T1D Exchange

Data Governance Committee Meeting

May 22, 2023

Data Governance Meeting Agenda

1. Welcome
2. Updates on Sponsored Projects – Dan and Carol
3. Antibody Screening and Monitoring project updates – Emma
4. Antibody discussion and considerations – Dan and Carol

Purpose of the T1DX-QI/T2DX-QI Data Governance Committee

To expand research focus through academic and industry support for projects:

- To have a better understanding of and improvement in patient care
- Reduction in health disparities
- Improvements in understanding impact of treatments

To expand opportunities for QI team members:

- To serve as PI or Co-Investigators at their sites
- Provide patient opportunities to engage in QI research

T1DX-QI Project Updates

CGM Analysis – Completed

Sponsor: Dexcom

Objectives:

1. Examine **patient profiles of rtCGM users vs. SMBG users** (using additional data from newly mapped sites).
2. Examine **patient attributes and clinical outcomes** among CGM initiators compared to a propensity score-matched comparison group.
3. **Describe patient profiles for people currently using Dexcom CGM with Tandem X2 pump and control-IQ software.**

Participating Centers: N/A; analyzing data from mapped centers

Project Status/Results: ✓Completed; paper accepted

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Manuscript Accepted

Title: An Observational Crossover Study of people using Real-Time Continuous Glucose Monitors (CGMs) vs. Self Monitoring of Blood Glucose (SMBG): Real-World Evidence using EMR Data from over 12,000 people with Type 1 Diabetes

Journal:	*Journal of Diabetes Science and Technology*
Manuscript ID	DST-23-0109
Manuscript Type:	Original Article
Date Submitted by the Author:	28-Mar-2023
Complete List of Authors:	Noor, Nudrat; T1D Exchange, QI and Population Health Norman, Gregory; Dexcom Inc, ; UCSD, Sonabend, Rona; Texas Children's Hospital Chao, Lily; Children's Hospital Los Angeles Kamboj, Manmohan; Nationwide Children's Hospital Golden, Lauren; NYU Langone Health Bekx, M Tracy; University of Wisconsin Madison School of Medicine and Public Health, Pediatrics Hsieh, Susan; Cook Children's Medical Center Levy , Carol; Icahn School of Medicine at Mount Sinai, Medicine Sanchez, Janine; University of Miami, Pediatric Endocrinology Rapaport, Robert; Mount Sinai Ebekozien, Osagie; T1D Exchange, ; University of Mississippi,

