QI Collaborative for Type 2 Diabetes

PROTOCOL

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KEYWORDS

Type 2 diabetes (T2D)

Quality Improvement (QI)

Clinical data

Practice improvement

Learning Collaborative

Performance Benchmarking

1.0 Introduction and Objectives

Quality improvement collaboratives bring together healthcare teams from various clinical settings to share best practices for improving care delivery. T1D Exchange Quality Improvement (T1DX-QI) Collaborative is one such learning healthcare collaborative, using the Model For Improvement, developed by Associates in Process Improvement. Incremental changes are tested using Plan-Do-Act-Study (PDSA) cycles across each collaborative member site. Established in 2016 to improve care for patients with diabetes. This collaborative hosts the largest type 1 diabetes (T1D) multi-center, patient-level, EMR data-derived databases in the U.S. which renders the opportunity to provide valuable insights on care delivery and health outcomes for patients with T1D.

While the existing T1DX-QI clinical collaborative has created a data platform to collect, store, analyze and share patient level data for T1D, the goal is now to expand to patients with type 2 diabetes who are insulin dependent.

Objectives:

1) To create a large database for Type 2 diabetes
2) Evaluate T2D benchmark and metrics for collaborative
3) Independent platform to share and disseminate patient level data for T2D

Methods

The T2D QI collaborative (T2D QIC) will build on recruitment of endocrinology clinics with a large patient volume of people with type 2 diabetes and are able to provide executive support for participation in this collaborative. Participating clinics will provide local resources for IT and data management activities required to map and transmit data to the T2D QIC repository. Clinics will also be required to participate in monthly calls for QI coaching and updates. There will also be a requirement for site representatives (such as PIs) to attend in-person meetings bi-annually.

2.0 Site Enrollment and Eligibility

Sites will be recruited and enrolled based on their patient population and their ability to document and report data within their EMR systems. Eligible sites will be caring for adult patients with a diagnosis of T2D.

Data collection:
Participating sites will provide partially identifiable patient level data from their electronic medical record (EMR) systems (this includes information such as demographics, encounters, observations, conditions, medications, and monitoring). Clinics will provide this EMR based data for all patients with type 2 diabetes cared for in their clinical practice. Data specifications (provided as Appendix 1) will be shared with participating sites to map EMR data in accordance with T2DX-QI database requirements. This will allow for standardized and consistent data collection across all sites.

EMR reporting on eligible patients
Patients with a confirmed T2D status from an endocrinologist will be included in the T2DX-QI database. Patients with T2D are defined as patients with evidence of type 2 diabetes as confirmed by ICD9 or ICD10 codes (250.0, 250.2, 250.40, 250.72 and E11.*).

3.0 Participation Benefits for clinics

Clinics will have the opportunity to learn and share with peer centers across the US. There are monthly calls for peer learning where clinics share updates on their projects and get their questions answered. There are also in-person two-day learning sessions where all the clinics come together to collaborate, present, and learn about new QI tools. Each clinic will also have access to our email distribution list where clinics can poll other centers and share resources. Further, to increase the utility of this dataset, the T1D Exchange will create a first of its kind, web-based, on-demand "T2D Exchange Portal" that serves dual functions: 1) reporting of site-level data and 2) benchmarking across participating sites.

Other benefits for participating site include:

