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Issue of Adjustment to Continuous Subcutaneous Insulin Infusion Devices

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ABSTRACT

Continuous subcutaneous insulin infusion with an insulin pump provides best practice for prevention of tertiary complications of insulin-dependent diabetes. **Purpose:** The aim of the study was to identify self-care adjustment issues to pump technology via a computer-based survey. **Method:** Internal reliability of the Adaptation to Insulin Pumps Survey was 0.765 (Cronbach's alpha). The validated survey was emailed to a convenience sample of 10,000 users. Logistic regression analysis was done on each binary variable, testing for Group effect, while controlling for age and gender. **Results:** There were 959 responders. Seventeen survey statements relating to barriers, intrusiveness, attitude, and adaptations had significance from $p < 0.0001$ to $p < 0.05$. **Conclusions:** Ninety-four percent of calculated p values of statements were higher for woman than men. Odds ratio estimates suggested that women may have higher risk for discontinuance of the biomedical device than men. Future research should identify women at risk and clarify the roles of different healthcare practitioners in addressing the self-care adjustment issues of women.

INTRODUCTION

The International Diabetes Federation reported that 371 million people worldwide had diabetes in 2012, surpassing prior projections of 380 million by 2025, and demonstrating that the global diabetes epidemic is rapidly exceeding expectations.¹ U.S. figures have forecasted that one third of the population may have diabetes by 2050.²

Two landmark studies established intensive management as the goal standard for diabetes care for people with type 1 diabetes mellitus (T1DM). The research demonstrated that tight control of blood glucose with either continuous subcutaneous insulin infusion (CSII) or multiple daily injections (MDI) prevented or delayed the onset of long-term peripheral micro- and macro-vascular complications, cardiovascular disease, nephropathy, and retinopathy. Additionally, tighter control was found to extend life by as much as five years. Yet, tighter control of glucose resulted in substantially more hypoglycemic episodes for people with T1DM.^{3,4} In 2009, the U.S. dominated the world market at \$394 million for CSII devices with tubes and at \$58.9 million for tubeless CSII devices. In addition, the U.S. market was forecasted to reach \$843 million and the worldwide market that was \$586 million was predicted to be \$1,051 million by 2016.⁵

CSII was found to be the superior treatment for reduction of the number of hyperglycemic episodes and for slowing down the onset of hypoglycemic symptoms.^{3,4} However, the longer the duration that people had T1DM, the more they were at greater risk for losing their ability to detect the symptoms of life-threatening hypoglycemia. For some people with T1DM that experienced elevated glucose in early morning hours (called the dawn phenomena), it was found that CSII devices offered an easier solution to control the elevation than by an injection before dawn.⁶ CSII has also been considered the best strategy for providing incremental infusions of insulin to maintain optimal glycemic control for people having T1DM.⁷ CSII provided a means for achieving near-normoglycemia, leading to improved metabolic outcomes, prevention and reduction of tertiary complications, improved quality of life, and sustained productivity of people with diabetes.⁸ CSII devices have been prescribed for some people with type 2 diabetes mellitus⁹ (T2DM) and for women with gestational diabetes.¹⁰ The terms CSII device and pump were used interchangeably throughout this paper.

Many meta-analyses have focused on the benefits and positive outcomes of CSII devices with children and adolescents, as researchers have been most concerned about the risks and benefits with youth rather than adults.¹¹ One meta-analysis performed an evaluation of 44 Randomized Controlled Trial (RCT) studies. It was found that MDI in children and adolescents with T1DM and T2 DM were as effective as CSII. They also showed that in adults with T1DM, the glycosylated hemoglobin A1c assay (HbA1c), the gold standard for determination of overall glucose control, was significantly more reduced in subjects with CSII than MDI.¹² Lower HbA1c readings have been associated with the best glycemic control.³

