Journal of Diabetes Science and Technology
Volume 7, Issue 4, July 2013

ORIGINAL ARTICLE

Challenges and Future Directions of the T1D Exchange Clinic Network and Registry

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Abstract

The T1D Exchange Clinic Network consists of 67 clinics throughout the United States. Among the more than 100,000 patients with type 1 diabetes mellitus (T1DM) who receive care at these centers, more than 26,000 have been enrolled in a registry. The registry includes participants over a wide age range, from age <1 to 93 years, and consists of both those newly diagnosed (more than 3000 diagnosed <1 year from the time of enrollment) and those with long-standing diabetes (more than 1000 with T1DM for at least 40 years). Data on diabetes history, insulin administration, diabetes management, monitoring, complications, medical conditions, medications, and laboratory results are collected at enrollment and annually through participant completion of Web-based questionnaires and data extraction from medical records. The clinic registry has provided a rich data set to address important clinical and public health issues, including important observations regarding the current state of treatment of T1DM in diabetes centers in the United States. Challenges encountered during the establishment of the clinic registry include establishment of criteria for a diagnosis of presumed autoimmune T1DM, standardization of data collected across clinics, data quality, and understanding of potential bias. Collecting the data and maximizing data quality has required considerable effort. Even with these efforts, certain data elements are difficult to capture in a meaningful way. A standard T1DM module used by all electronic health records could be developed based on the data collection instruments developed for the T1D Exchange clinic registry.

J Diabetes Sci Technol 2013;7(4):963–969

Introduction

The T1D Exchange was established in 2010 through a grant from the Leona M. and Harry B. Helmsley Charitable Trust and consists of three complementary parts: a clinic network of adult and pediatric diabetes clinics; a Web site called Glu, serving as an online community for patients to provide information that could be used for research while also learning, communicating, and motivating each other; and a biobank to store biological human samples for use by researchers. In addition, a statistical resource center has been established to provide statistical support to the Exchange

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Abbreviations: (BMI) body mass index, (CGM) continuous glucose monitor, (DKA) diabetic ketoacidosis, (EHR) electronic health record, (HbA1c) hemoglobin A1c, (SH) severe hypoglycemia, (SMBG) self-monitoring of blood glucose, (T1DM) type 1 diabetes mellitus

Keywords: clinic registry, database, diabetic ketoacidosis, electronic health record, severe hypoglycemia, type 1 diabetes mellitus

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as well as other type 1 diabetes mellitus (T1DM) researchers. The clinic network coordinating center and statistical resource center are located at the Jaeb Center for Health Research in Tampa, FL.

As of January 1, 2013, the T1D Exchange Clinic Network consists of 67 clinical centers throughout the United States. Twelve of the centers primarily care for adult patients with T1DM, 36 primarily care for pediatric patients, and 19 are a mix of both; 52 are institution based, 14 are community based, and 1 is in a managed care setting. The first initiative of the clinic network was to establish the T1D Exchange clinic registry. Among the more than 100,000 patients with T1DM who receive care at these centers, more than 26,000 have been enrolled in the clinic registry. The registry includes participants over a wide age range, from age <1 to 93 years, and consists of both those newly diagnosed (more than 3000 diagnosed <1 year from enrollment) and those with long-standing diabetes (more than 1000 with T1DM for at least 40 years). Data on diabetes history, insulin administration, diabetes management, monitoring, complications, medical conditions, medications, and laboratory results are collected at enrollment and annually through participant completion of Web-based questionnaires and data extraction from medical records, as previously described.[1] Participants complete questionnaires, mostly either using iPads or laptops during clinic visits or accessing the project's Web site through a home computer. Key data elements are updated annually to provide longitudinal data, and new data collection modules are added that address specific objectives in greater detail. The Web application for the questionnaire was developed such that the questionnaire completed by each participant can be customized. Approximately two-thirds of the collected data are similar for all participants. The other third is customized to address specific objectives in subsets of participants. For instance, participants using a continuous glucose monitor (CGM) complete a list of questions regarding CGM use. A woman who reports having been pregnant in the past year completes a pregnancy module that addresses outcomes of the mother and child. This customized software application provides considerable flexibility to add new questionnaire-based studies quickly for targeted groups of patients. Sites are compensated for each enrolled participant, and participants receive either a gift card or, alternately, can select a donation for a T1DM charity (of interest, approximately two-thirds have selected a gift card and one-third a donation).

