Implementing Best Practice Advisories to Reduce Inequities in Technology Use for people with Type 1 Diabetes

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Project Background and Rationale

Over the past decade, continuous advancements in diabetes technologies have helped to ease the burden of diabetes self-management for people with type 1 diabetes (PwT1D). CGMs and automated insulin delivery (AID) systems have not only led to improved quality of life but also better glycemic outcomes and reduced incidence of hospitalizations for severe hypoglycemia and diabetic ketoacidosis (DKA).[1,2] Given these clinical benefits, the American Diabetes Association now recommends that CGM be considered standard of care for all patients with T1D, and that AID systems be recommended to patients who are capable of safely using them.[3]

Despite proven clinical benefits, racial inequities in use of advanced diabetes technology (ADT) (automated insulin delivery (AID) systems, continuous glucose monitors (CGM), and insulin pumps) persist in both children and adults with diabetes. Unfortunately, access to diabetes technologies among PwT1D is not equitable in the United States, with significant racial disparities observed for both pediatric and adult PwT1D.[4,5] Compared to Non-Hispanic Whites, Black PwT1D have 1.5% higher HbA1C levels on average[6] and are more than 3-times as likely to be hospitalized for hypoglycemia or DKA[7], yet they are half as likely to receive technologies proven to improve glycemic outcomes.[8]

The role of race in healthcare provider decision-making has been extensively studied.[11] Individual values, communication, importance of race, patient-level issues, system-level issues, and bias/racism have been identified as factors that may contribute to racial/ethnic differences in patient care. [11] Individual barriers to using ADT may be related to cost concerns/insurance coverage issues [12], insertion pain or aesthetic/body image concerns, alarm anxiety or alert fatigue. [13-15] Provider level barriers may include insufficient knowledge/familiarity with devices [16] bias (e.g. assumptions about patient's likelihood to accept or be able to use devices) [17], provider perceived barriers for patients (e.g. patient's inadequate knowledge about how to respond to CGM information) [17] clinical decision making criteria that do not align with current guidelines (e.g. HbA1C level deemed too high for patient to be able to handle CGM or pump), and insurance requirements for coverage. [16,17] A recent (2023) consensus statement for the use of AID technologies emphasizes the importance of recognizing healthcare provider "preconceptions and unconscious bias… about [patient] attributes required to use AID effectively" and challenges

the longstanding notion that AIDs should be offered only to "tech savvy" patients who have already demonstrated good glycemic management.[18] At the system level, there are barriers related to insurance coverage, cost, and complicated processes in ordering devices (time-consuming process that requires coordination between clinical team and vendor) and having patient receive the device (requires high level of engagement from patient with the insurer, DME company, pharmacy, or device vendor).

In a 7-year retrospective cohort study from the Johns Hopkins University adult diabetes center, we found significantly lower rates of CGM discussions, prescribing, and use among Black PwT1D as compared with White patients, and these disparities persisted even after adjustment for demographics, social determinants of health (SDOH), and glycemic management at clinic entry.[19] Potential mechanisms for these racial inequities include unmeasured differences in diabetes self-management skills, subjective criteria for patient selection, factors influencing shared decision-making between patient and provider, and provider implicit bias. The T1DX-QI recently conducted a multi-center research study that evaluated implicit racial bias in prescribing ADT across 7 endocrinology centers in the US.[20] Implicit racial bias in prescribing ADT was present in approximately one-third of the 109 providers evaluated.

Root causes of racial inequities in ADT prescribing and use may be amenable to interventions using health information technology**.** Health information technology (HIT) encompasses various functionalities within the electronic medical record (EMR), including computerized provider order entry and clinical decision support tools, clinical documentation such as physician notes, patient communication (portal), population health tools (registries, telemedicine, remote patient monitoring), and data warehouse tools (reports). [21] Lopez et al, in the *Joint Commission Journal on Quality and Patient Safety*, outlined several recommendations for HIT to address some of the root causes for racial disparities in healthcare, including 1) automated and standardized collection of race/ethnicity and language data, 2) using collected data for identifying inequities and tailoring quality improvement efforts, 3) developing focused computerized clinical decision support systems in clinical areas identified as having significant health care disparities, and 4) including input from racial/ethnic minorities in the development of patient HIT tools to address disparities. This proposal would translate best practice recommendations for use of HIT by developing a best practice advisory (BPA) in a field with significant health care disparities using

both patient and provider feedback to refine the BPA designed to reduce disparities in ADT use among people with T1D.

