Effect of an Automated Advice Algorithm (CloudConnect) on Adolescent-Parent Diabetes-Specific Communication and Glycemic Management: A Randomized Trial

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ABSTRACT

Introduction: Because adolescence is a time of difficult management of Type 1 diabetes (T1D) in part from adolescent-parent shared responsibility of T1D management, our objective was to assess the effects of a decision support system (DSS) CloudConnect on T1D-related communication between adolescents and their parents and on glycemic management.

Methods: We followed 86 participants including 43 adolescents with T1D (not on automated insulin delivery systems, AID) and their parents/care-giver for a 12-week intervention of UsualCare + CGM or CloudConnect, which included a Weekly Report of automated T1D advice, including insulin dose adjustments, based on data from continuous glucose monitors (CGM), Fitbit and insulin use. Primary outcome was T1D-specific communication and secondary outcomes were hemoglobin A1c,

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time-in-target range (TIR) 70–180 mg/dl, and additional psychosocial scales.

Results: Adolescents and parents reported a similar amount of T1D-related communication in both the UsualCare + CGM or CloudConnect groups and had similar levels of final HbA1c. Overall blood glucose time in range 70-180 mg/dl and time below 70 mg/dl were not different between groups. Parents but not children in the CloudConnect group reported less T1D-related conflict; however, compared to the UsualCare + CGM group, adolescents and parents in the CloudConnect reported a more negative tone of T1D-related communication. Adolescent-parent pairs in the CloudConnect group reported more frequent changes in insulin dose. There were no differences in T1D quality of life between groups.

Conclusions: While feasible, the CloudConnect DSS system did not increase T1D communication or provide improvements in glycemic management. Further efforts are needed to improve T1D management in adolescents with T1D not on AID systems.

Keywords: Type 1 diabetes; Adolescents; Family communication; Glycemic control

Key Summary Points

Why carry out this study?

Adolescence is a difficult time for management of Type 1 diabetes (T1D), and the amount of T1D-specific communication between adolescents and their parents/caregivers is linked to improved T1D self-management

We hypothesized that a decision support system (DSS) called CloudConnect, which provided automated advice on T1D management on a weekly basis, would increase T1D-specific communication

What was learned from this study?

Use of CloudConnect, which families stated was helpful, did not increase T1D-specific communication or yield a sustained improvement in glycemia

Families seeking improvements in T1D management may be best looking beyond DSS systems to approaches that have provided more consistent improvements, such as automated insulin-delivery devices

INTRODUCTION

Adolescence remains the most challenging stage of life for Type 1 diabetes (T1D) from the standpoint of glycemic management, with the highest HbA1c levels of the lifespan [1]. This difficult management is fueled by evolving insulin requirements and psychosocial challenges such as increasing desire for autonomy, peer concerns contributing to less bolusing for carbohydrate, unpredictable schedules of exercise, and a lower concept of future consequences of poor T1D management [2–4]. These additional challenges in adolescence are overlaid on an already laborious set of responsibilities required to care for T1D, including calculating and administering insulin doses while also having to consider the potential need to adjust insulin doses in response to patterns of hypo- and hyperglycemia [5].

Adolescents are also in a long-lasting period of transition between T1D management choices managed predominantly by parents toward more independent management by the adolescent [6]. This shared responsibility can lead to conflict between adolescents and parents— while a more positive tone of communication regarding T1D management is associated with lower HbA1c values [2, 7].

One potential means of improving T1D management is through assistance with conceptual challenges of T1D using decision support systems (DSS) that aid in assessing for the need to change insulin dosing parameters in response to undesirable BG patterns [8]. DSS have been available for almost 40 years, with mixed results and with the complexity and interface developing over time [9–12]. It is unknown whether use of DSS in adolescence

alters the amount or tone of T1D-related interactions between the adolescent and parent.

Because of the shared role of T1D management in adolescents and their parents, we hypothesized that automated decision support delivered to both adolescents and parents would increase T1D-specific communication and improve T1D management. We formulated a decision support module called CloudConnect to provide T1D related guidance on insulin dosing and other factors based on input from continuous glucose monitors (CGM), timing of insulin dosing, and exercise. Our goal in the current study was to assess whether use of this system (compared to usual care plus CGM) would affect T1D-related communication between parents and adolescents, as well as other psychological assessments and outcomes related to T1D management in adolescence.

METHODS

This study was approved by the University of Virginia Institutional Review Board (HSR-IRB #20,958) and registered on clinicaltrials.gov (NCT03676465). Written informed consent was obtained from parents, and written assent was obtained from adolescent participants. Prior to study start, three participants were enrolled in a 4-week pilot trial to assess system functionality.

