

Facilitators and Barriers to Smart Insulin Pen Use: A Mixed-Method Study of Multidisciplinary Stakeholders From Diabetes Teams in the United States

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This study sought to identify barriers and facilitators to successful smart insulin pen (SIP) use and gauge prescribing practices and integration into clinical practice by assessing provider and care team perspectives at participating endocrinology clinics within the T1D Exchange Quality Improvement Collaborative. The identified provider-related, patient-related, and clinic- and operational-level barriers and facilitators varied based on clinic knowledge, capacity, and resources. Highimpact barriers included insurance coverage and prescribing processes; high-impact facilitators included improved diabetes clinic visit quality and use of SIPs as an alternative to insulin pump therapy. Findings indicated the need for provider and care team education and training on proper SIP features, use, and prescribing.

The use of smart insulin pens (SIPs) in clinical practice has the potential to improve medication adherence, glycemic management and control, time in the target glycemic range, and dose accuracy and reduce glycemic variability in patients with diabetes (1,2). Other benefits include remote monitoring capability and virtual care opportunities (3). A study conducted in Sweden using the IQVIA CORE Diabetes Model, projected that SIPs were associated with lower health care costs and improved health outcomes (i.e., they were a dominant treatment option) versus standard care in the base-case analysis and across all of the sensitivity analyses conducted (4).

SIP technology is a growing field with the potential for rapid expansion. The SIP available in the United States (InPen, Companion Medical/Medtronic Diabetes) was introduced in 2017 (5). SIPs fill a unique niche in the diabetes technology space and may serve as a template for future innovation.

In addition, SIPs can support and improve diabetes management by calculating doses based on current glucose levels and carbohydrate intake, helping to prevent missed doses, and sending dosing reminders (6). Other devices that may offer these same features have challenges that affect successful adoption by patients. For example, some of the barriers to the successful adoption of insulin pumps are cost, limits on lifestyle flexibility, and the need for technical expertise (7). Therefore, SIPs can function as a potential alternative for other diabetes technology devices, offering patients an opportunity to take a "pump holiday" (1) or more freedom in terms of lifestyle flexibility.

To advance the use of SIPs, providers must address challenges and barriers to their access and use and build clinic capacity to capture and report data successfully. In previous studies, researchers have examined barriers to accessing other types of diabetes technology such as insulin pumps. Identified barriers included individual motivation and interest, lack of awareness of

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devices, and structural health system—related issues (8). However, there is limited research relating specifically to SIPs (9). The purpose of this study was to identify facilitators, barriers, and operational challenges to successful SIP use and to gauge prescribing practices and integration into clinical practice by assessing provider and care team perspectives at participating endocrinology clinics within the T1D Exchange Quality Improvement Collaborative (T1DX-QI) (10,11).

Research Design and Methods

This was a mixed-method study conducted in two phases between November 2020 and June 2021. It was approved as nonexempt by the Western Institutional Review Board. Participants were recruited within the TIDX-QI. Centers participating in the T1DX-QI strive to improve care delivery and health outcomes and reduce barriers to care for everyone with type 1 diabetes by sharing best practices and data benchmarking (10).

In the first phase, six multidisciplinary clinic care teams—two adult clinics and four pediatric clinics—within the T1DX-QI participated in semistructured focus group discussions. Care team members included providers, nurses, educators, data analysts, and coordinators (Table 1). In addition, the design included a mix of pediatric and adult clinics with very high to very low SIP prescribing habits. Recruitment emails were sent to all member clinics of the collaborative inviting them to participate in focus groups. Of those that responded, we randomly selected six clinics to participate.

The first and second authors (E.O. and N.N.) conducted the interviews. Both interviewers were experienced in conducting qualitative interviews. Participants were aware of the goals of this research and provided verbal consent before the interviews. The focus group semistructured questions were tested and refined by a pilot group before the interviews. The focus group findings were shared with participants afterward via various meetings to ensure that the main themes identified reflected the conversations. Participants were not offered any financial compensation.

Focus group sessions were audio-recorded via the Zoom meeting platform. The audio recordings were de-identified and transcribed using TranscribeMe software (Transcribe Me, San Francisco, CA) and exported into NVivo, v. 1.4, software (QSR International, Burlington, MA) for analysis. A force field analysis was conducted analyzing high-, medium-, and low-impact forces identified in the analysis. Forces were identified as high-impact forces if they were mentioned at least once in five of the six focus groups or at least twice in a single focus group. Medium-impact forces were mentioned in three or four focus groups, and low-impact forces were mentioned in one or two focus groups.

