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Educating Families on Real Time Continuous Glucose Monitoring:

The DirecNet Navigator Pilot Study Experience

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Abstract

Purpose—The purpose of this article is to describe the process of educating families and children with type 1 diabetes on real time continuous glucose monitoring (RT-CGM) and to note the similarities and differences of training patients using continuous subcutaneous insulin infusion (CSII) versus multiple daily injections (MDI).

Methods—A total of 30 CSII participants and 27 MDI participants were educated using the Navigator RT-CGM in a clinical trial. Time spent with families for visits and calls was tracked and compared between patient groups. The Diabetes Research in Children Network (DirecNet) educators were surveyed to assess the most crucial, time intensive, and difficult educational concepts related to CGM.

Results—Of the 27 MDI families, an average of 9.6 hours was spent on protocol-prescribed visits and calls (not measured in CSII) and 2 hours on participant-initiated contacts over 3 months. MDI families required an average of 5.4 more phone contacts over 3 months than CSII families. According to the DirecNet educators, lag time and calibrations were the most crucial teaching concepts for successful RT-CGM use. The most time was spent on teaching technical aspects, troubleshooting, and insulin dosing. The most unanticipated difficulties were skin problems including irritation and the sensor not adhering well.

Conclusion—Educators who teach RT-CGM should emphasize lag time and calibration techniques, technical device training, and sensor insertion. Follow-up focus should include insulin dosing adjustments and skin issues. The time and effort required to introduce RT-CGM provided an opportunity for the diabetes educators to reemphasize good diabetes care practices and promote self-awareness and autonomy to patients and families.

As treatment of type 1 diabetes evolves, so does the expertise of the educators involved in the care of type 1 diabetes patients. The current role of pediatric diabetes educators includes teaching insulin management, blood glucose testing, sick day management, and treatment of hyperglycemia and hypoglycemia, all based on two sources of data: self monitoring blood glucose (SMBG) testing and blood/urine ketone testing. The standard of care for diabetes is shifting as technology advances with real time continuous glucose monitoring (RT-CGM) devices. RT-CGM devices record and report unprecedented detail about glucose levels and glucose trends over time. The devices offer additional benefits such as programmable glucose threshold alarms, trend analyses, event markers, and statistics. Currently, 4 devices are FDA approved for adults 18 years and older (the Medtronic MiniMed Guardian REAL-Time System, the Medtronic MiniMed Paradigm REAL-Time System, the DexCom STS,

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and most recently the Abbott FreeStyle Navigator). Two devices that are currently FDA approved for pediatric use are the Medtronic MiniMed Paradigm REAL-Time System (with the 522K/722K model pump) and the Medtronic MiniMed Guardian REAL-Time System (pediatric model). Because off-label prescription practices and widespread pediatric approvals are being sought, expansive use of RT-CGM in pediatrics is imminent. In addition to learning how to utilize RT-CGM in the clinic, the diabetes educator also needs to prepare for a paradigm shift toward RT-CGM as a primary management tool in diabetes care.

The Diabetes Research in Children Network (DirecNet) has been a pioneer in evaluating RT-CGM devices in the pediatric population.[1-6] DirecNet consists of 5 clinical centers, 1 data coordinating center, and 1 central laboratory. DirecNet is sponsored by the National Institute of Health. Each DirecNet research site is staffed with a minimum of 1 full-time research coordinator/educator to oversee the daily management of the DirecNet studies. The educator (a certified diabetes educator, nurse, nurse practitioner, or dietitian) has typically assumed the role as the patient's primary clinical case manager and educator for protocols that have tested the efficacy of RT-CGM in the treatment of youth with type 1 diabetes.

The DirecNet Study Group carried out an outpatient pilot study that utilized the Navigator (the FreeStyle Navigator™ Continuous Glucose Monitoring System, Abbott Diabetes Care, Alameda, California). The study involved two sets of patients: patients receiving continuous subcutaneous insulin infusion (CSII) and patients using multiple daily injection (MDI). The results of the study are published elsewhere.[7-9] In this article, we describe the process of educating families and children with type 1 diabetes on RT-CGM, and note the similarities and differences of training patients using CSII versus MDI.

