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Partner Perspectives on Closed Loop Systems

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ABSTRACT

Objective: Closed loop automated insulin delivery systems have the potential to transform diabetes management. Partners and relationships will be increasingly affected by these innovations. We examine current understanding of the partner's role in type 1 diabetes (T1D) management and technology, and provide an example of how to elicit partners' perspectives in technology research.

Research Design and Methods: We conducted a literature review and a small focus group with the partners of participants enrolled in a 5-day hybrid closed loop (HCL) clinical trial. Couples' questionnaire ratings of diabetes-related distress and hypoglycemia concerns were described.

Results: Partners play an integral and often helpful role in managing diabetes. They also report significant diabetes-related distress and fear of hypoglycemia, which have implications for relationships. Closed loop systems offer potential benefits such as hypoglycemia prevention and partners' online access to glucose data ("remote monitoring"). However, disruptive alerts, technical glitches, maintenance tasks, device size, and other drawbacks may strain partners and relationships. A partner focus group elicited several novel themes. Partners gained valuable insights about T1D from remote monitoring and identified hypoglycemia prevention as a major benefit. For all partners, hypoglycemia worries decreased during system use. However, partners also cited vicarious frustrations with the system, concerns about remote monitoring disrupting couple communication, and needs for technology-specific partner education.

Conclusion: Closed loop systems stand to affect partners and relationships. As researchers continue to design closed loop systems and devise their integration into standard clinical care, it will be vital to assess partner perspectives to increase satisfaction and success with this technology.

INTRODUCTION

Closed loop technologies—also known as automated insulin delivery or artificial pancreas systems—have the potential to transform diabetes management for individuals with type 1 diabetes (T1D) and their loved ones. Closed loop systems use a computer algorithm to administer insulin via a pump based on data from a continuous glucose monitoring (CGM) system and user inputs [1]. Anticipated benefits for individuals with T1D include better glucose control, reduced self-management burden, and improved quality of life [2-4]. Research has not examined possible effects of closed loop technology on spouses and partners. In response, we provide background on the partner's role in T1D and how this might be altered by closed loop technology, and we present an example of how to elicit partner perspectives through focus group research conducted as part of a hybrid closed loop (HCL) clinical trial.

Diabetes and the Role of Partners

The intensive nature of diabetes management means that partners often help individuals with diabetes to safeguard their health. Partners lend both emotional and practical support [5]. They can display understanding and compassion, and can provide frontline assistance to the individual in handling daily T1D care tasks [6]. Partners are uniquely positioned to intervene in episodes of severe hypoglycemia when the individual with T1D cannot help him or herself [7].

Partners make a difference in health and quality of life outcomes for couples in which one partner has T1D or type 2 diabetes (T2D). Higher relationship quality is associated with lower diabetes-related distress, better quality of life, and greater adherence to the medical regimen [8-11]. Partner encouragement may also help individuals with T1D get more benefit from CGM [12]. A recent T2D-focused study found positive effects on glycemic control for a couples-based health intervention [13].

Partners' Management Stresses

Difficulties managing T1D may take a toll on partners and on the relationship as a whole. Partners of those with T1D and T2D experience high levels of diabetes-related distress [8] and can be quite distressed even when the partner with diabetes is not distressed [14]. Partners worry about management issues, such as the individual's ability to reduce long-term health complications related to hyperglycemia [6]. Tension may arise because of conflicts over blood glucose checking or insulin dosing, and when the partner believes their loved one is not doing enough to manage T1D [11]. Partners may not feel skilled or knowledgeable enough to help with management tasks and may withdraw support or lend support in ways that frustrate the individual with T1D [5]. Partners also perceive low social support related to the diabetes challenges they experience [7, 8].

