DIABETES TECHNOLOGY & THERAPEUTICS
Volume 24, Number 4, 2022

DOI: 10.1089/dia.2021.0265

ORIGINAL ARTICLE

Specialized Technology Education for Pumps and Pens in Underserved Populations with Diabetes

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Abstract

Background: Health care disparities in the use of diabetes devices are particularly prevalent, especially given the high levels of health literacy and numeracy needed to understand their use.
Methods: To reduce this gap, we created lower literacy, English and Spanish multicultural guides for insulin pen and pump use. Focus groups provided input, nonbranded illustrations were designed, and simplified text was developed. The guides were implemented in our clinic for underresourced individuals in East Los Angeles, California. Subjects given the low literacy guides participated in guide-driven individual and group education, and measures were administered at baseline, 6 and 12 months.
Results: Sixty-three adults with type 1 diabetes (T1D) were included, and 43 (68%) completed all 12 months of the study. Initial HbA1c was 9.2 ± 1.97 (standard deviation) with no change over the study course (12-month A1C $= 9.3 \pm 1.92$). However, participants showed significantly reduced psychological distress due to diabetes, increased diabetes knowledge, improved self-report of health, and a trend toward reduced depression. There was also a reduction in rates of diabetic ketoacidosis (DKA). There was no change in rates of hypoglycemia, although there was an increase in fear of hypoglycemia.
Conclusions: Appropriately targeted teaching guides can be used to improve various patient-reported outcomes in people with T1D, specifically, overall self-report of health, distress due to diabetes, and diabetes knowledge. Targeted teaching guides also achieved improvements in rates of DKA in T1D. While these results are encouraging, more work is needed to make a significant impact on glycemic control. Clinical Trials registration number: NCT04550585.

Keywords: Diabetes technology, Education, Lower literacy.

Introduction

The use of technology has become integral to the management of type 1 diabetes (T1D) and is recommended that treatment consists of multiple daily injections (MDI) or insulin pump therapy along with continuous glucose monitoring (CGM).[1] Unfortunately, many people with T1D are not able to use these devices, particularly those from underresourced communities.[2,3] People with a lower socioeconomic status (SES) or those who are from a racial minority group have higher HbA1c levels and more diabetes-related complications.[4] Moreover, individuals from lower SES and lower educational level populations have more episodes of diabetic ketoacidosis (DKA) and are less likely to use insulin pumps.[5,6]

A significant barrier to the use of technology in poorer communities has been the reading and educational level needed to understand training manuals and guides and the lack of inclusion of images and references to people from diverse minority groups.[7,8] Starting people with lower literacy levels and fewer resources on diabetes technology also requires more time for education, follow-up, and on-call support systems in as we learned in a prior study implementing CGM in these individuals.[3]

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In this study, which began in 2016, we had the opportunity to teach our patients with T1D to use pens and insulin pumps because of changes in the health care system. CGM was not available at the time. Previously most were on MDI therapy using vials with 1 cc syringes and ½ inch 28G needle syringes. Our patients could not easily understand the instructions that came with pens and pumps, and we did not have a dedicated diabetes educator in clinic. The endocrine fellows do all the teaching, under the supervision of an endocrine attending.

Therefore, we created a simplified lower literacy, culturally and language appropriate approach, to teach our patients. We utilized focus groups to create and test our teaching guides, then implemented the program in our clinic. Measurements of the guides' utility included the ability to lower HbA1c's, improve time in range (TIR), reduce diabetes distress, and improve health-related quality of life without increasing DKA rates or severe hypoglycemia using continuous subcutaneous insulin infusion or pen therapy.

Research Design and Methods

Approval of the Institutional Review Board at The University of Southern California was obtained before data collection. The sample comes from patients in the T1D clinic at the Roybal Comprehensive Health Clinic, which provides outpatient services to the surrounding community. Roybal Comprehensive Health Clinic is located in a federally designated medically underserved area of Los Angeles, California, and patients are primarily of lower SES (<138% above the federal poverty limit). Most patients had MediCal (Medicaid) or some form of general relief (emergency MediCal or other) to cover their care.[9]

The project had two phases. In Phase 1, we held focus groups to help design educational materials to be used in Phase 2—the implementation phase of the study.

