Reducing therapeutic inertia and *Impro*ving workflow to *a*utomated *i*nsulin *d*elivery across the T1D Exchange quality improvement network (IMPROVAID)

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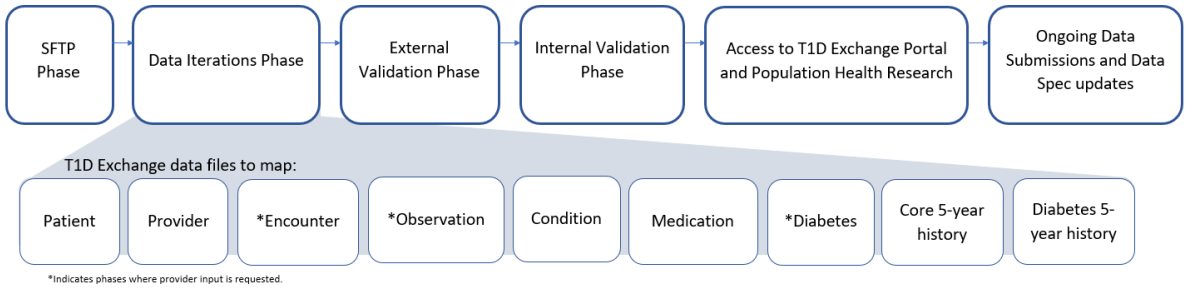
Project Background and Rationale

T1DX-QI centers share patient-level deidentified EMR data per T1DX-QI data specifications after completing an extensive data mapping and validation process (Figure 1). (1) Diabetes-related data variables collected include information on diabetes technology prescriptions, including automated insulin delivery (AID) system use. The T1DX-QI Data Science Committee (DSC) manages the T1DX-QI data specifications and makes updates at least annually to include changes in key measures, diabetes technology updates, and best practices.

Figure 1: T1DX-QI Data Mapping Process



Currently, about 35% of T1DX-QI centers provide data on AID system use. Additionally, centers that are reporting AID use may need to update their data mapping logic to include AID systems approved in the last two years. Enhanced data collection AID technology will provide a more accurate population-level understanding of AID system use in this large T1D patient database. Preliminary analysis of T1DX-QI center AID prescriptions suggests that approximately one-third of patients with T1D are using AID systems.(2) However, it is likely that this number is underreported of the true AID system users within the T1DX-QI network.

The proposed study, IMPROVAID, would enhance collection of clinical AID use data collection, identify factors impacting AID prescribing patterns and implement best practices to expand AID system use for newly diagnosed people with type 1 diabetes, while incorporating learnings from prior health equity quality improvement work on diabetes devices.

Project Objectives

There are three main objectives of this study:

Aim 1: Increase the percentage of T1DX-QI centers reporting AID system use and analyze real world data on AID use trends.

Aim 2: Complete qualitative analysis to understand factors that influence diabetes providers recommendations of AID systems.

Aim 3: Increase the percentage of newly diagnosed patients prescribed AID.

Aim 1 Methodology

Overview and Study Design

T1D Exchange will work with T1DX-QI center teams that are fully data mapped to enhance AID data collection. Individuals from T1D Exchange's team will work closely IT teams as needed to enhance AID data collection. This will include appointed IT representatives and leaders from the center's diabetes clinics, and data mapping specialists from T1D Exchange. Additionally, T1D Exchange's Data Science Committee (DSC) will propose best practice recommendations for documenting AID use in EMRs outside of the T1DX-QI network, enhancing standardization of data collection.

The participating centers will begin to report these metrics, if they have not in the past, or enhance their current reporting on these AID variables. T1D Exchange will analyze the expanded AID real world data, examining new trends and insights.

Data Collection Plan

Aggregate data will be shared monthly with the T1DX-QI coordinating center. The T1D Exchange data team will then retrieve, clean, and store this data. Run and statistical process control charts will be plotted to observe trends and shifts. Examples of the aggregate data variables to be analyzed include demographic information (race/ethnicity, insurance), glycemic outcomes (a1c, AID uptake,) device use data (CGM, pump, HCLS).

Data Management and Statistical Analysis

Basic patient and site-specific characteristics will be presented as mean and standard deviations for continuous variables, and frequencies and percentages for categorical variables. AID use for each site will be calculated as percentage both at baseline and the final follow-up. Trends in AID

use over time will be analyzed over the 18-month study period using incidence and prevalence rates of AID use. Incidence and prevalence rates will be estimated at different time points during the study follow-up period. Temporal change will be assessed using time-series analyses; piecewise regression models will be used to identify timepoints at which statistically significant changes in the trend of rates occur. P-values for these points will be estimated using Monte Carlo methods. Finally, multivariate models will be used to evaluate if the temporal changes remain statistically significant after adjusting for potential confounders.

Aim 2 Methodology

Overview and Study Design

Aim 2 will consists of approximately 20 focus groups with centers (15 Pediatrics and 5 Adult Centers) ranging from 2-5 individuals in each focus group, recruited from participating centers in the T1DX-Q to understand the many factors that influence the recommendation of AID systems. Furthermore, this study will help determine the role of the AID device clinical performance, cost, and access in recommending AID systems.