Clinical decision support (CDS) tools, such as “best practice advisories” or “care gaps” that standardize clinical care, have been demonstrated to reduce racial disparities in several conditions, including venous thromboembolism prophylaxis, [22] chronic disease management [23-25], and HIV screening. [26] For example, one study using CDS tools in patients with heart failure resulted in 21% more referrals to specialized heart facilities and ~10%-50% increases in guideline-recommended testing in non-Hispanic Black and Hispanic patients ($P < 0.001$).[27] Many quality improvement studies aiming to reduce racial disparities in care have used some form of CDS as a secondary component of the intervention. [28-36] Compared with other more manual approaches to improve practice, computer-based CDS systems such as automatic prescriptions and recommendations have been shown to be more effective and more likely to result in lasting improvements in clinical practice[37-40]. A recent (2021) meta-analysis of 45 studies assessing the effects of clinical decision support system for prescribing medication found patient outcomes and practice performance outcomes were improved when a computer-based CDS method was implemented for prescriptions in a variety of diseases, including insulin prescriptions for people with diabetes.[41]

There is evidence of success in the use of computer-based decision support in diabetes. [42-45] One cluster-randomized clinical trial consisting of fourteen primary care centers (66 primary care physicians and 697 T2D patients on insulin therapy) in Madrid, Spain successfully implemented a computer application designed to help primary care physicians make decisions about insulin therapy. [44] The design of the algorithm included the recommendation to change the insulin dose and the insulin regimen when necessary. The people receiving care at the 7 centers randomly assigned to use the algorithm had a significant reduction in HbA1c compared with the people at the 7 centers in the control group.[44]

Another meta-analysis of 70 randomized controlled trials conducted to identify features of CDS systems critical for improving clinical practice identified four features strongly associated with a successful center decision support system: 1) provided automatically as part of clinical workflow, 2) delivered at the time and location of decision making, 3) actionable recommendations provided such as prescriptions, and 4) computer based.[46]

For the proposed study we intend to implement all four approaches as well as require the provider to opt out if not prescribing ADT and to provide a reason for not prescribing in order to advance on the EMR screen. The addition of this functionality, forcing the provider to document the reason for a non-prescribing decision, has been shown to add benefit beyond the automation of the prescription.[38]

Project Objectives

There are three main objectives of this study (**Figure 1**):

Aim 1: To develop and implement an EMR-based BPA using stakeholder feedback to standardize the approach for prescribing and documentation of advanced diabetes technologies (ADT) (CGM, insulin pump, AID) among adult and pediatric PwT1D.

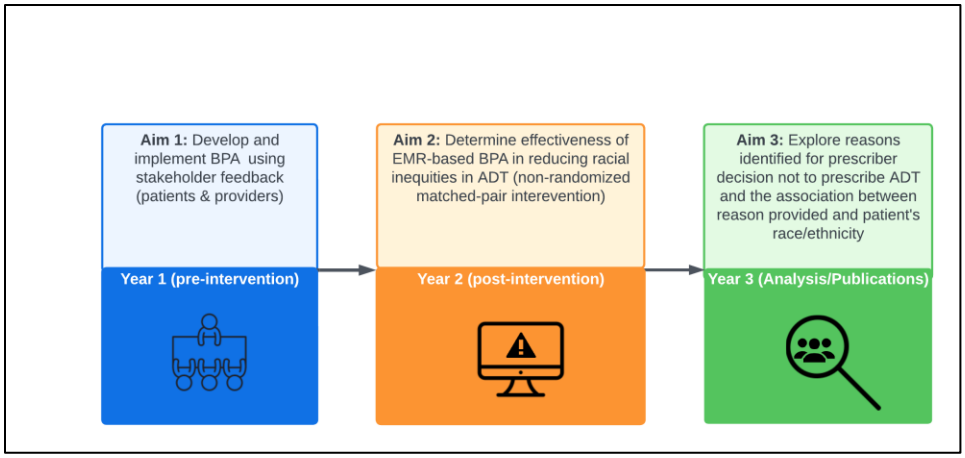
Aim 2: To determine the effectiveness of an EMR-based BPA in reducing racial inequities in ADT.