Methods

Participants

This study piloted the Navigator in two populations: children using CSII and children on MDI. The research was conducted at the 5 DirecNet clinical centers and patients were recruited from the clinical populations at these centers who expressed interest in research studies of RT-CGM. Institutional review board approval was obtained at each center and informed consent was obtained from all participants. A total of 57 participants with type 1 diabetes ages 4 to 18 years were enrolled in the study between August 2005 and October 2006. Of the participants enrolled, 30 were being treated with CSII and 27 with MDI. Eligibility included a clinical diagnosis of type 1 diabetes mellitus for less than 1 year and a stable insulin regimen using either CSII or MDI for the prior 6 months. Participants were excluded for asthma that was medically treated in the prior 6 months, cystic fibrosis, and other medical conditions or medications that, in the judgment of the investigator, could affect wearing the sensors or the completion of any aspect of the protocol. The clinical characteristics of the study participants are shown in Table 1.

Research Design

The study design included a 13-week structured protocol involving 1 enrollment visit, 1 baseline visit, 4 follow-up visits, and 5 scheduled phone calls with the clinical center. Participants were trained on a blinded Navigator at enrollment (could not see data), and then on an unblinded Navigator at baseline (normal function). For concerns between study visits, families contacted the study educator by phone and email. At the 13-week visit, participants were given the option to continue in the study with minimal follow-up once every 3 months. During the study, research participants were asked to wear the Navigator device continuously, change the sensor every 5 days, calibrate the device with fingerstick glucose readings at 10, 12, 24, and 72 hours following insertion of the sensor, and respond to alarms.

For the first 13 weeks, participants were additionally asked to download the device on a weekly basis. Participants were instructed on an insulin adjustment algorithm to use as a guideline when making these changes.[10]

The Educational Process

The Navigator training was divided into several visits. At each visit, the following points were discussed with families per study protocol.

Visit 1. Enrollment.

- Diabetes educators introduced family to the difference between RT-CGM and SMBG.
- Diabetes educators taught participants about the different components of the system including the sensor, transmitter, and receiver.
- Diabetes educators instructed participants how to use a blinded Navigator, which did not provide sensor glucose readings or alarms for hypoglycemia or hyperglycemia for one week.
- Diabetes educators introduced participants to blood glucose testing with the Navigator meter built into the receiver.
- Diabetes educators instructed participants to calibrate the device with blood glucose tests and emphasized the importance of calibrating when glucose levels are relatively steady.
- Diabetes educators instructed participants on how to insert a sensor. Participants then inserted a sensor while being observed.

Visit 2. Baseline, one week after blinded CGM wear.

- Diabetes educators provided the participants with a real time unblinded device.
- Diabetes educators instructed the participants on the use of RT-CGM, including how to use, set, and respond to alarms, trend arrows, and continuous monitoring values. They also discussed lag time between blood glucose and continuous monitoring data.
- Diabetes educators instructed participants how to download and view retrospective trend and statistical data and taught them how to alter diabetes management based on both the real time data and retrospective data.
- Diabetes educators instructed participants how to use a DirecNet insulin adjustment algorithm as a guideline when making management changes.[10]

Follow-up visits and phone calls—Taken place during week 1, 3, 7, 13 and 0.5, 2, 4, 8, 10 weeks.

- Diabetes educators assessed participants for understanding and compliance with using the Navigator.
- Diabetes educators troubleshot problems with the device, alarms, calibrations, and downloading.
- Diabetes educators reviewed insulin management guidelines.
- Diabetes educators reviewed RT-CGM data and reinforced teaching.

- Diabetes educators assessed participants for adverse skin reactions from sensor wear.

Data Collection Measures

Data collected in this study included time and content of all contacts with both MDI and CSII patients, as well as insight from the educator's experiences. Data from the MDI and CSII groups were compared (see Data Analysis section).

