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CLINICAL CARE AND TECHNOLOGY

Initiating hybrid closed loop: A program evaluation of an educator-led Control-IQ follow-up at a large pediatric clinic

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Abstract

Background: Control-IQ (Tandem Diabetes) is a hybrid closed-loop (HCL) system that users self-initiate after completing online training. Best practices for clinical follow-up are not known. Our quality improvement objective was to evaluate the usefulness of an educator-led follow-up program for new HCL users in a type 1 diabetes pediatric clinic.

Methods: We implemented an "HCLCheck-in" program, first determining when users started HCL, then having diabetes educators contact them for a follow-up call 2-weeks after start. Educators used a Clinical Tool to inform insulin dose and behavior recommendations, and used four benchmarks to determine need for further follow-up: ≥71% HCL use, ≥71% CGM use, ≥60% Time-in-Range (TIR, 70–180 mg/dL), <5% below 70 mg/dL. Family and educator satisfaction were surveyed.

Results: One-hundred-twenty-three youth [mean age 13.6 ± 3.7 y, 53.7% female, mean HbA1c 7.6 ± 1.4% (60 mmol/mol)] completed an HCLCheck-in call a median (IQR) of 18(15, 21) days post-HCL start. 74 users (60%) surpassed benchmarks with 94% HCL use and 71% TIR. Of the 49 who did not, 16 completed a second call, and improved median TIR 12.5% ($p = 0.03$). HCL users reported high satisfaction with the program overall [median 10 (9, 10) out of 10]. Educators spent a median of 45 (32,70) minutes per user and rated satisfaction with the program as 8 (7,9.5) and the Tool as 9 (9, 10).

Conclusion: Our HCLCheck-in program received high satisfaction ratings and resulted in improved TIR for those initially not meeting benchmarks, suggesting users may benefit from early follow-up. Similar programs may be beneficial for other new technologies.

KEYWORDS
hybrid closed loop, pediatrics, program evaluation, quality improvement, type 1 diabetes

1 | INTRODUCTION

Diabetes technology options have greatly increased for persons with type 1 diabetes (PWD) in the past decade, with the commercialization of multiple advanced insulin pumps, including hybrid closed-loop (HCL) systems.[1] HCL systems consist of an insulin pump, a connected continuous glucose monitor (CGM), and an algorithm to increase or decrease insulin delivery in response to glucose levels. The most recently available hybrid closed loop system, the t:slim X2 with Control-IQ technology ("Control-IQ", Tandem Diabetes), was commercially approved in the United States in January 2020 for PWD ages 14 and over and has since been approved for PWD ages 6 and

over.[2,3] The Control-IQ system consists of the X2 insulin pump, a Dexcom G6 CGM sensor, and a software algorithm that automatically adjusts insulin delivery to maximize the amount of time glucose is in target range.[2,4,5] The Control-IQ algorithm has previously demonstrated safety and effectiveness in numerous pediatric and adult trials.[6-11] The system works by automatically increasing the programmed basal insulin delivery rate when glucose levels are predicted to exceed 160 mg/dL, and decreasing the basal delivery rate when glucose levels are predicted to fall below 112.5 mg/dL. Control IQ automatically suspends insulin delivery if glucose levels are predicted to fall below 80 mg/dL and then resumes when glucose begins to rise again. In addition to modulating the basal rates, the system can also deliver an automatic correction bolus dose of insulin if glucose levels are predicted to rise above 180 mg/dL.[12,13] This occurs up to once per hour during normal operation, and delivers 60% of the dose calculated based on the user's insulin sensitivity factor. The system also has a "sleep activity" that narrows the target range to 112.5–120 mg/dL overnight, and eliminates the automatic correction boluses, and an "exercise activity" that increases the target range to 140–160 mg/dL. The Control-IQ software can be downloaded onto any X2 insulin pump, which means that individuals already using the X2 pump are able to install the Control-IQ software onto the pump using a home computer and a USB connection cable. Therefore, when the Control-IQ software became commercially available in February 2020, a large number of X2 insulin pump users started using the Control-IQ system at home after receiving a prescription from their provider, watching a training video from the manufacturer, and downloading the software onto their pump.