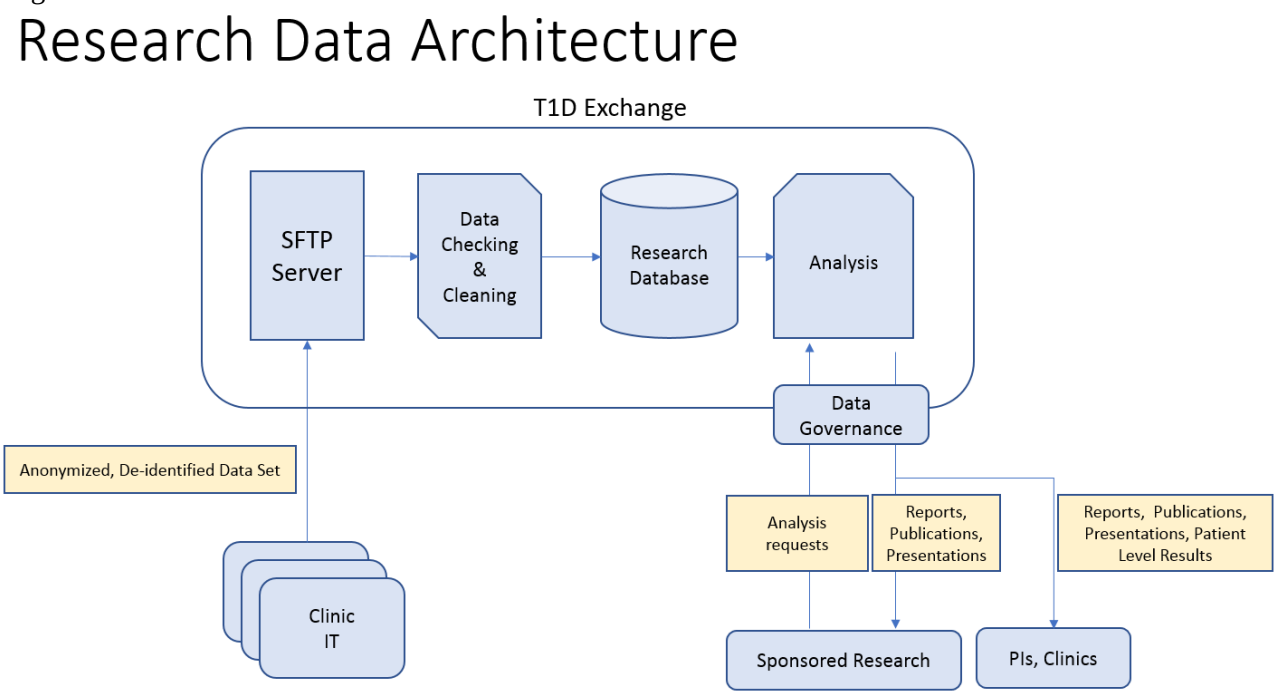
- Access to the T2D Exchange QI Portal which is a population health management tool that allows each clinic to monitor process and outcome measures for their patient cohort, tracking of progress across multiple QI interventions (e.g. run charts), and creation of related reports to support local care delivery.
- Performance benchmarking will take place across the T1D Exchange QI Collaborative; the portal benchmarks data so that clinics can assess their care processes and health outcomes with other participating clinics. Clinical sites are supported in transforming their data into an established standard to enable accurate and reliable comparisons.
- Opportunities to meet with a quality improvement coach quarterly to learn about QI implementation strategy, such as designing, implementing, and evaluating ongoing and planned QI projects. This includes the use of their Plan-Do-Study-Act (PDSA) cycles and the creation and evaluation of run charts.
- Participation in clinical research activities that have received the necessary IRB approval (e.g. waivers of patient consent and, if required, local IRB approval).
- Each year there are opportunities to collaborate on scientific or QI abstracts and manuscripts.

4.0 Data Access and Use Policy

The T2D Exchange QI Collaborative will collect demographic, clinical, and patient-reported data pertinent to the care of people with type 2 diabetes from U.S.-based outpatient clinics and hospital systems. Given the primary focus on quality improvement, there is no pre-specified enrollment target. Currently, ten clinical centers are participating, and efforts are underway to enroll additional sites. The T2D Exchange QI Collaborative aims to have longitudinal data across 15,000 patients in 6 clinical sites, though both numbers have no maximum. Data shared with the T1D Exchange is a limited dataset with protected health information (PHI) data restricted to dates and patient zip code. Participating sites were responsible for confirming if required, that patient consent was not required given the use of data for quality improvement initiatives. Participating sites are required to sign a standard BAA for participation in QI efforts. This data is made into a fully de-identified dataset at the T1D Exchange for use in all current and future planned activities. Projects will follow standard procedures, including feasibility assessments based on study question(s), data availability, and priority for available staff and resources. For clinical research projects, IRB approval will be required for access and use to the data. Participating sites will be notified of patient data derived from their clinical site for use in IRB-approved study protocols. Clinic site information may be used for both QI and research-related activities if the site and IRB approval, where required, have been obtained.

