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Continuous Subcutaneous Insulin Infusion and Multiple Daily Insulin Injections: A Patient- and Significant Other-Perceived Impact Study

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Abstract

Objective: To assess independently, paired patient (PT) and PT-selected significant other (SO) perceptions of the impact on glucose management and lifestyle of continuous subcutaneous insulin infusion (CSII) and multiple daily insulin injections (MDII) during intensive diabetes management (IDM). **Methods:** Four newly developed, parallel PT and SO survey instruments (CSIIpt and MDIIpt; CSIIso and MDIIso), based on Socio-Technical Systems Theory and the Life Patterns Model, were used to elicit demographic information and perceptions. **Results:** Both PTs and SOs rated CSII higher ($p<.001$) than MDII concerning PT perceived impact on disease management and lifestyle. SOs evaluating the impact of PT treatment method on their own lifestyles reported no difference. Of dependent variables and interactions examined, only "treatment method" and "age group" had significant effects: Increased age was positively associated with PT perceived impact on disease management and lifestyle for both CSII and MDII. **Conclusions:** Both CSII and MDII are effective IDM methodologies, but PTs perceive CSII more positively, suggesting CSII's greater potential for long-term compliance. Neither PT age nor formal education level achieved contraindicates choosing CSII for IDM. No other factor examined (diabetes type, gender, race, income level, employment status) predicts treatment method-associated perceived disease management or lifestyle impact during IDM.

Keywords: Type 1 diabetes, Type 2 diabetes, intensive diabetes management, lifestyle, patient impact, significant other impact, continuous subcutaneous insulin infusion, multiple daily insulin injections

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1. Introduction

The number of people with Diabetes Mellitus (DM) worldwide is projected to increase from 387 million in 2014 to more than 590 million by 2035 (IDF, 2014). A major cause of premature death and illness (IDF, 2012), more than 80% of DM-related deaths occur in low- and middle-income countries (WHO, 2011). Globally, 471 billion US$ were spent in 2012 due to DM (IDF, 2012).

In the United States, (a) 29.1 million people had either diagnosed or undiagnosed DM, (b) the disease cost Americans $245 billion in 2012, (c) average annual medical expenditures for people with DM were 2.3-fold higher than for people without DM, and (d) DM is the 7th leading cause of death and a major cause of heart disease, stroke, new adult blindness, kidney failure, and non-traumatic lower extremity amputations (ADA, 2014). Although the rates of DM-related complications decreased substantially from 1990 to 2010, the large disease burden persisted because of continually increasing DM prevalence (Gregg, Li, Wang, Burrows et al., 2014).

Two years following initiation of insulin therapy (but not intensive diabetes management (IDM)), glycosylated hemoglobin (HA1c) levels exceed 8% in 60% of people with Type 2 DM (Koro, Bowlin, Bourgeois & Fedder, 2014), but IDM protocols can maintain near normal ambulatory blood glucose levels (DCCT, 1993; Nathan, Cleary, Backlund, Genuth et al., 2005; Holman, Paul, Bethel, Matthews & Neil. 2008). By facilitating glucose control, IDM can reduce the system cost of DM care by avoiding acute and minimizing long-term complications while encouraging IDM program compliance by improving quality of life (Chantelau, Schiffers, Schutze & Hensen, 1997; Barnard & Skinner, 2008; Urzúa, Bravo, Ogalde & Vargas, 2011).

IDM is labor intensive (AHRQ, 2012), and tight glucose control can increase risk of hypoglycemia (Nathan, Cleary, Backlund, Genuth et al., 2005). Published guidelines (NIHCE, 2014) can help select the appropriate IDM method and guide education, follow-up protocols, or specialist referral as needed (Bode, Sabbah, Gross, Fredrickson & Davidson, 2002).

It is important to note, however, that individuals without access to specialty care tend not to achieve adequate DM control (Andrus, Kelly, Murphey & Herndon, 2004; Bellinger, Hassan & Rivers, 2010; Chen, Huang, Peng, Jong et al., 2011), but systematically shared primary and specialty responsibilities can deliver effective care (Smith, Allwright & O'Dowd, 2007; Smith, Allwright & O'Dowd, 2008).

IDM requires patient (PT) recognition of continuous management responsibilities (insulin, diet, activity, glucose monitoring) (Hoogma, Spijker, van Doorn-Scheele, van Doorn et al., 2004; Bradley, de Pablos-Velasco, Parhofer, Eschwège et al., 2011) that usually require lifestyle changes. Ongoing PT ownership and commitment, facilitated by family and significant other (SO) support, are essential for successful outcomes and HA1c levels at/below 7% (Koro, Bowlin, Bourgeois & Fedder, 2014).

Two IDM methods have demonstrated credible ambulatory glucose control: Multiple Daily Insulin Injections (MDII) and Continuous Subcutaneous Insulin Infusion (CSII) (AHRQ, 2012), and IDM of any type can impact quality of life beneficially (Pouwer & Hermanns, 2009; Urzua, Shirino & Valladares, 2011). However, while one third of PTs using MDII fail to achieve the HA1c goal (Holmann, Farmer, Davies, Levy et al., 2009), considerable evidence supports the effectiveness of CSII in adults (Edelmann, Walter, Biermann, Schleicher et al., 1987; Rubin & Peyrot, 2009; Reznik, Morera, Rod, Coffin et al., 2010), including individuals with Type 2 DM (Raskin, Bode, Marks, Hirsch et al., 2003; Fatourechi, Kudva, Murad, Elamin et al., 2009; Lynch, Riedel, Samant, Fan et al., 2010). Although declining vision, dexterity, and cognition must be considered in older individuals (Stephens & Jeffner, 2010), a Diabetes Technology Society consensus recommended that CSII be considered across all age groups (Klonoff & Reyes, 2009).