The baseline, cross-sectional data collected on more than 26,000 participants at enrollment into the registry have provided important observations regarding the current state of the art of treatment of T1DM in leading diabetes centers in the United States, including

- Most adults and children with T1DM do not achieve hemoglobin A1c (HbA1c) goals set by the American Diabetes Association;[2,3]
- Both children and adults who are under excellent glycemic control tend to manage their diabetes differently than those who are under poorer control, including decisions on how much insulin to take, when insulin boluses are given, frequency of blood glucose monitoring, and exercise;[4]
- Racial and socio-economic disparities exist in use of insulin pumps, with pump use being more frequent in non-Hispanic whites than non-Hispanic blacks or Hispanics, a relationship that persists even after adjusting for socio-economic status; in addition, non-Hispanic blacks have higher HbA1c levels than Hispanics or non-Hispanic whites in both pump and injection users after adjusting for socioeconomic status;[5]
- The frequency of home glucose monitoring is strongly associated with lower HbA1c levels;[6]
- A CGM is being used by only a small percentage of individuals with T1DM; among individuals who have used a CGM, two-thirds stopped using it;[7]
- Severe hypoglycemia (SH) resulting in seizure or loss of consciousness occurs more commonly in older adults with longstanding T1DM than has been appreciated;[8]
- In both children and adults, the rate of SH is not higher in individuals with tight glucose control (e.g., HbA1c < 7.0%) than it is in individuals with poorer control (e.g., HbA1c > 8.0%) in contrast to the findings of the Diabetes Control and Complications Trial;

- Diabetic ketoacidosis (DKA) does not occur any more frequently in insulin pump users than injection users;[4]
- Adolescents and young adults with T1DM have worse glucose control and are at higher risk for DKA than younger or older individuals with T1DM;[4] and
- The frequency of microalbuminuria in children, adolescents, and young adults is strongly associated with glycemic control, T1DM duration, and blood pressure.[9]

Another major aim of the T1D Exchange Clinic Network is to leverage the Network's research infrastructure and the experience and expertise of its investigators to develop and implement new investigator-initiated clinical trials and observational studies in T1DM in an efficient and cost-effective manner. Moreover, the efficiencies of having a large network of clinics with a single point of contact for contracting with the leading diabetes treatment centers in the United States, which have access to more than 100,000 patients with T1DM, has positive implications regarding collaborations with industry to promote future clinical trials in T1DM. Indeed, the existence of the registry helps to facilitate recruitment for such studies. Approximately 70% of the 26,563 participants enrolled in the clinic registry, as of April 1, 2013, have provided an email address to be contacted about studies for which they may be eligible (which can be ascertained from the registry data), allowing for a readily accessible patient population for clinical studies. This approach was demonstrated to be effective in recruitment of 2000 patients for a quality-of-life study in which the T1D Exchange collaborated with the RAND Corporation and the University of Southern California. Recruitment for the study was conducted by emailing eligible registry participants who provided an email address to be contacted about future studies. An initial email to 5433 led to 1301 participants enrolling into this study within a short time. Subsequent emails have led to additional participants enrolling.

Challenges of the Clinic Registry

Diagnostic Criteria for Type 1 Diabetes Mellitus

Although establishing criteria for a diagnosis of presumed autoimmune T1DM may seem straightforward, it was difficult to reach a consensus on the criteria, particularly for adults. Since individuals enrolling in the registry may have had diabetes for many years, medical records from the time of diagnosis were not always available, and pancreatic autoantibody testing may not have been obtained. A working group of clinic network endocrinologists developed criteria for registry eligibility and classification of an individual as definite or probable T1DM (**Tables 1** and **2**).

Table 1.
Eligibility Criteria for the T1D Exchange Clinic Registry

Eligibility criteria for the T1D Exchange clinic registry—all the following must be met:
1. Clinical diagnosis of presumed autoimmune T1DM by endocrinologist, even if antibody results are negative or not available (excluding pancreatic disease, cystic fibrosis, or secondary diabetes)
2. Documented hyperglycemia diagnostic of diabetes by ADA criteria (or convincing history of hyperglycemia consistent with diabetes if data for ADA criteria are unavailable) Diabetes diagnosed by ADA laboratory criteria a. Fasting glucose ≥ 126 mg/dl—confirmed b. 2 h oral glucose tolerance test glucose ≥ 200 mg/dl—confirmed c. HbA1c ≥ 6.5% documented—confirmed d. Random glucose > 200 mg/dl with symptoms e. No data at diagnosis are available, but the participant has a convincing history of hyperglycemia consistent with diabetes
3. Required insulin at diagnosis and continually thereafter or has one of following explanations for not starting insulin at diagnosis: a. Did not start insulin at diagnosis but upon investigator review, likely needed insulin, and did require insulin eventually and used continually b. Did not start insulin at diagnosis but continued to be hyperglycemic, had positive T1DM autoantibodies, and did require insulin eventually and used continually c. Insulin use history is unknown, but insulin is presently required and used continually d. Had an islet cell transplant or pancreas transplant and does not currently take insulin e. Antibody positive, but does not currently take insulin due to honeymoon phase
ADA, American Diabetes Association.