The data and IT infrastructure for access and use of Collaborative data for approved clinical research data are presented in figure 1 below. It illustrates data flow, storage, and use from the point of data collection to the point of research and data dissemination.

Figure 1.



5.0 Patient Consent

Quality improvement initiatives address the care and outcomes of clinic patients. Clinical research activities relate to the care and outcomes of clinic-based study participants. For purposes of this protocol, "patients" refer to clinic patients participating in QI initiatives as well as study participants enrolled in clinical research studies. Data is derived from these clinics and is de-identified at the T1D Exchange. Data that will be collected from the clinics participating in the QI project will include only de-identified data and the dataset will be stripped to not include dates, patient zip code, and medical record numbers. Patient consent is not required for QI use of the data as confirmed in the BAA. Clinical research studies will require review and approval by an IRB, either centralized and/or local (from participating sites). For clinical research studies, either patient consent or IRB approval for waiver of patient consent will be obtained before any study-related procedures, 45 CFR §46.116(d) (1994).

6.0 Adverse Events

The Collaborative will not conduct interventions for clinical research. Quality improvement interventions will evaluate permissible, non-investigational interventions at participating sites. Clinical research activities will be restricted to retrospective evaluations of available data. As such, this is a non-treatment, non-intervention data repository. The risk to patients is minimal and relates to possible breach and unauthorized dissemination of patient data to those who do not have the right to view the data. Data shared with participating sites will not have any patient identifiers. Safeguards are in place to protect the security and confidentiality of the data. For any breach of patient data containing protected health information, the T1D Exchange will work with clinical sites whose data was impacted and lead the effort to notify patients about the unauthorized acquisition of health information per the HIPAA privacy ruling.

7.0 Data Encryption

The QI Collaborative database will use PostgreSQL with cluster replication across multi-data centers. The database has auto-scaling on load and analytic requests.

Database storage is encrypted with a 256-bit AES-GCM key and regular key rotation mechanism in place, including daily basic incremental encrypted backup made in low load time with limited access to backup storage. There is an automatic restore on failure (either hard or soft) and on-demand restore is available by the Database Administrator (DBA). There is no external access to the database allowed, as users must either be on the internal network or use a VPN to access the QI Collaborative database. Role-based access control and password complexity policies are in place for QI Collaborative DBAs as well.

8.0 Analytical Considerations

The T1D Exchange QI Collaborative will be a significant source of data that can be used to address many aspects of type 1 diabetes management and related outcomes. Some analyses may be descriptive, such as the frequency of each pump manufacturer or the frequency of missing insulin doses. Other analyses may explore the association of factors and analytics modeling with outcomes such as HbA1c levels, severe hypoglycemia events, and diabetes ketoacidosis events. All results and data produced and shared in the research dataset will be shared at the aggregate level. No patient-level data or clinic/site identifiers will be made available to research partners, Data analysis will only be conducted by analytic staff based at the T1D Exchange who have completed CITI and HIPAA training and are approved by the local IRB to access the data for the intended purpose (e.g. quality improvement and/or clinical research). Data analyses for quality improvement will also be conducted dynamically through reporting algorithms and data displays on the portal.

8.1 Use of the Data

New data will become part of the Platform database, which is maintained by the T1D Exchange central office in Boston. Data analyses will be conducted by T1D Exchange statisticians, QI staff, and collaborating researchers, including clinical sites.