Patient and Public Involvement

Patients or the public were not personally involved in the design, or conduct, or reporting, or dissemination plans of our research. However, the development of the intervention was informed by needs of patients not using automated insulin delivery systems and their requirements to adjust insulin dosing on an ongoing basis according to patterns of hypo- or hyperglycemia. In addition, participants were in part recruited from pediatric diabetes clinics.

Inclusion/Exclusion Criteria

Participants were recruited from local pediatric diabetes clinics and the UVa Center for Diabetes Technology (CDT) database. Inclusion criteria were age 12–17 years and documented diagnosis of T1D for ≥ 12 months. Exclusion criteria included diabetic ketoacidosis or a severe hypoglycemic event (defined as seizure or loss of consciousness) in the past 12 months, use of an oral glucose-lowering agent including metformin, use of an automated insulin-delivery (AID) system (predictive low-glucose suspend systems were allowed), or any medical condition deemed high risk by the investigator. Individuals using non-AID insulin pumps or multiple daily injections of insulin (MDI) were eligible.

Enrollment Visit

The study design is outlined in Supplementary Material Fig. 1. Enrollment visits were performed in person or via secure internet video connection; medical history and insulin-use parameters were obtained. Documentation of a physical examination by a medical professional within the prior year was reviewed. For female participants, a urine pregnancy test was performed.

Randomization

Following confirmation of eligibility, participants were randomized by an external administrator to be in the CloudConnect or Usual Care + CGM groups in a 1:1 ratio using permuted blocks of four. Two UVa Center for Diabetes Technology team members not otherwise associated with the study had unique shared access to the randomization list. Once a participant's eligibility was confirmed, the research coordinator contacted one of these team members for the participant's randomization assignment. The contents of this list were otherwise not communicated to the study team.

Study Devices, Training, and Data Acquisition

Participants and their parents received training on the study devices and how to upload study data. Study participants were supplied with an

Apple iPhone with study apps. Participants used the Dexcom G6 CGM; study sensors and transmitters were generously provided by Dexcom, Inc. (San Diego, CA). CGM data were collected via the Clarity App. Subjects were fitted with a physical activity tracker (Fitbit® Charge 3), data from which was obtained through the FitBit App. Participants using MDI were supplied with an InPen (Companion Medical, Inc., San Diego, CA), which was connected via Bluetooth to the study phone; data were collected via Apple HealthKit. Participants on an insulin pump continued to use their home device; data were uploaded via associated website (Diasend, T:Connect or Carelink).

Description of Investigational System

The CloudConnect algorithm determining "actionable risk" related to BG trends was designed at UVa (by SDP), as was the software to generate the "Weekly Report" (by SDP and JPC). Briefly, the actionable risk assessment identifies regular patterns of low or high BG exposure that can be addressed systematically through changes in therapy and has been used in other DSS systems investigated at UVa. In this case the system evaluates multiple data inputs from 7 to 10 days prior to report generation, including from CGM, Fitbit, and insulin dosing (from insulin pump uploads among pump users and from InPen data from MDI participants). Participants were asked to upload data each Tuesday. The CloudConnect algorithm was then run on Wednesday or Thursday and the Weekly Report sent to families Friday afternoon. Participants with inadequate amounts of a particular data source (e.g., Fitbit) received alerts to increase use of that data source. The system considers meal ingestion as determined by carbohydrate announcement for pump users and InPen boluses for MDI users. The system also takes into account sleep based on time of day.

Risk for hyper- and hypoglycemia at any given time period during the input days was determined continuously across the time period from midnight to midnight and classified into low, moderate, and high risk. Depending on the extremes and variability of BGs at a given time of day, risk at a given time point could be moderate to high for both hyper- and hypoglycemia concurrently. This risk assessment was used to generate graphs showing degree of hyper- and hypoglycemia risk over time during the prior 7–10 days and also to generate automated advice regarding potential steps to improve T1D management.

The output of the CloudConnect system was a "Weekly Report," an example of which is shown in Supplementary Material Fig. 2. These reports provided multiple pieces of information related to decision support: (1) BG statistics, including average BG, time in range 70-180 mg/dl (TIR), and number of events of hypoglycemia < 70 mg/dl; (2) Graph of hyper- and hypoglycemia risk over the course of the day; (3) Achievements, providing positive feedback—either improvements in TIR or praise for having provided system inputs; (4) Automated advice compiling input sources to suggest potential insulin dose and other treatment changes—increasing basal insulin in response to excess risk of hyperglycemia overnight, increased insulin-to-carbohydrate ratio in response to risk of hyperglycemia after meals, and increased carbohydrate treatment before exercise in response to risk of hypoglycemia during exercise. Only the first two risk-associated time frames generated advice messages. Participants who were continually at risk for hyperglycemia (i.e., 24 h a day) received automated messages encouraging them to not miss insulin doses. The automated advice did not provide specifics on how much to change the insulin, only to consider making changes, with a final statement that "All recommendations are meant to be considered in the context of the care you receive from the medical team at your diabetes clinic." All messages were reviewed by the study physician before being sent to participants.