Our study's conceptual framework is based on Socio-Technical Systems Theory (STST) and the Life Patterns Model (LPM) which postulate that personal behavior changes are influenced by social and technical aspects of the lives of individuals and their SOs (Emery & Trist, 1960; Fox, 1995). The relevant sociocultural system in this study included roles, relationships, support groups, self-esteem, use of time, and life structure (daily routines). The technical system, MDII or CSII, included tools, techniques, procedures, knowledge, and devices employed monitoring and managing DM (Stachura, Rosenkoetter, Wood, Dias & Brown, 2011).

We hypothesized differences in the perceptions of CSII and MDII by both PTs and their paired SOs regarding IDM method impact on both DM management and life patterns.

2. Methods

2.1 Study Tools

Four parallel survey instruments (CSIIpt; CSIIso; MDIIpt; MDIIso) were based on STST, constructed using Tailored Design Methods (Dillman, Smyth & Christian, 2009) and tested for reliability and validity (Rosenkoetter, Stachura, Dias, Wood & Brown, 2014).In each survey instrument: *Section I* identified the subject's demographic characteristics, social setting, healthcare sources, insurance, and IDM methodology (CSII or MDII) used; *Section II* (18 five-point Likert-type items) assessed perceptions of IDM method effect on life patterns; *Section III* (25 five-point Likert-type items) assessed perceptions of the IDM method used, after switching to MDII or CSII from previous insulin administration methods; *Section IV* (2 five-point Likert-type items) assessed overall perceptions of CSII or MDII effects on satisfaction with impact on lifestyle and/or DM management; *Section V* (only on MDIIpt survey instruments) asked ten True/False questions about why PTs were not using CSII. Cronbach's alpha score for each of the instruments exceeded 0.9, indicating "excellent" internal consistency. Calculated instrument reading levels were compatible with PT- and SO-reported education levels (high school graduation: CSII 99%; MDII 96%) (Rosenkoetter, Stachura, Dias, Wood & Brown, 2014).

2.2 Power and Sample-Size Calculations

Definitive power and sample-size analysis were not possible because no normative data existed for the major outcome variables of this study in the subject population. Anticipated sample sizes allowed projected detection of relatively small to moderate standardized effect sizes with at least 80% power at the alpha=0.05 level of significance. With respect to identifying areas in which aggressive management and lifestyle issues should be pursued and monitored, projected detectable effect sizes were between 0.3 and 0.4 SD (Rosenkoetter, Stachura, Dias, Wood & Brown, 2014).

2.3 Participant Recruitment

PTs were recruited from university clinics, participants in other university clinical research projects who previously consented to future contact, practices of former university Endocrinology fellows, and non-university community clinics. All were Institutional Review Board (IRB) approved.

Male or female candidate inclusion criteria included age at or above 18 years, ability to read and/or speak English, diagnosed with Type 1 or Type 2 DM, using an MDII (minimally 3 daily injections) or CSII regimen (minimally 3 months), and willing to identify a SO (spouse, family member, co-worker, friend) familiar with the PT's DM and a frequent participant in PT thinking about DM management and consequences. Pregnancy, severe active retinopathy, and debility from impaired renal, hepatic or cardiac function were exclusion criteria. Independently consented SO participants, self-reporting an ability to read and/or speak English, were selected by and paired with PT candidates. Consented PTs and SOs were informed that available $25 gift cards would be awarded, but only after both returned completed study instruments. The university IRB approved all phases of the 3-year study (#0807002).

2.4 Statistical Methods

Survey instrument Section II and Section III scores were calculated separately as the average of all item responses. A Total Section II/III score also was calculated. Scores could range from 1 (lesser satisfaction) to 5 (greater satisfaction).Analysis of variance (ANOVA) was used to assess score (Section II, Section III, and Total) differences for PTs and for SOs. The primary factor of interest was IDM Method. The other factors included in the ANOVA were type of PT's DM, Age, Gender, Race, Education, Income, and Employment Status (Table 1). First-order interactions of IDM Method with each of the other factors were included in the ANOVA model.

Table 1: Factor-Level Descriptions for Each Factor

Factor	Label	Levels
IDM	Method	CSII; MDII
Patient's Diabetes	Type	Type 1; Type 2
Age of Subject	Age	< 41 (Young); 41-60 (Middle); > 60 (Old)
Gender of Subject	Gender	Male; Female
Race of Subject	Race	White; African-American; Other
Subject's Education Level	Education	Some College or Less; College Degree or Higher
Income of Subject	Income	<$50,000 (Low); $50,000 to <$100,000 (Middle); >/= $100,000 (High)
Employment Status	Employed	Yes; No

Wilcoxon's Rank-Sum test was used to compare Method medians for selected PT and SO items that reflected the LPM, and to compare PT and SO Method medians for the two Section IV items –(i) overall satisfaction with the current Method of diabetes management and (ii) the impact of the current Method on lifestyle.