Phase 1: focus groups

In Phase 1 of the study, we convened two focus groups of 4–6 English and Spanish speaking adults with T1D, some of whom had used technology and others who had not, to help simplify the educational process for using pens and pumps. Actions included creating new guides for essential T1D management and carbohydrate counting and the use of pens and pumps with the intent to lower the reading level (generally at 11th grade) to a 5th grade reading level in English and Spanish. Lower than a fifth grade reading level was not possible due to the technical terms included in technology use. Focus group participants first reviewed materials already available to patients and gave feedback as how to improve the information provided.

The group felt that materials needed significantly more illustrations and simple language. After developing a new educational guide, the focus groups reconvened to provided feedback on ease of use of the material and guidance as to additional information to be added. Four guides were developed—available in English and Spanish and included the following: Is the Insulin Pump Right for Me?, How Do I Use an Insulin Pump?, Is the Insulin Pen Right for Me?, and How Can I Manage My Diabetes Better? After the educational guides were developed, eight Instructor Guides were created to assist educators during group sessions. These guides are also available in English and Spanish with four guides focusing on the basic of diabetes management, two on the insulin pen and two on the insulin pump and were the tools used for the classes as well as individual teaching sessions.

Preparation of low literacy materials. In addition to our focus groups, experts in the field of health literacy and education provided input using the Centers for Disease Control and Preventions' ''Simply Put'' program[10] and the Clear Language Group.[11] The Clear Language Group is a consortium of experts in health literacy, simple language, and cross-cultural learning. A medical illustrator made the illustrations to be as generic as possible. We obtained no copyright to make all information freely available.

Phase 2: implementation

To be eligible for the implementation phase of the study, participants were required to be 18 years or older and have a scheduled appointment in the T1D clinic during the 12-month study period. They were required to speak English or Spanish and not have a significant barrier to learning, such as a severe mental illness or limited cognitive skills. After providing informed consent, an invitation to participate was extended to patients in our T1D clinic. Women who were pregnant or planning pregnancy within the next year were excluded from participation. The implementation phase was conducted from January 15, 2017 to August 30, 2019. Upon enrollment, participants completed a series of questionnaires and wore blinded CGM for 2 weeks.

After enrollment, we provided all subjects with a copy of our educational guides. We invited them to participate in up to four educational group classes. Classes were held every 2 weeks on Tuesday evenings and Saturdays as these times were most convenient for our patients. Subjects could also have one-on-one sessions. Education was provided by the study coordinator, an RD, CDCES, following the newly created instructor curricula and educational guides in group and one-on-one sessions. Classes included Basics of T1D Management, Carbohydrate Counting, Insulin Self-Adjustment, Sick Day Management, Physical Activity, and Insulin Adjustment. Components of the educational program included the basics of type 1 management: primary nutrition education, carbohydrate counting, insulin self-adjustment, sick day rules, and physical activity dose adjustments.

For subjects interested in using an insulin pen or pump, four additional classes were offered: Starting the Insulin Pen, Trouble Shooting the Insulin Pen, Starting the Insulin Pump, and Trouble Shooting the Insulin Pump. Our guides and training related to pens and pumps included the basics of how insulin pens and pumps work, the different types of devices available, and how to troubleshoot problems if their pen or pump did not work correctly. This sort of training is not formally available to our patients other than that provided by our endocrinology fellows and rotating dietitians who are largely familiar with working with people who have type 2 diabetes. The CDCES did not adjust medications or recommend new therapies and, instead, worked under the direction of the fellows. Throughout the sessions with the study coordinator, patients would be referred to the educational guides when discussing any device or diabetes management questions.

After patients completed the basic modules, we initiated additional, directed training. Participants who wished to start (or who had newly started) insulin pump therapy began training. Participants switching from syringes to pens had follow-up in a much shorter pen follow-up group.

