Recruiting historically under-represented individuals into Project ECHO Diabetes: using barrier analysis to understand disparities in clinical research in the USA

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ABSTRACT

Objectives  Individuals under-recruited in diabetes research studies include those not seen at endocrinology centres and those from rural, low socioeconomic and/or under-represented racial/ethnic groups. The purpose of this descriptive analysis is to detail recruitment and retention efforts of Project ECHO Diabetes clinical sites affiliated with Stanford University and University of Florida.

Design  Prospective collection of participant engagement and qualitative analysis of barriers and facilitators of research engagement within Project ECHO Diabetes, a virtual tele-education programme for healthcare providers in the management of individuals with insulin-requiring diabetes.

Setting  Data were collected at the patient level, provider level and clinic level between 1 May 2021 and 31 July 2022.

Participants  Participants and study personnel were recruited from 33 Project ECHO Diabetes sites in California and Florida.

Outcomes  We report study completion rates for participants recruited into 33 Project ECHO Diabetes sites. Using barrier analysis, a methodology designed for the real-time assessment of interventions and system processes to identify barriers and facilitators, study personnel identified significant barriers to recruitment and retention and mapped them to actionable solutions.

Results  In total, 872 participants (California n=495, Florida n=377) were recruited with differing recruitment rates by site (California=52.7%, Florida=21.5%). Barrier analysis identified lack of trust, unreliable contact information, communication issues and institutional review board (IRB) requirements as key recruitment barriers. Culturally congruent staff, community health centre (CHC) support, adequate funding and consent process flexibility were solutions to address recruitment challenges. Barriers to retention were inconsistent postal access, haemoglobin A1c kit collection challenges, COVID-19 pandemic and broadband/connectivity issues. Additional funding supporting research staff and analogue communication methods were identified as solutions address barriers to retention.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses barrier analysis, an established methodology that allows for objective, dynamic and real-time identification of barriers and facilitators to assess factors that impact recruitment and retention of under-represented individuals into clinical research.

⇒ The study methodology included engagement with community health centres to prioritise recruitment strategies to over-represent historically excluded populations.

⇒ A key limitation of the study is the inability to establish a causal relationship between barriers and solutions identified in this study with equity in clinical research.

Conclusions  Funded partnerships with CHCs, trusted by their local communities, were key in our recruitment and retention strategies. IRB consent process flexibility reduced barriers to recruitment. Recruiting historically under-represented populations is feasible with funding aimed to address structural barriers to research participation.

INTRODUCTION

The inclusion of marginalised groups representative of disease-specific populations is paramount to the generalisability of clinical research. Despite this, inequities in clinical research recruitment and participation continue to result in the systematic under-representation of racial/ethnic minority, low socioeconomic, publicly insured and other under-represented groups in research. The inadequacy of diverse representation in research is a moral, ethical and scientific concern, as clinical research drive the application of innovative, cutting-edge therapies in the specific groups studied. Further, the lack of disease-representative
recruitment and retention into clinical research has historically contributed to a variety of adverse health outcomes in understudied groups.\textsuperscript{3-5,7}

Five critical barriers to research participation for under-represented groups include: (1) mistrust, (2) lack of comfort with the research process, (3) lack of information about clinical research, (4) time and resource constraints and (5) lack of awareness of the existence and importance of clinical research.\textsuperscript{2,4,6-8} These barriers are intensified by stigma, fear, systematic and practical limitations, and ineffective research staff communication.\textsuperscript{8,9} Rigid protocols, non-inclusive eligibility criteria and provider-centred enrolment practices have presented substantial challenges for promoting diversity in research studies.\textsuperscript{9} Well-established reinforcement of this phenomenon are cultural-mediated, language-mediated and financial-mediated barriers which inhibit engagement in research for under-represented populations.\textsuperscript{2,13} Facilitators of participation including altruistic reasons such as community benefit, and positive impact for future generations are underappreciated by researchers and funders as drivers of clinical research participation in under-represented individuals.\textsuperscript{2} Additionally, as clinical research activities have become increasingly expensive and time-consuming, minoritised populations, who require additional resources to support successful participation in clinical research, are further disadvantaged.\textsuperscript{14} However, barriers to research participation in diabetes clinical research and solutions to increase diversity and representation are understudied.