Seven codes were created that reflected focus group questions and were based on an extensive literature review. These included Prescribing Comfort Level, Useful or Beneficial Tools, Provider Barriers, Quality of Visit, Operational Challenges, Patient Barriers, and Tools or Clinical Support to Increase Confidence Among Clinics. Coding occurred within NVivo for all transcripts. Any disagreements in coding were resolved among the authors. Themes were identified within each primary code, and direct quotes were pulled from the transcripts that reflected and supported these themes.

In the second phase of the study, clinics participating in the T1DX-QI were invited to complete an online survey on the research topic. Seventeen pediatric clinics (77%) and five adult clinics (23%) participated in the study's second phase. Clinics varied in the size and demographics of their patient populations. Table 2 summarizes the number of patients from clinics participating in the phase 2 survey and their racial/ethnic

TABLE 1 Multidisciplinary Roles in Phase One							
Role in Practice	Clinic A	Clinic B	Clinic C	Clinic D	Clinic E	Clinic F	
Pediatric endocrinologist	Х	Х	Х		Х	Х	
Diabetes advocate				Х			
Pediatric nurse practitioner or physician assistant		Х		Х			
Diabetes care and education specialist	Х	Х	Х			Х	
Registered nurse	Х	Х	Х	Х		Х	
Clinic manager/coordinator			Х			Х	

TABLE 2 Profile of Patient Populations Reported by Clinics Participating in Phase 2 (N = 22)

	Type 1 Diabetes	Type 2 Diabetes
Patients in clinic, <i>n</i>		
0-500	2 (9)	14 (64)
501-1,000	3 (14)	3 (14)
1,001-1,500	3 (14)	1 (5)
1,501-2,000	8 (36)	0 (0)
≥2,001	6 (27)	4 (18)
Race/ethnicity of patient population		
Unknown	4 (18)	9 (41)
NH White		
0-10%	0 (0)	2 (9)
11–30%	2 (9)	5 (23)
31-50%	2 (9)	2 (9)
51-75%	9 (41)	0 (0)
76–100%	5 (23)	0 (0)
NH Black		
0–10%	5 (23)	0 (0)
11-30%	8 (36)	5 (23)
31-50%	5 (23)	3 (14)
51-75%	0 (0)	1 (5)
76-100%	0 (0)	0 (0)
Hispanic	40 (45)	4 (5)
0-10%	10 (45)	1 (5)
11-30%	3 (14)	4 (18)
31-50%	1 (5)	3 (14)
51-75% 76-100%	2 (9)	1 (5)
76-100% Other	0 (0)	0 (0)
0-10%	15 (68)	3 (14)
11-30%	15 (68)	3 (14)
31-50%	0 (0)	0 (0)
51-75%	0 (0)	0 (0)
76-100%	0 (0)	0 (0)

Data are n (%) of participating clinics.

breakdown. The survey was administered using Qualtrics XM (Qualtrics, Provo, UT). Categorical data were represented as percentages of responses. Summary statistics, including frequency and percentage for categorical variables, were calculated for all clinical characteristics. This study adhered to the Consolidated Criteria for Reporting Qualitative Research standards (12). Supplementary Tables S1 and S2 provide the focus group guide and survey questions, respectively.

Results

Barriers and facilitators identified in focus groups and survey results were organized into three categories: 1) provider-related, 2) patient-related, and 3) clinic- and operational-level. The classification for some factors as facilitator or barrier varied depending on clinic resources or providers' and patients' knowledge or skills and were therefore categorized as both barriers and

facilitators. Table 3 provides sample direct quotes from focus groups illustrating the identified themes.

Barriers

A key theme within the category of provider-related barriers was provider and care team training and awareness. Low provider and care team awareness of the utility of SIPs and a lack of training on SIP use were considered a high-impact barrier. Sixty-three percent of clinics reported that provider preferences or limited training was a significant barriers to using SIPs in their practices (Figure 1). Low provider awareness often resulted in SIPs not being routinely mentioned when clinicians discussed other diabetes technology devices such as insulin pumps and continuous glucose monitoring (CGM) systems with their patients.

Key themes in the category of patient-related barriers included A) insurance coverage and cost; B) patient education and training; C) smartphone availability and functionality, and D) pediatric-specific barriers. Eightytwo percent of surveyed clinics identified patient health insurance and associated copay costs as barriers to SIP technology uptake in their clinics (Figure 2). Knowledge of insurance coverage for SIPs and how to navigate this process after prescribing the device was a significant concern to multiple providers. Additionally, 73% of the clinics identified education and training for SIP use as the most significant barriers observed among patients (Figure 2). Clinics underscored a lack of direct patient education and training during the SIP setup process. Care teams mentioned that having demonstration SIPs available in the clinic would facilitate a more meaningful discussion and setup process with their patients. Smartphone availability and functionality were considered a high-impact barrier among clinics serving a high proportion of low-income patients. During focus groups, care teams stated that issues with smartphone functionality and access to the Internet were more concerning than whether their patients owned a smartphone. Pediatric-specific issues included concerns expressed during focus group sessions about children living in multiple households, bringing their SIPs to school, and having access to a smartphone versus needing to rely on a guardian or parent to facilitate SIP use. Care teams described how miscommunication among family members and children moving between multiple households could lead to discrepancies in dosing and improper use of the SIP application (app). In addition, parents have shared concerns about their children bringing their SIPs to school and losing them.