While improved technologies may reduce user burden, proper training and follow-up remain essential to minimize device discontinuation and maximize proper device use.[14-16] The uniqueness of the at-home start up process and the novelty of a new HCL present new challenges for clinical training and follow-up. Clinicians may not be aware when users start new HCL systems like Control-IQ because of the remote start up process. Additionally, clinicians may lack sufficient knowledge to support the HCL user due to unfamiliarity with the new system.[17,18] Within this context, it is not known how to best provide clinical follow-up to new HCL users and families, especially at a large tertiary care pediatric clinic.

To proactively address these concerns at our diabetes center, our team built upon our previous quality improvement work on HCL implementation[19] to develop and pilot a new hybrid closed loop check-in (HCLCheck-in) program. The HCLCheck-in program consisted of: (a) an administrative workflow to generate prescriptions and identify when news users start the HCL system, (b) a diabetes educator-led follow-up phone visit 2-weeks after HCL start, and (c) an HCLClinical Tool for the diabetes educator to use during the follow-up call to assess relative success with HCL and guide diabetes education and insulin dose adjustment. The purpose of this program evaluation is to describe the development of the HCLCheck-in program at the Barbara Davis Center and report on the program's feasibility, effectiveness, and satisfaction of both educators and Control-IQ users over 3 months. These data are ultimately to determine whether this model should be used for future diabetes technology commercialization's within the context of our clinical Center.

2 | METHODS

Members of our pediatric clinic's team met in November 2019 to discuss how to best support new Control-IQ users. The team included pediatric endocrinologists, diabetes educators (from both clinic and clinical research), quality improvement staff, and clinic administrators. We aimed to develop an "HCLCheck-in" program to support the family/PWD starting a new diabetes technology at home via online module, while taking into consideration the time limitations of clinical staff to be able to provide extensive follow-up. We further aimed to develop a simple way to assess success in using the HCL system. The program was intended to run for the first 3–6 months that Control-IQ was available for commercial users, with potential long-term implementation. Diabetes educators were identified as the key providers to deliver the clinical follow-up for the HCLCheck-in program.

The diabetes educators were trained on the HCL system by industry representatives along with research nurse educators familiar with Control-IQ from clinical trials. Educators were required to attend a 1 hour-long training session facilitated by research nurses describing how Control-IQ worked and how to adjust insulin doses, interpret device download reports, and reinforce key educational concepts. Industry representatives were available to answer additional questions during their periodic visits to the clinic. Research nurses were available on site for ongoing questions with the HCLCheck-in program. The diabetes educators and research nurses met two times during the first 3 months of the program to review the HCLCheck-in program workflow, problem solving, and any technical questions related to the HCL system.

2.1 | HCLCheck-in workflow

The team first developed an administrative workflow to streamline the Control-IQ prescription process and determine when users planned to start using Control-IQ HCL. The first wave of Control-IQ users in our clinic were previous X2 insulin pump users who obtained the technology via software download to their pump. This onboarding and initial training were conducted via an online training module produced by the manufacturer, and then secure transfer of the Control-IQ software to their insulin pump via USB cable. The workflow occurred as follows:

1) The PWD requested a prescription for Control-IQ software from our pediatric clinic.

2) Our clinic processed the prescription and sent approval to the manufacturer to release the software.

3) Our clinic contacted the PWD/family and explained that a diabetes educator would follow-up with them approximately 2 weeks after starting HCL, and to ask when they planned to start.

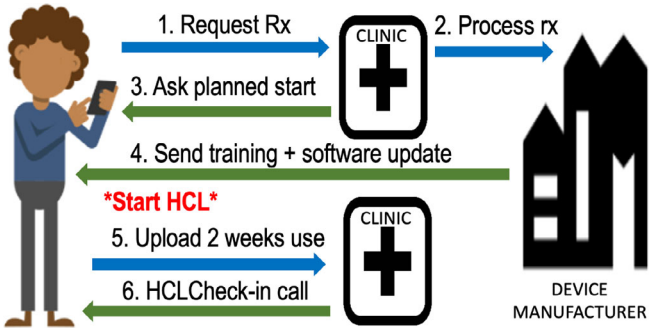

FIGURE 1 HCL check-in clinical workflow

4) The PWD participated in the mandatory training module from the manufacturer and then downloaded the Control-IQ software onto their X2 insulin pump to start using HCL.