Phone contacts—During scheduled phone contacts, participants were asked "Did you have any problems while using the Navigator since last contact?" They were then given 12 options to document what problems had occurred, including a write-in option. Time spent on scheduled phone contacts was recorded for both CSII and MDI participants on electronic case report forms. For concerns between scheduled study visits and phone calls, families contacted the study educator by phone and email. For these patient-initiated phone contacts, educators documented the reason for the call from 10 options on the case report forms, including a write-in option. Because these phone calls were initiated by the study participants/families, they represent the amount of additional help needed beyond the study protocol.

Study visits—During all scheduled visits, participants were again asked "Did you have any problems while using the Navigator since last contact?" They were then given the same options as during the phone contacts to document what problems had occurred. The total time spent and teaching time spent for scheduled study visits was recorded for the MDI group only because the collection of these data was added after the CSII participants were already enrolled. It is therefore not possible to compare the amount of protocol time spent on CSII versus MDI patients.

Educator surveys—After the initial 13-week study period was completed for both CSII and MDI participants, the educators were surveyed about their perception of the most crucial, most time consuming, and most difficult educational points related to RT-CGM. Each DirecNet clinical site returned one survey for analysis.

Data Analysis

Data were analyzed to characterize and compare the amount of time spent and the content of the education for the MDI versus CSII patient groups, Mean time spent on education (scheduled visits and calls) was calculated for the MDI participants and was broken down by visit types and phone calls. The frequency of patients reporting problems with the Navigator (scheduled visits and calls) and the nature of the problems were tabulated for both MDI and CSII participants. The total number and mean length of patient-initiated phone calls and visits were calculated and compared for both MDI and CSII participants. The Wilcoxon rank sum tests were performed to compare the number of and the time spent on patient-initiated calls for CSII versus MDI participants. Reasons for patient-initiated phone calls were tabulated in both MDI and CSII groups and compared. Educator surveys were compiled from the 5 clinical centers and responses compared for MDI versus CSII participants.

Results

Time Spent on Education

For the MDI participants whose time was recorded for protocol visits and phone calls (n = 27), an average of 9.6 hours of protocol-prescribed time was spent with the families during the first 13 weeks of the study (Table 2). This included the 6.2 hours that participants received on CGM training and diabetes management using the CGM. Diabetes management

and review of CGM data were the most time intensive aspects of the phone call and follow-up visits.

For both CSII and MDI participants, every protocol visit and phone contact included a question about whether the participant had any problems while using the Navigator since last contact. The results related to sensor insertion and adhesion are presented in Table 3.

Comparison of CSII and MDI on Patient-initiated Phone Contacts

Both MDI and CSII participants called the DirecNet educators in addition to the protocol-prescribed phone calls and visits. The MDI participants called more frequently than the CSII participants (13.3 calls per person vs 7.9 calls per person; $P = .05$) and required longer intervention (106 minutes per person vs 82 minutes per person), although this latter difference was not statistically significant (Table 4). The majority of the phone calls were related to problems and questions about the Navigator device in both groups (Table 5).

Educator Survey Results

The DirecNet educators responded to survey questions about the most crucial, most time intensive, and most difficult teaching points (Table 6).

Most Crucial Teaching Points

The study educators identified the explanation of lag time as one of the most crucial teaching points for families learning RT-CGM in both CSII and MDI participants. Lag time refers to the physiological lag between capillary blood glucose data and interstitial sensor data, which is approximately 4 to 10 minutes.[11] This concept was essential for families trusting the accuracy of the device and understanding the lag time discrepancies.

The educators also concurred that instructing how to identify good calibration times was crucial to the RT-CGM success. The study educators emphasized the importance of calibrating when glucose levels are stable, typically before a meal or 2 hours after rapid acting insulin or food has been given. Families were instructed that the RT-CGM data is more accurate if the blood glucose is stable during the calibration process, which then diminished the likelihood of a failed calibration.