CSII devices are programmable external pumps that continuously deliver short-acting insulin from a reservoir by means of a cannula that is inserted under the skin. Dosages with CSII devices can be fine-tuned to increments of 0.025, 0.05 or 0.01 of a unit of insulin to achieve precision control depending on the insulin pump product, thus providing less glycemic excursion for users. A continuous background of insulin (the basal rate) is delivered 24 hours/day. A single dose of insulin (called a bolus) is calculated from carbohydrate intake that can be given before meals, giving more flexibility for timing of meals than with MDI.¹³ Individualized treatment plans can be programmed into the device with: numerous basal rates introduced at different times of the day, calculated correction bolus doses based on individualized formulas that address high or low glucose readings, formulas for calculating insulin based on carbohydrate food intake, and suspension of basal rates during exercise. People on multiple daily doses may take as many as 1,460 injections or more per year, whereas pump sets are changed only every two to three days, creating less pain and increased lifestyle flexibility.¹³

People with diabetes who want to switch from MDI to CSII must demonstrate to their physicians and third party payers that they are capable of adapting to the technology before they are approved for the device. Third party payers have similar comprehensive criteria that candidates must meet before CSII can be considered as an option for treatment such as: history of diabetes education, taking three or more injections per day for six months, and checking blood glucose at least four times daily for two or more months. In addition, candidates must have one of the following medical necessity: a history of recurrent hypoglycemia, wide glycemic excursions, a glycosylated hemoglobin level > 7.0%, or a blood glucose > 200mg/dl before dawn.¹⁴

METHODS

Aim and Research Question

The aim of this pilot study was to inquire about issues of adjustment that may be experienced by users of CSII devices. The research question was: Are there adjustment issues to CSII devices that differ between first time users and second time users? Studying the differences between experienced and non-experienced users was deemed important because health care practitioners may want to seek early referrals from physicians to provide help to identified users, who seem to be making a poor adjustment, before they stop using the technology and forgo their opportunity to achieve their optimal health.

Setting, Timelines, and Support

The study was conducted at the researchers' university. There was a one year period allocated for literature review, design and testing of the survey, collection of data, statistical analysis, and thesis project completion, in order to provide faculty support to a candidate for a Master's degree in occupational therapy. Faculty included an occupational therapist, biomedical engineer and a statistician.

Participants

Participants comprised of a small nationwide convenience sample of insulin pump users, 18 to 71+ years, who were either First Time Users (FTUs) of tubeless a CSII device or Second Time Users (STUs) that switched from tube technology to tubeless pump technology, and had insurance coverage and computer access. Participants were acquired from the Insulet Corporation's 10,000+ e-mail distribution list. The Insulet Corporation manufactured the first tubeless type insulin pump, called the Omnipod.¹⁵

The manufacturer's sample provided our researchers access to users of a variety of CSII devices with tubes and without tubes.

Survey Development

Survey method was deemed to be adequate for gathering data about group adjustment to technology. Adaptation to Insulin Pumps Survey was a 17-item instrument that was developed by the two occupational therapist members of the research team. A university technology manager uploaded the survey online using PHP with Microsoft SQL as the database, and downloaded all data for the researchers.

An initial survey with 52 statements was derived using a 5-point Likert rating scale. The statements were allocated to represent one of four categories: barriers (defined as an obstacle that hinders or prevents action)¹⁶; intrusiveness (described as the perceived interruptions to participation in valued activities, due to considerations imposed by diabetes)¹⁷; attitude (termed, "the relatively stable set of beliefs, feelings, and behavioral tendencies in relations to something or someone"¹⁸; and adaptation (defined as "the internal process by which people respond to the demand for change").¹⁹

Content validity and face validity of the 52 statement survey was confirmed by an expert panel comprised of three university faculty with type1 diabetes, who used CSII devices, and 10 key informants from the Insulet Corporation, who were clinical service managers that trained clients in use of their new Omnipod devices. Panel members separately rated the statements and provided feedback regarding content brevity, clarity, realism, simplicity and readability. The researchers deleted one statement targeting intimacy, at the request of panel members, reducing the questionnaire to 51 statements.

To determine reliability, the questionnaire was given online to the first 15 men and 15 women volunteers that provided researchers with three participants in each of five age groups. The Cronbach's alpha coefficient, a measure of internal reliability, was 0.765 for the survey. Then, all statistically non-significant items were deleted. This resulted in an internally reliable 17 statement online survey that was emailed by the Insulet Corporation to potential participants as described below. Other test-retest reliability estimates were not done because of the time constraint that limited a test-retest opportunity.