For onset of diabetes less than age 10 years old, there was little debate over the diagnosis. However, with onset at older ages, the differentiation from type 2 diabetes is not always clear-cut. Elevated body mass index (BMI) by itself is not a differentiating feature since many individuals with T1DM have elevated BMI; in the T1D Exchange clinic registry data, 39% of participants with positive pancreatic autoantibodies and a diagnosis of T1DM were overweight or obese at the time of enrollment into the registry.

Table 2.
Criteria for Definite and Probable Diagnosis of Type 1 Diabetes Mellitus

Definite diagnosis of T1DM requires the eligibility criteria for T1D Exchange clinic registry be met and at least one additional characteristic from below:
1. Age <10 years old *at diagnosis*
2. Positive pancreatic autoantibodies *at any time* (GAD-65, IA-2, ICA, or ZnT8) or positive anti-insulin autoantibody *at diagnosis only (within 10 days of starting insulin)*
3. Two or more clinical indicators suggestive of T1DM: a. <40 years old *at diagnosis* b. Nonobese (BMI pediatric <95th percentile, adult <30 kg/m^2) *at diagnosis* c. DKA *at any time* d. Very low plasma C-peptide (fasting <0.8 ng/ml) and blood glucose > 80 mg/dl *at any time* e. Family history of T1DM (parent, sibling, or child)
A probable diagnosis of T1DM requires the eligibility criteria above to be met and the following if "definite" criteria are not met:
1. One or more clinical indicators suggestive of T1DM a. <40 years old *at diagnosis* b. Nonobese (BMI pediatric <95th percentile, adult <30 kg/m^2) at diagnosis c. DKA *at any time* d. Very low plasma C-peptide (fasting <0.8 ng/ml) and blood glucose > 80 mg/dl *at any time* e. Family history of T1DM (parent, sibling, or child) f. Caucasian g. Has two or more autoimmune conditions associated with T1DM [e.g., autoimmune thyroid disease (Hashimoto or Graves), adrenal insufficiency, autoimmune polyendocrine syndrome (type 2), premature ovarian failure, pernicious anemia, alopecia, vitiligo, and celiac disease]

Standardizing Data Collection for Registry

A working group of investigators was formed to determine the data elements to be collected for the registry. After this was established, an evaluation was performed with respect to the ability to collect the data from the clinics' medical records. Although data were retrievable for medical conditions, medications, and laboratory values, there was little standardization across clinics with respect to diabetes-specific, socioeconomic, lifestyle, and family history data, and many of the data elements related to details of diabetes management (such as the timing of a meal insulin bolus) were not captured in the medical record. For sites with electronic health records (EHRs), the availability of diabetes-specific data was no better and, in some cases, was more limited due to the restrictions placed on data entry into the EHR. Therefore, it was determined that the registry participants would need to be asked specific questions in order to obtain standardized data across clinics. This led to the development of questionnaires completed by the participants, with separate versions for participants ≥18 years old and parents of younger participants. For participants 13 to <18 years old, either the participant or parent could complete the questionnaire. The participant questionnaire comprises a series of modules that address diabetes history, management, monitoring, and complications; general health; lifestyle; family history; socioeconomic factors; and menstrual and pregnancy history. The medical record data extraction captures information on the diagnosis of T1DM, T1DM-related events (SH and DKA), medications, medical conditions (including diabetes-related complications), and laboratory results.

Completion of Annual Data Updates

After the initial data collection at enrollment, registry data are updated annually with some of the data, mainly medical conditions, medications, and laboratory values obtained from the medical record, and most of the data were again captured directly from the participant by completion of a Web-based questionnaire. Completion of the participant questionnaire during the patient's clinic visit has proven to be a challenge, particularly for clinics with a large number

of participants (e.g., 500 or more). As a result, greater emphasis has been placed on emailing participants and having them complete the questionnaire online from home.