The majority of current diabetes-specific research are not representative of the demographic profile of individuals living with diabetes, particularly in the USA.\textsuperscript{3,15} Equitable recruitment and retention strategies in diabetes research is both understudied and under-reported. Recruitment of under-represented individuals into diabetes-specific clinical research is optimised by harnessing the electronic medical record to identify potential participants, using clinician referrals to participate in clinical trials and increase touch-points with participants to optimise engagement.\textsuperscript{16-18} During the COVID-19 pandemic, the transition to virtual clinical research protocols resulted in barriers to recruitment and retention. Unique barriers highlighted by the COVID-19 pandemic for research participation included limited access and proficiency in using web-based survey tools, virtual video conferencing applications, and smartphones for the completion of study activities.\textsuperscript{19} Despite these challenges, shifting to a predominantly virtual platform did reduce some of the time and travel burdens that the study imposed on participants in typical clinical research protocols.\textsuperscript{19}

Project ECHO (Extension for Community Healthcare Outcomes) is a tele-education outreach model that aims to expand access to subspecialty diabetes care by democratising knowledge of subspecialty care to primary care providers.\textsuperscript{20-24} Here, we describe the processes, barriers, solutions and outcomes of our patient-level recruitment and retention efforts focusing on the engagement of individuals and community health centres (CHC) who are under-represented in clinical research.

**METHODS**

**Project ECHO Diabetes**

Building on the existing ECHO model,\textsuperscript{25-28} the University of Florida and Stanford University (research ‘Hubs’) jointly developed a tele-education programme that aimed to train healthcare providers and used targeted recruitment and retention methods, including the Neighbourhood Deprivation Index (a validated area-level measure of socioeconomic status) and provider geocoding (evaluating distance to a primary care provider or endocrinologist), to best reach underserved communities across Florida and California.\textsuperscript{20-24} The Project ECHO Diabetes programme provided participating health centres (‘spokes’): tele-education designed for providers, no-cost continuing medical education credits for participation, real-time support with complex medical decision-making and access to a Diabetes Support Coach (trained community members with diabetes employed by each Hub who provide peer support) for patient engagement. Unique to this Project ECHO Diabetes programme was the implementation a stepped-wedge study design with staggered control and intervention periods for spokes, healthcare providers and patients. Patient and provider outcomes were collected at baseline and 6-month intervals until the study end, alongside aggregated annual clinic-level metrics. Here, we present successes and challenges we faced with patient-level recruitment and retention.

**Study outcomes**

To outline and evaluate recruitment efforts at 33 clinical sites participating in Project ECHO Diabetes research across Florida and California, we employed systematic tracking of all patients who were eligible, approached and consented. Retention was evaluated as completion of at least one haemoglobin A1c (A1c) kit and/or surveys. A1c kits were offered three times and surveys were offered twice. Surveys, offered in both English and Spanish, gathered information related to participant demographics, diabetes care, technology use and comfort, physician trust, experiences during COVID-19 and diabetes distress.

Recruitment occurred from 1 May 2021 to 31 July 2022, which encompassed the COVID-19 pandemic. Participants were followed for up to 12 months; surveys were collected at two time points 6 or 12 months apart. University of Minnesota’s Advanced Research and Diagnostic Laboratory home A1c kits\textsuperscript{29,30} were collected up to three times at 6-month intervals. A1c data were additionally abstracted from the electronic medical record at these three time points if A1c kit data were missing. Research staff and diabetes support coaches followed up with participants at each data collection window, documented completion of study activities and updated patient status including those lost to follow-up, deceased or withdrawn.
Participant demographics (age, sex, race/ethnicity, insurance type and preferred language) were obtained at the time of recruitment, from surveys, via study staff or from their electronic health record. Participating clinical centres’ addresses were used to assign a rural–urban designation as defined by the US Department of Agriculture.31 classified into metropolitan/urban areas if the rural–urban code was between 1 and 3 or non-metropolitan/urban if the rural–urban code was >3. Non-metropolitan/urban areas are categorised as micropolitan (rural–urban codes 4–6), small town (rural–urban codes 7–9) or rural (rural-urban code 10).

Data were collected and maintained in REDCap; all data management and analyses were conducted using SAS V.9.4. Descriptive analysis of the participant demographics and engagement in study activities were evaluated. Univariate group comparisons in participant demographics were also evaluated between the two sites using Cochran-Mantel-Haenszel \( \chi^2 \) test.