TABLE 3 Focus Group Quotes Exemplifying for Categorized Barriers and Facilitators

Category Example Quotes

Barriers

Provider-related (e.g., provider and care team awareness, care team prescribing comfort level, no or limited training on SIPs)

"The biggest barrier is us either not having the appropriate training or just even talking about it with our patients. And, so, I think it just begins with us being a little bit more aware of that and really just talking about it more."

"Also, just kind of the lack of knowledge that we have right now. Hopefully, we would obviously receive a little bit more training, and then a little bit more information on how we are to prescribe it, and also how we can help best utilize it for our patients."

"Providers need to be shown and need to be walked through how this works, all the data that [are] available on it. And I think more providers would be willing to prescribe it because then they know what they're prescribing."

Patient-related (e.g., cost, insurance, SIP education and training, smartphone availability and functionality, technological difficulties, language barriers, and pediatric-specific issues)

"I think there was one time we tried to get someone set up in-clinic. And I think the cash price is \$35, and I know for some people, they can't even afford that."

"Just that price of them having to pay out of pocket is kind of the big thing for a lot of our patients."

"I think the insurance coverage right now has been challenging over the past several months. And I have been trying to meet with people to try and help streamline or come up with a different way of getting people the device, but it's a work in progress."

"I have to say that the biggest barrier is the insurance coverage."

"If we could have them on demand and [are] able to give them to them and train them while they're in clinic, I think that would be a much more effective way of doing it rather than having to send it off and hope they get it and reach out to get help to actually get started on it."

"It would be nice to have these pens on demand to just give out in clinic and then do whatever for billing afterward, so we could do that hands-on learning immediately rather than sending that prescription to the pharmacy and having them get it later. So, having a lot of other demo pens that we're able to produce right in clinic, give it to them more real-time rather than, oh, sending it off to your pharmacy and then wondering what happens."

"Most people do carry smartphones now. But the exact functionality of those smartphones is variable, what their . . . data plan is and that sort of thing. And, so, I do worry about that somewhat. Not for patients who I think we've managed to get on, but if we're trying to make this available to everyone, I worry about the equity of that. We run into issues."

"Yeah, I think most people have access. And I don't know that this would be a huge data thing, but I think they get worried about downloading apps that may charge them or use lots of data, or sometimes they have a smartphone, but the functionality of it is questionable sometimes."

"So, they might have one, but maybe not understand how to use it or how to use the app."

"There is a learning curve, there. And, we do have patients [who] do go on insulin pumps, and they don't know how to adjust their own settings in their pump. So, that is kind of concerning if they can't figure that out in the smartphone. So, definitely a lot of training, definitely a lot of reinforcing for the patients and parents, as well as educators and our providers."

"[For a] good part of our patient population that we work with, . . . either English [is] a second language or they don't speak English at all."

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TABLE 3 Focus Group Quotes Exemplifying for Categorized Barriers and Facilitators (Continued)

Category Example Quotes

"I think there was talk about [using it] for some of the younger population with parents being able to track the device and using the application on their phone, but then we had the barrier consideration [of] when the child goes to school and creating gaps in data. That would be difficult to trend by the providers and also be difficult for the parents to not necessarily cope, but there may be a lack of idea of what's going on, how much insulin the child's receiving at school when they have, now, been used to seeing what they're going to be dosed for—something like that."

"Some of the parents are worried about sending the pen to school. So, sometimes they don't use it for lunch because the parents are worried it's going to break or get lost. And, so, we don't always have the parents using it the kids using it for lunch."

Clinic- and operational-level (e.g., prescribing and follow-up processes, in-clinic report retrieval, care team prescribing comfort level, and telemedicine)

"Patients that . . . were enthusiastic in clinic, and it got prescribed, but they never did get started. There was maybe the need for prior authorization at the pharmacy or maybe something more that they needed to do in order to get it, and they never did get started."

"I think there's just a big gap between sending off the prescription and then making sure the family pairs up with the people at the start to get all of the training that would help make them successful."