Following randomization, participants randomized to the CloudConnect group received an explanation regarding the information contained in the "Weekly Report." Participants were requested to review these reports as a family during the weekend (for example, Sunday afternoons).

Questionnaires

Participants (parent and adolescent, separately) completed the following questionnaires at enrollment and study completion: Family Communication Inventory (FCI)(Supplementary Material Table 1) [7], Family Conflict Scale (FCS) [13], Child Self-management [7], and Child Parental Responsibility Questionnaire (adapted) [14], and adolescents completed the My-Q assessment of diabetes-related quality of life [15]. In addition, each Tuesday, parents and adolescents were sent questionnaires with the following questions: "During the past week did you talk with your parent/child about your/ their diabetes management?," "If yes, how good or bad was the tone of that conversation?" (5-point scale from very good to very bad), and "During the week did you change your insulin parameters?" These questions were sent by text or email, according to the participant's and parent's request.

At study completion, adolescent and parent participants in the CloudConnect group were also asked questions on the design and utility of the system, including rating (on a scale from 1 to 7) the ability to understand the Weekly Reports and the usefulness of these reports for T1D management as well as qualitative questions related to these topics. Qualitative responses were scored as "overall positive" or "overall negative" for adolescents and parents and sorted into individual themes.

Laboratory Assessment

HbA1c was measured at enrollment and study completion. Prior to the SARS-CoV2 pandemic, HbA1c measures were performed on a DCA2000 device. After the onset of the SARS-CoV2 pandemic, HbA1c measures were performed via a home HbA1c meter (A1cNow, Bayer Corp, Whippany, NJ).

Analysis

Analyses were performed on SAS 9.4 (SAS Institute, Inc., Cary, NC, USA) and Prizm (GraphPad Holdings, LLC, San Diego, CA, USA). Variables were examined for normality using the Anderson-Darling test. Comparisons between intervention groups utilized independent t-tests for variables that were normally distributed with equal variances and Wilcoxon signed-rank tests for non-normally distributed data and Mann-Whitney U test for categorical and binomial data. Comparisons within individuals or between adolescents and their parents were achieved using paired t-tests for normally distributed data and using Wilcoxon matched-pairs signed rank test for non-normally distributed data. The primary outcome of the study was FCI-Frequency at study completion for the CloudConnect vs. UsualCare + CGM groups. Secondary outcomes included final assessments of HbA1c, mean glucose overall (from CGM), percent time in range 70–180 (TIR) overall and TIR the final study week, and the other questionnaires. Change in outcome values between baseline and final measure was also assessed for all variables between intervention groups and between parents and adolescents. As a sensitivity analysis for the primary outcome, we also used linear regression to assess for difference between treatment groups in final FCI-Frequency adjusted for baseline FCI-Frequency. We also assessed for differences among families that had FCS in the upper half of the range observed. p values ≤ 0.05 were considered significant.

Power Calculation

We were originally powered to detect as little as an 8.5% difference in FCI between groups based on earlier use of this score [7], with a goal of completing 80 adolescent/parent dyads between groups (estimated 20% drop-out and with adolescents and parents counted separately, totaling recruitment target of 220 participants). However, due to changes in T1D treatment modalities (with increasing use of automated insulin delivery devices, an exclusion criterion), we experienced difficulties in recruitment and had to stop the study early. Because of this, we performed a post hoc analysis of the number of participants who would have been needed to determine a significant difference for the primary outcome between

Table 1 Participant characteristics

	Usual Care + CGM (study completed by 44 participants: 22 adolescents, 22 parents): mean (SD), median (IQR) or number (percent)[a]	CloudConnect (study completed by 42 participants: 21 adolescents, 21 parents): mean (SD), median (IQR) or number (percent)[a]
Age	14.8 (1.8)	14.8 (1.5)
Sex (male/female)	11/11	12/9
BMI	25.0 (8.1)	24.6 (4.3)
BMI z-score	0.93 (0.93)	0.96 (0.83)
Race/ethnicity		
White not Hispanic	20 (90.9%)	20 (95.2%)
Black not Hispanic	0 (0%)	1 (4.8%)
Hispanic	2 (9.1%)	0 (0%)
Diabetes duration	3.83 (2.47, 7.75)	3.88 (2.82, 6.99)
Pump	15 (68%)	15 (71%)
MDI	7 (32%)	6 (29%)
Current CGM use	14 (64%)	14 (67%)
Prior CGM use	5 (23%)	3 (14%)
Total daily insulin (TDI) units	60.0 (44.9, 70.0)	60.0 (46.0, 75.0)
TDI units/kg	0.85 (0.74, 1.03)	0.91 (0.75, 1.14)

[a]For continuous variables, data provided are mean (standard deviation) for normally distributed characteristics and median (intraquartile range) for non-normally distributed characteristics. For categorical variables data are number (percent). None of the differences between groups were considered statistically significant (all $p > 0.05$)

intervention groups at the pre-specified level and the level of difference observed between groups.