In addition to quantitative outcomes, research and study staff at Project ECHO Diabetes Hubs (Stanford University and University of Florida) and the 33 spoke sites employed qualitative evaluation using adapted barrier analysis methodology to identify significant barriers and to recruitment and retention, and mapped these to actionable solutions reflected by successful participant engagement. Barrier analysis is an established methodology that allows for objective identification of barriers. It is a dynamic and real-time method to identify barriers and facilitators to a certain behaviour (ie, consenting or completion of various study activities) for a certain population (ie, eligible and consented participants in Project ECHO Diabetes). It has been used in developing and tailoring interventions and system processes. Study staff systematically collected reported barriers to recruitment and engagement in study activities and compiled a comprehensive list of any and all barriers. As a second step employing barrier analysis, reoccurring and significant barriers were prioritised for review by the study team. Finalisation of key barriers and solutions was consolidated by five members of the Project ECHO Hub (AA, MH, LF, XR and CA-Z) and grounded in the analytical principles of barrier analysis.

**Patient and public involvement**
None.

**RESULTS**
The number of potential participants approached, and their recruitment rates differed in California (939 approached, 495 consented, recruitment rate: 52.7%) and Florida (1565 approached, 377 consented, recruitment rate: 21.5%). Participant demographics are available for 710 individuals of the 872 consented participants (table 1).

Cohort diversity varied considerably between states. In California, the cohort was predominantly English-speaking (88.9%), male (53.5%), non-Hispanic White (56.8%), followed by individuals who report Hispanic ethnicity (24.2%). The majority had forms of public insurance using Medicare (33.4%), Medicaid (32.3%) and those dually eligible (8.6%). In contrast, Florida had a majority female (58.2%) participant cohort, with a fairly balanced racial/ethnic distribution of black (35.4%), non-Hispanic white (32.3%) and Hispanic (28.4%) participants with only 3.9% reporting other. Insurance type varied with a majority citing Medicaid (32.3%), commercial (25.3%) or other (25.6%), a category that also encompasses those uninsured. Figure 1 maps participating CHCs; see online supplemental appendix A. In California, 40% of the clinics were located non-metropolitan/urban areas, as defined by the US Department of Agriculture.31 In contrast, all Florida clinics were located in metropolitan/urban areas (online supplemental table 1).

**Barriers and solutions to recruitment**
Barrier analysis revealed (1) lack of trust, (2) unreliable contact information, (3) communication limitations and (4) institutional review board (IRB) requirements as four key barriers to recruitment (figure 2). Lack of trust by potential participants in the researchers and clinical research protocol was attenuated by recruiting culturally congruent staff from under-represented populations. We also engaged CHCs to lead recruitment efforts as they know community needs and hold the trust of the local communities. In many cases, contact information for potential participants was inaccurate or out-of-date; a close working relationship with CHCs allowed us to receive updated contact information to facilitate recruitment and consent. Notable barriers in communication included low research/health literacy and limited English or Spanish proficiency to achieve truly informed consent. Funding culturally and linguistically congruent study staff and CHCs supported overcoming this barrier. CHCs received an annual base stipend of US$2500 for their participation in ECHO and additional financial support as needed for data consultation, research operations and support coach coverage.

A key logistical challenge for the University of Florida was their IRB’s interpretation of regulations requiring a signature to document the informed consent process. Both Stanford University and University of Florida classified the patient-level study activities (surveys and A1c kits) as minimal risk. Similarly, participants at both sites read and declared their understanding of a six-page consent document detailing all study procedures, risks, benefits, protected health information access/handling and compensation. Given the large rural population in the California sites, Stanford University’s IRB, Research Compliance Office and Hub teams collaborated on a solution to allow for a ‘waiver of signed informed consent’ designation that allowed verbal consent in place of a signature to document informed consent. However, in Florida, signatures of both the participant and person obtaining consent was required. The process
in Florida presented substantial challenges throughout the COVID-19 pandemic. Another logistical challenge at both sites was limitations to technology access, broadband capability and cellular connectivity. CHCs supported conversations with the research team when participants were in clinic, providing an alternate strategy for participant contact that does not rely on the participants’ phone or internet connectivity. Given the critical role CHCs played in successful recruitment, we also identified that consistent funding to our partnered CHCs for the research study execution was a solution to recruitment challenges unique to encouraging participation for under-represented individuals.