3. Results

3.1 Demographics of Study Participants

Table 2 summarizes the demographic characteristics of consented PTs and their paired SOs for both IDM methods.

Table 2: Selected Demographic Characteristics of Patients and Paired Significant Others (N=354)[a]

	CSII				MDII			
	PT		SO		PT		SO	
Variable	*n*	%	*n*	%	*n*	%	*n*	%
Treatment Method *(of PT)*								
Subjects	255	100.0	255	100.0	99	100.0	99	100.0
Diabetes Type *(of PT)*								
Type 1	243	95.3			56	56.6		
Type 2	12	4.7			43	43.4		
Age Group								
18-40 yrs	103	40.4	90	35.3	24	24.2	26	26.3
41-60 yrs	97	38.1	107	42.0	43	43.5	38	38.3
61->80 yrs	55	21.6	57	22.4	32	32.3	33	33.4
Gender								
Male	90	35.3	131	51.4	44	44.4	43	43.4
Female	165	64.7	122	47.8	55	55.6	56	56.6
Race								
White	228	89.4	232	91.0	72	72.7	69	69.7
African American	17	6.7	16	6.3	23	23.2	25	25.3
Hispanic & Other	10	4.0	7	2.8	4	4.0	5	5.0
Annual Household Income								
<$50,000	59	23.1	52	20.4	41	41.4	38	38.4
$50,000 - $100,000	91	35.7	90	35.3	28	28.3	29	29.3
>$100,000	74	29.0	79	31.0	15	15.2	15	15.2
Highest Educational Level								
< HS graduate	2	.8	3	1.2	6	6.1	7	7.1
HS grd +some College	193	75.7	201	78.8	80	80.8	77	77.8
College degr. or more	60	23.5	50	19.6	13	13.1	15	15.1

[a]Totals <100% due to rounding error and/or subject elected "Prefer not to Specify" or no response.

There were 354 responding pairs (255 CSII, 99 MDII), but "group totals" do not match the 354 total because "Prefer not to specify" was a response option.

Of responding CSII PTs: 243 (95.3%) had Type 1 and 12 (4.7%) Type 2 DM, a distribution that reflected insurance coverage for CSII use (CMMS, 2004; CMS, 2007; NCSL, 2011). Of responding MDII PTs: 56 (56.6%) had Type 1 and 43 (43.4%) Type 2 DM.

Respondent distribution by age group (see Table 1) was similar, although MDII outnumbered CSII in PTs older than 50, again consistent with expectations based on insurance coverage of CSII use in older populations.

Female PTs comprised the majority for both CSII (n=165,64.7%) and MDII (n=55,55.6%).

Most patients were White (CSII n=228, 89.4%; MDII n=72,72.7%). No identified income level was unrepresented, and most PTs reported at least high school graduation match their own.

3.2 ANOVA Results

The reported mean (parentheses) ANOVA results are estimated marginal means (least-squares estimated means adjusted for all model terms).

3.2.1 ANOVA Results for PTs

PT Survey Total Scores

There were significant ($p<0.001$) Method (CSII vs. MDII) differences for Total Scores: CSII PTs reported greater over-all satisfaction (4.07) than did MDII PTs (3.58).

Satisfaction differed with age ($p=0.013$): Increasing satisfaction was associated with increasing age – Younger (3.70), Middle (3.78), Older (4.00).

No other factors or interactions were significant.

PT Survey Section II (perceived IDM effect on life pattern) Scores:

Method - CSII PTs (4.01) reported greater satisfaction ($p<0.001$) than did MDII PTs (3.56). Satisfaction differed with age ($p<0.001$): Increasing satisfaction was associated with increasing age – Younger (3.64), Middle (3.72), Older (3.99).

No other factors or interactions were significant.

PT Survey Section III (perceptions of IDM method after change from previous method) Scores:

Method - CSII PTs (4.11) reported statistically significant greater ($p<0.001$) satisfaction than did MDII PTs (3.59).

Although there were no statistically significant different ($p=0.113$) Section III Age CSII scores, there was a trend of increasing satisfaction being associated with increasing age – Young (3.73), Middle (3.81), Older (4.00), similar to that seen in Section II scores.

No other factors or interactions were significant.

3.2.2 ANOVA Results for SOs

SO Survey Total Scores:

Method - CSII SOs reported statistically significant greater ($p=0.046$) satisfaction (3.48) than MDII SOs (3.29).

Income – Effects were statistically significant ($p=0.011$): Low(3.39), Middle (3.21), High(3.54).

No other factors or interactions were significant except Income (see below).

SO Survey Section II Scores:

Method - CSII SOs (3.32) reported statistically significant greater ($p<0.017$) satisfaction than MDII SOs (3.10).

No other factors or interactions were significant.

SO Survey Section III Scores:

Method - There was no significant (p=0.056) difference for Section III scores, but there was a trend with CSII SOs (3.64) reporting greater satisfaction than did MDII SOs (3.42).

Income - There were statistically significant (p=0.012) differences in Section III scores: Low (3.52), Middle (3.34), High (3.74).