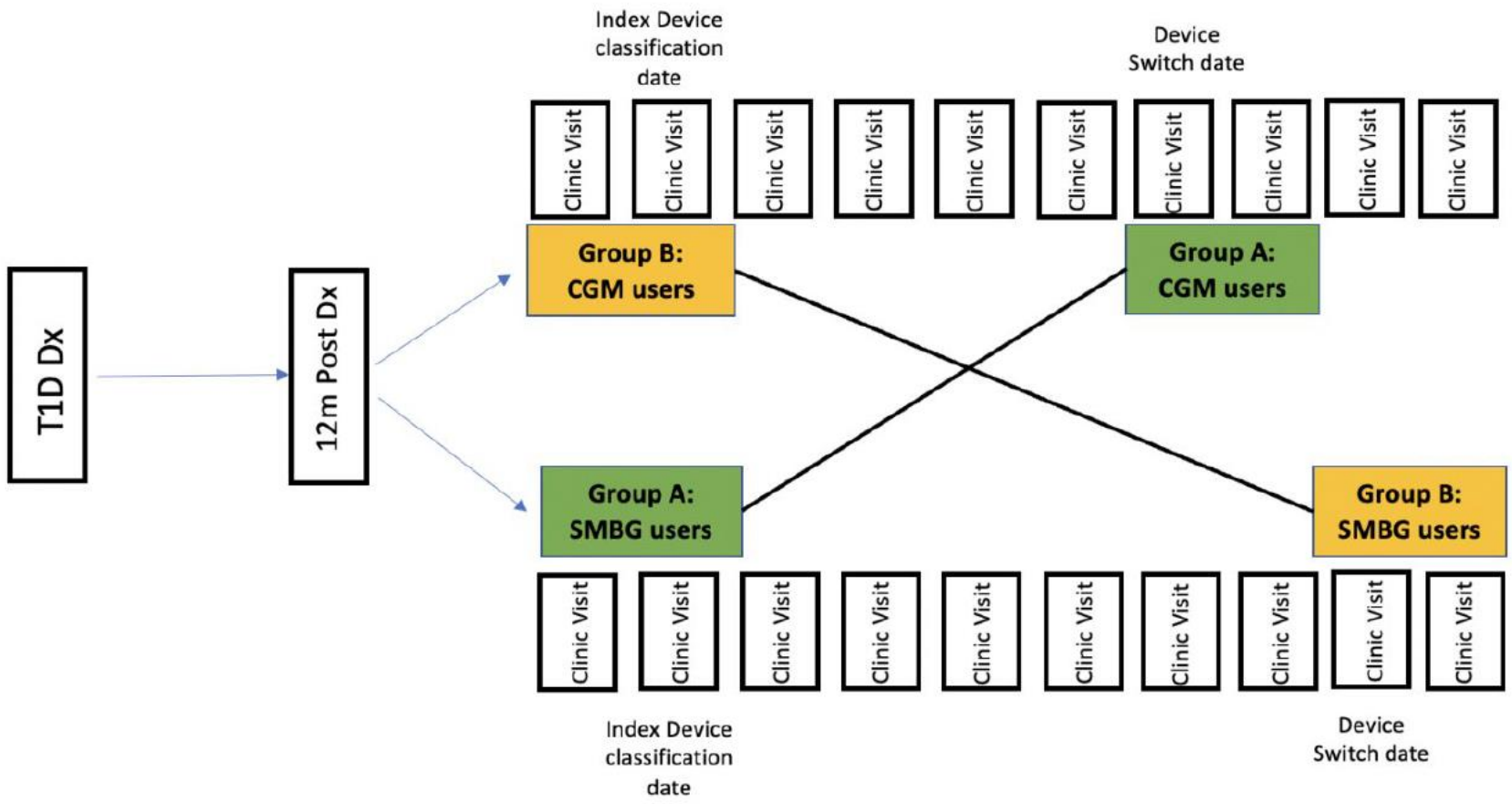
Observational, case-crossover study

Data from 20 clinics between 2017 and 2021

Pediatric and adult persons with:

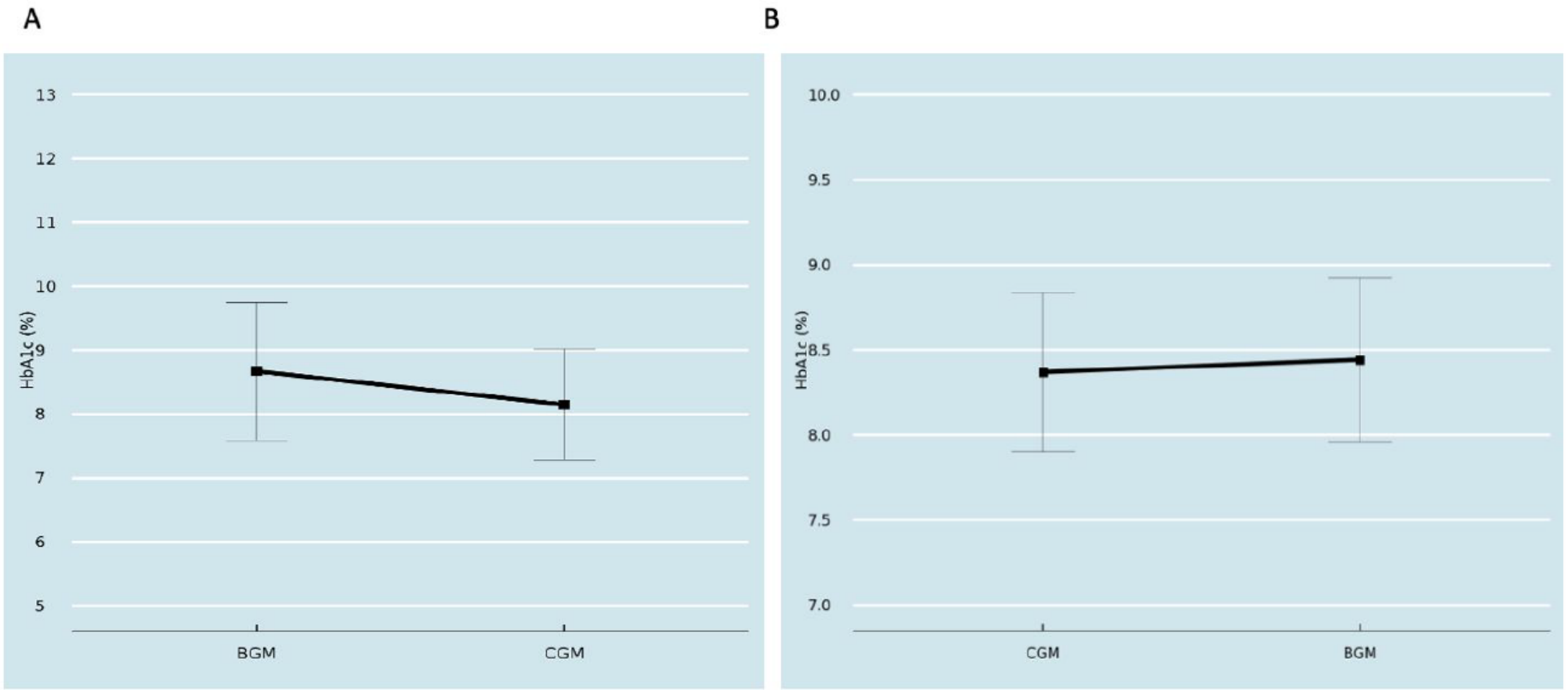
- T1D duration of at least one year
- complete information on CGM use or SMGB use at baseline and follow-up visits
- corresponding HbA1c values