Primary Objective: To compare the proportion of non-white (non-Hispanic Black and Hispanic) PwT1D with progression in ADT use (CGM, insulin pump, AID) at 6 centers in the T1DX-QI (3 pediatric and 3 adult centers) where the BPA intervention is implemented with matched control non-white PwT1D at T1DX-QI centers not receiving the intervention over a 12-month period, adjusting for baseline level of ADT use and other confounders.

Secondary Objective: To assess the difference in ADT use between White and non-white (non-Hispanic Black and Hispanic) PwT1D receiving care at the intervention centers compared with the racial difference in ADT use in matched control PwT1D.

Aim 3: To explore the reasons identified for providers decision to not prescribe ADT and whether they were patient or provider led, and the association between the reason provided and the patient's race/ethnicity.

Figure 1. Project Aims



Aim 1 Methodology

Overview and Study Design

Using the Agency for Healthcare Research and Quality (AHRQ) "Five Rights" for effective clinical decision support[53] and the T1D Exchange Health Equity Framework as guiding frameworks [51,52,] we will survey and conduct focus groups/structured interviews of pediatric and adult endocrine providers who are part of the T1DX-QI Collaborative and of patients/caregivers with T1D (See Figure 4 for sample questions). During the qualitative phase, we also will work with the T1D Exchange Health Equity Advancement Lab[54] (HEAL) Advisory Board which includes key stakeholders, including T1D Hispanic and Non-Hispanic Black patients/parents, community partners, health equity experts, state policy representatives, quality improvement experts, information technology experts, and T1D healthcare team. Results of the qualitative study in addition to input from the HEAL Advisors will be used to refine the BPA and the approach for documentation of provider/patient discussions.

Methods and Data Collection Plan

Stakeholder input will be collected by both providers and patients for aim one. Four to eight focus groups will be conducted with a diverse group of endocrine providers selected from the T1DX-QI collaborative to understand systems barriers to incorporating a BPA, how and when BPA should be triggered, and reasons for not prescribing/using ADT. All focus groups will be conducted by T1DX-QI staff trained in qualitative interviews. All participating sites will be using an Epic EMR system. We will use Epic's "Best Practice Advisories Setup and Support

Guide" as a reference to inform the questions for the focus group sessions and qualitative interviews. Respondents will receive a $150 payment for participation. Focus group sessions will be audio-recorded, transcribed and analyzed using appropriate software and will continue until thematic saturation is reached.

For patient input, the T1D Exchange Online Registry (a registry of ~ 19,000 caregivers/individuals with T1D who have consented to be contacted about additional studies) and the T1D Exchange Online Community (~ 50,000 members) will be sent a survey with a sample size of approximately 50 caregivers of youth with T1D and 50 adults with T1D. Participants completing the survey will be offered the opportunity to participate in a follow-up structured interview. We will conduct structured interviews with ~ 10 caregivers of youth with T1D and ~10 adults with T1D to understand the patient perspective in developing the BPA. For both the structured interviews and survey we will aim for 50% of the recruited sample to consist of non-Hispanic Black and/or Hispanic race/ethnicity. The structure interviews will be conducted by T1DX staff trained in qualitative methods. Participants will receive a $100 payment for time remuneration. The structured interviews will be audio-recorded, transcribed, and analyzed using appropriate software. Examples of questions for both provider and patient focus groups and survey are attached as a supplemental document.

Statistical Analysis Focus group and interview recordings will be uploaded to a vendor ("TranscribeMe!"), that will transcribe the transcripts verbatim. Each transcript will be reviewed and analyzed to address key topics of interest. A codebook will be created based on the interview guide and theories used. Themes will be developed using a mix of deductive and inductive coding. For each key topic, transcripts will be coded to label common themes across participants. For the survey, Data cleaning and analysis will be conducted using R software. Data cleaning will be conducted to screen outliers and missing values.

Descriptive statistics will be performed for all data, which will include frequencies and percentages for categorical measures and mean, standard deviation, median, minimum, and maximum for continuous measures. Free text entries from participant surveys will be reviewed and summarized thematically. The study team will review the results of the thematic analysis from the stakeholder surveys, interviews, and focus groups to build out the EMR-based BPA.