All study participants were managed in the specialty clinic for those with T1D with care provided by the fellows under the supervision of one of two attendings (one of whom is this project's principal investigator, Anne Peters, MD).

Measures

Health-related quality of life. A primary aim of this study was to measure whether new technology reduced psychological distress due to diabetes, reduced depression, increased diabetes knowledge, and improved self-report of health. To explore the degree to which health-related quality of life improved, we used five previously validated measures. To evaluate worries and concerns related to diabetes and its management, the 28 item T1D REDEEM diabetes distress questionnaire (range 1–6 scale, higher mean scores indicated higher levels of distress) was included.[12]

To evaluate change in feelings about hypoglycemia, the Hypoglycemia Fear Survey (HFS-II), which has 23 items and 2 subscales, HFS-B (Behavior subscale) and HFS-W (Worry subscale), was employed. The 15 items in HFS-B measure behaviors to avoid hypoglycemia and its possible negative consequences. The 18 items in HFS-W measure aspects relating to hypoglycemic episodes provoke anxiety. The items are rated on a five-point Likert scale ranging from 0 (never) to 4 (always). The HFS-II subscale scores and total score are sum scores of all or relevant subset of items ranging 0–60, 0–72, and 0–132 for the HFS-B, HFS-W, and HFS-II, respectively. Higher scores indicate higher fear of hypoglycemia.[13]

The eight-question PHQ8 survey was used to evaluate depression (range 0–24, a higher score indicates higher levels of depression).[14] To assess patient knowledge of diabetes, the simplified Michigan Diabetes Knowledge Test, a 23-item test to represent general diabetes knowledge, was included.[15] Finally, to evaluate overall well-being, we utilized the self-report of perceived health 1 item question (range 1 = excellent to 5 = poor).[16] This is the first question from the Short Form Health survey (SF36). Participants completed questionnaires at baseline, 6-, and 12-month visits.

Glycemic parameters. To ensure patients could safely transition to new technology without increasing the rates of DKA or severe hypoglycemia, participants were asked if they experienced DKA or severe hypoglycemia in the past 3 months. Information regarding emergency department visits or hospitalizations during the study period was obtained both from self-report and the electronic medical record platform Orchid used by Los Angeles County/the University of Southern California.

We measured HbA1c and glucose ranges (TIR, time below range [TBR], time above range [TAR]) at three points throughout the study period. An HbA1c level was obtained at the start of the program and at 6 and 12 months. Blinded CGM data at baseline, 6, and 12 months were analyzed for mean glucose level, TIR, TAR, and TBR. Initially the Dexcom was used, but due to patient preference, this was switched to the professional version of the Libre, which was worn by the majority of patients in the study. Patients wore the same blinded CGM at baseline for subsequent time points.

Method of insulin delivery. We assessed the mode of insulin delivery at baseline. We placed study participants into one of four categories: vial and syringe injection only, pen and vial/syringe injection, insulin pens only, and individuals recently (within 1 month) started on the insulin pump only. Participants were assessed for changes in insulin delivery mode from baseline to 12 months, with self-report or electronic medical record. We were able to verify the mode of delivery for total of 47 participants.

Data analysis

Descriptive statistics were used to summarize patient characteristics and illustrate the mean value and standard deviation for HbA1c, self-report of health, diabetes knowledge, depression, diabetes distress, hypoglycemia fear, rates of hypoglycemia and DKA, and glucose ranges.

Statistical analysis was performed using the statistical package StatPlus (RRID:SCR_014635). StatPlus is a data analysis tool that works with Microsoft Excel. Microsoft Excel for Mac 2011 Version 14.7.7 (Microsoft, Inc.) was used to operate StatPlus and generate tables. A two-tailed $P < 0.05$ was considered statistically significant.

To compare dropouts versus completers one-way ANOVA was used to compare baseline demographics, A1c, CGM measures, overall health status, level of depression, diabetes knowledge, diabetes distress, and hypoglycemia fear. Paired sample *t*-tests were used to analyze differences between outcome measures from baseline to 6 months and from baseline to 12 months.