### Barriers and solutions to retention

Two study activities, completion of surveys and home A1c kits, were tracked as key outcomes of our study. Survey completion rates were 72% (first collection) and 66% (second collection). A1c data (from A1c kits and electronic medical review) completion rates at the collection three time points were 68% (collected May–June 2021), 52% (collected November 2021–January 2022) and 64% (collected May–June 2022).

Four barriers to completion of study activities and the retention in the study were identified: inconsistent postal access, A1c kit collection challenges, COVID-19 pandemic and broadband/connectivity issues (figure 3). In addition to the previously identified inaccurate contact and mailing information that pose a challenge to recruitment, distributing A1c kits and surveys to participants was a challenge. Natural disasters in California (heat waves and wildfires) and Florida (heat waves, hurricanes and tornadoes) compromised the timeliness and integrity of the blood samples delivered to the University of Minnesota lab for processing. Rural homes were challenging for postal service and shipping companies to locate and deliver, and numerous participants reported theft of packages. This limited the ability to reliably deliver A1c kits. The protocol to collect and properly store blood samples for the A1c kits was also considered complicated and some participants relied on our culturally congruent

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Table 1  Participant demographics by state

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>California</th>
<th>Florida</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N, Recruited</strong></td>
<td>872</td>
<td>495</td>
<td>377</td>
</tr>
<tr>
<td>Among those reporting demographic information:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>400 (48.3)</td>
<td>246 (53.5)</td>
<td>154 (41.9)</td>
</tr>
<tr>
<td>Female</td>
<td>427 (51.6)</td>
<td>213 (46.3)</td>
<td>214 (58.2)</td>
</tr>
<tr>
<td>Intersex</td>
<td>1 (0.1)</td>
<td>1 (0.2)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Race/ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NH White</td>
<td>376 (46.0)</td>
<td>260 (56.8)</td>
<td>116 (32.3)</td>
</tr>
<tr>
<td>NH Black</td>
<td>149 (18.2)</td>
<td>22 (4.8)</td>
<td>127 (35.4)</td>
</tr>
<tr>
<td>Hispanic, any race</td>
<td>213 (26.1)</td>
<td>111 (24.2)</td>
<td>102 (28.4)</td>
</tr>
<tr>
<td>Other</td>
<td>79 (9.7)</td>
<td>65 (14.2)</td>
<td>14 (3.9)</td>
</tr>
<tr>
<td><strong>Insurance type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>176 (21.8)</td>
<td>86 (19.0)</td>
<td>90 (25.3)</td>
</tr>
<tr>
<td>Medicare</td>
<td>201 (24.9)</td>
<td>151 (33.4)</td>
<td>50 (14.0)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>261 (32.3)</td>
<td>146 (32.3)</td>
<td>115 (32.3)</td>
</tr>
<tr>
<td>Dual eligible</td>
<td>47 (5.8)</td>
<td>39 (8.6)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Indian Health Services</td>
<td>12 (1.5)</td>
<td>10 (2.2)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Other</td>
<td>111 (13.7)</td>
<td>20 (4.4)</td>
<td>91 (25.6)</td>
</tr>
<tr>
<td><strong>Diabetes diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>333 (38.2)</td>
<td>214 (43.3)</td>
<td>119 (31.6)</td>
</tr>
<tr>
<td>Type 2</td>
<td>538 (61.8)</td>
<td>280 (56.7)</td>
<td>258 (68.4)</td>
</tr>
<tr>
<td><strong>Preferred language</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>731 (84.4)</td>
<td>440 (88.9)</td>
<td>291 (78.4)</td>
</tr>
<tr>
<td>Spanish</td>
<td>135 (15.6)</td>
<td>5 (11.1)</td>
<td>80 (21.6)</td>
</tr>
</tbody>
</table>

P values denote differences in participant groups between the two states. NH, non-Hispanic.
research staff and/or the support coaches to help collect the A1c kits appropriately. Culturally and linguistically congruent staff developed video tutorials in English and Spanish to support appropriate A1c collection. Research staff and support coaches also offered individualised support via Zoom or at clinical sites and hosted events to facilitate community building and A1c kit collections.