5) The PWD uploaded their HCL system to the device-specific cloud-based software.

6) A diabetes educator called the user 2-weeks after anticipated start to conduct the HCLCheck-in phone call (Figure 1).

For individuals transitioning to Control-IQ from a non-Tandem insulin pump, industry trainers completed the initial insulin pump and HCL training with the user/family, and the HCLCheck-in occurred as indicated in Figure 1 with a clinic diabetes educator. For individuals transitioning to Control-IQ from insulin injections, our routine pump start process was followed: the user is trained by our clinic diabetes educators (certified pump trainers) and followed by this trainer for the first few weeks of use.

2.2 | HCLCheck-in phone visit

Our clinic maintained a detailed spreadsheet tracking when individuals upgraded to Control-IQ. An administrative staff member contacted families (step #3 above) to find out when they planned to upgrade to Control-IQ and recorded this information in the spreadsheet. Diabetes educators were notified of Control-IQ users who had started the system approximately 2-weeks prior, with instructions to reach out to family by phone or email and set up an HCLCheck-in phone visit to review the insulin pump download. Considering the high workload of the diabetes educators in our pediatric clinic, we determined that one HCLCheck-in call would be the standard amount provided, with additional calls available if needed. Check-in phone calls were evenly spread among 13 diabetes educators. Check-in could also be provided by email if the family could not be reached by phone.

Diabetes educators first asked the HCL user to upload their insulin pump to the commercial cloud-based software (t:Connect). These accounts were linked to our clinical (professional) account, enabling the diabetes educators to access information without asking for password information. The educators reviewed the last 1-week of device information and conducted the HCLCheck-in phone call.

2.3 | HCLClinical Tool

To simplify and standardize the check-in phone visit, we developed an "HCLClinical Tool" for diabetes educators to use (Appendix S1). This 3-page tool consisted of a short series of assessments of the user's HCL data, decision support for insulin dose adjustment, important educational points specific to the HCL system and reminders of important diabetes self-care behaviors (e.g. pre-meal blousing).

Firstly, educators assessed the percent of time CGM was active, percent of time the HCL feature was turned "on", percent time-below-target-range (TBR) <70 mg/dL, percent time-in-target-range (TIR) 70–180 mg/dL, and percent time-above-target-range (TAR) >180 mg/dL. We created four "benchmarks" using these metrics to determine if the user required additional follow-up after the initial call. We balanced international consensus metrics[20] with what was realistically achievable by users of a new system, to maintain a feasible program for educators based on the current workload and focus any additional follow-up on those who needed it the most. HCL users who did not meet these benchmarks were scheduled for a second or third check-in call 1–2 weeks after the first call. The chosen benchmarks were:

1. Using the HCL feature ≥5 days out of 7 days (≥71%)
2. Using the CGM ≥5 days out of 7 days (≥71%)
3. TIR (70–180 mg/dL) ≥ 60%
4. TBR (<70 mg/dL) < 5%

Next, the HCLClinical Tool provided decision support strategies for the educator to discuss with the HCL user. For example, if the user had >5% hypoglycemia, educators were prompted to assess behavioral factors (using exercise settings, treating hypoglycemia with appropriate carbohydrates, discouraging bolus overrides) as well as insulin dose settings. The tool provided suggestions for changing carbohydrate ratios or sensitivity settings if hypoglycemia was due to bolus insulin, or basal rate changes if not due to boluses. Further, a checklist of standard key education points was provided, including confirmation that the sleep activity was used every night, that users read the bolus prompts carefully, and the importance of bolusing before all meals and snacks. Educators documented the changes they recommended in the final section of the document. The full HCLClinical Tool is found in Appendix S1.