Results

Preliminary analysis

Sample characteristics. Of the ~200 patients receiving care for T1D at Roybal Comprehensive Health center during the study period, all eligible individuals were invited to participate. Sixty-three patients were enrolled, 51 (81%) remained at the 6 month follow-up, and 43 (68%) completed the intervention. Patient characteristics are summarized in Table 1. Participants, at baseline, were predominantly female ($n = 35$, 55%), low-income ($n = 32$, 51% making <25,000 per year), Hispanic/Latino ($n = 51$, 81%), and approximately one-third ($n = 23$, 36%) had not completed high school. Most participants had adequate functional literacy ($n = 50$, 79%), nine were marginal, and four were inadequate as measured by the Short Test of Functional Literacy.[17] The majority ($n = 49$, 78%) received medical coverage through government sponsored health insurance.

Participants' mode of insulin was tracked over time, as summarized in Figure 1. Of the 47 subjects we were able to track, 22 made a change in their insulin delivery. The most frequent change was from vials and syringes for insulin injections to the use of insulin pens only ($n = 10$). Availability of the specific insulin in pen form, including Lantus, Basaglar, and Tresiba, was believed to have contributed to the change in those participants. Specifically, the shift from vial/syringe injection to insulin pens only or adding a pen was 4 and 6 participants, respectively.

Table 1. Participant Baseline Characteristics

Characteristic	*All participants as baseline (*N = *63)*	*Dropouts (*N = *20)*	*Completers (*N = *43)*
Gender	Male $N=28$ (45%) Female $N=35$ (55%)	Male $N=8$ (42%) Female $N=12$ (58%)	Male $N=20$ (47%) Female $N=23$ (53%)
Age (years) (mean, SD)	45 ± 14	41 ± 11	46 ± 14
Age at diabetes diagnosis (years) (mean, SD)	25 ± 13	22 ± 14	23 ± 13
Race/ethnicity			
Non-Hispanic White	$N=4$ (6%)	$N=4$ (21%)	$N=4$ (8%)
Black/African American	$N=3$ (4%)	$N=1$(5%)	$N=1$ (2%)
Hispanic/Latino	$N=51$ (81%)	$N=13$ (64%)	$N=34$ (80%)
Asian	$N=4$ (6%)	$N=0$ (0%)	$N=3$ (6%)
More than one	$N=1$ (2%)	$N=2$ (10%)	$N=1$ (2%)
Primary language			
Spanish	$N=36$ (57%)	$N=3$ (15%)	$N=27$ (62%)
English	$N=27$ (43%)	$N=17$ (85%)	$N=16$ (38%)
Functional health literacy			
Inadequate	$N=4$ (6%)	$N=1$ (5%)	$N=3$ (6%)
Marginal	$N=9$ (15%)	$N=1$ (5%)	$N=8$ (19%)
Adequate	$N=50$ (79%)	$N=18$ (90%)	$N=32$ (75%)
Income			
<$25,000	$N=32$ (51%)	$N=8$ (42%)	$N=22$ (51%)
$25,000–$35,000	$N=6$ (10%)	$N=1$ (5%)	$N=5$ (11%)
>$35,000	$N=8$ (13%)	$N=3$ (16%	$N=3$ (7%)
Not provided	$N=17$ (27%)	$N=8$ (37%)	$N=13$ (31%)
Education			
No high school diploma	$N=23$ (36%)	$N=7$ (35%)	$N=15$ (36%)
High school diploma	$N=18$ (28%)	$N=2$ (10%)	$N=13$ (30%)
Some college	$N=16$ (26%)	$N=8$ (40%)	$N=11$ (25%)
College degree	$N=6$ (10%)	$N=3$ (15%)	$N=4$ (9%)
Insurance			
Government sponsored	$N=49$ (78%)	$N=12$ (58%)	$N=35$ (82%)
Private	$N=1$ (2%)	$N=2$ (10%)	$N=1$ (2%)
None	$N=1$ (2%)	$N=0$ (0%)	$N=1$ (2%)
Unknown	$N=12$ (18%)	$N=6$ (32%)	$N=6$ (14%)

SD, standard deviation.