No other factors or interactions were statistically significant except Income (see below).

3.2.3 Method-by-Income Interaction for SOs:

SO Survey Total Scores:

Method-by-Income interaction was statistically significant (p=0.017). While CSII, means for all three income categories (see Table 1) were approximately 3.5, MDII income category means were Low (3.29), Middle (2.97), and High (3.60) and statistically significant (p=0.017).

SO Survey Section III Scores:

Method-by-Income interaction: While CSII means for the three income categories were similar (~3.7), MDII, income category means were Low (3.42), Middle (3.03), and High (3.80).

3.2.3 Wilcoxon's Rank-Sum Results

Method - For both PT and SO surveys and for both Section IV items (CSII or MDII effects upon PT and SO satisfaction with impact on lifestyle and diabetes management), there were significant differences (p<0.001).

Both PTs and SOs reported greater overall satisfaction with the impact of CSII (median=4) on management of diabetes than with MDII (median=3).

Both PTs and SOs also reported greater overall satisfaction with impact of CSII (median=4) on lifestyle than with MDII (median=3).

Table 3 (upper portion) provides responses to selected parallel survey items reflective of the LPM for CSII and MDII Patients.

There were statistically significant ($p<0.015$) Method differences for CSII (median=5) compared to MDII (median=4) for the questions: "The insulin-pump/multiple-daily-injections does/do not interfere with my activities of daily living"; "I am more independent with the pump/multiple-daily-injections than before I began using it/started using this routine"; "Activities outside my home are easier to manage now that I am using an insulin pump/taking multiple daily injections"; "I have more flexibility with my activities". Differences were not found with the questions "I miss fewer days at work"; "I participate more in family activities"; "I participate more in outside activities".

Table 3 (lower portion) provides responses to selected parallel survey items reflective of the LPM for CSII and MDII SOs. There were statistically significant ($p<0.042$) Method differences for CSII (median=4) compared to MDII (median=3) for the questions: "Activities of daily living are easier for me to perform now that he/she has an insulin pump/began using multiple daily insulin injections"; "I am more independent than before he/she began using the insulin pump/multiple daily insulin injections"; "Activities outside my home are easier for me to manage now that he/she is using an insulin pump/taking multiple daily insulin injections"; "I have more flexibility with my activities". Differences were not found for "I miss fewer days at work"; "I participate more in family activities"; "I have more flexibility with my activities".

Table 3. Selected Parallel Survey Responses to Items Reflective of the Life Patterns Model (LPM) for CSII[a] (n=255) and MDII[b] (n=99)

PT Responses (Percent)

IDM[c]	Statement	1 SD	2 D	3 U	4 A	5 SA	Med.	p-val[e]
CSII	8. The insulin pump does not interfere with my activities of daily living.	1.2	6.8	4.4	33.1	54.6	5	0.014
MDII	8. Multiple daily injections do not interfere with my activities of daily living.	5.2	9.3	5.2	39.2	41.2	4	
CSII	14. I am more independent with the pump than before I began using it.	1.6	16.4	6.4	24.7	61.0	5	< .001
MDII	14. I am more independent with multiple daily injections than before I started using this routine.	0.0	17.8	12.2	43.3	26.7	4	
CSII	17. Activities outside my home are easier to manage now that I am using an insulin pump.	0.0	2.4	4.4	32.9	60.2	5	< .001
MDII	17. Activities outside my home are easier to manage now that I am taking multiple daily injections.	5.3	18.1	8.5	44.7	23.4	4	
CSII	7. I have more flexibility with my activities.	0.4	4.4	4.8	38.1	52.4	5	< .001
MDII	7. I have more flexibility with my activities.	3.1	12.5	15.6	49.0	19.8	4	
CSII	9. I miss fewer days at work.	6.0	15.0	14.3	27.1	37.6	4	0.91
MDII	9. I miss fewer days at work.	3.9	13.7	5.9	47.1	29.4	4	
CSII	10. I participate in more family activities.	2.8	19.0	17.6	31.5	29.2	4	0.809
MDII	10. I participate in more family activities.	2.3	13.6	19.3	45.5	19.3	4	
CSII	11. I participate in more outside activities.	3.1	19.2	16.1	32.6	29.0	4	0.924
MDII	11. I participate in more outside activities.	2.4	14.3	16.7	44.0	22.6	4	

SO Responses (Percent)[d]