The BPA will be built in Epic as all centers selected to participate are using the Epic EMR system. Each participating clinical center will evaluate the tool and provide feedback. Based on feedback from providers, we will refine the BPA prior to deployment. Providers at the 6 participating centers will receive training on the BPA prior to implementation. Once the study team has ensured that the target providers have received requisite training, the BPA will be moved into the Epic production environment (which will correspond to the start of the intervention phase of the study). The frequency of BPA firing after implementation, as well as all data inputs in the BPA, will be collected. Feedback from the providers at the 6 centers will be collected following the initial implementation of the BPA and at periodic intervals during the 12-month assessment period. Feedback received will be used to refine the BPA in an iterative fashion (Table 1).

Table 1. Five Rights Framework to Guide Electronic Surveys and Focus Group Sessions

Five Rights of Clinical Decision Support	Provider	Patients
Right information	How to translate ADA standards of care for CGM and insulin pumps into prompt/alert? Reason device not offered/declined?	What information would be helpful to you in making a decision about using ADT? Reasons device declined?
Right person	Who should receive the prompt? Endocrinologist or diabetes advanced practice provider? Primary care physician?	Who should receive the information about technology (patient only, parent, primary care physician)?
Right intervention format	Define BPA inputs	MyChart notification*
Right channel	Order entry Progress note template Level of service (closing chart) Health maintenance/care gap	MyChart notification Pre-visit questionnaire Post-visit questionnaire
Right timing	Pre-visit charting During encounter When closing encounter How often? Once, 3 months, 6 months, 12 months?	Prior to visit? After visit? How often? Once, 3 months, 6 months, 12 months?

Data Storage and Encryption

All qualitative data collected will be recorded using Zoom and stored on a password-protected computer where only the research team will have access. All data is secured with enterprise-grade security features including data encryption, redundancy, continuous network monitoring, and Single Sign-On.

Informed Consent

This study does not impose any form of intervention. Participants who are eligible for focus groups or interviews will be informed of the purpose of this study and the possible risks and benefits of participating; however, each member will have the option of moving forward with participation or not for Aim 1. For eligible members who are interested in participating, an online verbal consent process will be followed for focus groups. A record will be maintained of the documented process when obtaining informed consent verbally from each participant. Recorded consent may be archived and safely stored on a password protected computer only accessible by the study principal investigator.

The consent form will be read to each potential participant before beginning the interview. The individual will be required to agree that they understand this form and would like to continue. For survey participants, the consent form will be presented to each potential participant in an online format. The individual will be required to agree that they understand this form and would like to continue with the survey. These forms will provide the individual with contact information to resolve any questions or misunderstandings that they may have regarding the study. The T1D Exchange team will address each inquiry quickly and professionally. Every potential participant is made aware that their participation is completely voluntary and that they can choose to discontinue participation at any time with no negative repercussions.

Aim 2 Methodology

Overview and Study Design

Using a non-randomized matched-pair intervention design, we will compare ADT use following a BPA intervention among non-Hispanic Black and Hispanic PwT1D receiving care at 6 T1DX-QI centers with matched control non-Hispanic Black and Hispanic PwT1D receiving care at a non-intervention center over a 12-month period.

Six T1DX-QI centers that are data mapped to the T1DX-QI database by study initiation will be selected for the intervention centers. There will be four additional centers as possible back-up if one or more of the 6 anticipated centers are not able to participate. Matched “control” PwT1D will also be selected from centers with mapped data.

Patient Eligibility Criteria for Analysis:

1) Age ≥ 2 years with an EMR diagnosis of T1D for at least 6 months at baseline and receiving care at one of six intervention centers or a matched control at another T1DX-QI center.
2) For the primary outcome, only non-Hispanic Black and Hispanic individuals will be included. The secondary outcome will compare white vs. non-white patients (non-Hispanic black and Hispanic) and the sample size will be increased accordingly. Patients of mixed race/ethnicity will be counted in the non-white cohort for all analyses.
3) Exclusion criterion: PwT1D with evidence of use of AID at baseline (no room for progression, estimate ~ 20% of non-white PwT1D will be using AID at time of study start), pregnant, no clinic visit within 12-months prior to baseline

The T1DX QI Collaborative has a Collaborative Data Use Program waiver already in existence with IRB. This has been added as a supporting document.