Figure 1: Study Design



Significant improvement in A1c when switching to CGM

Figure 3: Mean HbA1c levels after switch from a) SMBG to CGM (Group A) and b) CGM to SMBG or BGM (Group B)



Device Equity Expansion – Status update

Sponsor: Medtronic

Objectives:

1. Reduce **inequities in CGM, insulin pump, and insulin pen** use between non-Hispanic White and non-Hispanic Black and Hispanic patients

Participating Centers: Wayne State, Penn, University of Miami (A), BDC (A), BMC, Grady, UCSF (A), CMH, University of Michigan, Rady Children's, Cook Children's

Project Status/Results: ✓ On track; Meeting monthly, sharing current processes and will develop a shared Fishbone diagram and KDD

Smart Pen Equity – Status update

Sponsor: Eli Lilly

Objective:

1. **Increase connected pen dosing data availability by 10%** from baseline in 9 months
2. **Increase shared decision-making documentation** using the Diabetes Technology Assessment tool for eligible patients on MDI from 0% to 25% in 9 months
3. **Increase % of patients on a smart/connected pen by 5% from baseline**
4. **Decrease % of patients on smart/connected pen with HbA1c >9% by 5% from baseline**
5. **Reduce % racial inequities** between NHW vs NHB & Hispanic patients in the availability of connected pen data reporting for clinical management

Participating Centers: Stanford (A + P), Northwestern (A), Montefiore (A), NYU (A) Mount Sinai (A), Washington University (A), Le Bonheur (P), Children's Healthcare of Los Angeles (P); **8 total**

Project Status/Results: ✓On Track; regular monthly meetings occurring and centers data-sharing; centers are preparing local-level manuscripts for publication, complete with a T1DX-QI Overview commentary

EMR Analysis – Status update

Sponsor: Vertex

Objective: Complete a **descriptive analysis of total daily dose (TDD) of insulin** across patients with T1D 2-25 years age group

Participating Centers: N/A; analyzing data from mapped centers

Project Status/Results: ✓On Track

Severe Hypo Feasibility Study – Status update

Sponsor: Vertex

Objective: Complete an analysis on the distribution of **patient attributes by the number of SHE events experienced**

Participating Centers: N/A; analyzing data from mapped centers

Project Status/Results: ✓On Track

Type 2 Diabetes expansion – Status update

Sponsor: Abbott

Objectives:

1. Establish a **large dataset for T2D patients**;
2. **Evaluate this T2D dataset for benchmarking and metrics** for the purposes of supporting quality improvement activities;
3. **Establish an independent data platform** to share and disseminate patient-level data for the T2D patient population