Fears specific to hypoglycemia have far-reaching consequences for partners and relationships. Some studies suggest that partners are often more concerned about hypoglycemia than are their significant others with T1D [15, 16], perhaps because the partner has firsthand experience witnessing the individual in a disturbingly altered or unconscious state during a severe low [7]. Partners of individuals with hypoglycemia challenges are at greater risk for diabetes-related distress, marital conflict, and sleep problems [15], and report intense anxiety and vigilance directed towards keeping their loved one safe, which can result in resentment and restriction of valued life activities [6, 7]. These anxieties can lead to diminished self-management, as individuals with T1D reduce insulin doses to spare their partners from hypoglycemia worries [5].

Partners and Diabetes Technology

Very little research has examined how advanced diabetes technologies affect partners, but the few relevant studies that exist describe technology as a positive force in family life and relationships. For example, insulin pumps are said to give more autonomy to the individual with T1D; partners report having little detailed knowledge of how the device works and feeling relieved from the burden of overseeing insulin dosing [6]. In our clinical experience, CGM use can reduce family conflict and hypoglycemia fears by providing greater information about glucose trends and alerting individuals to high- and low-range glucose levels. Remote monitoring, an additional feature of CGM, allows the individual with T1D to share data with a partner using an online platform, thus providing peace of mind even when couples are apart [1]. Some studies about the experience of remote monitoring have highlighted the reduced worry of parents, many of whom wake up on a nightly basis to check that their child with diabetes is not dangerously low [17]. A similar advantage is expected for partners, who report sleep loss related to hypoglycemia fears [7].

Closed loop systems are expected to offer additional advantages beyond the sum of their device parts by providing the advantages of the insulin pump and CGM with an algorithm that automates insulin delivery. In clinical trials, closed loop systems have demonstrated preliminary safety and efficacy, and have prolonged the amount of time spent in ideal blood glucose ranges without elevating risk for lows [2, 3]. A clinical trial of pregnant women on overnight closed loop therapy also found improved glucose control [18], a benefit that could help assuage couples' worries about hyperglycemia-related pregnancy complications [6]. Hybrid closed loop (HCL) systems still require user inputs, however, benefits have been seen in reducing glucose variability, particularly at night [19]. Given this finding, HCL would be expected to reduce worry about nighttime lows reported by partners. These benefits of closed loop are also expected to reduce the management-related distress that strains relationships.

Despite these positive expectations for closed loop technology, there are known drawbacks that are likely to affect partners. As with previous technologies, closed loop systems are likely to not work perfectly all the time, to be vulnerable to breakage, to interrupt sleep or activities due to alerts, and to create stress related to cost and insurance—all issues that come up in partner focus groups discussing pumps and CGM [6]. Clinical trial participants using closed loop systems at night report hassles such as disruptive alerts, the annoyance of CGM calibration, obtrusive device size, and technical glitches, which were echoed by parents of adolescent participants [4, 20]. Partners may feel similarly frustrated by these limitations.

Closed loop systems may also fundamentally change how couples handle diabetes-related issues in ways that affect relationship quality. By automating insulin dosing processes, the closed loop system asks the user to let go of some decision making and trust the system. This aspect may offer mental relief to some couples, foster new anxieties for others, or create discomfort when one individual is more trusting of the closed loop system than his or her partner. The remote monitoring feature of closed loop may bring peace of mind to partners, but could feel intrusive to individuals with T1D if they are used to handling their diabetes-related data and decision making independently. Conversely, the complexity of closed loop technology, with its multiple devices and detailed data, could lead individuals with T1D to seek more support from partners. For some couples, this partner involvement could lead to greater closeness and mutual understanding, whereas for others it could create new frustrations and put unwelcome stress on the relationship.

EXAMPLE OF OBTAINING PARTNER PERSPECTIVES ON CLOSED LOOP

To examine partner and relationship factors in closed loop technology, we convened a focus group of partners of individuals with T1D who had just finished participating in a clinical trial of an HCL system. Qualitative methods were used to explore, from the partners' perspective, how the HCL system affected couple life with T1D, including the experience of remote monitoring, benefits and burdens of the HCL system, and how system use affected couple relationship dynamics.