2.4 | Data collection

Data were considered quality improvement/program evaluation data and were exempt from institutional review board review per Department of Health and Human Service guidelines. The check-in phone calls were documented on the HCLClinical Tool, transcribed into the medical record, and entered into an electronic database for program evaluation. Data were collected for check-in calls conducted from February 7th -May 8th, 2020 (3 months). The quality improvement program was evaluated on whether it was feasible to implement, useful to the persons with diabetes (assessed by the HCLClinical Tool), and satisfactory to the HCL users and diabetes educators. Feasibility

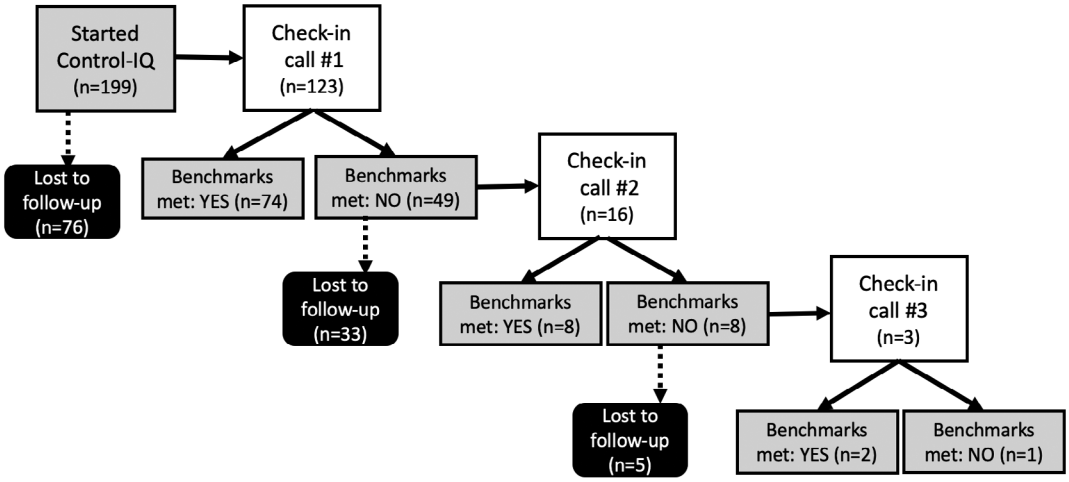

FIGURE 2 HCL check-in program flow chart and attrition

was quantified by the number of individuals who were able to complete the HCLCheck-in program. Usefulness of the program was measured by whether HCL users who received a first check-in improved benchmarks at the second check-in. Satisfaction was assessed by survey.

We designed and administered surveys to the HCL user and to the diabetes educators completing the check-in calls. The survey for the HCL user included questions on satisfaction, usefulness, and convenience of the initial training (via online module from the manufacturer) and for the HCLCheck-in phone visit. They also included questions on whether they would recommend the HCLCheck-in to others, what would make it more useful, and reasons for declining a check-in if they did not complete one. Answers were a combination of free text, 10 item scales, and categorical answers. The educator survey was anonymously completed by the participating diabetes educators, and included questions about workload/time spent for check-in calls, competence in instructing families how to use the HCL system, using the HCLClinical Tool, and satisfaction with the workflow. All surveys were administered via RedCAP.[21]

2.5 | Analysis

Descriptive statistics included counts and frequencies of users and educators. Demographic and glycemic information are displayed as means (± standard deviation) for normally distributed data, and medians (IQR) for non-normally distributed data. Wilcoxan signed rank tests were used to determine improvement in glycemic parameters between HCLCheck-ins, and Mann–Whitney U tests were performed to determine differences in survey responses between parents and HCL users.

3 | RESULTS

In total, 199 families started the HCL system during the 3-month period, and 123 (62%) completed the check-in call #1 (Figure 2). For completed calls, mean age of the HCL user was 13.6 ± 3.7 years old, 53.7% female, with duration of diabetes for 5.3 ± 3.8 years, and HbA1c of 7.6 ± 1.4% (60 mmol/mol). 60% of families completing call #1 passed the benchmarks, with all users achieving median 94% HCL use and 71% TIR (70–180 mg/dL) (Table 1). Basal rate changes were suggested for 39 HCL users, the majority of which were to increase basal rates (n = 18), followed by decreasing basal rates (n = 12) followed by unknown changes (n = 9). Most of the basal decreases were during the nighttime hours. Insulin to carbohydrate ratios (I:C) were changed for 32 users: most were made more aggressive (n = 17), a few were made less aggressive (n = 4), and some were unknown changes (n = 9). Correction factors were changed for 20 users, with most being made less aggressive (n = 11), followed by more aggressive (n = 5), and unknown (n = 4). Finally, behavior changes were recommended for many users (n = 57). These included pre-bolusing before meals (n = 39), setting and using the sleep activity (n = 17), decreasing carbohydrates for hypoglycemia treatment (n = 5), using the exercise activity feature (n = 5).