RESULTS

Participant Characteristics

From to 18 January 2019 to 13 January 2021, we randomized 94 participants as part of 47 adolescent/parent dyads, of whom 4 dyads from the UsualCare + CGM group withdrew from the study (lost to follow-up, refused to wear CGM, could not get insulin cartridges for InPen). This left 22 adolescent participants in the Usual Care + CGM group and 21 in the

CloudConnect group for final data analysis (Supplementary Material Fig. 3). Between groups, participants had similar ages (both 14.8 years), insulin pump use, current CGM use, and total daily insulin (Table 1). Similarly, there were no differences between groups in baseline HbA1c or baseline scores of FCI-Frequency, FCI-Tone, FCS, My-Q, Child Self-Management Scale, or Child-Parental Responsibility scale (Tables 2, 3, 4, 5, Supplementary Material Tables 2, 3).

Diabetes Communication

Our primary hypothesis was that use of the CloudConnect system would increase T1D-specific communication between adolescents and their primary care-giver, as assessed using

Table 2 Baseline and final communication-related scores

	UsualCare + CGM[a] N = 22		CloudConnect[a] N = 21	
	Adolescent	Parent	Adolescent	Parent
FCI Frequency				
FCI Frequency, baseline	12.2 (7.3) CI: (9.0, 15.4)	11 (9, 15)	12.0 (4.8) CI: (9.7, 14.3)	11 (10, 17)
FCI Frequency, final	11.5 (6.7) CI: (8.6, 14.5)	9 (7, 15)	12.3 (3.8) CI: (10.5, 14.1)	12 (7, 16)
p value difference baseline-final	0.640	0.252	0.747	0.727
FCI Tone				
FCI Tone, baseline	2.55 (0.71) CI (2.1, 3.0)	2.52 (0.65) CI (2.2, 2.9)	2.21 (0.76) CI (1.7, 2.7)	2.17 (0.51) CI (1.9, 2.5)
FCI Tone, final	2.54 (0.87) CI (2.0, 3.1)	2.44 (0.61)[b] CI (2.1, 2.8)	2.33 (0.74) CI (1.8, 2.8)	2.50 (0.51)[b] CI (2.2, 2.8)
p value difference baseline-final	0.980	0.076	0.524	0.152
Family Conflict Scale				
Family Conflict Scale, baseline	22 (20, 28)	23 (19, 31)	26 (23, 31)	26.5 (24, 30)
Family Conflict Scale, final	24.4 (5.1)	23 (19, 27)	25.4 (4.1) CI (23.4, 27.3)	25 (22, 27)
	CI (22.1, 26.7)			
p value difference baseline-final	0.533	0.214	0.202	**0.021**

Bolded *p* values denote statistical significance ($p < 0.05$)

[a]Data shown for normally-distributed variables are mean (SD) and 95% confidence intervals (CI) and for non-normally distributed data median (intraquartile range). Comparisons utilized independent t-tests for variables that were normally distributed with equal variances and Wilcoxon signed-rank tests otherwise

[b]$p = 0.014$ for change in FCI Tone among parents, CloudConnect vs. UsualCare + CGM

the FCI-Frequency scale (an overall range of 0 for never communicating on included topics and 36 for communicating multiple times daily). However, after 12 weeks of use, there were no differences in FCI-Frequency scores, for either adolescents (UsualCare + CGM 11.5 ± 6.7, CloudConnect 12.3 ± 3.8) or parents (median [intraquartile range]: Usual-Care + CGM 9 [7, 15], CloudConnect 12 [7, 16]) (Table 2). There was also no significant difference between intervention groups noted in a sensitivity analysis using multivariable linear regression with baseline values included in the model or when the analysis was restricted to families with FCS above the median (data not shown). With this high coefficient of variation (SD/mean), an additional 421 adolescent-parent dyads would have been required to observe a significant difference at our originally hypothesized difference of 8.5% between intervention groups, suggesting a degree of futility, even if the original target to complete 40 adolescent-parent dyads per intervention group had been achieved. Instead, given the number of participants and the degree of variation, we were powered to determine as little as a 27% difference in scores.