IDM[c]	Statement	1 SD	2 D	3 U	4 A	5 SA	Med.	Pval[e]
CSII	8. Activities of daily living are easier for me to perform now that he/she has an insulin pump.	6.3	10.8	12.7	42.9	27.8	4	< .001
MDII	8. Activities of daily living are easier for me to perform now that he/she is using multiple daily insulin injections.	9.8	21.3	29.5	29.5	9.8	3	0.001
CSII	14. I am more independent than before he/she began using the insulin pump.	5.3	10.7	19.5	44.4	20.1	4	0.001
MDII	14. I am more independent than before he/she began using multiple daily insulin injections.	12.9	19.4	24.2	33.9	9.7	3	
CSII	17. Activities outside my home are easier for me to manage now that he/she is using an insulin pump.	3.7	10.2	15.5	45.9	25.1	4	< .001
MDII	17. Activities outside my home are easier for me to manage now that he/she is taking multiple daily injections.	7.2	20.3	29.0	31.9	11.6	3	
CSII	7. I have more flexibility with my activities.	2.3	11.9	15.8	49.2	20.9	4	0.041
MDII	7. I have more flexibility with my activities.	5.5	20.5	11.0	52.1	11.0	4	
CSII	9. I miss fewer days at work.	6.3	18.1	22.0	35.4	18.1	4	0.064
MDII	9. I miss fewer days at work.	4.5	6.8	15.9	52.3	20.5	4	
CSII	10. I participate in more family activities.	4.7	17.8	26.0	34.3	17.2	4	0.171
MDII	10. I participate in more family activities.	3.2	17.7	9.7	53.2	16.1	4	
CSII	11. I participate in more outside activities.	4.7	19.2	23.3	34.4	18.6	4	0.687
MDII	11. I participate in more outside activities.	4.5	18.2	13.6	51.1	12.1	4	

[a] CSII Continuous Subcutaneous Insulin Injections;
[b] MDII Multiple Daily Insulin Injections;
[c] IDM Intensive Diabetes Management Method;
[d] 1-SD Strongly Disagree,2-D Disagree,3-U Undecided,4-A Agree,5-SA Strongly Agree
[e] Wilcoxon Rank-Sum Test of equality of IDM method medians.

3.2.4 Survey Section V Results

Section V sought information about why MDII patients were not using CSII and was included on patient MDII survey instruments only. Total responses for each question do not equal 99(the MDII n=99 total) because some patients elected not to answer some Table 4 questions.

Table 4: Section V responses for MDII patients (n=99)

Item	True/False
"I have never heard of an insulin pump"	8/88
"No one has explained an insulin pump to me"	22/73
"My primary provider has not told me about an insulin pump"	24/69
"I am afraid of technology like an insulin pump"	17/76
"My insurance will not cover an insulin pump"	29/52
"I have been told that I am not a good candidate for an insulin pump"	14/79
"I live too far from my provider's office to receive insulin pump care"	3/88
"An insulin pump would take too much of my time to care for"	28/63
"I do not want an insulin pump"	52/42

4. Discussion

We explored whether using either MDII or CSII for IDM resulted in PT- or SO-perceived advantage, even though either management method can enable PTs to achieve glucose control. Such a perceived differential impact on disease management and/or PT lifestyle could impact long-term self-management practices and success in general or for identifiable subgroups such as active and engaged individuals (Raskin, Bode, Marks, Hirsch et al., 2003) or older adults (Rosenkoetter, Stachura, Dias, Wood & Brown, 2013).

Our inclusion criteria intentionally defined a unique set of PTs: All were already practicing IDM using either MDII or CSII. Patients committing to IDM are highly motivated, and those who persist in the use of either MDII or CSII demonstrate both high organizational skills and self-responsibility for disease management. It was not surprising, therefore, that almost all participating patients reported completing at least high school education.

We aimed to capture a group of PTs who had been sufficiently dissatisfied with "usual care" to be willing to explore, comprehend, commit to, and execute the self-responsibilities required for successful IDM. Further, because actively practicing IDM for a defined minimum time period was also an inclusion criterion, these PTs presumably were more satisfied with whichever IDM they used, than they had been with "usual care".

We purposefully did not collect objective data such as HA1c or mean glucose values to sub-group participants; we were not attempting to duplicate previous studies of MDII and CSII effectiveness for normalizing blood glucose levels.

We hypothesized that differences in perceived impact on disease management and lifestyle among motivated PTs using one of two IDM methods (MDII and CSII) could influence whether these PTs would sustain IDM activities long enough to achieve the benefits of glucose control. Although better glucose control may have been an initial motivator for PTs to pursue IDM, we also hypothesized that the human cost of maintaining the particular IDM method compared to the perceived lifestyle benefits it conferred would define satisfaction.

We also explored whether PT efforts at IDM would be reinforced if the SOs with whom they regularly shared thoughts about DM and its consequences confirmed their impact perceptions, whether or not the SOs identified similar indirect benefits for themselves.

Not surprisingly, both MDII and CSII PTs perceived greater impact of their IDM method on disease management and lifestyle than previous "usual care" protocols had produced. CSII PTs, however, perceived significantly greater impact than did MDII PTs, as shown by lifestyle (Section II), management (Section III), and Total (Section II+III) scores.

Surprisingly, perceived impact increased with age among both MDII and CSII PTs, with the highest scores reported for CSII among those aged over 60 years. On the other hand, no such effect of PT gender, race, educational level, income, employment status, or DM type was demonstrable.

Similarly for SOs, both Section II (impact on lifestyle) and Total (impact on lifestyle and IDM) scores were significantly higher for CSII than for MDII, and although SO Section III (management) scores did not achieve statistical significance, CSII scores trended higher than MDII scores. We speculate that the lack of statistical significance for SOs in Section III (impact on IDM) may result from most SOs not being as closely involved in day-to-day disease management as are PTs.

In contrast to PT scores, there was no SO age effect, most likely because PTs frequently did not choose SOs whose age matched their own, and as with PTs, there was no effect of diabetes type, gender, race, educational level, income level, or employment status.