The following matching criteria will be considered for the matched-pair controls:

1) Age categories
2) Biological sex
3) Insurance status
4) Area deprivation index
5) Baseline Technology use
6) Duration of T1D bins
7) Baseline HbA1c

Intervention: The EMR-based BPA will be designed to recommend ADT prescription to patients not already using some type of ADT using a rule-based algorithm. ADT will include CGM, insulin pumps, and AID systems. We will work with each of the 6 centers to implement the BPA as part of the Epic EMR. The specific functionality of the BPA will be refined during Aim 1. However, the basic outline is as follows: The function will generate a BPA if patient is not utilizing a CGM or pump/AID. If the patient is not on a CGM, pump or AID system (if already using CGM and pump), the BPA will suggest discussing and/or prescribing CGM (or pump/AID) to the provider. The provider will answer in the affirmative or say, “not discussed” or “patient declined.” If the provider chooses to opt out of prescribing, they will be forced to provide a reason for not prescribing to advance the screen. Providers in each intervention center will be trained on the BPA process prior to implementation.

Primary Outcome Definition: Primary outcome: Progression in ADT use (as documented in EMR) during the 12-month study period. The primary outcome would be defined as positive for an individual if any of the following occurs:

- No CGM à Any CGM
- MDI à Insulin pump
- No AID à AID

Based on this definition, a PwT1D in any of the following technology transition states would be considered as meeting the primary endpoint:

- MDI/smartpen + no CGM *begins* using CGM
- MDI/smartpen + CGM *begins* using insulin pump
- Insulin pump + no CGM *begins* using CGM
- Insulin pump + CGM (without AID) *begins* using AID

Data Collection Plan

No procedures outside of standard of care will be conducted for PwT1D. De-identified patient level data will be collected via EMR data transfer to the T1DX-QI database. Types of data collected include demographics, medications, medical conditions, insulin dosing, ADT use, HbA1c and other lab data, occurrence of severe hypoglycemia, diabetic ketoacidosis (DKA), and device data. All available HbA1c and CGM data will be obtained during the study period. During Aim 1, we will work with all T1DX-QI centers on refining the documentation of ADT in the EMR, particularly AID use and the mapping of this data to the QI database to ensure uniform data quality.

Below is a table (Table 2) of the required sample size for the primary outcome for various levels of power and intervention group event proportions assuming an alpha of 0.05 and a matched-pair control proportion of 15%. The matched-pair control assessment of 15% progression in ADT (as defined above) is estimated from T1DX-QI data over a previous 12-month period.

Table 2. Sample Size Estimates

Total Number per group/matched pairs sample_size <- (z_alpha /2 + z_beta)^2 * (p1 * (1 - p1) + p2 * (1 - p2)) / (p1 - p2)^2				
*Assuming matched control group proportion of 15%	**Effect Size**		**Estimates of Power**	
		80%	**85%**	**90%**
Intervention ADT Progression				
20%	0.05	382	468	589
25%	0.1	105	129	161
30%	0.15	50	61	77

It is estimated that there will be approximately 3,000 eligible non-white (non-Hispanic black and Hispanic) PwT1D across the 6 clinical centers and 15,000 possible matched controls. The largest

sample size necessary for 90% power if the absolute difference in proportion of ADT progression is only 5% (relative increase of 25%) is 589 matched pairs. If possible, we will attempt to match intervention to control in a 1-2 fashion with 2 matched controls per intervention. An interim analysis of intervention group event rate may be conducted to inform if additional matched pairs are needed. For secondary analysis comparing White and non-White race we will increase sample size to include White PwT1D pairs

Data Management and Statistical Analysis

The T1DX-QI data portal has successfully automated the process for mapping EMR data, including ADT use and clinical outcomes into a central database using an SFTP. Currently around 75,000 PwT1D have EMR data in the QI database. Mapped outcome data includes, among other variables, ADT use, HbA1c, severe hypoglycemic events and diabetic ketoacidosis (DKA) events and is automatically transmitted to the T1DX-QI database monthly.

Efficacy assessments will be collected over a 12-month period via EMR data transferred to T1DX-QI database as described above.

Primary: Progression in ADT use in the intervention group compared with matched-pair controls adjusting for number of encounters, correlation of matched pairs, and random center effects.

Secondary: Analysis will mimic the primary analysis for adjustment of confounders.

- Progression in AID use in the intervention group compared with matched pair controls
- Progression in CGM use in the intervention group compared with matched pair controls
- Progression in Insulin Pump use in the intervention group compared with matched pair controls
- Change in the proportional difference in CGM use between white and non-white individuals (non-Hispanic black and/or Hispanic) in the intervention group compared with matched pair controls.
- Change in the proportional difference in insulin Pump use between white and non-white individuals (non-Hispanic black and/or Hispanic) in the intervention group compared with matched pair controls
- Change in HbA1c (lab result closest to end date of period) from baseline in the intervention group compared with matched pair controls

Exploratory: Analysis will mimic the primary analysis for adjustment of confounders.

