T1D Exchange QI Collaborative Data Use Program

PROTOCOL

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KEYWORDS

Type 1 diabetes (T1D)

Quality Improvement (QI)

Clinical data

Practice improvement

Learning Collaborative

Performance Benchmarking

1.0 Introduction and Objectives

Established in 2016[1], the T1D Exchange Quality Improvement (QI) Collaborative is a learning health system focused on sharing knowledge and best practices across clinical sites involved in the care of persons with type 1 diabetes. The T1D Exchange has created a data platform to track network progress and collect, store, manage, analyze, and disseminate information about persons living with type 1 diabetes from participating clinical sites. Shared learnings[2] are used to drive quality improvement initiatives at clinical sites and across the entire QI Collaborative focused on high-value interventions[3], e.g. to reduce acute and chronic complications, improve patient-reported outcomes, and/or reduce the cost burden to patients or their clinical practices[4-8].The platform helps to track our milestones and progress towards network goals. Each participating site has signed a data use agreement with T1D Exchange to share demographic, clinical diabetes device, and patient-reported data for all patients with type 1 diabetes to support the goals of the QI Collaborative. Examples of such efforts include tracking care improvement work (eg, frequency of screenings and clinical visits) and population management (determining ways to improve care for all T1D patients in the clinic). Data is collected and shared as a limited dataset that include patient identifiers of dates and patient zip code required for the QI efforts, such as identifying patients eligible for targeted interventions.

The T1D QI Collaborative is generating a large and unique dataset that has the opportunity to provide valuable insights for care delivery and related health outcomes for this population that could inform optimal care strategies beyond participating sites. Indeed, this collaborative is the largest, multisite, U.S.-based repository of data for individuals with type 1 diabetes. The T1D Exchange and participating sites recognize the emerging value of using the data, when appropriate, to address fundamental questions that may be applicable for the entire population of individuals with type 1 diabetes. As such, we propose to establish the framework for using the clinic-derived patient data for the conduct of HIPAA-compliant population health studies. Details regarding the various facets of establishing, using, and disseminating patient data for population health studies follow in the sections below.

2.0 Site Enrollment and Eligibility

Patients are eligible for participation in the T1D Exchange QI Collaborative if they have a diagnosis of type 1 diabetes and are receiving care at a participating site. Participating clinics are committed to providing:

- Executive support or sponsorship for participation in the Collaborative.
- Local resources for IT and data management activities required to map and transmit data to the T1D Exchange data repository.
- Partially identified (dates and patient zip code), patient-level data for all patients with type 1 diabetes cared for in their clinical practice.
- A multi-disciplinary QI team composed of a clinical champion (MD, DO, or NP), a patient/parent representative, a nursing/certified diabetes educator, a QI specialist and/or analyst, and a site coordinator; one person may fill multiple roles.
- Staff time to participate in the monthly calls.
- Attendance to in-person meetings up to two times annually.

QIC governs in concert with a Clinical Leadership Committee. As new sites are onboarded and on an annual basis, T1D Exchange checks investigators against FDA debarment and disqualification list to ensure maintaining the integrity and trust placed in the Collaborative.

2.1 Participation Benefits

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 also has access to our email distribution list where clinics can poll other centers and share resources.

The T1D Exchange QI Collaborative has made a significant investment to establish a secure, HIPAA-compliant data repository for receiving and managing patient data. To increase the utility of this dataset, the T1D Exchange has created a first of its kind, web-based, on-demand "T1D Exchange Portal" that serves dual functions: 1) reporting of site-level data and 2) benchmarking network milestones across participating sites.

Participation benefits include:

- Access to the T1D 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 QI/Population health activities that fall under the scope determination that the work is NHSR and that patient consent is not this protocol required and,
- Each year there are opportunities to collaborate on scientific and QI abstracts and manuscripts.

3.0 Data Access and Use Policy

3.0.1. Data Source

The T1D Exchange QI Collaborative collects demographic, diabetes device, and patient-reported data pertinent to the care of people with type 1 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, 31 clinical centers are participating and efforts are underway to enroll additional sites. The T1D Exchange QI Collaborative aims to have longitudinal data across 50,000 patients in 50 clinical centers, though both numbers have no maximum.

