The T1D Exchange Clinic Registry

Roy W. Beck, William V. Tamborlane, Richard M. Bergenstal, Kellee M. Miller, Stephanie N. DuBose, and Callyn A. Hall, for the T1D Exchange Clinic Network

Jaeb Center for Health Research (R.W.B., K.M.M., S.N.D., C.A.H.), Tampa, Florida 33647; Yale University (W.V.T.), Pediatric Endocrinology, New Haven, Connecticut 06520; and International Diabetes Center at Park Nicollet (R.M.B.), Minneapolis, Minnesota 55416

Context: The T1D Exchange includes a clinic-based registry, a patient-centric web site called Glu, and a biobank.

Objective: The aim of the study was to describe the T1D Exchange clinic registry and provide an overview of participant characteristics.

Design: Data obtained through participant completion of a questionnaire and chart extraction include diabetes history, management, and monitoring; general health; lifestyle; family history; socioeconomic factors; medications; acute and chronic diabetic complications; other medical conditions; and laboratory results.

Setting: Data were collected from 67 endocrinology centers throughout the United States.

Patients: We studied 25,833 adults and children with presumed autoimmune type 1 diabetes (T1D).

Results: Participants ranged in age from less than 1 to 93 yr, 50% were female, 82% were Caucasian, 50% used an insulin pump, 6% used continuous glucose monitoring, and 16% had a first-degree family member with T1D. Glycosylated hemoglobin at enrollment averaged 8.3% and was highest in 13 to 25 yr olds. The prevalence of renal disease was ≤4% until T1D was present for at least 10 yr, and retinopathy treatment was ≤2% until T1D was present for at least 20 yr. A severe hypoglycemic event (seizure or coma) in the prior 12 months was reported by 7% of participants and diabetic ketoacidosis in the prior 12 months by 8%.

Conclusions: The T1D Exchange clinic registry provides a database of important information on individuals with T1D in the United States. The rich dataset of the registry provides an opportunity to address numerous issues of relevance to clinicians and patients, including assessments of associations between patient characteristics and diabetes management factors with outcomes. **(*J Clin Endocrinol Metab* 97: 4383–4389, 2012)**

Clinical, translational, and epidemiological research in type 1 diabetes (T1D) has benefited from the development of large-scale population and clinical center-based patient registries, such as the DPV Scientific Initiative of Germany and Austria that has followed thousands of patients with diabetes (1) and the Hvidore Study Group, an international consortium of diabetes centers that has focused on T1D in pediatrics (2). However, no similar, large-scale registry of patients with T1D in the United States had been established before 2010.

This need was addressed by the establishment of the T1D Exchange in 2010, through a grant from the Leona M. and Harry B. Helmsley Charitable Trust. The T1D Exchange consists of three complimentary parts: a network of adult and pediatric diabetes clinics that is prospectively collecting clinical data on a large population of patients with T1D; 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 (not a source of the data

ISSN Print 0021-972X ISSN Online 1945-7197
Printed in U.S.A.

doi: 10.1210/jc.2012-1561 Received March 1, 2012. Accepted August 27, 2012.
First Published Online September 20, 2012

Abbreviations: CGM, Continuous glucose monitor; DKA, diabetic ketoacidosis; HbA1c, glycosylated hemoglobin; T1D, type 1 diabetes.

reported herein); 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 as well as other T1D researchers.

The first initiative of the T1D Exchange Clinic Network was the establishment of a registry of adults and children with T1D. The registry is collecting core clinical and laboratory data on persons with T1D to: 1) identify and address pertinent clinical issues; 2) conduct exploratory/hypothesis-generating analyses; and 3) categorize participants for future clinical studies. The aim of enrolling more than 25,000 individuals with T1D, spanning all age, racial/ethnic, and socioeconomic groups, was achieved in June 2012, less than 2 yr from the commencement of enrollment in September 2010. In this paper, we will describe the clinic network and provide an overview of the baseline characteristics of the 25,833 participants enrolled as of August 1, 2012.

Subjects and Methods

The T1D Exchange Clinic Network is coordinated by the Jaeb Center for Health Research, a nonprofit clinical research coordinating center in Tampa, Florida. Clinical centers were selected to provide a broad representation of pediatric and adult patients with T1D. As of August 1, 2012, 67 clinical centers are participating, with a wide distribution throughout the United States, covering states that have typically not had centers in diabetes-related registry studies such as North Dakota, South Dakota, Montana, and Idaho (Fig. 1). Twelve of the centers primarily care for adult patients with T1D, 36 primarily care for pediatric patients, and 19 are a mix of both; 52 are institution-based, 14 are community based, and one is in a managed care setting. The 67 clinics care for more than 100,000 patients with T1D.