Table 3 Responses to weekly questions regarding communication and insulin parameter changes for UsualCare + CGM and CloudConnect

	UsualCare + CGM $N = 21$		CloudConnect $N = 20$	
	Adolescent	Parent	Adolescent	Parent
Number of weekly responses over 13-week study	11.55 (1.77)	11.45 (2.46)	11.55 (2.04)	11.30 (3.03)
Did you communicate about diabetes in the past week? (mean percent of weeks (SD) answering "yes")	89% (31)	94% (24)[a]	88% (32)	96% (21)[b]
If so, what was the tone of the conversation? (average of 5-point scale, 1 = very bad, 5 = very good)	3.84 (0.87)[c]	3.82 (0.92)	3.58 (0.90)[c]	3.54 (0.79)[d]
Did you change your insulin doses/settings? (mean percent of weeks (SD) answering "yes")	0.12 (0.33)	0.13 (0.33)	0.36 (0.48)[e]	0.45 (0.50)[f]

Participants and parents were asked weekly regarding whether they communicated about diabetes and whether they changed insulin settings, generating a percentage of weeks that each family communicated about diabetes, a mean score from those responses, and percentage of weeks they changed insulin settings. Data here represent the mean percents and scores for each intervention group. Comparisons for all items utilized the Mann-Whitney U test

[a]Parent vs. adolescent UsualCare $p = 0.011$

[b]Parent vs. adolescent CloudConnect $p = 0.002$

[c]Adolescent UsualCare vs. CloudConnect $p = 0.001$

[d]Parent UsualCare vs. CloudConnect $p < 0.001$

[e]Adolescent UsualCare vs. CloudConnect $p < 0.0001$

[f]Parent UsualCare vs. CloudConnect $p < 0.0001$

There also was no difference in the tone of T1D-related conversations as assessed by the FCI-Tone (rated on a 5-point scale from very bad to very good); this was true for both adolescents (UsualCare + CGM 2.54 ± 0.71, CloudConnect 2.33 ± 0.74) and parents (UsualCare + CGM 2.44 ± 0.61, CloudConnect 2.50 ± 0.51), though there was a significant difference in the change in FCI-Tone from baseline to final, with a decrease in UsualCare + CGM and an increase in CloudConnect ($p = 0.014$)(Table 2). Final scores on the FCS were also very similar for adolescents and for parents between intervention groups (with higher scores representing more T1D-related conflict)(Table 2). Regarding changes between baseline and final FCS, only among parents in the CloudConnect group was there a decrease in FCS over the course of the study (27.4 ± 5.1 vs. 24.6 ± 4.0, $p = 0.02$).

We also assessed T1D-specific communication via weekly questions regarding interactions over the prior week (Table 3). This also revealed a similar frequency of T1D-related communication between groups for both adolescents (UsualCare + CGM: T1D-related communication 89 ± 31% of weeks vs. CloudConnect: 88 ± 32% of weeks) and parents (UsualCare + CGM: 94 ± 24% of weeks vs. CloudConnect: 96 ± 21% of weeks). The proportion of weeks for which T1D-related interactions occurred was higher according to parents vs. adolescents for both UsualCare + CGM ($p = 0.011$) and CloudConnect ($p = 0.002$) (Table 3) .

On the weekly questionnaire, we next asked about the tone of T1D-specific conversations by weekly questionnaire. Interestingly, the Usual-Care + CGM group reported a significantly more pleasant tone than the CloudConnect group, according to both adolescents (Usual-Care + CGM 3.84 ± 0.87, CloudConnect 3.58 ± 0.90, $p = 0.001$) and parents (Usual-Care + CGM 3.82 ± 0.92, CloudConnect 3.54 ± 0.79, $p < 0.001$).