Presurvey and postsurvey presented additional challenges. Some individual participants were not able to complete survey activities due to device access and/or broadband issues. For these individuals we used analogue methodology which included the distribution of surveys via postal mail or phone calls. California had 164 requests for paper surveys and 42 requests for phone surveys. Study staff facilitated the manual entry of these analogue survey responses into the REDCap database for data collection. Request for paper surveys (n=17) was a less common request in Florida, but approximately half of the participants (n=206) requested phone survey delivery. Once shelter-in-place restrictions were lifted, bridging the digital divide with support from support coaches and CHCs was less burdensome. Extra A1c kits were sent frequently to participants for a variety of reasons including lost kits, improper collection and inability to process sample, missing parts, mail misdelivery and theft. In total, 3003 A1c home kits were sent (Stanford University: 1637 and University of Florida: 1366). Funding to ensure a surplus supply of A1c kits, postage for survey packets and salary support for coaches and study staff to re-engage with participants to obtain kits and surveys was critical to addressing this barrier. Cost of delivering A1c home-kits are outlined in online supplemental appendix B.

The COVID-19 pandemic itself and the associated shelter-in-place and social distancing requirements posed a significant challenge to data collection. Guidelines for shelter-in-place and social distancing were dynamic and changing through the study period and varied by both state and university regulations. Although this study was designed to be remote and virtual, the added burden and isolation during the COVID-19 pandemic limited how we were able to support participants and required the use of home A1c kits as in-person clinic visits were largely replaced by telehealth visits. With additional funding to increase support coach and staff support, we were able to address many unique challenges participants faced in completing study activities on an individual basis. Study staff and health coaches supported participants in navigating communication with the research and clinical teams during the pandemic.

DISCUSSION
Recruiting historically under-represented populations is feasible with adequate planning, flexibility from research staff and IRBs, and commitment from funding agencies.

Figure 1  Map of community health centres participating in project ECHO diabetes in California and Florida. Florida is working with 14 centres (red) and California is working with 19 centres (green) as project ECHO diabetes research sites. All participating centres are either federally qualified health centres or are located in an area of high deprivation (online supplemental appendix A).
RECRUITMENT

Figure 2 Barriers and solutions to recruitment. Four key barriers to recruitment were (1) lack of trust in the medical and research institutions (lack of trust), (2) inaccurate and outdated contact information (inaccurate contact info), (3) limitations in health literacy and language barriers (communication challenges) and (4) in-person consenting and limited access to technology (logistical issues) were barriers identified by study staff. Solutions (culturally congruent staff, partnerships with CHCs, funding and IRB flexibility) often addressed more than one barrier. CHCs, community health centres; IRB, institutional review board.

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to fund CHCs and culturally congruent study staff. Our success in recruiting and retaining participants during COVID-19 is in contrast to other reports that access to, and familiarity with, technology were insurmountable challenges for completing enrolment during the pandemic.\(^\text{19}\) The lessons learnt to recruit and retain minoritised individuals during the pandemic are lessons that continue to be applicable. The inequities highlighted during the COVID-19 pandemic predate the pandemic itself, thus the results presented in this analysis are strategies to advance research equity.

Partnership with the CHCs was a critical component of recruiting and retaining this large and diverse cohort. Adequate funding was requisite to engage CHCs, hire linguistically and culturally congruent staff, and address the unique barriers we encountered working with this under-represented research cohort. This funding allowed us to overcome challenges that typically exist in recruiting under-represented populations and clinics. We recruited and retained study participants who typically had at least one under-represented characteristic (receive diabetes care solely from primary care providers, are from minority-raced racial/ethnic groups, have public insurance and/or live in rural communities). These populations have historically been considered challenging to engage and sustain in research. CHCs, who have the trust of the local community and are equipped to address local needs, were critical to our recruitment and retention strategy. Limited English proficiency, a common exclusion criteria and barrier to recruitment of under-represented individuals, was overcome through multilingual study staff. We were able to troubleshoot many challenges to engage in clinical research through the infrastructural support offered by funding linguistically and culturally congruent research staff, peer mentorship with health coaches and CHCs.