Over-all PT and SO perceived CSII satisfaction with impact (Survey Section IV – impact on IDM change) scores were higher than MDII scores for both disease management and lifestyle, but perceived impact Section II and Section III scores revealed an important difference (Table 3). Whereas CSII consistently and with statistical significance outscored MDII on issues of both disease management and the ease with which life activities are integrated with the IDM protocol used, there was no difference between CSII and MDII with respect to PT and SO behavior with family, social groups, or the workplace. In other words, while these highly motivated IDM PTs and their SOs discerned a difference in the ease with which they could integrate MDII and CSII into their lives, they would not allow either their disease or the effort required for its management to interfere with the conduct of their lives or their relationships with people important to them.

As documented in Table 4, barriers limiting CSII use in Type 2 DM include lack of patient knowledge about CSII, CSII's complexity, concern about lifestyle interruptions, misinformation, and cost (Bode, Sabbah, Gross, Fredrickson & Davidson, 2002), but initial concerns that CSII patients might experience decreased life quality appear unfounded (Hoogma, Spijker, van Doorn-Scheele, van Doorn et al., 2004). Our results confirm other reports that given the choice (Table 4), many patients prefer CSII over MDII(Gentry, Cross, Ross, McFarland & Bestermann, 2011), given the choice.

The over-all cost of implementing and maintaining IDM is complex. An early study suggested that while reducing costs of complications, IDM could increase per patient treatment costs compared with conventional management (Gray, Raikou, McGuire, Fenn et al., 2000). A more recent study of relationships between glycemic control and medical costs determined that direct medical costs related to Type 2 DM were 16% lower for good versus fair and 20% lower for good versus poor control (Oglesby, Secnik, Barron, Al-Zakwani & Lage, 2006).

In the US, insurance coverage for CSII varies by state program, insurance carrier and qualifying specifications, (NCSL, 2011). CSII is an optional and additional coverage for Medicare recipients with Type 2 DM, and approval requires a blood C-peptide level characteristic of Type 1 DM and unlikely in Type 2 DM (CMMS, 2004; CMS, 2007; Ko, So, Tong, Chan et al., 2009). The requirement effectively excludes CSII coverage for Americans aged 65 years and older, those with the highest percentage (26.9%; 10.9 million) of affected individuals and those where Type 2's predominance over Type 1 DM is most pronounced (National Diabetes Fact Sheet, 2011)

Our finding that both PTs and their SOs perceive CSII to more successfully integrate IDM into daily living than does MDII (thereby encouraging compliance, promoting healthy lifestyles, and maintaining glucose control), supports reconsideration of policies and regulations that limit CSII use.

This project focused on the use of MDII and CSII. It was limited by the use of a relatively small sample size from one geographical region and the fact that no attempt was made to include clinical data. An expanded study involving a more heterogeneous population sub-grouped by level of management success could refine the profiles of patients expected to succeed with IDM. Our model, however, is generic, and could be used to ask similar questions about other chronic conditions characterized by physician-directed long-term patient self-management protocols employing valuable, but potentially intrusive, technologies.

5. Conclusions

Among patients who committed to pursue IDM, CSII more positively impacted disease management and lifestyle than MDII according to both patients and the SOs with whom they consistently interact about their disease.

CSII's more positive perception was present across all age groups, including seniors. Neither age nor level-of-education achieved are contraindications to employing CSII for IDM. Neither diabetes type, age, gender, race, education, income, existing health insurance, living circumstance drive the choice of CSII or MDII when recommending an IDM protocol. However, clinicians recommending IDM should be aware that while both MDII and CSII are potent methodologies for achieving glucose control, CSII produces greater patient satisfaction with impact on disease management and lifestyle, and is therefore more likely to positively support long-term compliance.

6. Anecdotal Study Observations

6.1 Clinical

Although DM management is perceived to be improved by using IDM with either CSII or MDII, fear of hypoglycemia resulting from previous severe episode is not allayed. Both PTs and SOs remain anxious about a repetition. The experience of a severe hypoglycemia event is not forgotten; it creates caution about tight management goals.

6.2 Educational

A significant proportion of SOs were unaware of how to suspend insulin pump function in the event they found the PT in a state of lessened cognition or even coma, potentially due to hypoglycemia. An even larger proportion of PTs did not believe their own SOs possessed this important knowledge. PTs and SOs should both be included in teaching sessions about basic insulin pump controls and risks of hypoglycemia.

6.3 Social

In several instances, PTs who were positive about CSII-improved lifestyle and independence were noted to be paired with SOs who were displeased with the impact of PT IDM on themselves. In each of these instances, the SO self-identified as "husband".

Apparently, while use of CSII for IDM increased PT independence and ability to become involved in life activities, that independence was perceived by the SO to negatively impact the couple's relationship. Unanticipated secondary effects of otherwise beneficial interventions can have unfortunate consequences.

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7. References

ADA (2014). American Diabetes Association Statistics about Diabetes, from the National Diabetes Statistics Report, 2014. Available: http://www.diabetes.org/diabetes-basics/statistics/?loc=db-slabnav (December 19, 2014).

AHRQ(2012).Methods for insulin delivery and glucose monitoring.Comparative Effectiveness, Agency for Healthcare Research and Quality Effective Health Care Program, Comparative Effectiveness Review Number 57. AHRQ Publication No.12-EHC034-EF.