Maximizing Data Quality

Considerable effort has been made to evaluate the data that are being collected to identify any limitations that may affect interpretation. Several data elements were collected from both the participant questionnaire and the medical records, including DKA and SH events, frequency of self-monitoring of blood glucose (SMBG), use of a CGM, insulin pump use, and total daily insulin dose. The agreement between self-reported and clinic-reported data was not high for most of these data elements, except for pump use (**Table 3**). Across all age groups, participants reported more frequent DKA and SH events than what was captured in medical records. On the participant questionnaire, DKA events were explicitly defined as including hyperglycemia and ketosis requiring hospitalization and SH events were defined as a low blood sugar in which seizure or loss of consciousness occurred. The latter definition was used instead of a "needing assistance" definition to provide greater standardization of responses. From discussions with clinic staff with respect to the discordance between the participant-reported and clinic-reported frequencies of DKA and SH, we concluded that some events likely were not being captured in the medical record and thus there was underreporting by the clinics. On the other hand, for SMBG data, it is likely that the participant-reported frequency is a slight overestimate compared with the data captured from clinic downloads of meter data.

Table 3.
Self-Reported and Clinic-Reported Data Comparison[a]

	Overall	Age group (years)						Overall statistics and 95% CI
		<6	6–<13	13–<18	18–<26	26–<50	>50	
Frequency of ≥ 1 SH event in past 12 months	7.0%/2.4%	5.3%/1.9%	4.2%/1.5%	5.5%/2.5%	6.6%/2.3%	10.2%/2.9%	13.5%/4.5%	K = 0.35 (0.32, 0.38)
Frequency of ≥1 DKA event in past 12 months	7.5%/5.4%	7.8%/5.0%	6.3%5.0%	10.1%/7.5%	9.8%/6.3%	5.4%/4.0%	4.0%/2.2%	K = 0.50 (0.47, 0.52)
CGM use	10.5%/6.5%	5.2%/2.9%	6.2%/3.0%	5.9%/2.4%	7.8%/4.1%	22.2%/15.3%	18.9%/14.7%	K = 0.59 (0.57, 0.61)
Insulin pump use	50%/51%	33%/32%	47%/47%	49%/49%	51%/51%	60%/60%	58%/57%	K = 0.97 (0.97, 0.97)
SMBG per day, mean ± standard deviation	5.8 ± 2.5/ 4.9 ± 2.9	7.1 ± 2.6/ 6.6 ± 3.0	6.7 ± 2.3/ 5.8 ± 2.7	5.2 ± 2.2/ 4.2 ± 2.5	4.6 ± 2.4/ 3.7 ± 2.8	5.6 ± 2.7/ 4.6 ± 3.2	5.7 ± 2.4/ 5.0 ± 3.1	Rho = 0.65 (0.64, 0.66)
Total daily insulin for pump users (U/kg), mean ± standard deviation	0.7 ± 0.5/ 0.6 ± 0.4	0.7 ± 0.4/ 0.6 ± 0.4	0.8 ± 0.5/ 0.7 ± 0.3	0.9 ± 0.5/ 0.8 ± 0.3	0.7 ± 0.4/ 0.6 ± 0.3	0.4 ± 0.2/ 0.3 ± 0.2	0.3 ± 0.2/ 0.3 ± 0.2	Rho = 0.70 (0.69, 0.71)

CI, confidence interval; K, kappa statistic; Rho, correlation
[a] Data are listed as "self-reported/clinic-reported."

An unexpected problem was the discordance between participant-reported and clinic-reported CGM use. We presumed that participants may have been confusing CGM and SMBG. As a result, we added a very explicit definition of real-time CGM on the participant questionnaire: "Do you regularly (at least once a month) use a real-time continuous glucose monitor (CGM) that shows your glucose values every 5 to 10 minutes while you have a sensor inserted underneath your skin? A continuous glucose monitor is often referred to as CGM. It consists of a sensor that is inserted underneath the skin and a monitor that shows your glucose values every 5 to 10 minutes. Currently available CGMs include the Navigator, Dexcom, Paradigm, and Guardian." This change reduced the discordance between patient and clinic reports, although not completely. For analyses comparing current CGM users and nonusers, we have required clinic and participant concordance to include the participant's data in the analysis.

Two other areas of data collection that have been problematic are family history of T1DM and diabetic retinopathy. For family history, we found that the available medical record data were insufficient and therefore asked the participant directly. We also limited the data collection to inquiring about T1DM in first-degree relatives to minimize uncertainty as to whether diabetes was T1DM or T2DM in more distant relatives. For classification of retinopathy status, we found that a recent eye examination report often was not available in the medical record and, even when present, was not sufficient to determine the level of retinopathy. Therefore, we limited data collection to asking the participant if he/she had been treated for diabetic retinopathy with interventions such as laser, injections, or vitrectomy.