Table 4 Glycemic outcomes for UsualCare + CGM and CloudConnect

	UsualCare + CGM[a] N = 22	CloudConnect[a] N = 21	p value
HbA1c baseline	8.40 (1.20)	8.06 (0.83)	0.304
	CI (7.88, 8.90)	CI (7.66, 8.46)	
HbA1c final	7.71 (1.11)	7.58 (0.94)	0.681
	CI (7.24, 8.18)	CI (7.13, 8.04)	
p value difference baseline-final	**0.003**	**0.016**	
HbA1c	− 0.69 (0.95)	− 0.48 (0.79)	0.456
change	CI (− 1.08, − 0.28)	CI (− 0.86, − 0.10)	
CGM			
Overall			
Mean glucose (mg/dl)	201.0 (27.6)	198.2 (28.2)	0.749
	CI (189.0, 212.9)	CI (185.4, 211.1)	
Time in range 70–180 mg/dl (%)	44.3 (12.4)	43.9 (11.2)	0.933
	CI (38.9, 49.6)	CI (44.0, 49.1)	
Time above range (> 180 mg/dl) (%)	54.0 (12.8)	53.6 (12.8)	0.911
	CI (0.48, 0.60)	CI (0.48, 0.59)	
Time below range (< 70 mg/dl) (%)	1.2 (0.7, 2.5)	1.1 (0.6, 2.9)	0.981
Low blood glucose episodes (average number per week)	3.3 (1.2, 5.3)	2.75 (1.8, 6.35)	0.722
Final 2 weeks			
Mean glucose (mg/dl)	206.2 (34.0)	203.1 (37.5)	0.786
	CI (189.9, 222.6)	CI (1858.6, 220.7)	
Time in range 70–180 mg/dl (%)	42.6 (14.6)	42.3 (15.7)	0.955
	CI (35.6, 49.6)	CI: (35.0, 49.7)	
Time above range (> 180 mg/dl) (%)	56.0 (15.1)	55.4 (17.6)	0.908
	CI (0.49, 0.63)	CI (0.47, 0.64)	
Time below range (< 70 mg/dl) (%)	0.6 (0.1, 2.3)	1.1 (0.1, 2.8)	0.332
Low blood glucose episodes (average number per week)	2.5 (1.0, 4.5)	2.5 (0.75, 4.75)	0.675

Bolded p values denote statistical significance ($p < 0.05$)

[a]Data shown for normally distributed variables are mean (SD) and 95% confidence intervals (CI) and for non-normally distributed data median (intraquartile range). Comparisons utilized independent t-tests for variables that were normally distributed with equal variances and Wilcoxon signed-rank tests otherwise

Table 5 Assessment of CloudConnect utility by users at end of study

	Adolescents[a] N = 20	Parents[a] N = 20	p value
How easy was it to understand the information provided in the weekly reports?	6 (5,7)	7 (6,7)	0.0379
(7-point scale with 1 being not at all useful and 7 being very useful)			
How useful were the weekly reports in helping you communicate with your parents/ child about managing your/your child's diabetes?	5.5 (4, 7)	5.5 (4, 7)	1.000
(7-point scale with 1 being not at all useful and 7 being very useful)			

[a]Data shown represent median (intraquartile range). Comparisons utilized the Mann-Whitney U test

Glycemic Management

Regarding glycemic management, there was no difference between treatment groups in final HbA1c (UsualCare + CGM 7.71 ± 1.11, CloudConnect 7.58 ± 0.94); both groups experienced a reduction in HbA1c during the study (Table 4). Overall TIR was also similar between groups (UsualCare + CGM 44.3 ± 12.4, CloudConnect 43.9 ± 11.2), as was overall mean glucose (UsualCare + CGM 201.0 ± 27.6, CloudConnect 198.2 ± 28.2). Other measures of glycemia were also similar, both overall and in the last 2 weeks (Table 4).

Child Self-Management and Child-Parental Shared Responsibility

The Child Self-Management questionnaire addresses difficulties in self-management of T1D care practices, assessing the frequency over the past week of omitting T1D-related tasks for insulin dosing (higher scores representing more missed T1D-related tasks). Final scores were similar between groups for both adolescents (median [intraquartile range]: UsualCare + CGM 4 [2, 6], CloudConnect 4 [3, 9.5]) and parents (UsualCare + CGM 5.0 ± 4.6, CloudConnect 6.7 ± 3.5) (Supplementary Material Table 2). The Child-Parental Shared Responsibility questionnaire assesses division of individual T1D tasks between the adolescent and parent (higher scores representing the adolescent assuming more responsibilities). Again, scores were similar between groups for

adolescents (UsualCare + CGM 23.1 ± 4.5, CloudConnect 21.3 ± 3.1) and parents (median [intraquartile range]: UsualCare + CGM 25 [21.0, 26.0], CloudConnect 21 [19.5, 23.0]) (Supplementary Material Table 2). Only parents in the UsualCare + CGM group exhibited a change in scores over time (23.5 [20, 26] to 25 [21.0, 26.0], $p = 0.004$).

Diabetes Quality of Life

Finally, we assessed for T1D-specific quality of life using My-Q (Supplementary Material Table 3). My-Q scores were similar between groups, both in terms of final score (UsualCare + CGM 95.8 ± 10.7, CloudConnect 93.5 ± 11.9) and change from baseline (UsualCare + CGM − 2.2 ± 7.6, CloudConnect + 0.3 ± 4.4). Similarly, the WHO-5 scores were similar between groups in terms of final score (median [intraquartile range] UsualCare + CGM 58 [48, 68], CloudConnect 64 [60, 72]) and change from baseline (UsualCare + CGM − 7.0 ± 24.6, CloudConnect + 0.8 ± 14.3).