Most Time Intensive Teaching Points

The majority of educators (60%) believed that teaching insulin dosing with the DirecNet guidelines was the most time intensive teaching point for CSII, whereas only 20% chose this for the MDI group. The MDI group answers were split between technical troubleshooting and skin issues/sensor insertion as the most time intensive points. The skin issues/sensor insertion issues were identified only for the MDI group as the most time intensive aspect, reflecting more time spent on teaching the insertion of the Navigator sensor and working with the skin issues associated with sensor placement.

Most Difficult Teaching Point

The insulin dosing guideline/algorithm instruction was considered one of the most difficult teaching points for both groups. The guidelines were tailored for insulin modality so the CSII guidelines and MDI guidelines included the same dosing principles but different practical applications. Skin issues/sensor insertion were also selected in both groups as most difficult (40%), with 20% of educators choosing this option for MDI and CSII groups respectively. Lag time was chosen for the CSII group only (40%) and technical/troubleshooting for the MDI group only (20%).

Discussion

The data in the DirecNet education process are a combination of quantifiable data and the qualitative experience of the educators and families. The procedural experience was intensified by families being invited to contact the study staff freely regarding questions and concerns about the device. Overall, the educators were surprised by the amount of time devoted to assisting families with CGM questions.

The number of patient-initiated phone contacts for the CSII versus MDI groups shows a difference in the amount of education and reinforcement needed. MDI families required more contact to carry out study procedures, specifically wearing the Navigator CGM. This can be explained by the fact that MDI families had less experience with technical devices related to diabetes. For most MDI participants this was also their first exposure to wearing a device attached to the skin, whereas the CSII group had already become accustomed to wearing a pump infusion set. The data do not allow for a robust comparison of CSII and MDI education requirements, as time was not recorded for the CSII patients' procedural visits.

In regard to teaching the concept of lag time, one educator expressed that, "The first and continuing roadblock in people's minds when they first use the [Navigator] is that the values aren't matching up exactly. Until [the family] understands the lag time issue and the value of trends, there is a reliability issue and mistrust of the system." Thorough lag time discussion alleviated anxiety associated with the families seeing the disparity between the sensor glucose and the blood sugar values. A secondary benefit included opportunity to discourage families from inappropriately dosing insulin based on RT-CGM values. Overall, the educators emphasized the value of trend information with RT-CGM and addressed the lag time and variability of individual sensor readings.

Proper calibration technique is important with the Navigator device. Unlike other RT-CGMs, the Navigator has a 10-hour warm-up period after sensor insertion and before the first calibration value is required. Careful timing of insertion allowed families to feel more in control of when the device would request a calibration blood glucose. With careful instruction, families could anticipate when blood glucose levels were most likely to be stable, dependable, and accepted for the purpose. The education further alleviated frustration from calibration failure alarms and having to repeat the process multiple times.

The educators agreed that both CSII and MDI participants required extensive technical training and troubleshooting on the Navigator device. Because both groups were RT-CGM naïve, they received the same education during the enrollment and baseline visits. Differences between the groups' technical aptitudes were not noted in the educators' survey.

The majority of educators listed insulin dosing guidelines as most time intensive for CSII, and one site listed this as most time intensive for MDI. Interestingly, this response also tied for the most difficult teaching aspect in both groups. Insulin dosing was implemented using the DirecNet algorithm/guideline for insulin adjustments both in the clinic setting and in their own home. The guidelines were conceptually the same for both groups and they were modified for insulin modality. The survey results do not necessarily reflect the comments from educators on teaching dosing guidelines. Many educators commented about the difference between CSII and MDI families in the educator survey. The following are excerpts of the responses:

> The MDI patients are not used to taking extra doses of insulin, and they were challenged to make more [insulin] corrections, such as after school. Usually, they would just wait until dinner.

> I found it simpler to identify dosing changes with MDI patients, but behaviorally it was more difficult to implement. It is easier to discuss reprogramming a basal rate in a pump than to convince a child to take an extra shot of insulin during the day.
>
> Because adjustments are more difficult to make in subjects using MDI, it would take a lot of time and feedback to make our MDI subjects feel more comfortable about making any dose adjustments.
>
> The guidelines took longer on some MDI patients since we had to convert [sliding scale dosing] from insulin to carbohydrate ratios.