Participating Centers: BMC, Grady, UPMC; **3 total adult centers**

Project Status/Results: ✓On Track; monthly meetings initiated; centers have been invited to contribute to the development of a T2D data specification

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Type 2 Diabetes QI – Status update

Sponsor: ADA

Objectives:

1. Provide **data analysis and quality improvement coaching support** for Know Diabetes by Heart T2D centers

Participating Centers: TBD; **8 total**

Project Status/Results: Contract approved; identifying centers

Antibody Screening QI Project– Status update

Sponsor: JDRF

Objectives:

1. Establish **data elements for antibody screening and patient outcomes** (i.e., stages of T1D diagnosis, DKA events)
2. **Implement the Model for Improvement and PDSA cycles** to identify best practices for antibody screening
3. Host **focus groups** with clinical staff for lessons learned on **establishing a standardized screening process**

Participating Centers: University of Florida (P), Rady Children's (P); **2 total**

Project Status/Results: ✓On Track; implementation materials and protocol complete; IRB and SOW under review

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Screening and Monitoring newly diagnosed patients with T1D

JDRF Antibody Project

Rationale:

- Annually, ~64,000 new cases of T1D are diagnosed in the US.
- Screening for autoantibodies can support monitoring of progression through T1D stages and reduce severe outcomes (like DKA).
- Clinical settings would benefit from recommended process and best practice solutions in this area.

Objectives:

1. Develop and test new diabetes centers workflows for T1D autoantibody screening and monitoring in the real-world setting.
2. Identify care team perceptions of operational challenges to the screening process.

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Participating Centers

University of Florida

- Gainesville, FL
- ~70 patients newly diagnosed with T1D annually
- ~1300 established patients with T1D receiving care
  - 32% publicly insured
  - 60% NHW, 20% NHB, 13% Hispanic