Data Interpretation and Understanding Potential Biases

Although the registry data are collected from a large number of individuals with T1DM across the United States, it is not population based. Participation in the registry is predicated on being followed by an endocrinologist. This is more of an issue with respect to representativeness of the adult cohort than the pediatric cohort since pediatric patients with T1DM generally are cared for by an endocrinologist whereas adult patients with T1DM may or may not be. Another issue is that written informed consent from adult patients and parents of children is required to be included in the registry. It is noteworthy that only approximately 2.5% of individuals who were asked to join the registry declined.

As a result of these limitations, caution is needed in relating frequencies of factors and events to population prevalences. Some of the data likely provide unbiased estimates of population prevalences, while other data likely are overestimates or underestimates. This is particularly relevant from a broad public health perspective but is less likely to affect the interpretation of associations between one variable and another. It should be noted that the pediatric participant characteristics generally are similar to those of participants in the SEARCH for Diabetes in Youth Study, a study of individuals <20 years old with diabetes in six areas of the United States that began in 2001.[1,10] The potential bias that all patients must be under the care of an endocrinologist to be included is difficult to explore, especially in adults, since we do not have a direct comparative cohort of patients with T1DM who are not followed by an endocrinologist.

It is possible that a small number of patients could have been misdiagnosed as T1DM. However, we presume that the number is small because a diagnosis of T1DM by an endocrinologist was required. For analyses, a small percentage of misclassified patients are not likely to have a meaningful effect on results.

Data in the T1D Exchange clinic registry, so far, are largely cross-sectional. Although some data have been retrospectively available for analyses, such as HbA1c values, which were recorded in the database for the past 10 years, most data are from a single time point closest to the date of enrollment. As a result, it can be difficult to ascertain the order of relationships between variables and whether an association indicates a cause-and-effect relationship. For instance, a cross-sectional analysis of CGM use and SH events would be difficult to interpret. Such an analysis might show a higher SH frequency in CGM users than nonusers that reflects CGM having been prescribed because an individual was having frequent SH events rather than CGM being causally related to increased SH risk.

Another challenge in interpretation of analyses is the possibility that an observed association is due to chance. With a database comprising many variables, there is the ability to conduct many analyses. Some associations will occur strictly by chance, and the challenge is in identifying which associations are likely due to chance and which are real. As much as possible, we attempt to consider biases and articulate a hypothesis before conducting an analysis and then interpret results not just on the size of the p value but on the weight of evidence, including biologic plausibility and consistency with other studies.

Summary

The T1D Exchange clinic registry has provided a rich data set to address important clinical and public health issues. A considerable effort has been made to collect the data and maximize data quality. Even with these efforts, certain data elements are difficult to capture in a meaningful way. We had hoped that EHRs would provide a readily accessible source of data that could be compiled across centers to create a large clinical research database without requiring much effort at the diabetes practices. Although there are informational technology challenges to do this, these could be

overcome. The main problem is that diabetes-specific data are not collected with the standardization and specificity that are needed. In addition, downloads of device data (glucose meters, CGMs, and insulin pumps) into standard formats are not yet available. Both of these needs can be addressed. A standard T1DM module used by all EHRs could be developed based on the data collection instruments developed for the T1D Exchange clinic registry. Development of tools to download and integrate pumps, CGM devices, and blood glucose meters into a standard data format should be possible. These accomplishments would provide an extraordinary database for research, as well as streamline office visits and improve care. If device and patient-report data were automatically uploaded to a cloud prior to a visit and these data seamlessly incorporated into the EHR in a standardized format, health care providers could focus on improving care during office visits rather than collection of data, which can consume a large amount of visit time. Such is the vision for the future.

Funding:

This work was supported through the Leona M. and Harry B. Helmsley Charitable Trust.

Disclosures:

Kellee Miller and Dongyuan Xing are full-time employees of the Jaeb Center for Health Research. William Tamborlane has received consultant payments from Medtronic and Animas. Richard Bergenstal has served on a scientific advisory board, consulted or performed clinical research with Abbott Diabetes Care, Amylin, Bayer, Becton Dickinson, Boehringer Ingelheim, Intuity, Calibra, DexCom, Eli Lilly, Halozyme, Helmsley Trust, Hygieia, Johnson & Johnson, Medtronic, Merck, National Institutes of Health, Novo Nordisk, ResMed, Roche, Sanofi, and Takeda; his employer, Park Nicollet, has contracts with the listed companies for his services, and no personal income goes to Dr. Bergenstal; he has inherited Merck stock and has been a volunteer officer of the American Diabetes Association. Roy Beck's nonprofit employer has received consultant payments on his behalf from Sanofi and Animas and a research grant from NovoNordisk with no personal compensation to Dr. Beck.

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