Of the 49 HCL users not meeting benchmarks at check-in #1, 16 (33%) completed a second check-in call. For these participants, median HCL use improved from 91% to 95% (p = 0.08) at check-in #2, with 14 of 16 users improving HCL use (Table 1). TIR improved from 54% to 66.5% (p = 0.029) at check-in #2, with 100% of participants improving TIR compared to check-in #1. Eight families did not meet the benchmarks at check-in #2, and three of the eight (37.5%) completed a third check-in. Two (67%) of the three families met the benchmarks after check-in #3.

3.1 | User satisfaction

For the user/family satisfaction survey, we received 122 responses: 84 who participated in the HCLCheck-in program and 38 who started the HCL device but did not participate in the check-ins (Appendix S2). Parents filled out 102 of the surveys, and the HCL users filled out 20. On scale of 1 to 10 (10 = high), survey respondents reported median

TABLE 1 HCL Check-in calls: system use, glycemic metrics, and insulin and behavioral recommendations

	HCLCheck-in #1 (n = 123)		HCLCheck-in #2 (n = 16)		HCLCheck-in #3 (n = 3)	
	Median (IQR)	n (%)	Median (IQR)	n (%)	Median (IQR)	n (%)
# days from start of Control-IQ	18 (15, 21)		26 (22, 32)		40 (29, n/a)	
Percent time Control-IQ active	94 (89, 96)		95 (92, 96)		95 (81, n/a)	
Percent time CGM active	96 (93, 99)		96 (96, 98)		96 (82, n/a)	
Percent TIR (70–180 mg/dL)	71 (60, 79)		67 (49, 75)		62 (57, n/a)	
Percent TBR (<70 mg/dL)	2 (1, 3)		1 (1, 3)		1 (0, n/a)	
Percent TAR (>180 mg/dL)	27 (17, 38)		33 (24, 50)		37 (34, n/a)	
All 4 BENCHMARKS met		74 (60.2%)		8 (50%)		2 (66.7%)
BENCHMARK: Control-IQ active ≥ 71%		115 (93.5%)		15 (93.8%)		3 (100%)
BENCHMARK CGM active ≥ 71%		119 (96.8%)		15 (93.8%)		3 (100%)
BENCHMARK: TIR ≥ 60%		93 (75.6%)		9 (56.3%)		2 (66.7%)
BENCHMARK N (%) with TBR < 5%		106 (86.2%)		15 (93.8%)		3 (100%)
Basal changes recommended		39 (31.7%)		5 (25%)		1 (33.3%)
Insulin-to-carb ratio changes recommended		32 (26.0%)		3 (18.8%)		2 (66.7%)
N (%) sensitivities ratio changes recommended		20 (16.3%)		3 (18.8)		2 (66.7%)
N (%) behavior changes recommended		57 (46.3%)		10 (62.6%)		2 (66.7%)