- Change in proportion of sustained ADT Use in in the intervention group compared with matched pair controls. Sustained use defined as at least two consecutive EMR records with ADT use documented during the post period.

The primary outcome will evaluate the impact of the BPA intervention on patients' progression of ADT use utilizing a Generalized Linear Mixed Model (GLMM) to account for matched pairs and random center effects. GLMM handles missing data using a direct likelihood model that allows for the incorporation of all available data for a given subject even if only baseline data are available. The model will be adjusted for number of encounters and other possible confounders not already matched.

Secondary analyses comparing if the differences in ADT use between non-white and white PwdT1D is different in the intervention and control groups will be assessed using an interaction term in a GLMM. This model will focus on estimating differences for the interaction term to evaluate the interventions impact on reducing the racial gap in technology use.

Additional secondary and exploratory outcomes will be assessed using the appropriate statistical model for the outcome adjusting for patient and center level confounders. Exploratory analysis assessing pediatric and adult centers separately will be performed.

Aim 3 Methodology

Overview

We will explore if the reasons technologies are not recommended/accepted differ by race and other factors. This aim is exploratory, and the extent of the analysis will ultimately depend on information collected as part of the BPA developed during Aim 1. If patient race is associated with differences in rates of technology prescribing/use, these findings will inform further interventions to address the contributing causes.

Methods and Data Collection Plan

It is anticipated that the BPA developed in Aim 1 will include an option for providers to designate the reason why diabetes technologies are not offered or accepted by patients BPA responses will be quantified as provider-led or patient-led reasons for not advancing ADT use. Multivariable logistic regression analysis will be performed to evaluate whether patient characteristics (demographics, race/ethnicity, diabetes characteristics and complications) are

associated with the reasons that technologies are not offered or declined. Participating centers will be surveyed to quantify the racial/ethnic minority representation of the providers and the types of prescribing providers (MD/DO, APPs) in the corresponding center.

Timeline

The total duration of this project is three years. Aim 1 will last approximately 12-15 months. Aim two will last approximately 18 months and aim 3 will last approximately 6 months.

Figure 3: Project Timeline

	Mo 3	Mo 6	Mo 9	Mo 12	Mo 15	Mo 18	Mo 21	Mo 24	Mo 27	Mo 30	Mo 33	Mo 36
Start-up	x											
Aim 1												
Qualitative Study		x	x									
BPA development/refinement			x	x	x							
Publication				X								
Aim 2												
BPA deployed					X	x	x	x	x			
Data collection						x	x	x	X	x		
Data analysis								X	X	X	X	
Aim 3												
Data analysis										x	x	x
Publications											X	x

Publications

The publication policy of the T1DX-QI developed by the T1DX-QI publication committee will guide the publication process. The publication committee will review and approve abstracts, presentations, and publications derived from the trial. We expect to submit at least one manuscript to a scientific journal and one conference abstract from the project.

Communication/Publication Plan

Following the project plan, the findings from the project will be presented to the over 60 endocrinology centers in the T1DX-QI network during one of the regular collaborative-wide annual learning session conferences and webinars. Findings will be disseminated at scientific meetings (e.g. American Diabetes Association, JDRF, Epic Physician Advisory Group), and the BPA tool will be uploaded into the Epic community library, where they can be immediately accessed by outside health systems using Epic. The T1DX-QI collaborative allows for wide dissemination to many other T1D focused centers around the country we will create a change package to guide other centers in replicating what was done in this study. The developed Change Package developed will serve as a guide for any of the centers in the network.

Protection Against Risk

Data collected is protected under the T1DX-QI data use agreement. T1DX-QI receives a limited dataset from centers for analysis, trending, and quality improvement purposes. Only aggregate data will be published. The study team considers any patient data's confidentiality to be of the utmost importance. All staff at the study center will maintain strict confidentiality regarding the data collected. Each center will obtain relevant approval as appropriate. The risks of participating in this study are minimal since no patient identifiable data will be transmitted beyond the local site. All centers have an existing data use agreement with the T1DX-QI coordinating center to facilitate data sharing. T1DX-QI has received exempt status IRB approval for our routine QI projects. We will seek ethical review and approval from the Western Institutional Review Board upon notification of the award.

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