Insulin pump use was more variable. Three participants transitioned from insulin pen to pump only. Another three switched from insulin pump to insulin pen only ($n=2$) and vial/syringe ($n=1$). Of the three participants who stopped using the pump, reported reasons were cost, interference with daily activities, and difficultly of use.

At baseline, 11 participants (11/63, 17%) who agreed to participate in the intervention, did not agree to wear a CGM and cited ''not wanting to use a device that was worn on their body'' as the reason for lack of participation. Ten subjects who left the clinic with a CGM in place did not return with readable sensor data.

As a result, we were not able to capture average daily glucose or TIR levels in 22/63 (35%) of participants. Of the 42 subjects at baseline with readable data, 5 (12%) wore Dexcom and 37 Libre. At 6 months, of the 40 who wore a CGM, 33 (83%) had readable data with 7 wearing Dexcom (2 of whom did not have readable data at baseline), and 26 Libre. Blinded CGM data were captured for 31 of the 36 (86%) participants who completed the study. Of the 31 completers with readable data, 6 wore Dexcom (1 of whom did not have readable data at baseline), and 25 Libre. Participants who wore a CGM had an average of 12.8 blinded days of CGM data collected at baseline, 13.4 days at 6 months, and 12.6 days at 12 months.

Our population maintained their glycemic values well above the target range, as shown in Table 2, and we found no significant improvements in glycemic parameters or any CGM-derived values across the 6- and 12-month study period. In Table 3, we compared the dropouts and completers at baseline and found no differences in glycemic parameters. Changes in additional measures of blood sugar control and health-related quality of life are summarized in Table 4. Similar to CGM values, there were no statistically significant improvements in A1C or rates of severe hypoglycemia at 6 and 12 months. Rates of DKA, however, were reduced and reached statistical significance at both 6 and 12 months ($P=0.038$ and $P=0.017$, respectively).

To track our intervention, we recorded the number of classes and mode of education subjects received. All 64 subjects received a copy of our educational guides. Thirty-five subjects only attended the Basics of T1D Management class, while 26 subjects attended both the Basics of T1D Management and Carbohydrate Counting classes. Fourteen subjects participated in three courses, including Basics of T1D Management, Carbohydrate Counting, and Insulin Adjustment. Finally, 12 people attended all 5 classes adding Sick Day Management and Physical Activity and Insulin Adjustments to those listed above. Four people