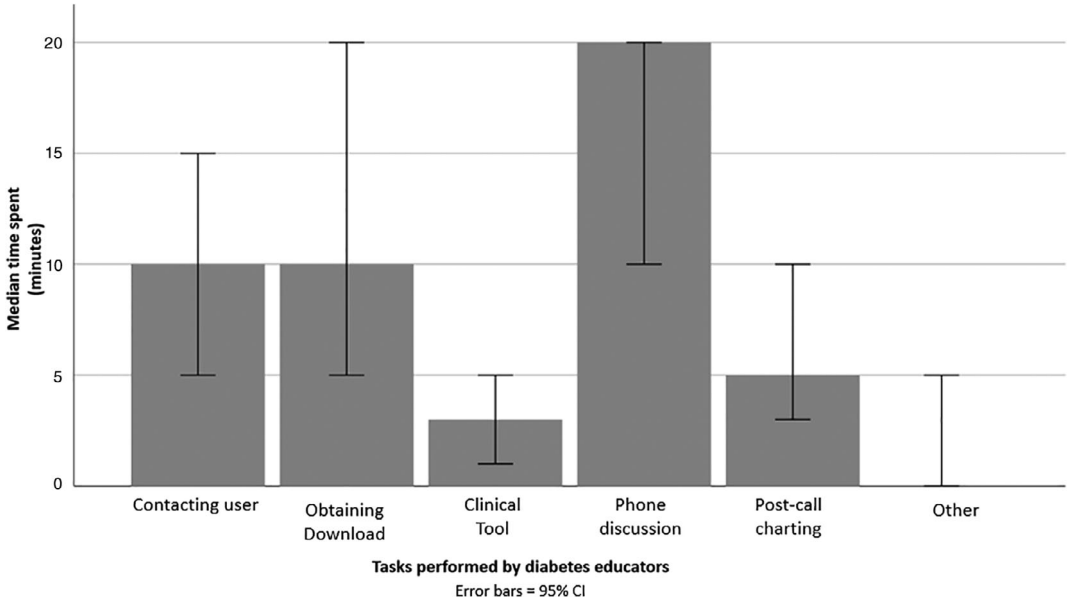

FIGURE 3 HCL check-in program: median time spent by diabetes educators per task

high satisfaction [9 (8, 10)], convenience [10 (9, 10)], and usefulness [9 (8, 10)] of the remote start-up process (watching the online training module and downloading the Control-IQ software onto their insulin pump), with no differences in response between parents or HCL users (p = 0.57, 0.78, and 0.16 respectively). 83% would recommend remote onboarding for starting future diabetes technologies, 3% would not, and 13% were unsure. For the respondents who did not complete an HCLCheck-in call, the most frequent reasons cited were that they did not know about the HCLCheck-in (38.9%), they did not think an HCLCheck-in was necessary (22.2%), and they did not remember receiving an HCLCheck-in call (13.9%).

For the 86 respondents who participated in the HCLCheck-ins, 51% completed the check-ins exclusively by phone, 35% by phone and email, and 14% by email only (Appendix S2). Respondents reported high

satisfaction [10 (9, 10)], high convenience [10 (9, 10)], and high usefulness [10 (9, 10)] of the check-in call. There were no differences between parents and HCL users for any of the items (p = 0.33, 0.17, 0.44 respectively). The majority (85.7%) would recommend a similar HCLCheck-in program for starting new diabetes technologies, 3.7% would not, and 10.7% were unsure. When asked what elements of the HCLCheck-ins could be improved, 6 respondents said it was difficult finding a time to connect over the phone, and 4 respondents wanted more specific advice for system use than what was given.

3.2 | Educator satisfaction

Diabetes educators completed a median of 2 (2, 2.5) HCLCheck-in calls per week, and reported they felt like they could have incorporated up to 4 (3, 4.5) per week in their current workload. The average overall time spent by educators for each HCL user was 45 (32, 70) minutes, with the most time spent on the actual phone call itself (Figure 3).

Educators reported low difficulty with contacting HCL users, interpreting data, and making insulin dosing adjustments, and moderate difficulty getting the HCL user to upload their system and/or accessing the reports from the cloud-based software (Appendix S3). On a scale of 1 to 10 (10 = highest), educators reported satisfaction with the HCLCheck-in workflow [8 (7, 9.5)], high satisfaction with the HCLClinical Tool [9 (9, 10)], and perceived the HCLCheck-in to be highly useful to the user/family [9 (8.5, 10)]. All 13 educators would recommend a similar follow-up for future diabetes technologies within our Clinic. In order to improve a similar program in the future, educators suggested finding ways to have the workflow and HCLClinical Tool integrated into the electronic health record, figuring out a better way to determine when the user started the HCL system, and finding a smoother process for obtaining downloads.