"So many failures of those prescriptions because then patients come back 3 months, 6 months later, and they never got this pen. They never used it, and they said the pharmacy didn't give it to us, so it was too expensive."

"I will say, as far as just comfort level, we're just not really sure where we are supposed to send the prescription for, whether it's coming from a durable medical equipment company or if it's coming from a pharmacy."

"I was not really that comfortable with even suggesting it for the longest time, because I didn't really know how to tell the families how it worked."

"[Telemedicine visits are a] significant barrier because of the patients who are not savvy, they are not savvy to join to the visit on time. And then, the visit takes longer, or they disconnect, or when they connect, then when I talk, I hear my echo voice, and that's annoying, and it's just impossible to talk. Then, I have them connect and disconnect several times, and it works for 5 minutes, then it goes back to this echo again."

Facilitators

Provider-related (e.g., quality of clinic visits and generated reports)

"It can really help to structure the clinic visits and make them more productive, even to the point where, for a lot of our patients that really just struggle being in clinic and just paying attention, this could actually be a really driving force to help with motivation and really help with ongoing diabetes care."

"I think anything that allows you to be able to see and track your data really helps to facilitate the conversation in clinic, because, especially for the care team and our primary focus of not only monitoring it for complications and making sure that insulin dosing is appropriate and appropriate dosages are in place, but more of getting our patients and families comfortable with looking at the data, to be able to problem-solve and figure out what to do, because there's a lot that happens in between the clinic visits. And, it just gives them so much more information to be able to do that."

"I mean, it's just a lot clearer to see if the timing is off, if the correction is off. There [are] a lot of things that you can see from the report."

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TABLE 3 Focus Group Quotes Exemplifying for Categorized Barriers and Facilitators (Continued)

Category Example Quotes

Patient-related (e.g., used as an alternative to pump therapy, improvement in diabetes management: dose visibility and accountability, and dose calculations and adjustments)

"I think there [are] a lot of patients who wanted the benefit of a pump but didn't want to wear a pump. And, I mean, obviously, you don't have a basal rate, but you still get a lot of the benefits of pump calculation. And, I think a lot of parents like that. And, especially for the kids who didn't want to go on a pump, they can still have a lot of that without using a pump."

"I thought it was brilliant, because there are so many patients who do not want multiple devices attached to them, and it's like they have a [continuous glucose monitor] and a pump, and this was still a great way—and especially having had a lot of patients who were great about, even when they are on the pump, the basal is going, but they don't bolus because they don't remember. And, so, you have them sitting at an A1C of 10%, and you're every time trying to troubleshoot with them how to remember, and they tend to forget. [This] gives us this great opportunity that you're still able to track and log what doses they're giving, which again, when you're seeing them in the clinic, oftentimes we hear that, 'Yeah, I don't know if I did,' or, 'I forgot.' But, at the same time, it gives them the freedom that they're not actually tethered to another device."

"I think it helps with the quality of life, too, because they can see their progress. They can see when the reports start improving. It's nice feedback for them, and they think they feel more involved rather than standing back and having a doctor tell them what to do. They actually can see it for themselves. They can see what's going on."

"The value is being able to really see what's happening day in and day out and for the families to be really responsible and accountable for their own data, to really be able to talk intelligently about how things have been, how blood sugars have been trending, and what changes they feel need to be made, or what's been a positive or what's been a challenge."

"If you send us these reports in between appointments, we can help you with dose adjustments, and it's just a matter of them essentially hitting the button to send the report. And, I've had several people [who] have never done dose adjustments before take us up on that."

"So, it's immediate feedback as to how the therapy is affecting them. And, you can also see if they're-as long as they're using the insulin, you can see when they're missing doses. So it's just, I guess compliance and the effect of their treatment pretty much."

"I've found it really beneficial just for communication purposes in general for children, because kids have a lot of shifts and different caregivers."

"It gives an excellent opportunity for patients to simplify the guessing of the insulin administration. And, also, what you need to do, you need to decide that, basically, the amount of insulin basal, you can choose three modalities, right? For meals, which can be the [carbohydrate] counting type of meal or a fixed dose, okay. And so, these remove most of the guess work for most of the patients. And it fits, also, the need of those patients, and I think here about the older population with type 1 diabetes. They may struggle more, okay, especially [with] . . . carb counting."

Clinic- and operational-level (e.g., care team prescribing comfort and telemedicine)

"Yeah, so I feel very comfortable prescribing the InPen. I had to do a fair amount of partnering with the previous InPen [representative] to fully understand the device and be able to teach my patients appropriately: what the features are and the pros and the cons of it."

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TABLE 3 Focus Group Quotes Exemplifying for Categorized Barriers and Facilitators (Continued)

Category Example Quotes

"In general, our clinic is very comfortable [prescribing SIPs] . . . thanks to people in our clinic, we have plenty of opportunities for education for them to learn the technology."

