youth with higher HbA_{1c} values and youth who experienced negative emotions

related to blood glucose monitoring expressed higher levels of positive expectancy for an automated insulin delivery system. Adults who reported higher levels of quality of life also reported higher levels of positive expectancy, which is consistent with findings that pump use was associated with higher quality of life [11,18]. In addition, youth participants who used either an insulin pump or a CGM expressed higher levels of positive expectancy. Adult participants who used an insulin pump and their partners similarly expressed higher levels of positive expectancy. These results are consistent with Naranjo *et al.*'s [11, 18] finding that CGM and pump users have more positive attitudes towards diabetes technology use than non-users. It may be that those who are already familiar with diabetes technology have more experience and thus remain positive with high expectations about automated insulin delivery systems. Similarly, adults who were younger and had a shorter duration of diabetes reported higher levels of positive expectancy.

Discriminant validity was supported by the minimal to low correlations between INSPIRE measures and other psychosocial and health-related variables of quality of life, glucose monitoring satisfaction, fear of hypoglycaemia, affect specific to blood glucose monitoring (except for youth), diabetes distress and HbA_{1c} (except for youth), supporting the unique construct of positive attitudes toward automated insulin delivery systems.

The large sample size in each participant group, recruited through the Type 1 Diabetes Exchange increases the likelihood of representation of, and generalizability to, the larger population of persons living with Type 1 diabetes and parents as well as partners. However, it must be acknowledged that despite several attempts to recruit from diverse populations, the sample was mainly white insulin pump users with private insurance. Socio-economic and cultural diversity were not adequately achieved in the current study. This partially reflects the greater occurrence of Type 1 diabetes in white populations. It also reflects the current sociodemographics of participants in automated insulin delivery trials [1–4]. In addition, it could be a consequence of recruitment methodology and underlying assumptions regarding computer use and Type 1 Diabetes Exchange membership. Although this subgroup of individuals with Type 1 diabetes are more likely to use existing technology, further studies are needed to assess the utility of the measures among more diverse populations. Furthermore, the predictive utility of these measures regarding uptake and continued use of automated insulin delivery systems requires investigation as clinical trials continue and commercialized products become increasingly available.

In conclusion, this study presents data on the rigorous process to create and validate short yet comprehensive baseline measures that capture the expectancies and hopes of automated insulin delivery. Initial analyses suggest that these questionnaires are valid and reliable. This study is an important first step in the validation and psychometric assessment of the INSPIRE measures. As automated insulin delivery systems become commercially available and longitudinal studies are completed, further assessment of the measures' predictive utility in understanding uptake and continued use will be necessary. In addition, future studies assessing stakeholders' perceptions regarding benefits vs. barriers is needed. Used clinically, these current questionnaires may provide the diabetes care team with information on the expectations of potential users and offer an avenue to discuss trust and engagement with the system. Used in research and commercial settings, these measures open up the possibility of examining change in response to updates and improvements in automated insulin delivery systems and may reveal targets for interventions to bolster use and optimize the efficacy of the systems.

Funding sources

The study was funded by the Leona and Harry Helmsley Charitable Trust

Competing interests

None declared.

Acknowledgements

We thank the participants in the study, without whom there would be no study. We also thank Kimberly Garza, Anthony Vesco and Lindsay Anderson from Lurie Children's Hospital who helped with manuscript preparation and critical review.

Author contributions

J.W.B., K.K.H., L.L. and K.B. were responsible for the study design and data collection. J.W.B., K.K.H., L.L., K.B., J.S. and D.N. were responsible for data analysis. All authors were responsible for manuscript preparation. All authors reviewed and edited the manuscript. All authors approved the final version of the manuscript. J.W.B. is the guarantor of the article's content.

References

1 Haidar A, Legault L, Messier V, Mitre T, Leroux C, Tabaselhorel R. Comparison of dual-hormone artificial pancreas single hormone artificial pancreas, and conventional insulin pump therapy for glycemic control in patients with type 1 diabetes. *Lancet Diabetes Endocrinol* 2015; **3**: 17–26.