4 | DISCUSSION

Our results indicate the HCLCheck-in program was highly satisfactory to new HCL users and educators at our tertiary pediatric diabetes clinic and shows preliminary evidence for improving glycemic control with insulin dosing adjustments and reinforcement of diabetes self-care behaviors. To our knowledge, this is the first evaluation of a program initiated by a diabetes center to prospectively engage Control-IQ users within the first weeks of using the new technology. Our center has similarly described previous efforts to engage new 670G users,[19] and used this experience to help inform the design of this program.

Overall, the program was feasible for our Clinic to carry out for a 3-month period. Given the remote start-up process and not knowing when users started the HCL program, educators had to rely on contacting PWD/families by phone and email to complete the HCLcheck-ins. We were successful in completing check-ins for 62% of users/families starting HCL, which is relatively large percentage for a clinical program. The number dropped for subsequent check-in calls, as only 32% of users who did not meet benchmarks at the first HCLCheck-in could be reached for a second check-in. Reaching PWD by phone or email is a common challenge in clinical practice, and frequent attempts to contact PWD/families is time-consuming for busy clinicians. It's possible we could have reached more HLC users with more clinical resources; however this was not realistic for our Center given the high volume of new users.

The HCLCheck-in program offers preliminary evidence of improving system use and glycemic control for HCL users. The four benchmarks were useful in prioritizing which users needed extra support from our clinical educators and also for measuring improvement with additional follow-up for these individuals. Of the 16 HCL users who completed a second check-in call, all 16 (100%) had significant improvements in TIR compared with check-in call #1, indicating those who were willing to complete the calls benefited from the extra help. The benchmark most difficult to achieve for the HCL users was the ≥60% TIR. While international consensus suggests a goal of 70% TIR,[20] we determined the lower benchmark of 60% TIR would minimize burden on educators while addressing individuals with the greatest need. In hindsight, this decision seemed appropriate with 76% of users reaching the ≥60% TIR benchmarks, and only 24% requiring a second check-in call. Further, as adolescents have more difficulty achieving glycemic targets,[22] it is not surprising that the TIR benchmark was most difficult to achieve.

Possible reasons for improvement between the first and second HCLCheck-in call were the insulin dose adjustments and the Control-IQ specific education and behavioral recommendations from the HCLClinical Tool. Overall, many basal rates and I:C ratios were increased to make dosing more aggressive. Unlike the 670G (other commercially proved hybrid closed loop system), basal rates, I:C ratios, and sensitivities can all be adjusted with Control-IQ HCL, so all of these changes meaningfully alter insulin delivery.[23] For behavior change recommendations, most suggestions related to bolusing for meals prior to consumption of the meal, and underscores the point that hybrid closed loop devices are not able to fully compensate for missed meal boluses effectively.[24,25] User initiated food boluses are still essential on Control-IQ and all commercially available diabetes technologies to date. Recommendations to program the sleep activity for every night were common as well. The sleep setting is unique to the Control-IQ system, so users could have easily missed setting this parameter, and not understood its importance. The educators often explained that the sleep activity had two benefits: keeping the user in a tighter range overnight with basal modulation, and eliminating the auto-boluses from occurring, thus minimizing chance of hypoglycemia. Future research studies should elucidate, which adjustments and recommendation are most impactful to glycemic control.

Finally, users were highly satisfied with the HCLCheck-in program. The majority stated they would recommend a similar program for starting new diabetes technologies, indicating their perception of benefit from the check-in. It was also valuable to learn why some families did not complete the HCLCheck-in call. Many reported that they did not know about the call, indicating some gaps in our

administrative process, or potentially the families not checking voice or email messages. Others cited that they did not think it was necessary, suggesting that not all new HCL users need additional help.

Educators were overall satisfied with the program as well and reported low difficulty with the different components overall. Device uploads were reported as the highest difficulty, which is an ongoing frustration in clinical practice as well[26,27]. Several months after the evaluation of this program, the device manufacturer released a cloud-connected app for Control-IQ, which will reduce burden with obtaining device downloads in the future. Educators further reported high satisfaction with using the HCLClinical Tool, which served the dual purpose of standardizing the clinical follow-up and providing experiential learning for educators who needed to rapidly build skills and knowledge of the HCL device. Lack of knowledge of diabetes devices is a barrier to providing care for HCL users, with one survey indicating 74% of clinicians having concerns about being able to answer user questions about devices.[17] Practical, timely resources for on diabetes technology that can be incorporate into a clinical workflow are lacking,[28] and the HCLClinical Tool was unique in its function.We have made a version of this tool available for free use and distribution on our PANTHER (Practical AdvaNced THERapies for Diabetes) Program website, http://BDCPantherDiabetes.org.