"For the people [who] are already using the pen, when they have their telemedicine appointment, I think it facilitates a more meaningful discussion with telemedicine in general, because it can be really challenging for families to upload a meter, figure out how to get us continuous glucose monitor data, and all of . . . [the] scans or logs that they have."

"That's the nice thing about the report. [If] they say they haven't sent it after they've been on it for a week, you can see quickly. But I think most of the patients we know, so then we talk through . . . even now on telemedicine, I can be like . . . 'Okay, show me your InPen settings.' They can put the screen up and I can see, 'Yeah, you did that correctly.'"

"It's easier to do telemedicine because of this, I think, and get the reports."

In the category of clinic- and operational-level barriers, the following themes emerged: *A*) clinic workflow, *B*) care team prescribing comfort level, and C) telemedicine. Forty-one percent of clinics reported that obtaining and using data reports was a barrier in their practice (Figure 2). Clinic workflow was viewed as a barrier in many clinics, as issues arose with report retrieval, prescribing, and education for SIP use. In addition, during focus groups, clinics highlighted their lack of knowledge regarding how to download information and a disconnect between the prescribing process and patient retrieval of pens from the pharmacy. As one respondent put it, "Prescriptions go off into a black hole." Twenty-seven percent of clinics highlighted providers' comfort level in prescribing SIPs as a barrier, a finding amplified during the focus group discussions. In addition, prescribing comfort level was lower for clinics that do not regularly prescribe SIPs to their patient population. Eighteen percent of clinics stated that remote monitoring during the coronavirus disease 2019 pandemic was a barrier for their clinic (Figure 3). During focus groups, clinics with low prescribing comfort and a limited number of patients already prescribed SIPs viewed telemedicine visits as a barrier to quality care.

Facilitators

Key themes related to the category of provider-related facilitators included *A*) improved quality of the clinic visit and *B*) reports (Figure 3). With regard to improve visit quality, 82% of clinics selected data visualization in real-time as a benefit of SIP use, 73% selected

shifting to constructive conversations and problem-solving, and 50% selected improvements in child/parent/guardian relationships (Figure 4). With regard to reports, 77% felt very confident interpreting reports from SIPs. No respondents reported limited or no confidence in interpreting reports. During focus groups, providers mentioned that patients can send reports between visits, allowing providers to make dosing adjustments in a timely manner.

Under the category of patient-related facilitators, researchers found themes including A) used as an alternative to pump therapy, *B*) improvements in diabetes management, and C) pediatric-specific facilitators. During focus groups, SIPs were seen as a tool to engage patients in their diabetes self-management and increase accountability for diabetes care. Improvements in adolescent engagement were reported. In addition, SIPs were viewed as an acceptable alternative to pump therapy. Respondents identified specific improvements in diabetes management, including dose visibility and accountability and dose calculations and adjustments. Fifty percent of clinics reported seeing improved medication adherence and improved glycemic management in patients using SIPs; 64% reported seeing improved dose accuracy, and 59% reported seeing improved confidence in dosing (Figure 4). Features of SIPs such as dose reminders and dose calculator functions were viewed as facilitators, and care teams mentioned the positive effects these functions had on their patients, allowing them to take ownership and accountability of their disease. Respondents also noted that some SIP

• Low provider and care team awareness of SIPs and their Provider-related availability barriers • Limited training of SIPs • Insurance coverage and cost Patient-related · SIP education and training barriers · Smartphone availability and functionality · Report retrieval Clinic- and operational-• Low care team prescribing comfort level and the prescribing process related barriers • Telemedicine

FIGURE 1 Barriers categorized as provider-related, patient-related, and clinic- and operational-level factors.

features can facilitate improved care for pediatric and adolescent patients. Fifty percent of clinics reported that SIP use can potentially improve relationships between caregivers and children/adolescents with diabetes, as well as visit quality. During focus groups, providers mentioned witnessing increased ownership and accountability for diabetes self-care among adolescent patients and said that reports allowed for constructive conversations and the potential for positive communication within families. Care teams mentioned that children prescribed SIPs who are living in multiple households can benefit from these reports as they provide visibility and a platform for communication among family members and guardians living in separate homes.

In the category of clinic- and operational-level facilitators, researchers identified themes including *A*) care team prescribing comfort level and *B*) telemedicine. Fifty-nine percent of centers reported high comfort with prescribing and using SIPs, and 27% reported a mild comfort level. During focus groups, clinics with a higher rate of SIP prescribing reported having a higher comfort level with both prescribing and educational opportunities. Fifty percent of clinicians stated that the virtual care opportunities (i.e., telemedicine) afforded by SIP use were a benefit. During focus groups, care teams noted that, for patients already prescribed SIPs, telemedicine appointments were enhanced.