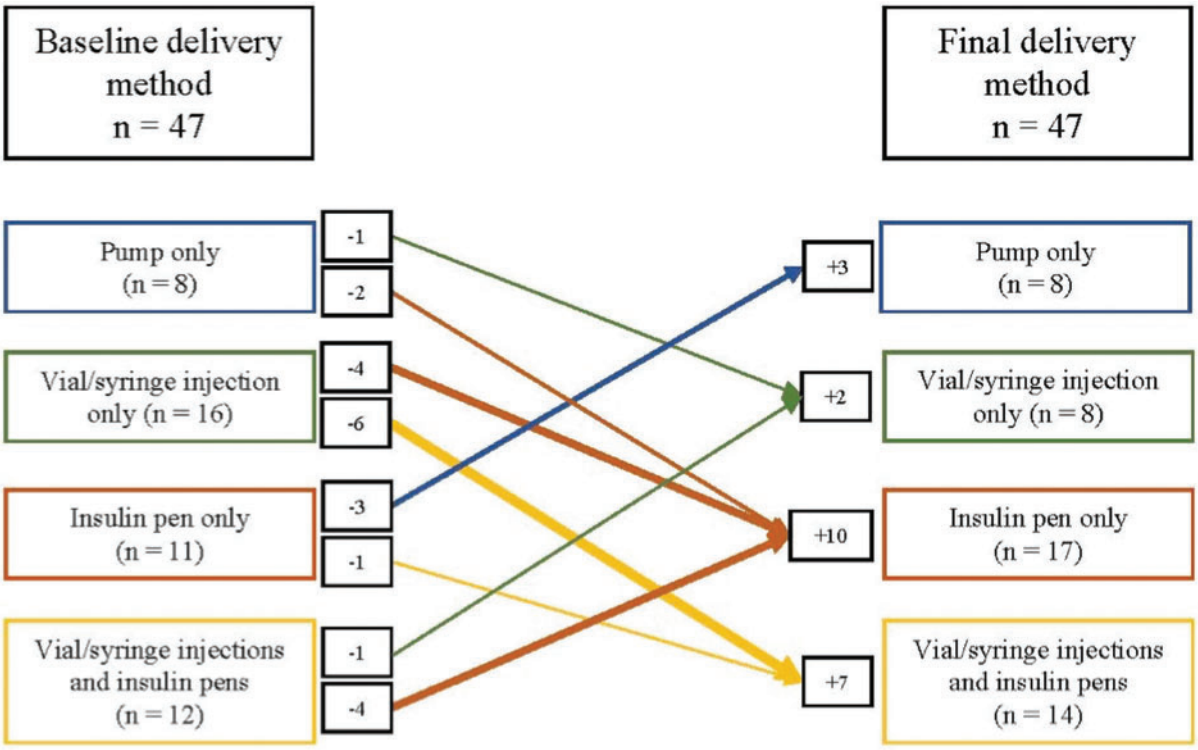

FIG. 1. Changes in modes of insulin delivery. Depiction of the changes in insulin delivery throughout the study period. The minus (−) sign denotes how many patients changed and which mode of therapy they changed to. Twenty-two patients changed their mode of insulin delivery. The blue boxes depict those on an insulin pump and the blue arrows are people who changed to an insulin pump. The green boxes show participants using a vial/syringe and the green arrows show those who switched to a vial/syringe. The red boxes show participants on the insulin pen only and the red arrows show those who switched to insulin pens. The yellow boxes show participants on vial/syringe and pens and the yellow arrows show those who switched to the vial/syringe and pens. Color graphics are available online.

participated in Starting the Insulin Pen, three attended Trouble Shooting the Insulin Pen, and three people attended both pump classes.

Several subjects requested additional education beyond the classes provided and received it either in person or by phone. Before month six, 31 subjects requested additional help totaling 48 visits. Additional help requested was on basics of type 1 management 27% ($N=13$), carb counting 63% ($N=40$), insulin adjustment 6% ($N=3$), sick day management 6% ($N=3$), physical activity 2% ($N=1$), starting the pen 2% ($N=1$), starting the pump 6% ($N=3$), and troubleshooting the pump 8% ($N=4$).

Between months 6 and 12, thirty-four subjects required additional intervention totaling 52 visits. The specifics of intervention requested were basics of type 1 management 12% ($N=6$), carb counting 62% ($N=32$), insulin adjustment 2% ($N=1$), sick day management 15% ($N=8$), physical activity 4% ($N=2$), troubleshooting the pen 2% ($N=1$), starting the pump 13% ($N=7$), troubleshooting the pump 17% ($N=9$), insurance assistance 2%($N=1$), getting diabetes supplies 6% ($N=3$), and scheduling diabetes appointments 4% ($N=2$). Of note, percentages are greater than 100% as some participants required help with more than one issue per visit. Sixteen of these individuals requesting additional help had not attended any classes.

Most patient-reported outcomes showed statistically significant improvements at 12 months, including self-report of health ($P=0.01$), diabetes knowledge ($P<0.01$), and

Table 2. Baseline, 6, and 12 Month Continuous Glucose Monitoring Results

	Baseline (N = *42*)		*6 Months* (N = *33*)		*Significance Baseline to 6 months*	*12 Months* (N = *31*)		*Significance Baseline to 12 months*
Variable	*Mean/%*	*SD*	*Mean/%*	*SD*	P	*Mean/%*	*SD*	P
CGM—average daily glucose	203	65.9	203	61.5	0.71	199	58.3	0.58
CGM—TBR	*N* = 5 (11%)	15.7	*N* = 3 (10%)	8.2	0.23	*N* = 3 (10%)	11.7	0.73
CGM—TAR	*N* = 26 (64%)	21.7	*N* = 22 (66%)	20.8	0.36	*N* = 21(66%)	22.5	0.14
CGM—TIR	*N* = 11 (25%)	8.8	*N* = 8 (24%)	15.2	0.82	*N* = 7 (24%)	17.0	0.15

CGM, continuous glucose monitoring; TAR, time above range; TBR, time below range; TIR, time in range.