Procedures

The Investigative Review Board (IRB) provided approval. The researchers followed all procedures listed in the protocol. An online informed consent form described study benefits and risks, voluntary participation, withdrawal at any time without penalty, and clarified that all procedures followed IRB approved standards for non-disclosure of identity. Selecting the agreement icon, signified an automated signature of informed consent by a participant.²⁰ The study was approved for adults over 18 years. Children and women with gestational diabetes were excluded.

An invitation from the Insulet Corporation was emailed to potential participants that provided a link directing volunteers to the university web-host site to complete the survey. Only people receiving the email could take the validated survey. The survey took approximately 5 to 7 minutes to complete. After completion, responders automatically received a thank you email from Insulet Corporation. The survey results were accessible on the website for a period of 30 days. A follow-up invitation was sent again by the Insulet Corporation at the two week midpoint to increase the survey's response rate. The 30-day window limited the response rate, as did the distribution during the period after Thanksgiving and before Christmas; however, this was a graduate student project that required completion by graduation. Demographic questions helped to determine two tracks to separate FTUs from STUs. FTUs had no experience with insulin pumps with tubes prior to purchasing a tubeless pump. STU participants had been using insulin pumps with tubes for at least 5 years and had switched to the tubeless devices within the previous year.

Completed surveys were removed by the database manager after study completion. A unique identifier was assigned to each participant to ensure that only one response was received.²⁰ To insure confidentiality, the corporation never had access to the survey database and the university never had access to participant names and emails.²⁰ Only participants who rated every statement were included in the study.

RESULTS

Statistical Analysis

The descriptive statistics of all variables were presented as means and standard deviations in frequency tables and graphs. Answers to the statements, grouped as Agree/Disagree, were the binary response variables of main interest. The logistic regression analysis was used to evaluate the effect of Group (FTUs versus STUs) on each of the binary variables, while controlling for age (18 to 25 years, 26 to 35 years, 36 to 50 years, 51 to 70 years, and 70+ years) and gender (female versus male) categories in the model. SAS® software version 9.2 was used to perform all statistical analyses. All tests were conducted at the 0.05 level of significance. Percentages did not total 100. The neutral position (number 3) on the Likert scale was excluded

from calculations because none of the participants chose this answer. Wald Chi Square calculations were used to test the true value of the association.²¹ P-values and odds ratio estimates were reported.²¹ An odds ratio estimate of one showed equal odds of occurrence for each group under consideration.²¹

Demographics

There were 959 complete responses to the survey or approximately 10% of the distribution. This was a low response rate, as 24% to 76% response would be more typical.²⁰ The nationwide convenience sample was comprised of people from 39/52 states. The researchers were unable to send repeated reminders to increase the response rate because of semester and funding time limitations. In addition, the majority (95%) of participants in the study were Caucasian, with American-Indians, African-Americans, Latino-Americans constituting just 5% of the sample. Table 1 depicted the age, gender, ethnicity, type of diabetes, and duration of diabetes. The majority of users (99.75%) had insurance reimbursement for durable medical equipment and coverable supplies by prescription.

Table 1. Demographic Characteristics by Groups

Characteristics by Groups	First Time Pump Users FTUs (n = 534)		Second Time Pump Users STUs (n = 425)	
	n	%	n	%
Age				
18 to 25	74	13.86	53	12.47
26 to 35	120	22.47	102	24.00
36 to 50	174	32.58	140	32.94
51 to 70	159	29.78	127	29.99
71+	7	1.31	3	00.71
Gender				
Male	243	45.51	161	37.88
Female	291	54.49	264	62.12
Ethnicity				
American Indian	0	0.00	0	0.00
Alaska Native	2	0.37	1	0.24
Asian	1	0.19	0	00.00
African-American	11	2.06	7	1.65
Latino-American	16	3.00	11	2.59
Native Hawaiian or other Pacific Islander	0	0.00	0	0.00
White	493	92.32	400	94.12
Ethnicity withheld	11	2.06	6	1.41

Data Analysis

The two groups were comprised of FTUs (n= 534) and STUs (n= 425). Additionally, most of the respondents had Type I diabetes mellitus (84% FTUs, 92.71% STUs) n = 853 (88% of the sample). The largest group representations were by 36 to 50 year olds (32.58% FTUs, 32.94% STUs), females (54.49% FTUs, 62.12% STUs), and non-Hispanic whites (92.32% FTUs, 94.12% STUs). Participants with diabetes for 10 to 25 years represented 35.02% FTUs and 36.94% STUs.