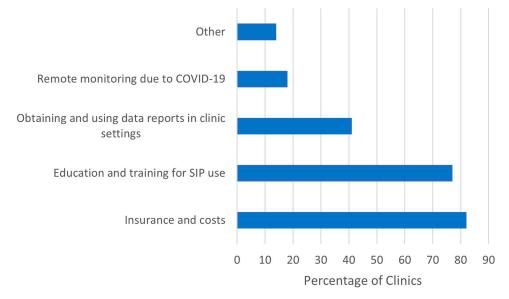


FIGURE 2 Major barriers to successful prescribing of and training for SIPs. COVID-19, coronavirus disease 2019.

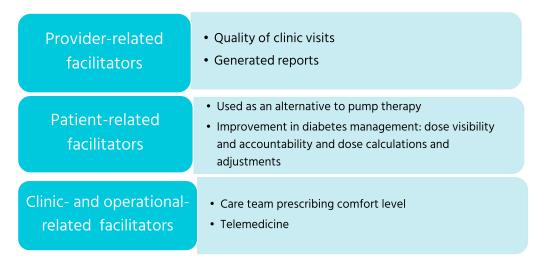


FIGURE 3 Facilitators categorized as provider-related, patient-related, and clinic- and operational-level factors.

Overall, 63% of clinics stated that they were able to observe minor or major improvements in health outcomes after prescribing SIPs to their patients. Clinic respondents stated that they would like to see more SIP prescribing within their practice, with >90% reporting this in survey results. In addition, 91% indicated either strongly or somewhat agreeing that potential improvements in the care of patients with type 1 diabetes from SIP use outweigh the barriers identified (Table 4).

Discussion

This study identified provider-related, patient-related and clinic- and operational-level barriers and facilitators to successful SIP prescribing and use. These findings varied depending on clinics' knowledge, capacity, and resources. These results demonstrate that major barriers to successful SIP use and training include lack of provider training and awareness, cost, limited insurance coverage, lack of direct patient education and training, and cumbersome prescribing processes within clinics. Major facilitators and benefits of SIP use include enhanced quality of endocrinology visits both in-person and virtually, reports that provide dose visibility, and the use of SIPs as an alternative to pump therapy.

The need for provider and care team education and training on SIP features, use, and prescribing was highlighted in the findings. Providers reported that their unawareness and lack of training were major barriers in their clinic and contribute to SIPs not being at the forefront of patient conversations in the clinic. Pediatric-

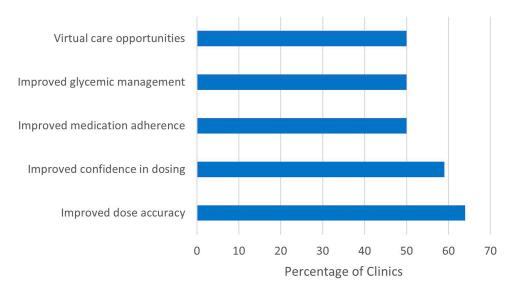


FIGURE 4 Major facilitators of successful prescribing of and training for SIPs.

TABLE 4 Benefits Observed From SIP Use Reported by Participating Clinics **Participating Clinics Replying** Question Have you seen improvements in health outcomes after prescribing smart insulin pens Major improvement 6 (27) Minor improvement 8 (36) No 0(0)Depends 4 (18) 4 (18) Unsure Do you feel that the potential improvements in patients with type 1 diabetes from smart insulin pen use outweigh these barriers? 13 (59) Strongly agree Somewhat agree 7(32) Neither agree nor disagree 2 (9) Somewhat disagree 0(0)Strongly disagree 0(0)

Data are n (%) of participating clinics.

specific barriers include multiple caregivers and concerns about losing pens at school. A recent study exploring pediatric SIP use highlighted the possible concern that, if the device is lost or the app is malfunctioning, users will need to perform calculations manually, which could function as a barrier (13).

In general, diabetes providers had a favorable view of SIPs. They viewed them as a tool to increase dose accuracy and improve patient confidence in calculating insulin doses, medication adherence, and glycemic management (Figure 4). These are all key components of successful diabetes management and may lead to improved quality of life for patients living with diabetes. The data reports generated by SIPs were viewed as helpful for both patients and providers, providing dose visibility and helping to shift to constructive conversations and thereby enhance visit quality. Having a complete picture of glucose levels, meal intake, and insulin doses was identified as a benefit for both in-person and telemedicine visits and as a means of limiting providerpatient or caregiver-child conflict around diabetes management. This aspect of SIP use may be particularly helpful because consistent engagement in diabetes selfmanagement has been found to be correlated with the attainment of positive health outcomes, including blood glucose control, fewer complications, improved quality of life, and reduced risk of diabetes-related death (14).