These excerpts support the educators' perception of the additional complexity with the MDI group guidelines. It could be suggested that MDI participants were less accustomed to making insulin management changes on their own and the consequences of those changes were more traumatic (ie, taking additional injections). Practically speaking, there was a larger psychological cost to MDI patients versus CSII patients pertaining to dosing adjustments. RT-CGM data easily uncovered glucose patterns in both groups that required action to be taken on the part of the educator as well as the family. The DirecNet educators have learned from this experience that both CSII and MDI patients will require a large amount of training and reinforcement of dosing guidelines using RT-CGM. It will require further study to determine whether there is a difference between groups in adjustment frequency.

Perhaps the most unexpected difficulty for both CSII and MDI patients involved the magnitude of skin issues related to Navigator use. During the 476 scheduled phone calls and completed visits, 306 reports of skin and sensor issues occurred, including the sensor not inserting properly (7 for CSII, 7 for MDI), too much bleeding during insertion (20 for CSII, 22 for MDI), a sensor being pulled out accidentally/not sticking adequately (35 for CSII, 21 for MDI), and a sensor was removed because of discomfort (7 for CSII, 8 for MDI). The study procedures did not breakdown the reasons as indicated above for the 109 (CSII) and 134 (MDI) patient-initiated phone calls.

Primary concerns included sensors not adhering to the skin and rashes from the tape. A variety of adhesive agents were used to supplement the built-in sensor tape, and they were evaluated for effectiveness and reactivity on each participant. DirecNet educators worked intensively with families to create combinations of products and skin preparation regimens that would work for the individual child. One educator noted, "I felt like I was in arts and crafts class, trying different combinations of tapes and skin preps and sites to make that sensor stick on a sweating, swimming child." The educators universally reported difficulty with having the sensor stick adequately to children. Often, combinations of products were needed to keep the sensors on for the 5-day wear. This will be a concern in commercial use of CGMs, when families are paying for sensors and relying on them lasting for the expected duration.

Future Applicability

The DirecNet experience in the Navigator pilot studies will apply to diabetes educators who work with RT-CGM in initial education and continued use. As RT-CGM evolves into routine diabetes care, all educators will need to identify and emphasize key teaching issues surrounding the technology. Our experience has shown that RT-CGM, like diabetes itself, is a practical, psychological, family-centered process. The diabetes educator must use assessment skills throughout the training process to competently address family needs, including assessing knowledge, fears, and learning capabilities. Initial emphasis is well placed on physiological explanation of lag time and the importance of calibrations. Technical training and sensor insertion immediately follow. Additional time may be needed

with MDI participants on sensor insertion. Follow-up focus should build on how to use RT-CGM data as a tool to assist in making insulin adjustments.

The intensity of the DirecNet experience will be mediated in clinical use by the utilization of company support helplines. The helplines will provide support for commercial RT-CGM products, thus removing the bulk of device troubleshooting by the clinical staff. Much of the inherent frustration in starting the device is mitigated over time as the family gets the hang of it. It is important to note that our families were very satisfied with the information that the Navigator provided[8] and with the algorithms that they were taught to adjust their insulin regimens.[10] Most important overall, RT-CGM provided an opportunity for our diabetes educators to reemphasize good diabetes care practices and promote self-awareness and autonomy to patients and families with type 1 diabetes.