2 Thabit H, Lubiana-Solomon A, Stadler M, Leelarathna L, Walkinshaw E, Pernet A *et al*. Home use of closed-loop insulin delivery for overnight glucose control in adults with type 1 diabetes: a 4-week multi-center randomized crossover study. *Lancet Diabetes Endocrinol* 2014; **2**: 701–709.

3 Bergenstal RM, Garg S, Weinzimer SA, Buckingham BA, Bode BW, Tamborlane WV *et al*. Safety of a hybrid closed-loop insulin

delivery system in patients with type 1 diabetes. *JAMA* 2016; **316**: 1407–1408.
4 Russell SJ, El-Khatib FH, Sinha M, Magyar KL, McKeon K, Goergen LG *et al*. Outpatient glycemic control with a bionic pancreas in type 1 diabetes. *N Engl J Med* 2014; **371**: 313–325.
5 Kovatchev B, Cheng P, Anderson SM, Pinsker JE, Boscari F, Buckingham BA *et al*. Feasibility of long-term closed-loop control: a multi-center 6-month trial of 24/7 automated insulin delivery. *Diabetes Technol Ther* 2017; **19**: 18–24.
6 Barnard K, Wysocki T, Thabit H, Evans M, Amiel S, Heller S *et al*. Psychosocial aspects of closed- and open-loop insulin delivery: closing the loop in adults with Type 1 diabetes in the home setting. *Diabet Med* 2015; **32**: 601–608.
7 Barnard K, Wysocki T, Ully V, Mader J, Pieber T, Thabit H *et al*. Closing the loop in adults, children and adolescents with suboptimally controlled type 1 diabetes under free living conditions: a psychosocial substudy. *J Diabetes Sci Technol* 2017; **11**: 1080–1088.
8 Weissberg-Benchell J, Hessler D, Fisher L, Russell S, Polonsky W. Impact of an automated bihormonal delivery system on psychosocial outcomes I adults with type 1 diabetes. *Diabetes Technol Ther* 2017; **19**: 1–6.
9 Weissberg-Benchell J, Hessler D, Polonsky W, Fisher L. Psychosocial impact of the bionic pancreas during summer camp. *J Diabetes Sci Technol* 2016; **10**: 840–844.
10 Hendrieckx C, Poole L, Sharifi A, Jayawardene D, Loh M, Horsburgh J *et al*. It is definitely a game changer: a qualitative study of experiences with in-home overnight closed loop technology among adults with type 1 diabetes. *Diabetes Technol Ther* 2017; **19**: 410–416.
11 Naranjo D, Tanenbaum M, Iturralde E, Hood K. Diabetes technology: uptake, outcomes, barriers and the intersection with distress. *J Diabetes Sci Technol* 2016; **10**: 852–858.
12 Russell SJ, Beck R. Design considerations for artificial pancreas pivotal trials. *Diabetes Care* 2016; **39**: 1161–1167.
13 Naranjo D, Suttiratana S, Iturralde E, Barnard K, Weissberg-Benchell J, Hood K *et al*. What end users and stakeholders want from automated insulin delivery systems. *Diabetes Care* 2017; **40**: 1453–1461.
14 Walsh TR, Irwin DE, Meier A, Varni JW, DeWalt D. The use of focus groups in the development of the PROMIS Pediatric Item Bank. *Qual Life Res* 2008; **17**: 725–735.
15 Rebok G, Riley A, Forrest CB, Starfield B, Green BF, Robertson J *et al*. Elementary school-aged children's reports of their health: a cognitive interviewing study. *Qual Life Res* 2001; **10**: 59–70.
16 Woolley ME, Bowen GL, Bowen NK. The development and evaluation of procedures to assess child self-report item validity. *Educ Psychol Measure* 2006; **66**: 687–700.
17 Willis GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design*. Thousand Oaks, CA: SAGE, 2005.