Survey on CloudConnect Design and Utility

At study completion, participants in the CloudConnect group were asked about their perceived utility of the CloudConnect system, including the Weekly Report (Table 5). A complete list of adolescent and parent comments is provided in the Supplemental Material section. When asked, "On a scale of 1–7, with 1

being very difficult and 7 being very easy, how easy was it to understand the information provided in the weekly reports?," adolescents responded with median (intraquartile range) scores of 6 (5,7) while parents responded with a 7 (6,7) (*p* = 0.0379). When asked to further explain their score, adolescents provided overall positive responses in 14 cases and overall negative response in 5 cases. Parents provided overall positive responses in 21 cases and negative in 2 cases. Representative comments included,

- "...because it told me my overall blood sugar and how to keep it level and it was very straight forward."
- "Visually, it was very easy to read. The charts and graphs highlighted the important information and made it easy to see changes week to week. The bulleted suggestions and achievements were direct and to the point."

When asked, "On a scale of 1–7, with 1 being not at all useful and 7 being very useful, how useful were the weekly reports in helping you communicate with your parents/child about managing your/your child's diabetes?," adolescents rated 5.5 (4, 7) while parents rated 5.5 (4, 7). When asked to further explain their answer, adolescents provided overall positive comments in 12 cases and negative comments in 7 cases. Parents provided overall positive responses in 12 cases and negative in 9 cases. Representative comments included,

- "My mom and I would ask each other if we had completed the surveys, and after we both looked at the graph on Thursdays, we would make changes to my insulin together."
- "I didn't really read them too much so my mom just told me what was suggested."
- "It was a 'reason' to take the time to 'sit down' and discuss the managing of her diabetes. The report showed in an easy way to discuss what time of day she was high."
- "Reports were fine, he does not want to discuss diabetes management at all."

When asked to provide final comments, adolescents provided overall positive comments in two cases and negative comments in two cases. The parents provided overall positive comments in 12 cases and negative comments in 4 cases. Individual comments included:

- "It was espionage hard to follow the reports because it was summer and most weeks were inconsistent with different activities and sports if it had been in the school year with a more consistent schedule than it probably would have helped a lot more."
- "These reports just opened up our conversations in a nice way and we only really talked about diabetes on Friday unless there was a low or just something we needed to talk about but the majority of the conversation was when we got the report so she didn't feel like we were talking diabetes all the time."

DISCUSSION

While AID systems offer improvements in management of T1D [16–20], there remains a large subset of the T1D community who could benefit from DSS approaches to assist in adjusting traditional T1D treatment with MDI or non-AID insulin pumps [8]. We tested whether the CloudConnect system with automated T1D guidance to adolescents and their primary care giver would facilitate an increase in T1D-focused communication, which itself has been linked to lower HbA1c values [7]. We did not see changes in the amount of T1D-related communication among families who received a Weekly Report with automated advice toward improving BG management. In fact, by one measure families who received this guidance rated a more negative tone to communication than among those not receiving the Weekly Report. Moreover, whereas families in the CloudConnect group reported more frequent insulin adjustment, there was no difference between groups in HbA1c, TIR, or measures of T1D distress and quality of life after 3 months of system use. Altogether, these negative results are important in that they continue an impression that while DSS approaches are feasible and by some measures appreciated by caregivers, they most frequently do not provide sustained improvements in T1D

communication or management [9–12]. For more reliable improvements in glycemia, practitioners and families should continue to consider using AID systems.

We chose to assess this system among adolescents, given their ongoing challenges in T1D management [1]. Adolescents struggle through the dichotomy of desiring independence but also not having a fully mature sense of the future consequences of poor management—emphasizing the importance of ongoing involvement of primary caregivers (most commonly parents) and the importance of communication. Struggles with T1D-related conflict and less communication have been linked to poorer management [7]. While we did not see a change in T1D communication with CloudConnect use as assessed with validated scales, it should be noted that the current cohort had less frequent communication at baseline than a prior cohort (mean FCI prior cohort 18.9 vs. CloudConnect 12.1) of similar age but higher HbA1c (prior cohort 8.7 vs. CloudConnect 8.2) [7]. A limitation of the study is that the FCI has otherwise not been assessed in other cohorts. Certainly the effectiveness of a DSS approach like this can depend on the population assessed, and a cohort under better management at baseline (and willing to participate in a 3-month clinical trial) may already have established T1D communication patterns—but also may not require as frequent of interactions regarding insulin doses. Future efforts to incorporate a wider group with less communication at baseline and higher HbA1c would allow greater room for improvement in T1D communication and care.