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Appendix

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References

1. Diabetes Research in Children Network (DirecNet) Study Group. The accuracy of the GlucoWatch G2 biographer in children with type 1 diabetes: results of the Diabetes Research in Children Network (DirecNet) accuracy study. Diabetes Technol Ther. 2003; 5:791–800. [PubMed: 14633344]
2. Diabetes Research in Children Network (DirecNet) Study Group. Accuracy of the GlucoWatch G2 Biographer and the continuous glucose monitoring system during hypoglycemia: experience of the Diabetes Research in Children Network. Diabetes Care. 2004; 27:722–726. [PubMed: 14988292]
3. Chase HP, Beck R, Tamborlane W, et al. A randomized multi-center trial comparing the GlucoWatch Biographer with standard glucose monitoring in children with type 1 diabetes. Diabetes Care. 2005; 28:1101–1106. [PubMed: 15855573]
4. Tansey MJ, Beck RW, Buckingham BA, et al. Accuracy of the modified Continous Glucose Monitoring System (CGMS) sensor in an outpatient setting: results from a Diabetes Research in Children Network (DirecNet) study. Diabetes Technol Ther. 2005; 7:109–114. [PubMed: 15738708]
5. Fiallo-Scharer R. Eight-point glucose testing versus the continuous glucose monitoring system in evaluation of glycemic control in type 1 diabetes. J Clin Endocrinol Metab. 2005; 90:3387–3391. [PubMed: 15784705]
6. Diabetes Research in Children Network (DirecNet) Study Group. Psychological aspects of continuous glucose monitoring in pediatric type 1 diabetes. Pediatr Diabetes. 2006; 7:32–38.
7. Wilson DM, Beck RW, Tamborlane WV, et al. The accuracy of the FreeStyle Navigator Continuous Glucose Monitoring System in children with type 1 diabetes. Diabetes Care. 2007; 30:59–64. [PubMed: 17192334]
8. Buckingham B, Beck RW, Tamborlane WV, et al. Continuous Glucose Monitoring in Children With Type 1 Diabetes. J Pediatr. 2007; 151:388–393. [PubMed: 17889075]
9. Weinzimer S, Xing D, Tansey M, et al. FreeStyle Navigator Continuous Glucose Monitoring System use in children with type 1 diabetes using glargine-based multiple daily dose regimens: Results of a pilot trial Diabetes Research in Children Network (DirecNet) Study Group. Diabetes Care. 2008; 31:525–527. [PubMed: 18096811]
10. Diabetes Research in Children Network (DirecNet) Study Group. Use of the DirecNet Applied Treatment Algorithm (DATA) for diabetes management with a real-time continuous glucose monitor (the Freestyle Navigator). Pediatric Diabetes. 2008; 9:142–149. [PubMed: 18221427]
11. Boyne MS, Silver DM, Kaplan J, Saudek CD. Timing of changes in interstitial and venous blood glucose measured with a continuous subcutaneous glucose sensor. Diabetes. 2003; 52:2790–2794. [PubMed: 14578298]

Table 1

Demographics of Participants Stratified by Insulin Modality

	CSII Participants, n = 30 (%)	MDI Participants, n = 27 (%)
Female	12 (40)	14 (52)
Race/ethnicity		
White	28 (93)	25 (93)
Hispanic/Latino	1 (3)	1 (4)
Asian	1 (3)	1 (4)
Age, y		
4 to 12	17 (57)	15 (56)
12 to 18	13 (43)	12 (44)
Mean ± SD	11.2 ± 4.1	11.0 ± 3.9
Diabetes duration, years	5.8 ± 3.0	4.0 ± 3.1
Severe hypoglycemia in past 6 months	0	0
A1C		
≤ 7.5%	24 (80)	10 (37)
>7.5%	6 (20)	17 (63)
Mean ± SD	7.1% ± 0.6%	7.9% ± 1.0%
BMI percentage		
≤ 50	2 (7)	2 (7)
>50 to 75	8 (27)	9 (33)
>75 to 100	20 (67)	16 (59)

Abbreviations: CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

Table 2

Total Time Spent and Teaching Time Spent per Contact (MDI Participants Only)

	MDI Participants (n = 27)		
	Average Time Spent per Contact, Minutes	**Number of Contacts per Participant**	**Average Total Time Spent per Participant, Minutes**
Enrollment visit	131	1	131
Teaching time	75		75
Device teaching	54		54
Data review	6		6
Diabetes management	15		15
Baseline visit	125	1	125
Teaching time	91		91
Device teaching	30		30
Algorithm teaching	26		26
Data review	18		18
Diabetes management	17		17
Follow-up visits	68	3.7	253
Teaching time	43		158
Device teaching	7		27
Algorithm teaching	5		20
Data review	15		57
Diabetes management	15		54
Follow-up phone calls	16	4.2[a]	68[a]
Teaching time	12		51
Device teaching	3		11
Algorithm teaching	1		4
Data review	4		15
Diabetes management	5		20

Abbreviation: MDI, multiple daily injections.