18 Sudman S, Bradburn NM, Schwarz N. *Thinking About Answers: The Application of Cognitive Processes to Survey Methodology*. San Francisco, CA: Jossey-Bass, 1996.
19 Varni JW, Seid M, Kurtin PS. PedsQL 4.0: reliability and validity of the Pediatric Quality of Life Inventory version 4.0 generic core scales in healthy and patient populations. *Med Care* 2001; **39**: 800–812.
20 Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 wellbeing index: a systematic review of the literature. *Psychother Psychosom* 2015; **84**: 167–176.
21 Polonsky WH, Fisher L, Hessler D, Edelman SV. Development of a new measure for assessing glucose monitoring device-related treatment satisfaction and quality of life. *Diabetes Technol Ther* 2015; **17**: 657–663.
22 Cox DJ, Irvine A, Gonder-Frederick L, Nowacek G, Butterfield J. Fear of hypoglycemia: quantification, validation, and utilization. *Diabetes Care* 1987; **10**: 617–621.
23 Gonder-Frederick L, Nyer M, Shepard JA, Vajda K, Clarke W. Assessing fear of hypoglycemia in children with Type 1 diabetes and their parents. *Diabetes Manag (Lond)* 2011; **1**: 627–639.
24 Hood KK, Butler DA, Volkening LK, Anderson BJ, Laffel LM. The Blood Glucose Monitoring Communication questionnaire: an instrument to measure affect specific to blood glucose monitoring. *Diabetes Care* 2004; **27**: 2610–2615.
25 Evans M, Davis L, Weissberg-Benchell J. Psychometric properties of the child and parent problem areas in diabetes measures. *Poster presented at the 76th Annual Scientific Sessions of the American Diabetes Association*, New Orleans, LA, USA, 2016.
26 Shapiro JB, Evans M, Vesco A, Hood K, Antisdel J, Weissberg-Benchell J. Validation of the Problem Areas in Diabetes measure-parents of teens: associations with psychosocial and metabolic outcomes. *Poster session presented at the annual meeting of the International Society for Pediatric and Adolescent Diabetes*, Valencia, Spain, 2016.
27 Markowitz JT, Volkening LK, Butler DA, Antisdel-Lomaglio J, Anderson BJ, Laffel LMB. Re-examining a measure of diabetes-related burden in parents of young people with Type 1 diabetes: the Problem Areas in Diabetes Survey – Parent Revised version (PAID-PR). *Diabet Med* 2012; **29**: 526–530.
28 Fisher L, Polonsky WH, Hessler DM, Masharani U, Blumer I, Peters AL *et al*. Understanding the sources of diabetes distress in adults with type 1 diabetes. *J Diabetes Complicat* 2015; **29**: 572–577.
29 Polonsky WH, Fisher L, Hessler D, Johnson N. Emotional distress in the partners of type 1 diabetes adults: worries about hypoglycemia and other key concerns. *Diabetes Technol Ther* 2016; **18**: 292–297.
30 Vesco A, Garza K, Jedraszko A, Weissberg-Benchell J. Continuous glucose monitoring (CGM) associated with less diabetes-specific emotional distress and lower a1c among adolescents with Type 1 diabetes. *J Diabetes Sci Technol* 2018; **12**: 792–799.
31 Wong JC, Boyle C, DiMeglio LA, Mastrandrea LD, Abel KL, Cengiz E *et al*.; T1D Exchange Clinic Network. Evaluation of pump discontinuation and associated factors in the T1D Exchange Clinic Registry. *J Diabetes Sci Technol* 2017; **11**: 224–232.
32 Wong JC, Dolan LM, Yang TT. Hood KK Insulin pump use and glycemic control in adolescents with type 1 diabetes: predictors of change in method of insulin delivery across two years. *Pediat Diabetes* 2015; **16**: 592–599.