Participants

Participants were 3 adult partners (mean age 29.4 ± 8.5; 2 male and 1 female) of individuals with T1D who were using an HCL system as part of a clinical trial. Clinical trial participants were required to be between 18 and 40 years of age, have a daily insulin need of more than 0.4 units per kilogram, and have had T1D for a year or longer. Current pregnancy, recent diabetic ketoacidosis, recent severe hypoglycemic episode, and other severe medical or psychiatric condition were exclusion criteria for the clinical trial.

Procedures

Clinical trial. The clinical trial consisted of a 5-day, 24-hour test of an early generation Android-based HCL system using a proportional-integral-derivative with insulin feedback (PID-IFB) algorithm. The study was designed to allow users to engage in ordinary day-to-day activities, including work, meals, exercise, and interaction with their partners. Day and night, partners were given a device that allowed them to remotely monitor and review their significant others' glucose data. Remote monitoring was recommended but study personnel did not measure how much partners accessed glucose data. All study procedures were approved by the research site's Institutional Review Board. More study details are available elsewhere [21].

Focus groups. At the conclusion of the trial, partners of the trial participants were convened for an hour-long focus group. Using a semi-structured interview approach, the

Table 1. Characteristics of Partner Participants and Individuals with T1D				
Measure	*Partner (N = 3)*		*Individuals with T1D*	
Age (mean ± SD)	29.4 ± 8.5		27.9 ± 7.4	
Sex	2 male; 1 female		2 female; 1 male	
Diabetes duration	—		17.7 ± 5.0	
Hemoglobin A1C	—		6.7 ± .45	
	Baseline	*Follow-up*	*Baseline*	*Follow-up*
DDS-SP (mean ± SD	1.98	1.54	—	—
T1-DDS (mean ± SD)	—	—	1.60	1.74
HFS-W (mean ± SD)	1.57	.89*	.94	.68

Note. DDS-SP = Diabetes Distress Scale-Spouse/Partner mean score; T1-DDS = Type 1 Diabetes Distress Scale mean score; HFS-W = Hypoglycemia Fear Survey-Worry subscale mean score. * Significant change from baseline score ($p < .05$).

interviewer asked partners to reflect on how the HCL system affected themselves, their significant others with T1D, and their relationships. The discussion was audio-recorded, transcribed, and coded by the first author in NVivo software [22] using a codebook previously generated for a related study not including partners. Codes that carried over to the current study included: the learning and adjustment process of using the system, attitudes about future system use, giving up control to the system, experiences wearing or handling the system, and codes reflecting the system's usability, accuracy, algorithmic decision making, data outputs, burdens, and performance in different situations. Coding adjustments were made in consultation with the second author (MT) who independently reviewed the transcript. This review process identified a new code (relationship-related aspects of system use), which was then applied. Based on a content analysis approach [23], themes were abstracted from the data and summarized.

Quantitative measures. Clinical trial participants and their partners completed validated measures of diabetes-related psychosocial factors before the clinical trial and 6 days afterward, once HCL system use had ended. Trial participants completed the 28-item Type 1 Diabetes Distress Scale (T1-DDS) [24], which assessed degree of emotional distress related to different aspects of managing T1D using a 1-to-6 Likert scale (baseline Cronbach's $\alpha = .93$). Partners completed a 21-item version of the DDS for spouses and partners (DDS-S/P) [8] assessing, for example, degree of frustration "that my partner shuts me out of his or her diabetes" (1-to-5 scale; baseline $\alpha = .96$). Each member of the couple completed the 18-item Hypoglycemia Fear Survey-Worry Subscale (HFS-W) [25, 26], which assessed how much the respondent worried about issues faced during a hypoglycemic episode by the individual with T1D, such as, "my partner passing out in public" (0-to-4 scale; baseline αs = .77 for partners, .96 for trial participants). The trial participant's hemoglobin A1C was also measured at baseline from a blood draw.