There were gender effects that have been listed in Table 2 below showing the frequency of agreement/disagreement, p values and odds ratio estimates. Of the survey results reported by statements shown in Table 2, four were statistically significant ($p < 0.05$), three were very significant ($p < 0.01$), and ten were highly significant ($p < 0.0001$) for Group effect with women. Findings for men revealed that three statements were significant, four were very significant and one was highly significant for men and very significant for women and eight had no significance. Odds ratio estimates predicted that adult females as a group were 4.5 times more likely to worry about how they would wear their clothing than males, followed by 26 to 35 year olds that were the 2.9 times more likely than 51+ year olds to be concerned. These predictions suggested that females may be more vulnerable and at risk for discontinuance of CSII. Knowledge of this result may alert clinicians to support females to better manage their self-care through active practice in developing problem-solving abilities and coping strategies.

Table 2. Group Effect: Significant Statements Comprising the Adaptation to Insulin Pumps Survey for Statistical Comparisons of First Time Pump Users (FTU) and Second Time Pump Users (STU)

Survey Statements	FTU % (n=534)	STU % (n=425)	Odds Ratio [95% CI]	Odds Ratio [95% CI]
	Agree/Disagree	Agree/Disagree	p-value Female	p-value Male
B= I thought my pump would prevent me from doing daily activities.	32.002/ 55.43	22.83/ 66.59	1.73 [1.27, 2.34] p<0.0004	0.98 [0.72, 1.33] p<0.8882
B= I was concerned how I was going to wear my clothing.	55.99/32.21	72.00/22.82	0.55 [0.40, 0.76] p<0.0001	4.49 [3.28, 6.15] p<0.0002
B= I was afraid I wouldn't be able to operate my pump.	23.59/66.48	18.35/73.88	1.58 [1.13, 2.21] p<0.0071	3.41 [2.37, 4.92] p<0.0001
B= I was concerned that the pump would not be secure on my body.	61.99/27.90	56.47/33.18	4.95 [3.64, 6.73] p<0.0001	1.47 [1.08, 1.99] p<0.0141
B= I thought that I would gain weight.	22.47/52.99	24.94/52.94	0.15 [0.11, 0.21] p<0.0001	1.87 [1.35, 2.59] p<0.0002
B= I was concerned about the cost of supplies.	67.23/20.79	66.35/23.53	33.05 [22.02, 49.62] p<0.0001	1.15 [0.79, 1.66] p<0.4680
B= I didn't receive enough information about operating the pump.	10.11/81.65	8.71/84.47	0.66 [0.44, 0.97] p<0.0356	1.04 [0.69, 1.55] p<0.8600
A= I feel better with more stable blood glucose wearing my pump.	82.02/6.18	89.88/3.53	0.51 [0.27, 0.96] p<0.0379	0.91 [0.50, 1.65] p<0.7554
A= I'm open to the benefits of using a pump.	93.63/3.00	96.47/0.47	0.15 [0.03, 0.64] p<0.0105	0.32 [0.10, 0.99] p<0.0473
AD= The pump improved my quality of life.	91.20/3.38	93.64/1.18	0.32 [0.12, 0.89] p<0.0280	0.64 [0.27, 1.55] p<0.3258
AD= I'm able to do more fun and enjoyable activities.	38.77/15.55	52.23/9.65	0.46 [0.30, 0.70] p<0.0003	1.15 [0.76, 1.74] p<0.5058
AD= I enjoy a wider variety of foods.	55.24/15.73	71.53/8.71	0.43 [0.28, 0.66] p<0.0001	1.03 [0.69, 1.54] p<0.8966
I= Pump interferes with leisure or social activities with family and friends.	13.85/ 74.53	35.29/49.41	0.26 [0.19, 0.36] p<0.0001	1.16 [0.83, 1.62] p<0.3852
I= Pump interferes with physical activities.	24.53/64.61	50.59/39.29	0.28 [0.21, 0.38] p<0.0001	0.91 [0.68, 1.22] p<0.5348
I= Pump interferes with religious practices.	1.31/74.91	4.70/67.05	0.26 [0.11, 0.64] p<0.0031	2.62 [0.97, 7.10] p<0.0583
I= Pump interferes with my community activities.	6.18/77.72	18.12/59.53	0.26 [0.17, 0.40] p<0.0001	1.12 [0.73, 1.73] p<0.6097
I= Pump interferes with the way I look.	27.15/59.18	35.30/45.88	2.84 (2.06, 3.92) p<0.0001	0.63 (0.47, 0.86) p<0.0032