[a]Averaged over all participants (ie, include participants with zero contacts).

Table 3

Results From Scheduled Phone and Visit Contacts Related to Problems With Sensor Use and Adhesive Issues During the 3-month Study

	CSII Participants, n = 30 Number of Contacts (%)	MDI Participants, n = 27 Number of Contacts (%)
Total contacts	262	214
Did the participant have any problems while using the Navigator since last contact?		
No	103 (39)	67 (31)
Yes	159 (61)	147 (69)
If Yes, did any of the following occur?[a]		
Sensor did not insert properly	7 (3)	7 (3)
Too much bleeding at area of sensor insertion	20 (8)	22 (10)
The sensor was pulled out accidentally	35 (13)	21 (10)
The participant removed the sensor due to discomfort	7 (3)	8 (4)
Other reasons not related to sensor insertion and adhesion	102 (39)	103 (48)

Abbreviations: CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

[a]Participants could select more than one reason in same contact so the numbers do not add up to the total.

Table 4

Time Spent on Patient-initiated Phone Calls for CSII Versus MDI Participants During the 3-month Study

	Unscheduled Phone Calls	Unscheduled Visits[a]
CSII participants (n = 30)		
Number of contacts	238	19
Average time spent per contact, minutes	10	NA
Average number of contacts per participant[b]	7.9	0.6
Average total time spent per participant, minutes[b]	82	NA
MDI participants (n = 27)		
Number of contacts	360	13
Average time spent per contact, minutes	8	23
Average number of contacts per participant[b]	13.3	0.5
Average total time spent per participant, minutes[b]	106	11

Abbreviations: CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

[a] Time was not tracked for CSII patients.

[b] Averaged over all participants (ie, include participants with zero contacts).

Table 5

Patient-initiated Phone Calls by Reason for CSII Versus MDI Participants

	CSII Participants (n = 30)			MDI Participants (n = 27)		
	Number of Phone Calls	Number of Participants	Average Number of Calls per Participant[a]	Number of Phone Calls	Number of Participants	Average Number of Calls per Participant[a]
Unscheduled phone calls	238	29	7.9	360	27	13.3
Problem with algorithms	5	4	0.2	0	0	0
Problem/question on Navigator	109	26	3.6	134	24	5.0
Problem/question with HGM	3	3	0.1	2	2	0.1
Skin reaction	3	1	0.1	6	4	0.2
Hyperglycemia	11	9	0.4	2	2	0.1
Hypoglycemia	6	3	0.2	1	1	0.0
Problem/question downloading	23	14	0.8	27	15	1.0
Visit scheduling	28	13	0.9	39	13	1.4
Additional supplies	5	3	0.2	15	8	0.6
Other	90	22	3.0	187	26	6.9

Abbreviations: CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

[a]Participants could have more than one call over 3 months and check more than one reason on same call. The average number of calls per participant was averaged over all participants (ie, include participants with zero calls).

Table 6

DirecNet Educator Survey Results

	CSII Participants	MDI Participants
Most crucial teaching point for each group	Lag time (2/5)	Lag time (2/5)
	Calibrations (2/5)	Calibrations (2/5)
	Guidelines insulin dosing (1/5)	Skin issues/sensor insertion (1/5)
Most time intensive teaching point	Guidelines/insulin dosing (3/5)	Technical/troubleshooting (2/5)
	Technical/troubleshooting (2/5)	Skin issues/sensor insertion (2/5)
		Guidelines/insulin dosing (1/5)
Most difficult teaching aspect	Guidelines/insulin dosing (2/5)	Guidelines/insulin dosing (2/5)
	Lag time (2/5)	Skin issues/sensor insertion (2/5)
	Skin issues/sensor insertion (1/5)	Technical/troubleshooting (1/5)

Abbreviations: DirecNet, Diabetes Research in Children Network; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.