The lack of change in frequency of communication was striking because both adolescents and parents indicated that they found CloudConnect useful in helping communication (5.4 on a 7-point scale). This may reflect that their communication, while not more frequent, was more directed than previously. It may also reflect a degree of recall bias where they felt like they were communicating more frequently while using the tool but in reality had not changed. Notably, parents in the CloudConnect group reported a decrease in diabetes-related conflict as measured by the FCS—potentially due to improved communication quality.

In assessing for T1D-related communication, we were aware that irrespective of the amount of communication, the tone of the communication may not always improve. Prior studies have demonstrated that T1D-related conflict is associated with higher HbA1c, though it is not clear whether there is any causal relationship in this association [13]. We were interested to see that according to weekly surveys, both adolescents and parents in the CloudConnect group reported a more negative tone to their T1D-related communication. While the reason for this is not certain, it is notable that the Weekly Report provided parents with an opportunity to see more information showing poorer glycemic management. Additionally, some adolescents reported that their parents took the lead on assessing the automated advice (e.g., "I didn't really read them too much so my mom just told me what was suggested"), which could have had the opposite effect of the shared-management discussions that we had envisioned when designing the Weekly Report. Multiple users stated a desire for more specific T1D advice, which may have helped facilitate more agreement between parents and adolescents. The overall effect of this negative tone is unclear; however, since by study completion, parents in the CloudConnect reported a decrease in T1D-related conflict. This was a rare case in this study where parents and adolescents were not in agreement and may serve as a reminder that caregivers and patients may view the nature of their communication differently.

Other DSS systems have varied in terms of the specificity and frequency of advice provided [11, 12], with many systems providing real-time advice through apps run on cell phones [9, 10]. Even these systems that provide in-the-moment dose advice have frequently not resulted in changes in TIR or HbA1c—and with unclear influence on T1D-specific communication [9, 10]. Our approach was based on long-term trends in glycemia related to lifestyle patterns including food intake and exercise timing, as opposed to immediate advice on bolus recommendations for specific meals. This was intended to stimulate thoughtful deliberation,

increasing T1D engagement by adolescents and parents in a way that more immediate DSS systems may not accomplish. Nevertheless, this also may have streamlined communication to only result in one additional conversation (however thoughtful it may have been) about T1D management, tending against a clear increase in the amount of communication. The lack of an increase in communication or durable TIR may also indicate that families are already saturated with T1D information or distracted by other life stressors. In addition, the means of delivering advice—through a single compilation of data weekly—required additional time to review in ways not required for more immediate feedback systems [21, 22]. It is also possible that some adolescents simply want to ignore their diabetes, and presenting them with more data may not improve their drive toward better management [23].

This study benefited from a robust system for automated advice for insulin adjustments over a reasonable (3-month) time frame. Study limitations include that the study was limited in recruitment, related to increasing use of AID devices—a study exclusion criterion—and was stopped just over halfway to target enrollment. However, we found a higher-than-anticipated variation in family T1D-related communication, which would have rendered it difficult to conclude differences in communication levels even at the target enrollment. Additionally, this represented a cohort with baseline management that is better than seen nationally in this age range [1]. We also lacked an unbiased means of assessing how much the participants spent reviewing the Weekly Report, how often insulin changes were recommended or which insulin changes were directly performed in response to automated suggestions—which may have helped determine whether following these suggestions would have been associated with improvements in T1D management. We further lacked a means of determining what difference in T1D-based communication would be considered clinically significant. And we lacked a means of assessing the processes families used for determining changes as part of usual care. Finally, we lacked information on parental education and other sociodemographic factors that might have influenced T1D-related communication.

CONCLUSION

In conclusion, we did not note an increase in T1D-secific communication with the use of the CloudConnect DSS system in adolescents, despite an increase in reported insulin dose adjustments. In addition, we did not note improvements in TIR for the CloudConnect group vs. UsualCare + CGM. While parents perceived a decrease in T1D-related conflict with system use, the tone of communication was still overall more negative among CloudConnect users as compared to those on UsualCare + CGM. While previous evaluations of DSS systems revealed a pattern of lack of efficacy in improving T1D management, the current study provided further support against these systems altering T1D communication between primary care givers and adolescents. Outside of AID systems, algorithm-driven improvements in T1D management in adolescents remain elusive.

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Compliance with Ethics Guidelines. This study was approved by the University of Virginia Institutional Review (HSR-IRB #20958). Written informed consent was obtained from parents and written assent was obtained from adolescent participants. The study was performed in accordance with the Helsinki Declaration of 1964 and its amendments. Clinical Trials Registration Number: NCT03676465.

Data Availability. Study data is available upon reasonable request to corresponding author.

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