RESULTS

Sample. Descriptive data of the participants and their significant others with T1D are shown in Table 1. Couples consisted of opposite-gender partners. Clinical trial participants had been living with T1D for an average of 17.7 years (SD = 5.0) and had hemoglobin A1C in clinically recommended range (mean SD = 6.7 ± .45). None of the partners themselves had T1D diagnoses. Partners and significant others reported low levels of diabetes-related distress (average item endorsement of "slight" or "a little"). They did not significantly differ on level of hypoglycemia worries, which happened "rarely" to "sometimes," based on the average item response. For partners only, hypoglycemia worries significantly decreased from baseline to follow-up (pre-study mean = 1.57; post-study mean = .89; $t = 6.08$; $p = .03$). As shown in figure 1, all three partners reported reduced hypoglycemia worries at the end of the clinical trial, compared to 6 days earlier just before the HCL system was started.

Partner Perspectives. Major themes that emerged from the focus group discussion concerned: knowledge gained

from remote monitoring; benefits of the HCL system for preventing hypoglycemia; vicarious frustrations with the system; concerns about intruding on the privacy of the significant other with T1D; and needs for greater technology-specific partner education.

"I've learned a lot more." Partners remarked that remote monitoring gave them new insights into how T1D affects their significant others' bodies. They found it an interesting learning experience to see glucose trend data and to study how the HCL system handled rising glucose levels after a meal. Partners expressed some awe at seeing firsthand how much goes into glucose management. They noted that remote monitoring allowed them to observe what was previously an "invisible" experience without having to bother their significant others. Some of this new knowledge applied to life after the trial. As one participant stated, "It takes an hour and a half for her blood sugar to start rising from a meal. I didn't know that. I figured it happened almost immediately. So now I can be prepared for those events."

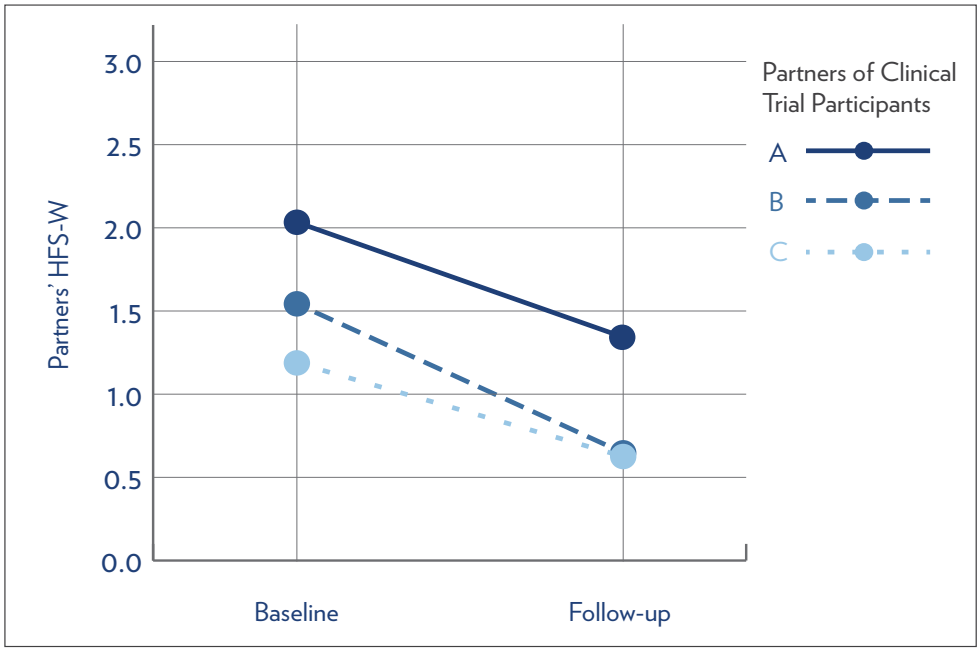
Of note, within this group, participants did not see themselves as needing to monitor these data closely, as they saw their significant others as self-sufficient in T1D tasks. They drew distinctions between themselves and parents of young children, who might need to watch remote monitoring data closely to help their loved one manage out-of-range glucose. They also noticed an increased mental burden from the greater awareness created by remote monitoring. As one participant noted: "My partner's T1D was more top of mind whereas sometimes his management can be to the point where I forget he's a Type 1 diabetic which is just crazy, and awesome."