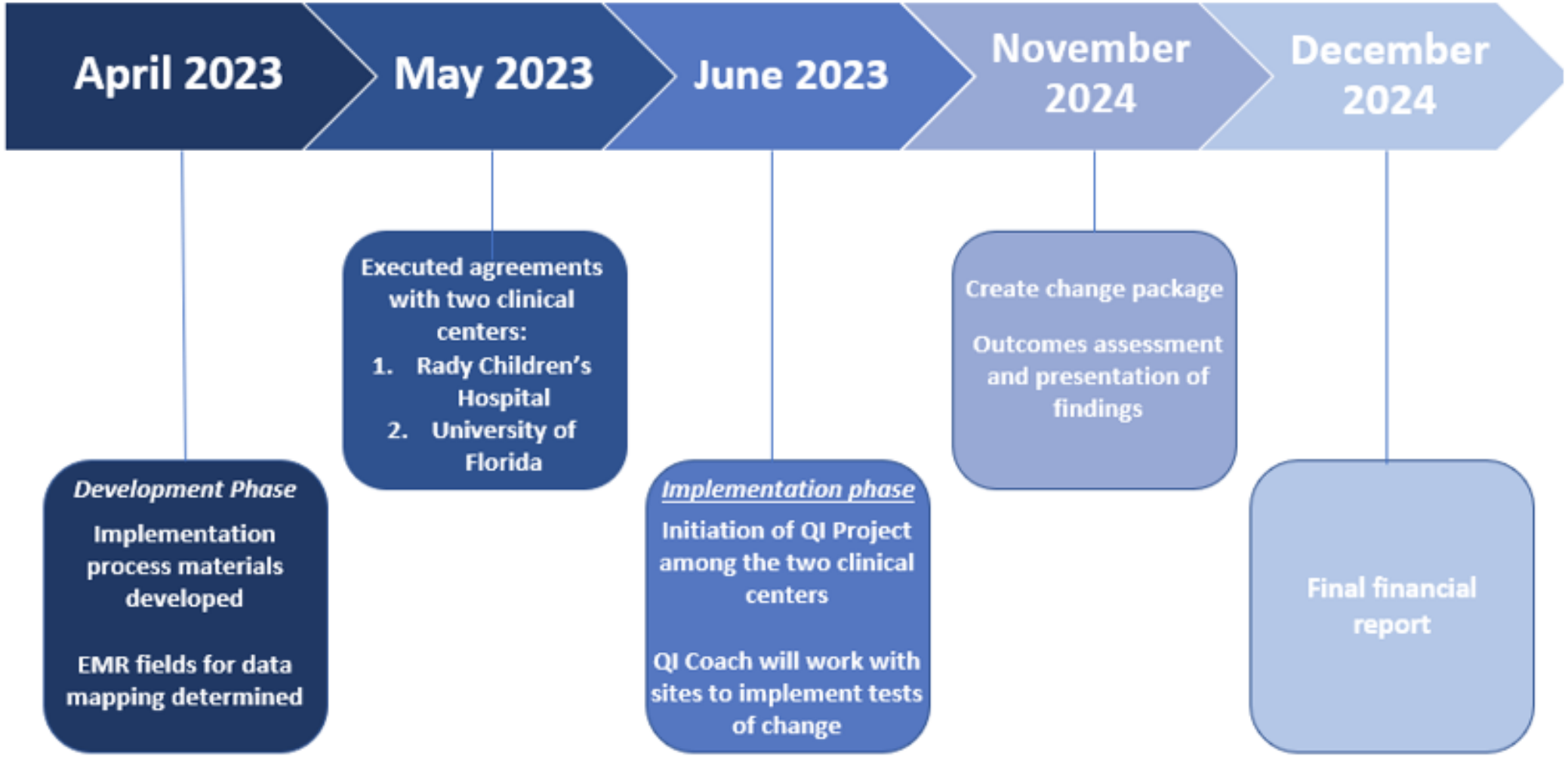
Dr. Laura Jacobsen, PI

Rady Children's Hospital

- San Diego, CA
- ~190 patients newly diagnosed with T1D annually
- ~1500 established patients with T1D receiving care
  - 46% publicly insured
  - 58% NHW, 33% Hispanic, 5% NHB

Dr. Carla Demeterco-Berggren, PI

Timeline


April 2023
May 2023
June 2023
November 2024
December 2024
Development Phase
Implementation process materials developed
EMR fields for data mapping determined
Executed agreements with two clinical centers:
1. Rady Children's Hospital
2. University of Florida
Implementation phase
Initiation of QI Project among the two clinical centers
QI Coach will work with sites to implement tests of change
Create change package
Outcomes assessment and presentation of findings
Final financial report

Stages of T1D Diagnosis

Stage	Definition
Stage 1	Multiple islet autoantibodies, normal blood glucose, pre-symptomatic
Stage 2	Multiple islet autoantibodies, abnormal glucose tolerance, usually pre-symptomatic
Stage 3	Blood glucose above ADA diagnostic thresholds
Stage 4	Established T1D

Besser REJ, Bell KJ, Couper JJ, Ziegler AG, Wherrett DK, Knip M, et al. ISPAD Clinical Practice Consensus Guidelines 2022: Stages of type 1 diabetes in children and adolescents. Pediatr Diabetes. 2022;23(8):1175-87.

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Measures

Measure	Definition
Stage [1-4] diagnosis	# of patients who have a documented stage [1-4] T1D diagnosis
New onset patients	# of individuals in project population who have been diagnosed with T1D in the last month
Autoantibody screening	# of individuals in project population who have been screened for T1D antibodies
Autoantibody labs	# of individuals in project population that screen positive for antibodies [GAD65, Anti-IA2, Tyrosine Phosphatases IA2 and IA-2β, ZnT8]
Follow-up visits	# of endocrinology visits after receiving a positive autoantibody screening results
DKA events	# of individuals in project population with a reported DKA event
HBA1c	HbA1c for all individuals that are screened within this study

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T1DX-QI Annual Survey 2023

Antibody screening and monitoring questions

- Please rank your preference for screening company (Trial-Net; JDRF; LabCorp; Quest; Local lab; other)
- Which screening company do you use most often?
- How often are providers in your practice asking patients and families about their interest in autoantibody screening (scale of 'all the time' to 'never')
    - If yes, how are you communicating? (in person at or after dx, email, flyers, other)
- Have your clinic practices changed since the release of Teplizumab?
    - If yes, what? (screening all new-onset patients, screening first-degree relatives, other)

Future considerations for the collaborative

Survey questions feedback

How is this data captured? In your EMR? For Research?

How do you capture data for people that are not yet “patients”?
    Any concerns with sharing that data?

What are your current processes for screening and monitoring?

Which autoantibodies are you capturing?

Are there specific considerations for adult clinics?