To be enrolled in the clinic registry, an individual must have a clinical diagnosis of presumed autoimmune T1D and either islet cell antibodies present, or, if antibodies were negative or unknown, then insulin must have been started at or shortly after diagnosis and used continually thereafter (except in the case of a pancreas or islet cell transplant). The diagnosis of T1D is classified as definite or probable based on available information. Definite T1D requires that at least one of the following is present: 1) age less than 10 yr 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 d of starting insulin); or 3) the presence of two or more of the following clinical indicators suggestive of T1D: a) age at diagnosis less than 40 yr; b) nonobese at diagnosis according to body mass index ($<$95th percentile pediatric and $<$ 30 kg/m^2 adult); c) diabetic ketoacidosis (DKA) at any time; d) plasma C-peptide level below 0.8 ng/ml (with blood glucose $>$ 80 mg/dl if available) at any time; and e) family history of T1D in a first-degree relative (parent, sibling, or child). If these criteria are not met, most often due to unavailability of prior complete medical records, the case is considered to be probable T1D.

FIG. 1. Location of T1D Exchange clinical sites. As of August 1, 2012, the T1D Exchange Clinic Network consists of 67 sites and 25,833 participants. Each *dot* on the U.S. map represents the city of a T1D Exchange Clinic Network site.

Written informed consent is obtained from adult participants and parents/guardians of minor participants, who are required to understand either English or Spanish to participate. Minor participants provide written assent, according to Institutional Review Board requirements. During the period of enrollment of 25,833 individuals into the registry, 668 have declined participation (56% male, 69% white non-Hispanic, median age 17 yr).

Data are collected for the registry database at enrollment and then once a year. Data are obtained through: 1) completion of a questionnaire by the participant or parent of participant (parent completes questionnaire if participant's age is $<$ 13 yr, and either the participant or the parent may choose to complete questionnaire if participant's age is 13 to $<$18); and 2) retrieval of information collected from the office chart (Supplemental Table 1, published on The Endocrine Society's Journals Online web site at http://jcem.endojournals.org). Both English and Spanish versions of the questionnaire are provided. The majority (52%) of participants have completed the questionnaire electronically in the clinic on project-supplied iPads or laptop computers, 28% in the clinic on paper (34% of those $\geq$50 yr old, and 27% of those $<$50 yr old), and 20% from home, either on paper or through an internet connection. The participant questionnaire is comprised of a series of modules that address diabetes history, management, monitoring, and complications; general health; lifestyle; family history; socioeconomic factors; and menstrual and pregnancy history. At annual follow-up, some of the modules are repeated to provide longitudinal data, and new modules are added that address specific objectives. The clinic chart data extraction captures information on the diagnosis of T1D, T1D-related events (severe hypoglycemia and DKA), medications, medical conditions including diabetes-related complications, and laboratory results. Glycosylated hemoglobin (HbA1c) levels were obtained from the medical chart for up to the past 10 yr. For the most recent HbA1c lab value, 74% were obtained with a DCA point of care device, 4% were obtained with other point of care, 19% were obtained with laboratory assay, and 2% were unknown. At the time of freezing of the database, 25,004 had both the participant and clinic portions of the data collection completed, and 829 had only the clinic portion completed.

Demographic and clinical characteristics were tabulated according to age group. Logistic regression was used to evaluate racial differences between participants at least 18 yr old and those less than 18 yr old. Linear regression models were performed to assess the association between demographic and clinical characteristics and HbA1c.

All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC). Replication of analyses limiting

the cohort to participants classified as definite T1D are provided as Supplemental Tables 2–4.

Results

The 25,833 participants ranged in age from less than 1 to 93 yr, with 820 being less than 5 yr old and 2,861 at least 50 yr old; 50% were female, and 82% were Caucasian. The number enrolled per clinic ranged from 53 to 1451 (median 280; see Supplemental Appendix 1 for listing with number of participants per clinic). Criteria for a diagnosis of definite T1D were met for 22,502 (87%) participants. Among the 22,502 with definite T1D, 79% had either onset at less than 10 yr old or positive pancreatic autoantibodies, and 21% had onset at age 10 yr or older and either negative or unavailable autoantibodies but met at least two of the criteria described in *Subjects and Methods*. Among the 10,068 participants for whom pancreatic autoantibody test results were available, at least one positive autoantibody was present in 84%. Among participants with available height and weight measurements at diagnosis (n = 7362), 24% were overweight or obese (≥85th percentile for ages 2 to <20 and ≥25 kg/m^2 for ages ≥20) at the time of diagnosis.