Telemedicine was considered both a barrier to and facilitator of SIP use. For patients who are already using SIPs, telemedicine was considered to be a facilitator during remote patient care, allowing providers the opportunity to visualize patients' insulin dosing. However,

for patients who are less savvy regarding technology or those who are good candidates for SIPs but not yet using them, telemedicine was viewed as a barrier to patient care. In addition, providers' and care teams' comfort level with SIPs was directly associated with their current prescribing habits and viewed as both a barrier to and facilitator of SIP use. Providers who were aware of SIPs and comfortable prescribing them reported often recommending them to patients. However, providers lacking awareness reported a lower comfort level prescribing, leading to lower likelihood of recommending and prescribing them in their clinics.

SIPs may be viewed as a more user-friendly option for older adults who do not want devices such as an insulin pump attached to their body. The functionality of SIPs and their app-generated reports increase visibility of missed or extra doses for patients who may have cognitive impairments or other ailments. This information can be used by nurses or caregivers to remind patients to take their insulin and to more closely monitor dosing (15).

A previous study demonstrated multilayered barriers related to technology use in diabetes self-management. Walker et al. (16) found that the most commonly described barriers for technology use in the endocrinology setting were related to provider-level factors and interpersonal communications during clinical encounters. These findings were comparable to ours; however, these results were assessed from patients' perspective, whereas ours are unique in that they were assessed from the perspective of multidisciplinary endocrinology care teams.

Although there are barriers to successful prescribing and use of SIPs for both providers and patients, the potential benefits of adhering to SIP therapy may outweigh the identified barriers. Diabetes self-management requires significant effort from patients and caregivers. For example, Cavanaugh et al. (17) discussed how a single dose calculation for rapid-acting insulin requires multiple mathematical skills, and lower numeracy skills have been associated with reduced perceived self-efficacy and fewer diabetes-self management behaviors. The generated reports and dosing calculation features of SIPs may help to alleviate the burden of such calculations for patients and caregivers. Future enhancements of SIP technology are expected to offer built-in advanced decision support, including weight-based insulin dosing settings, data-driven education, and dynamic dose titration (18). Offering more tools for diabetes management will further enhance support for people living with diabetes, leading to advancements in care and overall improvements in quality of life.

Targeted intervention areas may be identified to address barriers to while emphasizing facilitators of SIP use. Providing such intervention could restructure patterns of SIP prescribing and use, help to redesign clinic workflows, and improve efficiency and intentionality regarding improving patient access by reducing identified barriers. In a previous study carried out by the T1DX-QI (19,20), clinics implemented various interventions to increase the use of insulin pumps and CGM systems.

Additionally, there are implications for health equity in efforts to reduce barriers and facilitate the use of SIPs. A previous study by the T1DX-QI (21) found that use of advanced diabetes technology varies by population. Such inequity may be exacerbated with the proliferation of new technologies if barriers to access are not addressed (22,23).

Limitations

Limitations of this study include bias that is present when conducting focus groups. Additionally, patient-related barriers and facilitators were reported by providers rather than by patients themselves. The findings of this study are not generalizable on a national basis because both phases of the study were conducted with academic diabetes centers. Despite these limitations, this work increases understanding of the current state of SIP use and standing in the United States in 22 clinics providing care for patients with type 1 or type 2 diabetes.

Conclusion

This study assessed the perspectives of multidisciplinary diabetes care teams who treat adult, adolescent, and pediatric patient populations. This triangulated approach provides a detailed look into SIP use among varying patient demographics and geographically located clinics. Findings can shed light on targeted areas for intervention to reduce barriers to and accelerate facilitators of SIP use in endocrinology clinics. Future studies investigating patient perspectives and addressing barriers to SIP use through implementing interventions or quality improvement methodologies may be beneficial.

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DUALITY OF INTEREST

O.E. is a Health Equity Advisory Board member for Medtronic Diabetes. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

E.O. wrote the manuscript and researched data. N.N. and E.O. analyzed the data and reviewed/edited the manuscript. N.R., F.S.M., M.B., J.I., F.V., and J.Sa. contributed to the discussion and reviewed/edited the manuscript. J.Sc., M.L.S., and O.E. conceptualized the study. G.N., E.O. is the guarantor of this work and, as such, had access to all of the data and take responsibility for the integrity of the data and the accuracy of the data analysis.