"Prevention of lows is the thing I liked the most." Partners were impressed with how often the HCL system appeared to keep their significant others out of hypoglycemic range. They were struck by how the system suspended insulin delivery to head off a low and prevented prolonged lows overnight. Although they viewed their significant others as adept in T1D self-management, they cited lows as a common issue. As one partner stated, "He didn't go below 80 at all really and that was awesome because that's not my experience day to day." The system's benefit in this regard took some burden off the partners. One partner could measure the benefit in terms of supplies needed to treat lows: "The whole week she only had one juice box. That was it. [Outside this study,] I feel like I'm constantly at the store buying juice boxes."

"I just got frustrated." Although overall perceptions of the HCL system were positive, especially in terms of preventing hypoglycemia, partners experienced, along with their significant others, frustration with burdens of the system. Participants complained of "too many alerts," which caused them to silence or ignore the remote monitoring data. As one partner explained, "I didn't need that much information."

Partners were vicariously annoyed by the need to wear the multiple components that comprised the HCL system: "You have two dif-

Figure 1.
Partners' Hypoglycemia Worries Before and After Their Significant Others Took Part in the Hybrid Closed Loop Clinical Trial



Note. Individual partners are represented by lines A, B, and C. HFS-W = Hypoglycemia Fear Survey-Worry subscale mean score (possible score range of 0 to 4). Follow-up rating was collected 6 days after baseline.

ferent sites and you have to change those sites regularly. This thing has to have a battery and there's just too much going on." One partner complained that the system was hard to trust because the algorithm did not match his wife's own expertise in controlling hyperglycemia: "She seemed to hover around a little too high for too long." For this partner, it was difficult to wait and allow the system to intervene.

"That would be a marriage problem." Participants discussed problems of privacy that could arise from using the remote monitoring data. "It depends on the person," said one participant. "I can see when they ate, when they're exercising, when they're checking their fingers…. You can tell when they woke up…. It may be invasive to some people." Participants worried that remote monitoring could diminish their relationships as equal partners. As one partner stated, "I felt like a parent…. I felt like I was watching over her.... I felt like now she needs to explain herself. 'Well, I ate a late lunch or'—I felt like she was in the spotlight. She didn't have to be and it's not my place to put her there." Participants remarked that outside of the study, it would be important to set limits on use of the data. In one exchange, they imagined a scenario in which remote monitoring data could threaten marital harmony:

> RESPONDENT 3: Outside of the context of the study, it wouldn't have been good.
>
> INTERVIEWER: [Remote monitoring] wouldn't have gone well?
>
> RESPONDENT 3: That would be a marriage problem.
>
> RESPONDENT 1: [Pretending to speak to significant other] "Wow, you're eating dinner right now? What are you doing?"
>
> RESPONDENT 3: That is exactly what would happen. And he'd be like, "I'm eating, leave me alone."
>
> RESPONDENT 1: "Hey, what are you eating dinner for? We were supposed to go out and do something tonight."
>
> RESPONDENT 3: Or like, "We're going out to dinner in an hour and a half. Why are you eating a peanut butter sandwich right now?"
>
> RESPONDENT 2: So they'd either have to cheat on the system or acknowledge [eating at an unplanned time].

The overall view of the group was that remote monitoring could provide useful insights into the experience of their significant others, but that caution was necessary to respect the autonomy and privacy of individuals with T1D.

"I don't really know the ins and outs of it." One participant raised the issue that partners receive little education about how to support their significant other with T1D, and that some training would be helpful to navigate the specific opportunities and challenges posed by closed loop systems. Couples-based education would help partners learn how to make the most use of system data and "defuse some of that interpersonal tension" that may happen as couples discuss remote monitoring data.