Andrus, M. R., Kelly, K. W., Murphey, L. M., & Herndon, K. C. (2004). A comparison of diabetes care in rural and urban medical clinics in Alabama. J Community Health, 29:29-44.

Barnard, K. D., & Skinner, T. C. (2008). Cross-sectional study into quality of life issues surrounding insulin pump use in type 1 diabetes. Pract. Diabetes Int., 25(5):194-200.

Bellinger, J. D., Hassan, R. M., &Rivers, P. A. (2010) Specialty care in US patients with chronic diseases. Int J Environ Res Public Health, 19:35-43.

Bode, B. W., Sabbah, H. T., Gross, T. M., Fredrickson, L. P.,& Davidson, PD. (2002). Diabetes management in the new millennium using insulin pump therapy. Diabetes Metab Res Rev.,Suppl 1:S14-21.

Bradley, C., de Pablos-Velasco, P., Parhofer, K. G., Eschwège, E., Gönder-Frederick, L., & Simon, D. (2011) PANORAMA: A European study to evaluate quality of life and treatment satisfaction in patients with type-2 diabetes mellitus-study design. Prim Care Diabetes, 5(4):231-9. Epub 2011 Jul 14.

Chantelau, E., Schiffers, T., Schutze, J., & Hensen, B. (1997).Effect of patient-selected intensive insulin therapy on quality of life. Patient EducCouns., 30(2):167-73.

Chen, M. Y., Huang, W. C., Peng, Y. S., Jong, M. C., Chen, C. Y., &Lin, H. C. (2011). Health status and health-related behaviors among type 2 diabetes community residents. J Nurs Res., 19:35-43.

CMMS (2004). Centers for Medicare and Medicaid Services. Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-00092R). Continuous Subcutaneous Insulin Infusion (CSII) Pumps. Effective for Services Performed On or after December 17, 2004.US Dept of Health and Human Services.Available at: http://www.cmms.hhs.gov/medicare-coverage-database/details/ncadecision-memo.aspx?NCAId=109&ver=23&NcaName=Insulin+Pump*3a%24+C-Peptide+Levels+as+a+Criterion+for+Use&NCDId=223&ncdver=1&IsPopup=y&bc=AAAAAAAAIBAA&

CMS (2007). Medicare National Coverage Determinations Manual.Chapter 1, Part 4 (Sections 200 – 310.1). Coverage Determinations. 280. 14 – Infusion Pumps Reviewed July 2007. Issued: 02-04-05, Effective: 12-17-04, Implementation: 02-18-05. Washington, DC: Centers for Medicare and Medicare Services. Available: http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf.

DCCT (1993).Diabetes Control and Complications Trial Research Group.The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. N Engl J Med., 329(14):977-86.

Dillman, D., Smyth, J., & Christian, L. (2009). Internet, mail, and mix-mode surveys. The Tailored design method.Hopken, NJ; John Wiley & Sons, Inc.

Edelmann, E., Walter, H., Biermann, E., Schleicher, E., Bachmann, W., &Mehnert, H. (1987). Sustained normoglycemia and remission phase in newly diagnosed type I diabetic subjects. Comparison between continuous subcutaneous insulin infusion and conventional therapy during a one year follow-up.Horm Metab Res. 19(9):419-21.

Emery, F., & Trist, E. (1960).Socio-technical systems. In C.Churchman&M.Verhulst (Eds.) Management Sciences, Models and Technique. London: Pergamon.

Fatourechi, M. M., Kudva, Y. C., Murad, M. H., Elamin, M. B., Tabini, C. C., &Montori, V. M. (2009). Clinical review: Hypoglycemia with intensive insulin therapy: a systematic review and meta-analysis of randomized trials of continuous subcutaneous insulin infusion vs multiple daily insulin injections. J Clin Endocrinol Metab., 94(3):729-40.

Fox, W. (1995). Sociotechnical system principles and guidelines: Past and present. J Applied Beha Sc., 31(1):91-105.

Gray, A., Raikou, M., McGuire, A., Fenn, F., Stevens, R., Cull, C., Stratton, I., Adler, A., Holman, R., & Turner, R. (2000). Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial. The United Kingdom Prospective Diabetes Study Group.BMJ.,(20)373-8.

Gregg, E. W, Li, Y., Wang, J., Burrows, N. R., Ali, M. K., Rolka, D., Williams, D.E., & Geiss, L. (2014). Changes in diabetes-related complications in the United States, 1990-2010. N Engl J Med., 370:1514-23.

Holman, R. R., Paul, S. K., Bethel, M. A,, Matthews, D.R., & Neil, H. A. (2008). 10-year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med., 359(15):1577-89.

Holman, R. R., Farmer, A. J., Davies, M. J., Levy, J. C., Darbyshire, J. L., Keenan, J. F., Paul, S. K, &; 4-T Study Group (2009). Three-year efficacy of complex insulin regimens in type 2 diabetes. N Engl J Med., 361:1736-47.

Hoogma, R. P., Spijker, A. J., van Doorn-Scheele, M., van Doorn, T.T., Michels, R.P., van Doorn, R. G., Levi, M., &Hoekstra, J .B. (2004). Quality of life and metabolic control in patients with diabetes mellitus type 1 treated by continuous subcutaneous insulin infusion or multiple daily insulin injections. Neth J Med., 62(10):383-7.