In the interest of advancing knowledge about this disease and innovation in the production of new therapies and tools for people living with type 2 diabetes, aggregated data will be provided to other researchers, both academic and industry. Requests for data will be reviewed by the T1D Exchange Data Governance Committee for merit and detailed hypotheses. Data will only be shared with industry partners, after approval from the Data Governance Committee, to fulfill the T1D Exchange mission of advancing research and development of resources, tools, devices, medications. Objectives will be formalized in the research process. When a dataset is provided to external researchers, the aggregated data will be fully de-identified and anonymized. The Data Governance Committee rules on usage to ensure that all associated projects are supporting what is best for patients. T1D Exchange will use the data with industry partnerships; the revenue from which will be used to cover internal costs (e.g., staff time) to carry out our mission-related activities and will not exceed our expenses.

8.2 Dissemination of Results

Results of data analyses may be disseminated in scholarly and industry publications and presentations as well as publicly accessible websites. No PHI will be disclosed in the dissemination of results, and clinical sites and hospitals will only be named with the hospitals' permission. Fully de-identified, anonymized, aggregated data also may be made publicly available: we plan to reference our work on our social media and our website so that people living with type 2 diabetes, and their families, can be informed about diabetes health statistics that are relevant to their lives, their treatments, and their care. These will reference our research and links to future publications on our work.

Appendix 1:

Measures/Goals	Description	Numerator	Denominator	Measure Steward
Comprehensive Diabetes Care: Hemoglobin A1C (HbA1c) testing	The percentage of members 18-75 years of age with diabetes (type 1 and type 2) who received an HbA1c test during the measurement year.	Total number of patients with type 2 diabetes who received an HbA1c test during the measurement year	Total number of patients with type 2 diabetes who are currently enrolled as patients at clinic	National Committee for Quality Assurance
Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)	The percentage of members **18-75** years of age with diabetes (type 1 and type 2) whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year	Total number of patients whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year	Total number of patients with type 2 diabetes who received an HbA1c test during the measurement year	National Committee for Quality Assurance
Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)	The percentage of members **18-75** years of age with diabetes (type 1 and type 2) whose most recent blood pressure (BP) reading is <140/90 mm Hg during the measurement year.	Total number of patients with type 2 diabetes whose most recent blood pressure (BP) reading is <140/90 mm Hg during the measurement year.	Total number of patients with type 2 diabetes who received a blood pressure screening during the measurement year	National Committee for Quality Assurance

Comprehensive Diabetes Care: Eye Exam	The percentage of members **18-75** years of age with diabetes (type 1 and type 2) who received a retinal or dilated eye exam during the measurement year or a negative retinal or dilated eye exam in the year prior to the measurement year.	Total number of patients with type 2 diabetes who received a retinal or dilated eye exam during the measurement year or a negative retinal or dilated eye exam in the year prior to the measurement year	Total number of patients with type 2 diabetes who are currently enrolled as patients at clinic	National Committee for Quality Assurance
Diabetes: Foot exam	The percentage of patients **18-75** years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection with either a sensory exam or a pulse exam) during the measurement year.	Total number of patients with type 2 diabetes who received a foot exam (visual inspection with either a sensory exam or a pulse exam) during the measurement year	Total number of patients with type 2 diabetes who are currently enrolled as patients at clinic	National Committee for Quality Assurance
Comprehensive Diabetes Care: LDL-C Screening	The percentage of members 18-75 years of age with diabetes (type 1 and type 2) who received an LDL-C test during the measurement year.	Total number of patients with type 2 diabetes who received an LDL-C test during the measurement year	Total number of patients with type 2 diabetes who are currently enrolled as patients at clinic	National Committee for Quality Assurance

Depression Screening		Number of patients in (A), ages 18 and older, who met eligibility criteria* for depression screening for reporting month	The number of patients with T2D (ages 18 and older) at your center with a minimum duration of diabetes ≥ 12 months with 1 or more HbA1c values in the preceding 12 months, of which the last visit (either in-person or telehealth visit) was from the reporting month.	QIC
Screening or Evidence of Nephropathy	TBD	Total number of patients with type 2 diabetes who received screening for evidence of Nephropathy during the measurement year	Total number of patients with type 2 diabetes who are currently enrolled as patients at clinic	QIC