Median duration of T1D was 7 yr at enrollment, with 970 participants having had T1D for more than 40 yr and 226 for more than 50 yr (Fig. 2). Median age at diagnosis was 9 yr; 21,569 participants were diagnosed with T1D at less than 18 yr of age, and 4,259 participants were diagnosed at 18 yr of age or older (Supplemental Fig. 1). Fifty percent were insulin pump users, and 6% were using a real-time continuous glucose monitor (CGM). A history of T1D in a first-degree family member was reported by 16%. Participant characteristics according to age are shown in Table 1. The adult participants (age ≥18 yr) were more likely to be non-Hispanic White than the pediatric participants (age <18 yr) (87 *vs.* 78%; $P < 0.001$).

The overall mean HbA1c at enrollment was 8.3%, with 8% having an HbA1c level below 6.5%, and 12% having a level above 10.0%. HbA1c levels varied by age group ($P < 0.001$), with mean HbA1c levels being lowest in participants at least 26 yr old (7.7%) and highest in those 13 to less than 26 yr old (8.7%) (Table 2 and Fig. 3). Across all age groups, only a minority of participants met the American Diabetes Association (ADA) HbA1c goal of less than 7.0% for adults (3) or the International Society of Pediatric and Adolescent Diabetes (ISPAD) goal of less than 7.5% for children and adolescents (4) (Table 2). In both the adult and pediatric age groups, white race, higher household income, higher participant or parent education, private insurance, insulin pump use, CGM use, and more frequent self-monitoring of blood glucose were associated with lower HbA1c levels ($P < 0.001$).

As shown in Table 3, the prevalence of renal disease was ≤4% (92% microalbuminuria) until T1D was present for at least 10 yr. After 40 yr, the prevalence of renal failure/kidney transplant was 5% (Supplemental Fig. 2). The prevalence of treatment for retinopathy was ≤2% until T1D was present for at least 20 yr (Table 3). A severe hypoglycemic event (seizure or loss of consciousness) in the prior 12 months was reported by 7% of participants and DKA in the prior 12 months by 8% (Table 1).

Among participants not using a real-time CGM, the self-reported number of home blood glucose meter tests per day averaged 5.6 (Table 1), with 8% testing 10 or more times a day and 16% testing three or fewer times. Fewer than 3% of participants reported downloading their glucose meter to a home computer and reviewing the data at least once a week (Supplemental Table 5).

The registry participants represent about one fourth of the patients with T1D who are followed at one of the 67 clinics (median, 24%; interquartile range, 12 to 46%). The weighted race-ethnicity distribution of patients followed at the 67 clinics is 77% white non-Hispanic compared with 82% in the registry patients; 61 *vs.* 75%, respectively, have private insurance; and 41 *vs.* 50% use an insulin pump.

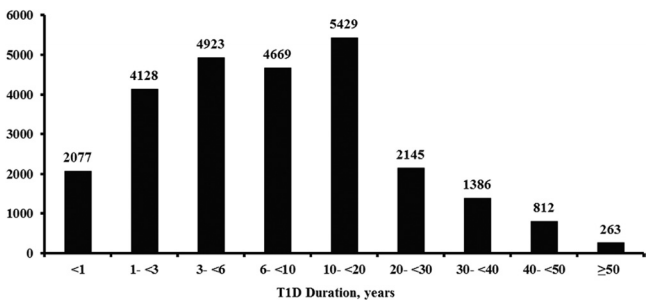

FIG. 2. T1D duration. Each *bar* represents the number of participants with the corresponding duration of T1D, in years. Duration data were not available for one participant.

Discussion

The T1D Exchange clinic registry provides a large database of information on individuals with T1D in the United States that will be useful in developing a better understanding of the disease and in working to improve the care of patients. Registry participants, whose residence is over a wide geographic distribution in the United States, cover a wide range of age, ethnic, racial, and socioeconomic groups and include a large number of young children, as well as older adults who have had T1D for many years. It is noteworthy that the cohort includes more than 1,000 individuals with T1D for at least 40 yr.