Note: Statement key: B=Barriers, A=Attitude, AD= Adaptations, and I=Intrusiveness
There were no differences between the groups in adaptation statements.

DISCUSSION OF FINDINGS

This study appeared to provide the first survey for insulin pump users in the literature that compared barriers, intrusiveness, attitudes, and adaptations between inexperienced and experienced users of CSII biomedical devices.

The American Diabetes Association set standards that recognized the need for psychosocial screenings to assess an individual's attitude towards diabetes, emotional well-being, overall management, quality of life, and psychiatric comorbidities. Any gross non-adherence, cognitive impairments, depression or other dangers to the client warranted referrals to experts for treatment.²² Likewise, the American Association of Diabetes Educators (AADE) suggested health educators should refer people with adjustment issues to psychologists and social workers for support.²³

The odds ratio estimates suggested that women may be more vulnerable to discontinuation of insulin pumps than males that had been reported in children and adolescents. Psychosocial factors of adjustment using CSII were recognized as important considerations in the child/adolescent population, but less has been written about other psychosocial adjustments to CSII devices in other age groups.^{24,25} Most importantly, it was reported that low confidence in one's ability to succeed with CSII therapy portends failure.²⁶

SIMILAR FINDINGS

Adapting to wearable biomedical device technology may pose many challenges, but information about people who made poor adjustment to the technology was limited. Only two studies were identified that reported discontinuance of CSII devices, where the participants chose to return to MDI. In a pediatric retrospective study of 530 CSII users with T1DM during 2000 to 2008, researchers reported 11.3% of users discontinued pump use between three days and five years, and 9.1% discontinued in 3 months.²⁷ Additionally, females >10 years old had the highest frequency of discontinuation representing 46% of the 75 females in the study ($p < 0.001$), with 80% of participants being greater than 10 years old when they discontinued CSII. Other researchers conducted a meta-analysis of 52 studies on (1,547 participants) comprised of adults, adolescents and children using CSII, in order to study the impact of the therapy on metabolic and psychosocial outcomes.²⁸ These researchers discovered five retrospective studies about discontinuation of pump therapy that were obtained during clinic visits and by follow-up questionnaires. The studies indicated 32% of 400 adult participants discontinued CSII devices because of: the discomfort of wearing pumps, lack of improved glycemic control, and the frequency of diabetic ketoacidosis, pump malfunction, hypoglycemia, site infections, or catheter occlusions. Discontinuance in this meta-analysis was correlated with psychiatric problems, females, younger age, single or divorced status, and shorter duration of diabetes.²⁸

Only one qualitative study was found regarding the psychosocial adjustment to CSII devices.²⁹ The researchers identified themes about the shared lived experiences and cultural perspectives of six Mexican-American adults, who had transitioned from insulin injections to CSII. Although the duration of time that participants used CSII devices ranged from 6 months to 7.5 years, all participants experienced the frustration of re-learning how to manage diabetes differently than when they used MDI. Males agreed that their adaptation to the technology seemed easier for them than for females in the group. Everyone agreed that their expectations for the CSII device were unrealistic at first, thinking that a pump was magically going to make their lives easier. They also perceived that wearing a pump publically demonstrated that they had diabetes and revealed a personal weakness to others. Women perceived that their weakness was less apparent with MDI than when using CSII. Both genders had perceived that the pump interfered with intimacy. Women had more challenges in finding strategies to adapt their various types of clothing to hide their pumps. For all participants, the adaptation process challenged them to redefine their self-perceptions.²⁹ Findings of this qualitative study were similar to those revealed by the Adaptation to Insulin Pumps Survey, which suggested that women might need additional assistance during the adjustment process to the technology, in order to help them improve their problem-solving abilities and coping skills regarding issues of self-care.