IDF Diabetes Atlas (2012), 5th Edition, 2012 Update, Brussels: International Diabetes Federation: 2012.

IDF Diabetes Atlas (2014), 6th Edition Update, International Diabetes Federation, Available: http://www.idf.org/worlddiabetesday/toolkit/gp/facts-figures .

Klonoff, D. C., & Reyes,J. S. (2009). Insulin pump safety meeting: summary report. J Diabetes Sci Technol., 3(2):396-402.

Ko, G. T., So, W. Y., Tong, P. C., Chan, W. B., Yang, X., Ma, R. C., Kong, A. P., Ozaki, R., Yeung, C. Y., Chow, C. C., & Chan, J. C. (2009). Effect of interactions between C peptide levels and insulin treatment on clinical outcomes among patients with type 2 diabetes mellitus.CMAJ.,180(9):919–926.

Koro. C. E., Bowlin, S. J., Bourgeois, N., & Fedder, D.O. (2014). Glycemic control from 1988-2000 among US adults diagnosed with type 2 diabetes: a preliminary report. Diabetes Care, 27(1):17-20.

Lynch, P. M., Riedel, A. A., Samant, N., Fan, Y., Peoples, T., Levinson, J., & Lee, S. W. (2010). Resource utilization with insulin pump therapy for Type 2 diabetes mellitus. Am J Manag Care., 16(12):892-6.

Nathan, D. M., Cleary, P. A., Backlund, J. Y., Genuth,S. M., Lachin, J. M., Orchard, T.J.,Raskin, P. &Zinman, B. (2005). Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. N Engl J Med., 353(25):2643-53.

National Diabetes Fact Sheet (2011).National Center for Chronic Disease Prevention and Health Promotion.Division of Diabetes Translation. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

NCSL (2011).Providing diabetes health coverage: State laws &programs.National Conference of State Legislatures. Issues& Research. Health 2011. Available at: http://www.ncsl.org/IssuesResearch/Health/DiabetesHealthCoverageStateLawsandPrograms/tabid/14504/Default.aspx

NIHCE (2014).National Institute for Health and Clinical Excellence. Available at: http://www.nice.org.uk/usingguidance/commissioningguides/insulinpumps/specifying.jsp

Oglesby, A. K., Secnik, K., Barron, J., Al-Zakwani, I., &Lage, M. J. (2006). The association between diabetes-related medical costs and glycemic control: a retrospective analysis. Cost EffResourAlloc., 4:18-26.

Pouwer, F., &Hermanns, N. (2009). Insulin therapy and quality of life: A review. Diabetes Metab Res Rev. 2009, Suppl 1:S4-S10.

Raskin, P., Bode, B. W., Marks, J.B., Hirsch, I. B., Weinstein, R. L., McGill, J.B., Peterson, G. E., Mudaliar, S. R., & Reinhardt, R. R. (2003). Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes. A randomized, parallel-group, 24-week study.Diab Care., 26(9):2598-603.

Reznik, Y., Morera, J., Rod, A., Coffin, C., Rousseau, E., Lireux, B., & Joubert, M. (2010). Efficacy of continuous subcutaneous insulin infusion in type 2 diabetes mellitus: a survey on a cohort of 102 patients with prolonged follow-up. Diabetes Technol Ther., 12(12):931-6.

Rosenkoetter, M. M., Stachura, M. E., Dias, J. K., Wood, E. A., & Brown, D. J. (2014). Assessment of Insulin Administration Methods: Perceptions by Patients and Significant Others.(Journal of Nursing Measurement, In Press).

Rubin, R. R., & Peyrot, M. (2009). Treatment satisfaction and quality of life for an integrated continuous glucose monitoring/insulin pump system compared to self-monitoring plus an insulin pump. J Diabetes Sci Technol., 3(6):1402-10.

Smith, S. M., Allwright, S., & O'Dowd, T. (2007). Effectiveness of shared care across the interface between primary and specialty care in chronic disease management. Cochrane Database Syst Rev., 3:CD004910.

Smith, S. M., Allwright, S., & O'Dowd, T. (2008). Does sharing care across the primary-specialty interface improve outcomes in chronic disease? A systematic review. Am J Managed Care.,14:213-24.

Stachura, M. E., Rosenkoetter, M. M., Wood, E. A., Dias, J., & Brown, D. (2011). Continuous Subcutaneous Insulin Infusion and Multiple Daily Injections: An Impact Study, Diabetes Technology Society Annual Meeting, San Francisco CA

Stephens, E. A., & Jeffner, J. (2010). Evaluating older patients with diabetes for insulin pump therapy. Diabetes TechnolTher., Suppl 1:S91-7.

Urzúa,M. A., Bravo, M., Ogalde, M., & Vargas, C. (2011). Quality of life of older people living in Antofagasta, Chile. Rev Med Chil.,139(8):1006-14.

Urzúa, M. A., Shirino, A., &Valladares, G. (2011). Health related quality of life among patients with type 2 diabetes mellitus. Rev Med Chil.,139(3):313-20.

WHO (2011). Diabetes: Key facts. Available at: http://www.who.int/mediacentre/factsheets/fs312/en/#