Methods and Data Collection Plan

Focus groups will be comprised of a diverse group of team members from each center including providers, nurses, educators, and other care team members selected from the T1DX-QI collaborative to understand the many factors that influence the recommendation of AID systems. All focus groups will be conducted by T1DX-QI staff trained in qualitative focus groups. Each team will receive 300 dollars for focus group participation. Focus group sessions will be approximately one hour long and audio-recorded using the zoom platform.

Statistical Analysis Focus group recordings will be uploaded to a vendor (“TranscribeMe!”), that will transcribe the transcripts verbatim. Transcripts will be uploaded into NVivo qualitative software (QSR International, Doncaster, Australia) for data organization and management. Each transcript will be reviewed and analyzed to address key topics of interest. A codebook will be created based on the interview guide. 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. All labeled transcript sections will be summarized under each coding theme to

generate the final summary. Transcripts will be de-identified after analysis to remove participant names and any other identifiable information.

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 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 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.

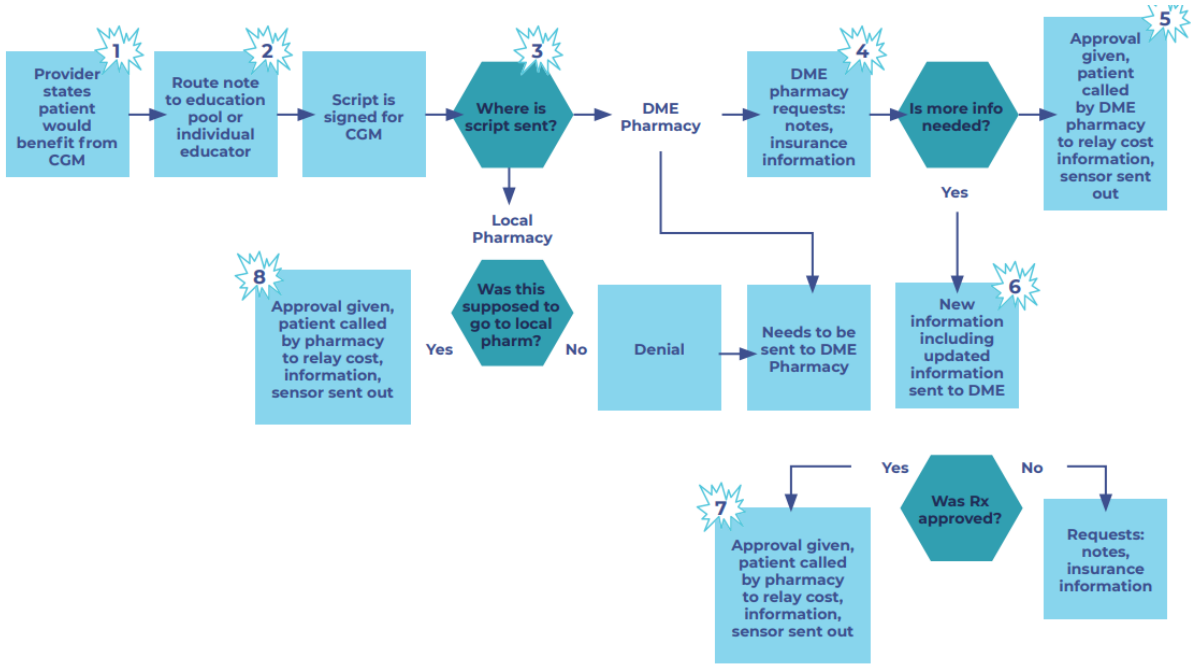
The consent form will be read to each potential participant before beginning the interview. The individual will be required to agree that they understand this form and would like to continue. For survey participants, the consent form will be presented to each potential participant in an online format. 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 3 Methodology

Overview

T1DX-QI will recruit twelve centers (eight pediatric and four adult) to participate in this phase of the project. The T1DX coordinating center will coach centers in the Ten-Step Equity Framework and quality improvement (QI) methodologies to identify best-practice recommendations in prescribing AID in new-onset patients and describe results in pilot centers. The QI coach will work with centers directly to test and incorporate new workflows and process changes and facilitate the use of QI tools (see Figure 2: Sample Process Map) to support effective prescribing of AID. T1D Exchange will monitor relevant metrics before, after, and at appropriate time intervals.

Figure 2: Sample Process Map



Timeline

The total duration of this project is 24 months long, dating from November 2024, with the start of Aim 1. There will be some overlap between aim 1 and aim 2, which both of these will feed into aim 3.

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.

References

1. Mungmode A, Noor N, Weinstock RS, Izquierdo R, Indyk JA, DeSalvo DJ, et al. Making Diabetes Electronic Medical Record Data Actionable: Promoting Benchmarking and

Population Health Improvement Using the T1D Exchange Quality Improvement Portal. Clinical Diabetes. 2022;41(1):45-55.

2. Ebekozien O, Mungmode A, Sanchez J, Rompicherla S, Demeterco-Berggren C, Weinstock RS, et al. Longitudinal Trends in Glycemic Outcomes and Technology Use for Over 48,000 People with Type 1 Diabetes (2016-2022) from the T1D Exchange Quality Improvement Collaborative. Diabetes Technol Ther. 2023;25(11):765-73.