This study adds to the literature by suggesting that adult females may have greater risk for discontinuance of the state of the art biomedical technology for people with diabetes. Those women who show signs of discontent may quit without intervention. Findings of this research may provide doctors, physician's assistants, nurse practitioners, nurses, health educators, clinical service managers, biomedical engineers designing such devices, and occupational therapists, insight as to why some adults do well with the adjustment process to a CSII device and some return to MDI. All members of the treatment team should be involved in secondary prevention in diabetes care, which in this case would be prevention of discontinuance of this life-extending technology by poorly adapted users.

Implications

Occupational therapists may be missing team members. Meta-analyses have indicated that female adults, adolescents and children using CSII devices may be at risk for discontinuation. Occupational therapists have expertise in helping people manage

self-care and can help people adapt to daily living challenges in all health care settings, schools and after school programs. Their education enables them to provide activities to facilitate psychosocial adjustment and to learn to adapt to new situations. They are also accustomed to working assistive technologies. Occupational therapists work by prescription from physicians, physician's assistants, and nurse practitioners. Their treatment plans engage clients in occupation-based activities that involve practice of the everyday activities of people with diabetes who use CSII devices, in order to help their clients expand their problem-solving and coping skills. Occupational therapy interventions may be reimbursed in state insurance codes under billing for self-care. To promulgate referrals to occupational therapists, health care practitioners will need to learn more about the day-to-day challenges of living with diabetes, and particularly the specifics of CSII management in people from various cultures.³⁰ Recently, occupational therapists have provided evidence-based practice in secondary prevention of the tertiary complications of diabetes, but there was only one study on CSII devices.³¹⁻³⁵

Limitations

Results of this study needed cautious interpretation, as only 10% of potential respondents participated in the study. There were several limitations. People who discontinued CSII devices were not recruited in this study. The majority of respondents were non-Hispanic white-Americans. Minorities with health disparities were not well-represented in the sample, perhaps because they lacked health insurance (to defray some of the expenses associated with CSII devices) and/or Internet access. Younger participants, who use computers more than adults over age 70, dominated this sample survey. There was an expected difference between groups because STUs were already familiar with the technology, whereas FTUs had no experience using the biomedical device; however, the details of those differences were undiscovered. Lastly, thirteen states were not represented in the sample.

FUTURE STUDIES

Future studies should investigate a larger multi-ethnic sample of CSII device users. The issues faced by those who are contemplating purchasing a CSII device should be identified. Surveys could be given by paper and online to capture a broader adult sample. Those practitioners who engage in this research should perform long-term studies to document retention rates and reduction in complications that would enable third party providers to see the benefits of CSII devices in the future, in order to reduce health disparities, the high cost of care, and sustain long-term usage of CSII devices.

CONCLUSIONS

This paper presented the results of a nationwide survey that was constructed to determine the issues that persons with diabetes may experience when adjusting to CSII devices. The subjects were divided into two groups to determine whether experience with CSII made a difference when learning to use CSII devices. Age was also a factor in successful adaptation. The validated survey instrument reported 17 perceived barriers, intrusiveness issues, attitudes and adaptations of responders using CSII devices. Ninety-four percent of calculated p values of statements were higher for woman than men. Odds ratio estimates suggested that women may be more vulnerable and have greater risk for discontinuation of CSII devices, the amazing health promoting biomedical technology that can lengthen lifespan and reduce complications. Future research should identify women at risk and clarify the roles of different healthcare practitioners in addressing the self-care adjustment issues of women.

It will also be necessary to identify the evidence-based interventions that improve outcomes for women at risk, in order to expand practice in this area of secondary prevention.

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REFERENCES

1. International Diabetes Federation [IDF]. IDF Diabetes Atlas (5th ed.). 2012; Retrieved November 20, 2013 from <http://www.idf.org/diabetesatlas/5e/Update2012>
2. Centers for Disease Control [CDC]. National Agenda for Public Health Action: A National Public Health Initiative on Diabetes and Women's Health.2012;Retrieved November 15, 2013 from <http://www.cdc.gov/diabetes/pubs/factsheet11.htm>
3. Diabetes Control and Complication Trial [DCCT] Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. *N Engl J Med.* 1993 Sep 30;329(14):977-86. doi:10.1056/NEJM199309303291401. [PMID: 8366922].
4. Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, Raskin P, Zinman B;The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complication [DCCT/EDIC] Study Research Group.

- Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *N Engl J Med*. 2005 Dec 22;353(25):2643-53. [PMID:16371630]
5. PRLOG: Press Release Distribution. Insulin Pumps-Global Pipeline Analysis, Opportunity Assessment and Market Forecasts to 2016 (July 22, 2010). Retrieved from <http://www.prlog.org/10809952-insulin-pumps-global-pipeline-analysis-opportunity-assessment-and-market-forecasts-to-2016.html>
 6. Everett J. The role of insulin pumps in the management of diabetes. *Nurs Times*. 2004 Apr 20-26;100(16): 48-9. [PMID: 15132065]
 7. Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J. Cochrane Metabolic and Endocrine Disorders Group. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*. 2010. doi: 10.1002/14651858.CD005103.pub2.
 8. Thabit H. Insulin pump therapy in type 1 diabetes: merging technology with diabetes care. *JAMA*. 2012;3(2):93-9. doi: 10.3844/amjsp.2012.93.99
 9. Leinung MC, Thompson S, Luo M, Leykina L, Nardacci E. Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections. *Endocr Pract*. 2013;19(1):9-13. doi: 10.4158/EP12104.OR. [PMID:22982794]
 10. Farrar D, Tuffnell DJ, West J. Continuous subcutaneous insulin infusion versus multiple daily injections for pregnant women with diabetes. Intervention review. *Cochrane Database Syst Rev*. 2011 Sep 11;10:1-31. Retrieved September 15, 2013 from <http://www.update-software.com/pdf/CD005542.pdf>
 11. Toth GH. Continuous subcutaneous insulin infusion in children and adolescents with type 1 diabetes: Do the benefits outweigh the risks? *Paediatr Child Health*. 2005;10(1):28-30. [PMID:19657442]
 12. Golden SH, Sapir T. Methods for insulin delivery and glucose monitoring in diabetes: summary of a comparative effectiveness review. *J Manag Care Pharm*. 2012;18(6 Suppl):S3-S17. Retrieved March 12, 2013 from <http://ce.effectivehealthcare.ahrq.gov/programs/CER39/AHRQ-CER39-Diabetes.pdf>
 13. Medtronic MiniMed. Insulin pump therapy backgrounder: Questions about insulin pump therapy. 2013. Retrieved March 12, 2013 from http://wwwp.medtronic.com/Newsroom/LinkedItemDetails.do?itemId=1101851556056&itemType=backgrounder&lang=en_US
 14. CMS.gov Centers for Medicare & Medicaid Services (Implementation 2/18/2005). National Coverage Determination for Infusion Pumps (280.14). Publication number 100-3. Retrieved September 18, 2012 from http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&NCAId=109&NcaName=Insulin+Pump*3a%24+C-Peptide+Levels+as+a+Criterion+for+Use&IsPopup=y&bc=AAAAAAAEAAA&
 15. Omnipod. About Omnipod Diabetes Insulin Pump. 2013. Retrieved from <http://www.myomnipod.com/about-omnipod/>
 16. Barrier. In Merriam-Webster Dictionary online. Retrieved March 12, 2011 from <http://www.merriam-webster.com/dictionary/barrier>
 17. Talbot F, Nouwen A, Gingras J, Bélanger A, Audet J. Relations of diabetes intrusiveness and personal control to symptoms of depression among adults with diabetes. *Health Psychol*. 1999 Sep;18(5):537-42.
 18. Donatelle RJ. *Health: The basics* (6th ed.). San Francisco, CA: Pearson Education, Inc., 2005. p.20.
 19. Moyers P. Introduction to Occupation-Based Practice. In Christiansen CH, Baum CM, Bass-Haugen J (Eds.), *Occupational therapy performance, participation, and well-being*. (pp. 221-234). 2007; Thorofare, NJ: SLACK Incorporated. p.230.
 20. Sue MV, Ritter LA. *Conducting online surveys*. (1st ed.) Thousand Oaks, CA: Sage Publications Inc., 2007.
 21. Der G, Everitt BS. *A Handbook of Statistical Analyses using SAS* (3rd ed). Boca Raton, Florida: Chapman and Hall, 2010.
 22. American Diabetes Association. Standards of medical care in diabetes-2011. *Diabetes Care*. 2011 Jan;34(S1):S11-61. doi: 10.2337/dc11-S011. [PMID:21193625]
 23. Williams A, Sokol-McKay DA, Bartos B, Chynoweth M, Gerwitz A, Kleinbeck C, et al. Disabilities position statement of the American Association of Diabetes Educators. *Diabetes Educator*. 2009;35(1):41-4. Retrieved March 30, 2012 from http://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/Continuous_Subcu_Insulin_Pump_2009.pdf
 24. Cameron FJ, Northam EA, Ambler GR, Daneman D. Routine psychological screening in youth with type 1 diabetes and their parents: A notion whose time has come? *Diabetes Care*. 2007 Oct;30(10):2716-24. doi: 10.2337/dc07-0603 Epub 2007 Jul 20. [PMID:1764461]
 25. Cortina S, Repaske DR, Hood KK. Sociodemographic and psychosocial factors associated with continuous subcutaneous insulin infusion in adolescents with type 1 diabetes. *Pediatr Diabetes*. 2010 Aug;11(5):337-44. doi: 10.1111/j.1399-5448.2009.00593.x [PMID:19761529]
 26. Floyd JC Jr, Cornell RG, Jacober SJ, Griffith LE, Funnell MM, Wolf LL, Wolf FM. A prospective study identifying risk factors for discontinuance of insulin pump therapy. *Diabetes Care*. 1993 Nov;16(11):1470-8.
 27. de Vries L, Grushka Y, Lebenthal Y, Shalitin S, Phillip M. Factors associated with increased risk of insulin pump discontinuation in pediatric patients with type 1 diabetes. *Pediatr Diabetes*. 2011;12(5):506-12. doi: 10.1111/j.1399-5448.2010.00701.x. Epub 2010 Aug 15. [PMID:20723097]