The HCLCheck-in program had several strengths that could be leveraged for future diabetes technology programs within our setting, though may not be generalizable. One key to successful implementation was the careful planning and input from our diabetes educators, providers, and administrative staff. Due to the remote downloading of the HCL software and remote start, the administrative process was complex, involving several steps and coordination between administrative and clinical staff. Therefore, careful pre-planning was important. Another key component was creating the time for our administrative staff to take on the new workflow for identifying when users would start Control-IQ to schedule HCLCheck-in calls. This took some redistribution of administrative roles, thus having buy-in from the entire administrative and clinical team was important to be able to adapt and adjust as needed. Industry representatives were helpful in communicating with our administrative team and helping ease the flow of prescription processing and tracking individuals staring the system. Finally, by planning the program weeks before Control-IQ became commercially available, we had time to train the diabetes educators on the Control-IQ system and HCLCheck-in program. Other strengths to the program include the HCL Clinical Tool, and the use of "benchmarks" to quickly assess use of the HCL system. These components of the program will likely be retained for future program development within our clinic.

There were limitations to the long-term feasibility of this HCLCheck-in program as well. The largest limitation is the time spent by diabetes educators and administrative staff. Time and workflow are ongoing concerns in our clinical practice, and are identified in the literature as a common barrier to clinicians' ability to embrace advanced diabetes technologies.[18,26] It is not realistic that our Clinic could indefinitely support nurses spending 45 minutes of time following up on new HCL users when the task is not currently reimbursable by insurance. Thus, we only attempted to sustain this program for the first 3–6 months of commercial availability of Control-IQ. If programs aimed at improving use and outcomes of new devices can be shown to sustain improvement in glycemic control, perhaps future insurance paradigms while provide cost coverage for the services. It is also not known whether our program would be as useful long-term, or only needed when new technologies are commercialized. As our clinicians and users get more familiar with new technologies, there may be less of a learning curve when working with more established diabetes devices.

Overall, the HCLCheck-in program was highly satisfactory to new HCL users and educators at our pediatric diabetes clinic, and shows preliminary evidence for improving glycemic control with insulin dosing adjustments and reinforcement of diabetes self-care behaviors. As the diabetes technology field continues to expand with new devices and models of care, follow-up will be needed to meet the needs of both PWD and the clinicians caring for them. Brief interventions at the start of new device initiation may be an effective use of time and resources to help device users "start off on the right foot". Programs such as the HCLCheck-in can be examples of this goal, and could be adapted and modified as needs change for new diabetes devices.

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CONFLICT OF INTEREST

LHM has received speaking/consulting honoraria from Tandem Diabetes, Dexcom, and Capillary Biomedical. Her institution receives research/project grants from Medtronic, Tandem Diabetes, Dexcom, Abbott, Beta Bionics, and Insulet Corp. CB – no disclosures AE has received honoraria for serving on the Medtronic Diabetes Educator Board. LT- no disclosures RS receives research funding from Medtronic, Dexcom, Insulet, Tandem. GPF receives research funding from Medtronic, Dexcom, Abbott, Insulet, Tandem and Lilly and has served as a speaker/consultant for Medtronic, Dexcom, Insulet, Tandem and Lilly.

AUTHOR CONTRIBUTIONS

L.H.M. designed the program evaluation, administered follow-up phone calls, analyzed data and wrote the manuscript. C.B. designed the program evaluation, administered follow-up phone calls and reviewed/edited the manuscript. A.E. designed the program evaluation, administered follow-up phone calls and reviewed/edited the manuscript. L.T. provided administrative support for the program, performed data entry, contributed to the methods and reviewed/edited the manuscript. R.S. designed the program evaluation, and reviewed/edited the manuscript. G.F.P. designed the program evaluation, and reviewed/edited the manuscript. L.H.M. is the guarantor of this work.

PEER REVIEW

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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