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REFERENCES

- 1. Sy SL, Munshi MM, Toschi E. Can smart pens help improve diabetes management? J Diabetes Sci Technol 2022;16:628–634
- 2. Adolfsson P, Hartvig NV, Kaas A, Møller JB, Hellman J. Increased time in range and fewer missed bolus injections after introduction of a smart connected insulin pen. Diabetes Technol Ther 2020;22:709–718
- 3. Harbison R, Hecht M, MacLeod J. Building a data-driven multiple daily insulin therapy model using smart insulin pens. J Diabetes Sci Technol 2022;16:610–616

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- 4. Jendle J, Ericsson Å, Gundgaard J, Møller JB, Valentine WJ, Hunt B. Smart insulin pens are associated with improved clinical outcomes at lower cost versus standard-of-care treatment of type 1 diabetes in Sweden: a cost-effectiveness analysis. Diabetes Ther 2021;12:373–388
- 5. Gildon BW. InPen smart insulin pen system: product review and user experience. Diabetes Spectr 2018;31:354–358
- 6. Monostra M. New diabetes technology expected to improve customization, availability of real-time data. Available from https://www.healio.com/news/endocrinology/20210816/new-diabetes-technology-expected-to-improve-customization-availability-of-realtime-data#:~:text= Advancements%20in%20connected%20insulin%20pens, teams%2C%20according%20to%20two%20speakers. Accessed 22 August 2021
- 7. Schade DS, Valentine V. To pump or not to pump. Diabetes Care 2002;25:2100-2102
- 8. Gajewska KA, Biesma R, Bennett K, Sreenan S. Barriers and facilitators to accessing insulin pump therapy by adults with type 1 diabetes mellitus: a qualitative study. Acta Diabetol 2021;58:93–105
- 9. Heinemann L, Schnell O, Gehr B, Schloot NC, Görgens SW, Görgen C. Digital diabetes management: a literature review of smart insulin pens. J Diabetes Sci Technol 2022;16:587–595
- 10. Weinstock RS, Prahalad P, Rioles N, Ebekozien O. T1D Exchange Quality Improvement Collaborative: a learning health system to improve outcomes for all people with type 1 diabetes. Clin Diabetes 2021;39:251–255
- 11. Alonso GT, Corathers S, Shah A, et al. Establishment of the T1D Exchange Quality Improvement Collaborative (T1DX-QI). Clin Diabetes 2020;38:141–151
- 12. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19:349–357
- 13. Ilkowitz J, Wissing V, Gallagher MP. Pediatric smart insulin pen use: the next best thing. J Diabetes Sci Technol 2022:16:635–640

- 14. Adu MD, Malabu UH, Malau-Aduli AEO, Malau-Aduli BS. Enablers and barriers to effective diabetes self-management: a multi-national investigation. PLoS One 2019;14:e0217771
- 15. Toschi E, Munshi MN. Benefits and challenges of diabetes technology use in older adults. Endocrinol Metab Clin North Am 2020;49:57–67
- 16. Walker AF, Hood KK, Gurka MJ, et al. Barriers to technology use and endocrinology care for underserved communities with type 1 diabetes. Diabetes Care 2021;44: 1480–1490
- 17. Cavanaugh K, Huizinga MM, Wallston KA, et al. Association of numeracy and diabetes control. Ann Intern Med 2008;148:737–746
- 18. Warshaw H, Isaacs D, MacLeod J. The reference guide to integrate smart insulin pens into data-driven diabetes care and education services. Diabetes Educ 2020;46(Suppl. 4): 35–205
- 19. Lyons SK, Ebekozien O, Garrity A, et al. Increasing insulin pump use among 12- to 26-year-olds with type 1 diabetes: results from the T1D Exchange Quality Improvement Collaborative. Clin Diabetes 2021;39: 272–277
- 20. Prahalad P, Ebekozien O, Alonso GT, et al. Multi-clinic quality improvement initiative increases continuous glucose monitoring use among adolescents and young adults with type 1 diabetes. Clin Diabetes 2021;39:264–271
- 21. Ebekozien O, Agarwal S, Noor N, et al. Inequities in diabetic ketoacidosis among patients with type 1 diabetes and COVID-19: data from 52 US clinical centers. J Clin Endocrinol Metab 2021;106:e1755-e1762
- 22. Majidi S, Ebekozien O, Noor N, et al. Inequities in health outcomes in children and adults with type 1 diabetes: data from the T1D Exchange Quality Improvement Collaborative. Clin Diabetes 2021;39:278–283
- 23. Ebekozien O, Odugbesan O, Rioles N, Majidi S, Jones NHY, Kamboj M. Equitable post-COVID-19 care: a practical framework to integrate health equity in diabetes management. J Clin Outcomes Manag 2020;27:256-259