There was a notable difference in the recruitment rate in California vs Florida in our cohort. Although there were demographic differences between the state specific cohorts, we hypothesise the waiver of documentation of signed informed consent approved in California but not in Florida played a major role in our differing recruitment rate. In both states, study staff prioritised explaining the study to ensure informed consent following IRB policies\(^\text{35}\) and were provided a copy of the full informed consent. However, for the Stanford IRB verbal consent satisfied the requirement for documentation of consent whereas the University of Florida IRB required a signed informed consent form. In Florida, the requirement for a signed consent was a significant barrier that contributed to the lower recruitment rate. Our study demonstrates that individual IRB interpretations of documentation requirements vary and can directly impact the recruitment and participation of under-represented individuals.
To reduce the logistical burden of participating in research, we engaged a strong clinical research partnership between study investigators, research staff, allied community members such as support coaches and CHCs. Additionally, we developed protocols and hired diverse staff to address the psychosocial burden and barriers of research participation for under-represented populations. Through adequate funding for the research team and their allied partners, we were able to provide solutions to minimise system level barriers. Funding linguistically and culturally congruent study staff and support coaches, along with providing all study materials in English and Spanish, allowed for a greater proportion of potential participants to opt into the study and complete study activities effectively. Finally, the time that study staff dedicated to frequent reminders (telephonic, electronic and postal), mailing and tracking study activities, and supporting participants, support coaches, and CHCs contributed to the recruitment and retention success. The funded CHC partnerships created a sense of community and therefore camaraderie in executing this study and thus, CHCs were identified as a consistent solution to both recruitment and retention barriers.

Limitations to using barrier analysis include subjectivity and an inability to establish causal relationship between barriers and solutions. The barriers and solutions identified represent two geographic areas and may not be generalisable to all states in the USA. However, it is noteworthy that California and Florida each have a Diversity Index that places them, respectively, as the second (Diversity Index 69.7%) and ninth (Diversity Index 64.1%) most diverse states in the USA in 2020. We observed differences in the participants by state likely due to differences in the population served by the clinics, healthcare delivery and research practices. Our cohort includes the overrepresentation of historically excluded populations and addresses a gap in the literature on strategies to diversify clinical research participants in diabetes which is a strength of our study.

**CONCLUSION**

Despite the added challenge of the COVID-19 pandemic and disruptive natural disasters, we demonstrated that recruiting historically under-represented individuals into clinical research is feasible with appropriate funding and a research plan focused on using frequent touch points, culturally and linguistically congruent staff, and allied partnership with CHCs. IRB flexibility regarding documentation of consent and funded partnerships with CHCs provided solutions to typical barriers to recruitment and retention. Transferring the logistical challenges of clinical research from the participants to the research team and funded CHCs supported our ability to recruit and retain historically under-represented individuals into Project ECHO Diabetes. Lessons learnt from the Project ECHO Diabetes process should be applied to future clinical research studies. Barriers to recruitment and retention include...
retention of historically under-represented in research populations can be addressed to improve generalisability of clinical research studies in diabetes.

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Contributors AA, MJH, DMM and AFW formulated the clinical question. AA, SLF, LF, DMM and AFW structured the analysis. AA, MH, LF, XR and CA-Z conducted barrier analysis. AA, SLF, LF and AFW completed the statistical analysis and AA created the figures. MJG, MJH, MJH, DMM and AFW supervised the analysis and interpretation of the data. AA and MH conducted the literature review. AA wrote the manuscript with critical contributions from MJH, DMM, LF and AFW. All authors have edited, reviewed and approved the manuscript. This work was presented as an oral abstract presentation at the 82nd American Diabetes Association Scientific Sessions. AA and AFW are the guarantors and accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Competing interests RL has consulted for Abbott Diabetes Care, BioIling, Capillary Biomedical, Deep Valley Labs, Morgan Stanley, Glooko, and Tidepool. DMM has received research support from the National Institutes of Health, JDRF, NSF and the Helmsley Charitable Trust; and his institution has received research support from Medtronic, Dexcom, Insulet, Bigfoot Biomedical, Tandem and Roche. He has consulted for Abbott, the Helmsley Charitable Trust, Sanofi, Novo Nordisk, Eli Lilly, and Insulet, and is supported by grant number P30DK116074. MJH has reserved research support from the NIH, JDRF and the Helmsley Charitable Trust and has been a consultant for Mannkind and Sanofi. Theremaining authors have no potential conflicts of interest relevant to this article.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and Institutional Review Boards at Stanford University (protocol number 54198) and University of Florida (IRB201900382) approved this study. Participants gave informed consent to participate in the study before taking part.

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