3.0.2. Dataset Description

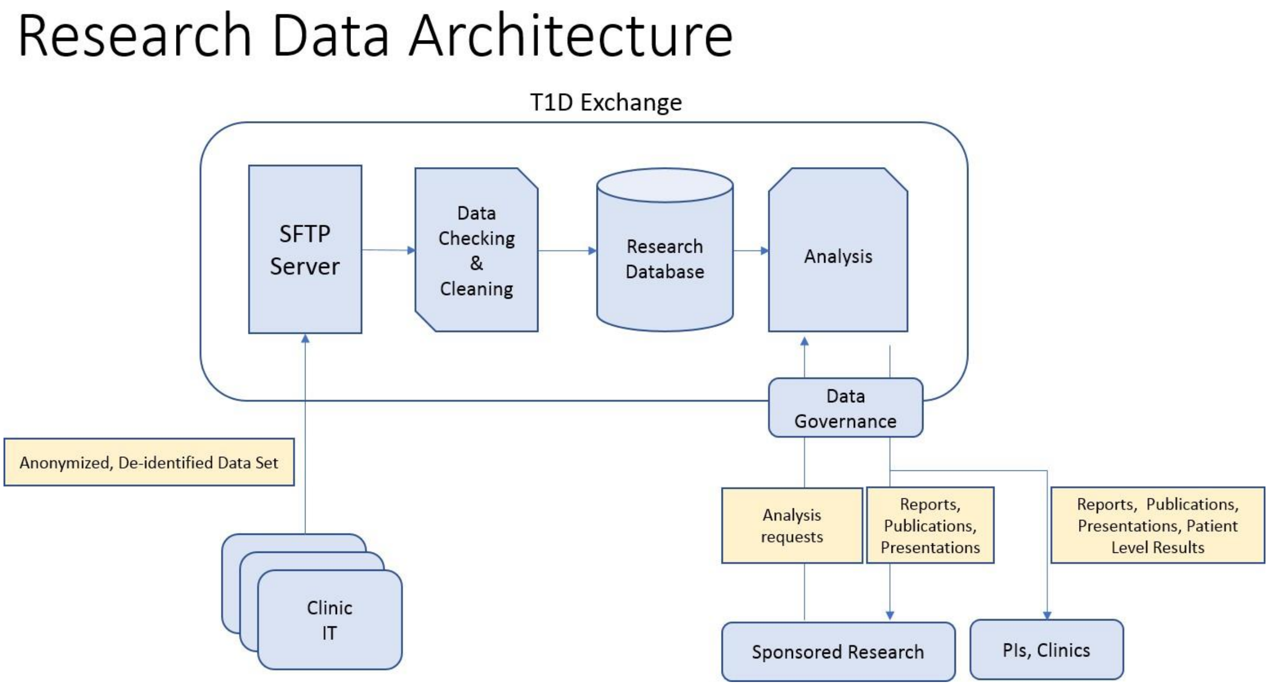
Data shared with the T1D Exchange is a limited dataset with protected health information (PHI) data restricted to dates and 5 digit patient zip code. Participating sites were responsible for confirming if required, that patient consent was not required given the use of data for quality improvement initiatives.

Participating sites are required to sign a standard data agreement for participation in QI efforts. This data is made into a 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 population health projects, IRB approval will be required for access and use to the limited dataset. Special projects that access and use data that has been stripped of identifiers is considered part of the Collaborative activities in this protocol. Anonymized information may be used for both QI and Population Health-related activities.

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

Figure 1.



3.1 Patient Consent

Quality improvement initiatives address the care and outcomes of clinic patients. Population health 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 population health 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 program will include only de-identified data and the dataset will be stripped to not include dates or patient zip code. Patient consent is not required for QI use and Population health management of the data as confirmed in the BAA. Clinical research studies that do not contain patient identifying data will not require a separate review and approval by an IRB. For population health studies that involve patient identifiers, 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).

4.0 Adverse Events

The Collaborative will conduct interventions for population health. Quality improvement interventions will evaluate permissible, non-investigational interventions at participating sites. 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.

5.0 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.

6.0 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 population health 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 population health management). Data analyses for quality improvement will also be conducted dynamically through reporting algorithms and data displays on the portal.

6.1 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 1 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.

6.2 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 1 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. For example, we may display a run chart, showing HbA1c results of people on continuous glucose monitoring (CGM) sensors vs not on CGM sensors[3]. We disseminate our learning to the public, not just in academic journals. We will also disseminate our learning on topical areas that are impacting the course of care and treatment today and tomorrow.[9-10]

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For more information on data usage, please refer to section 6. I of the Data Usage Agreement, which appears in the appendix.

Appendix