Table 3. Comparison of Continuous Glucose Monitoring Wearers—Dropouts to Completers at Baseline

	Dropouts who wore CGM (N = 11)		*Completers who wore CGM (N = 31)*	
Variable	*Mean*	*SD*	*Mean*	*SD*
CGM—average daily glucose	226	86.7	203	61.5
CGM—TBR	10%	7.4	10%	8.2
CGM—TAR	66%	23.6	66%	20.8
CGM—TIR	24%	12.9	24%	15.2

diabetes distress ($P = 0.04$) except for fear of hypoglycemia, which significantly increased ($P < 0.001$) at 6 and 12 months (Table 3). Although not reaching statistical significance, results showed a trend toward improvement in depression ($P = 0.083$).

Participant dropout occurred during the 6- and 12-month study periods. Those who dropped out were more likely to be non-Hispanic white, speak English, and have a higher education and income level. Most participants who did not complete the study had an adequate functional literacy level; one was lower and one marginal. Compared to those who completed the study, the dropouts had fewer participants in the inadequate and marginal literacy groups as summarized in Table 1. Those who dropped out were also less likely to want to wear the CGM. However, there were no statistical differences in these groups when comparing the outcome measures of CGM, A1c, overall health status, level of depression, diabetes knowledge, diabetes distress, hypoglycemia fear, and literacy levels.

We also examined our outcome measures by dose of education, which included receiving educational guides only, receiving one-on-one education only, attending one class, attending two classes, and attending three or more classes. Due to the small number of individuals in each category, we did not have enough power to detect any significance, however, our results suggested that those only receiving educational guides or attended only one class did not improve as much as those who attended a one-on-one session or two or more classes.

Discussion

By utilizing focus groups, experts in medical illustration, and implementing lower literacy teaching guides, we were able to create generic tools for teaching patients with T1D about essential diabetes management as well as the use of insulin pens and pumps. Although we did not show improvements in glycemic control, we did show significant gains in several patient-reported outcomes not consistently seen in other studies.[18,19] Through the educational program we developed for study participants, including the basics of type 1 management, carbohydrate counting, insulin self-adjustment, sick day rules, and physical activity dose adjustments, we were able to show significantly improved self-report of health, representing a shift toward ''good'' or ''excellent'' in T1D patients.

Importantly, diabetes knowledge and worries and concerns about diabetes management also significantly improved. Encouraging was a trend toward improvement in the degree of depressive symptoms although not reaching statistical significance. In addition to patient-reported outcomes, there was a significant reduction in rates of DKA, particularly impactful in our underserved population, where episodes of DKA are common. Participants in this study described more fear about ''going low'' and reported that they ''feel better when they run a bit high.'' The only health-related quality-of-life measure that did not improve in our study group was fear of hypoglycemia at 6 and 12 months, which we suspect may be related to their increased diabetes-related knowledge.

This study had encouraging results in improving health-related quality of life, specifically in knowledge, distress, depression, and perceived health. While we were discouraged to find that improved perception of health did not translate into better glycemic control in our participants, further research is needed to see where the gaps lie. Many of our patients experience challenging life circumstances and hypoglycemia fears, and limited access to self-monitoring of blood glucose make achieving more normal glucose difficult. Having persistently high blood glucose levels is perceived as safer when faced with stressors, including jobs requiring manual labor, food insecurity, illness or disability of a family member, fear of eviction or deportation, job loss, and other hardships.[20] In this study population, these stressors overwhelm their ability to focus on diabetes management.[21,22]