CONCLUSIONS AND IMPLICATIONS

Spouses and romantic partners of individuals with T1D have a significant effect on their loved ones' health behavior and diabetes-related quality of life, and they themselves are affected by the challenges of T1D. As diabetes care becomes more and more technologically complex, partners stand to make an important impact on how well these systems work for their significant others. The current study shares a few partner perspectives regarding what it is like to perform remote monitoring of an HCL system and the potential impacts this new role could have on relationships.

Despite the small number of participants assessed in this study, the issues raised in the focus group echoed and expanded upon past findings regarding partner experiences. Partners in this study felt a sense of connection but also apartness from their loved ones with T1D. On one hand, partners seemed to understand their loved ones' diabetes-related challenges, but they also acknowledged that, as people without T1D, they were somewhat protected from the daily mental burdens faced by their significant others. They appreciated the ability to see constant CGM data through remote monitoring, but they also wanted to preserve the independence of their partner with T1D.

As with other partner-focused studies, worries about hypoglycemia figured prominently here. Although partners viewed their significant others as "high functioning" in their T1D management, they recognized that hypoglycemia was a frequent danger, and they experienced relief from the HCL system's potential to reduce lows. For all three partners, hypoglycemia worries decreased over the course of the 5-day HCL trial. Given that hypoglycemia fears

are a major source of diabetes-related distress and marital conflict for couples managing T1D [8, 15], HCL systems have the potential to reduce this burden and positively affect relationship quality.

Of note, the experience of remote monitoring, which is a feature of current CGM systems and is discussed in the literature largely in positive terms for loved ones [27], received a mixed reaction from this study's participants. Partners gained greater understanding of their significant others' management challenges, but worried that remote data could lead to nagging, invasion of privacy, and greater relationship tension. The limited research on remote monitoring tends to focus on the benefits for parents in terms of managing hypoglycemia. However, the distinct nature of couple relationships might necessitate boundaries that balance safety considerations with needs for partner autonomy. As noted by one participant, partner education is needed to foster communication skills that maximize the benefits of closed loop technology while preserving relationship functioning.

It is important not to assume that the viewpoints shared by partners in this study apply to all partners of individuals with T1D who may use closed loop systems in the future. The small sample size, brief time period on the HCL system, and the unique characteristics of the trial sample (relatively young age, hemoglobin A1C in recommended range, "self-sufficient" in diabetes tasks, low self-rated diabetes distress) limit the generalizability of these findings. Individuals with greater self-management challenges may encounter different benefits or struggles with a closed loop system, which may then impact their partners and relationships. Given that closed loop systems are still in an investigative stage, there are limits to how many trial participants and partners can currently be assessed regarding their system experiences. Nevertheless, as suggested by the current study, meaningful data can be obtained from even a small number of individuals and we hope to encourage other investigators to capture the partner perspective in their studies. As these systems become more widely available, future investigations should build on this work through assessment of larger and more representative samples with longer-term experience of closed loop systems.

Loved ones' perspectives are critically important to individuals' satisfaction with closed loop technologies yet partner viewpoints have not been assessed in a systematic fashion. The current study contributes preliminary information about how partners may react to closed loop systems and how this technology will affect the relationships of individuals with T1D. More work is needed with diverse populations to broaden these insights. Recently, investigators have assembled the INSPIRE (Insulin Delivery Systems: Perceptions, Ideas, Reflections, and Expectations) study working group to develop psychosocial measures that can be integrated into closed loop system research; these measures will capture the viewpoints of multiple stakeholders, including partners [28]. As researchers continue to design closed loop systems and devise their integration into standard clinical care, it will be vital to assess partner perspectives to increase individuals' satisfaction and success with this technology.

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CONFLICT OF INTEREST DISCLOSURES

The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no potential conflicts of interest relevant to this article.

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