29. Weissberg-Benchell J, Antisdell-Lomagilio J, Seshadri R. Insulin pump therapy: a meta-analysis. *Diabetes Care*. 2003 Apr; 26(4):1079-87. doi:10.2337/diacare.26.4.1079. [PMID: 12663577]
30. Piven EF, Nazeran H. The experience of Mexican-Americans transitioning to insulin pump technology. *Journal of Community Medicine and Health Education*. 2013;3(4):222-27. doi:10.4172/2161-0711.1000222
31. Occupational therapy practice framework: Domain and process. *Am J Occup Ther*. 2002;56:609-39. [PMID: 12458855]
32. Pyatak EA, Sequeira P, Peters AL, Montoya L, Weigensberg MJ. Disclosure of psychosocial stressors affecting diabetes care among uninsured young adults with Type 1 diabetes. *Disclosure of psychosocial stressors affecting diabetes care among uninsured young adults with Type 1 diabetes*. *Diabet Med*. 2013 Sep;30(9):1140-4. Epub 2013 Jun 26. doi:10.1111/dme.12248. [PMID: 23758145]
33. Haltiwanger EP. Experience of Mexican-American elders with diabetes: a phenomenological study. *Occup Ther Health Care*. 2012;Apr-Jul;26(2-3):150-62. doi: 10.3109/07380577.2012.694585. Epub 2012 Jun 21. [PMID:23899139]
34. Haltiwanger EP, Brutus H. A culturally sensitive diabetes peer support for older Mexican-Americans. *Occup Ther Int*. 2012 Jun;19(2):67-75. doi: 10.1002/oti.320. Epub 2011 Jul 20. [PMID:21774018]
35. Haltiwanger EP, Galindo DM. Reduction of depressive symptoms in an elderly Mexican-American female with type 2 diabetes mellitus: A single-subject study. *Occup Ther Int*. 2013 Mar;20(1):35-44. doi: 10.3109/07380577.2012.694585
36. Pyatak EA. Participation in occupation and diabetes self-management in emerging adulthood. *Amer J Occup Ther*. 2011 Jul-Aug;65(4):462-69. doi:10.5014/ajot.2011.001453. [PMID:21834462]

KEY TERMS

Insulin Pump, Discontinuance, Psychosocial Issues, Occupational Therapy, Biomedical Devices