Table 4. Baseline, 6-, and 12-Month Results

	Baseline (N = 63)		*6 Months (N = 51)*		*Significance Baseline to 6 months*	*12 Months (N = 43)*		*Significance Baseline to 12 months*
Variable	*Mean*	*SD*	*Mean*	*SD*	P	*Mean*	*SD*	P
HbA1c	9.42	2.20	9.04	1.75	0.16	9.24	1.93	.33
Self-report of health	3.53	0.99	3.41	0.90	0.308	3.12	1.03	0.01
Diabetes knowledge	0.69	0.17	0.73	0.17	0.084	0.77	0.15	<0.01
Depression	6.75	6.02	6.59	6.68	0.832	5.44	5.82	0.083
Diabetes Distress	2.23	0.91	2.10	1	0.49	1.89	0.94	0.037
Hypoglycemia fear	1.4	0.70	2.2	0.73	<0.01	2.2	0.75	<0.01
Rates of severe hypoglycemia in the past 3 months	0.73	1.47	0.45	1.06	0.29	0.82	1.68	0.922
Rates of DKA in the past 3 months	0.64	1.58	0.27	0.98	0.038	0.13	0.40	0.017

DKA, diabetic ketoacidosis.

Finally, during our study period, our patients did not have routine access to CGM due to a lack of coverage, a situation that has since improved. Therefore, we are completing our guides to CGM. All of our guides are freely available at: https://www.uscdiabetes.com/simple-guides.

This study has several limitations. First, this was a single-center observational study with no comparison to nonparticipants during the same study period. In the adult population that our study targeted, we do not know what selection biases might have contributed to why some TID chose to respond to the study invitation and others did not. Second true randomization was not possible because pumps and pens were only available to a subset of patients based on their insurance benefits; therefore, the patients were grouped by mode of insulin delivery at baseline. Third, we were unable to capture average daily glucose or TIR levels on all participants. Finally, as our study population was less ethnically and racially diverse than the overall United States and Los Angeles County population, we could not capture other underrepresented minorities and underserved communities' experiences.

Ideally, patients would have easy access to group and one-on-one education no matter where they receive diabetes care. Unfortunately, not all patients have such access or can accommodate their time for in-depth education into their schedules. Our findings suggest that those who attended more than one group session and received our guides were more likely to have better outcomes. We also found the guides alone to be beneficial. Our educational guides allow providers, at a minimum, to have easy-to-read diabetes management and insulin pump/pen education to hand out to their patients. For providers with the ability to offer formal classes, our instructor guides provide step-by-step instructions on how to conduct each session.

In conclusion, utilizing focus groups in an underserved health care system, we created generic, freely accessible lower literacy guides in English and Spanish to manage T1D. We addressed specifics regarding the use of insulin pens and pumps with accompanying instructor guides. The medical illustrator paid careful attention to include people of color depicted throughout the materials. The use of the educational guides was associated with improvements in patient-reported health-related quality-of-life measures and a reduction in rates of DKA. How to translate these improvements into improved glycemic control is an area for further investigation.

Authors' Contributions

Substantial contributions to the conception or design of the work (A.P., V.R.); or the acquisition, analysis, or interpretation of data for the work (A.P., V.R., S.O.); Drafting the work and revising it critically for important intellectual content (A.P., V.R., S.O.); Final approval of the version to be published (A.P., V.R., S.O.); Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (A.P., V.R., S.O.).

Acknowledgments

We are grateful to Martha Walker, RD, CDCES, and to our patients who helped us create these tools and G. Michael Roybal, MD, MPH, for supporting our diabetes program.

Author Disclosure Statement

A.L.P. has served on an advisory committee for Abbott Diabetes Care, Astra-Zeneca, Eli Lilly, Medscape, Novo-Nordisk, Vertex, Zealand, obtained research funding from: Abbott Diabetes Care, Dexcom and Insulet and has stock options for Omada Health and Teladoc. V.R. has no conflicts. S.O. has stock options in GoodRx.com.

Funding Information

This work was funded by a generous grant from the Leona M. and Harry B. Helmsley Charitable Trust.

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