TABLE 1. Participant characteristics by age group

		Age (yr)							
	Total	<6	6 to <13	13 to <18	18 to <26	26 to <31	31 to <50	50 to <65	≥65
n	25,833	1,278	6,973	6,341	3,890	1,050	3,440	2,153	708
Gender, female[a]	50	44	49	48	49	58	55	52	51
Race/ethnicity									
White non-Hispanic	82	79	77	78	81	86	89	94	97
Black non-Hispanic	5	5	6	6	5	4	4	3	2
Hispanic or Latino	8	9	10	10	10	6	4	1	<1
Native Hawaiian/other Pacific Islander	<1		<1	<1	<1	<1	<1		
Asian	1	<1	1	1	1	1	1	<1	<1
American Indian/Alaskan Native	<1	<1	<1	<1	<1	<1	<1	<1	<1
More than one race	3	5	4	3	2	2	1	<1	<1
Income[b]									
<$25,000	12	12	11	11	20	13	10	10	11
$25,000 to <$35,000	8	9	8	8	10	13	5	6	9
$35,000 to <$50,000	12	12	12	10	12	17	9	11	19
$50,000 to <$75,000	17	19	17	17	14	22	18	19	23
$75,000 to <$100,000	17	17	18	18	15	16	19	16	18
≥$100,000	34	30	34	36	29	20	39	38	20
Education[c]									
Less than a high school diploma	4	2	3	4	NA	2	2	3	4
High school diploma/GED	36	28	30	31	NA	24	27	35	36
Associate degree	11	13	13	13	NA	10	11	11	6
Bachelor degree	28	31	29	28	NA	44	36	27	25
Master degree	15	19	18	17	NA	15	17	17	20
Professional or doctorate degree	6	7	7	8	NA	5	7	7	10
Insurance status[d]									
Private	75	72	73	73	74	82	84	81	56
Other	23	28	26	26	24	14	14	17	43
No insurance	1	<1	<1	<1	2	3	2	2	<1
First-degree family member with T1D	16	14	13	14	13	17	22	26	27
Criteria met for definite T1D[e]	87	100	99	94	87	77	72	60	55
Pump use	50	31	46	49	51	58	60	59	53
CGM use	6	2	3	2	3	12	14	15	8
Self-monitoring of blood glucose (mean ± SD)[f]	5.6 ± 2.5	6.8 ± 2.6	6.5 ± 2.2	5.2 ± 2.1	4.4 ± 2.4	5.1 ± 2.8	5.2 ± 2.6	5.5 ± 2.5	5.6 ± 2.2
Severe hypoglycemia[g,h]	7	5	4	5	7	9	11	13	16
Diabetic ketoacidosis[h]	8	8	6	10	10	5	5	4	4

Data are expressed as percentage, unless specified otherwise. NA, Not available.

[a] Total of nine transgenders in cohort.

[b] n = 18,614 for household income. Participants living on their own but still supported by caregivers are asked to estimate family income.

[c] n = 23,925 for education level. For participants less than 18 yr of age, education reported is highest parent education. Data were not included for the 18 to <26 yr old group because education level is not meaningful.

[d] n = 22,904 for insurance status.

[e] Definite T1D requires that at least one of the following is present: 1) <10 yr 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 d of starting insulin); or 3) presence of two or more of the following clinical indicators suggestive of T1D: a) age at diagnosis < 40 yr; b) nonobese at diagnosis according to body mass index (<95th percentile pediatric and <30 kg/m^2 adult); c) DKA at any time; d) plasma C-peptide level <0.8 ng/ml (with blood glucose >80 mg/dl if available) at any time; and e) family history of T1D in a first-degree relative (parent, sibling, or child).

[f] Excluding CGM users.

[g] Defined as seizure or coma (loss of consciousness). Overall n = 19,100, and the age groups are proportionally reduced (reduced number because data were not collected with this definition from the beginning of study.)

[h] One or more events in prior 12 months.

As would be expected, the diagnosis of T1D was more certain with onset during childhood than onset during adulthood. Diagnosis of adult-onset T1D was particularly problematic when antibody results were not available. Thus, the adult-onset portion of the cohort could include some participants with type 2 diabetes who were misdiagnosed as type 1.

In evaluating the data generated from this large registry, it is important to recognize that the cohort is not pop-

TABLE 2. HbA1c levels by age group

		Age (yr)							
	Total	<6	6 to <13	13 to <18	18 to <26	26 to <31	31 to <50	50 to <65	≥65
n	25,171[a]	1,248	6,862	6,229	3,780	1,009	3,294	2,066	683
HbA1c (mean ± SD)	8.3 ± 1.6	8.4 ± 1.3	8.4 ± 1.5	8.8 ± 1.8	8.5 ± 1.8	7.8 ± 1.5	7.7 ± 1.4	7.7 ± 1.2	7.4 ± 1.0
<7.0%	18	10	12	12	17	30	30	27	34
<7.5%	32	23	26	23	30	48	48	46	52
<8.0%	49	42	45	37	44	64	65	66	73
<8.5%	63	59	61	52	57	74	78	80	86
Distribution of HbA1c values									
<6.0%	3	<1	2	2	3	6	5	4	5
6.0 to <6.5%	5	3	3	3	4	10	9	9	11
6.5 to <7.0%	10	7	7	7	10	15	16	14	17
7.0 to <8.0%	31	32	33	25	27	34	35	39	40
8.0 to <9.0%	26	32	30	27	24	20	20	23	19
9.0 to <10%	13	16	14	16	14	8	8	8	6
10.0 to <11%	6	6	6	9	8	4	4	2	2
≥11.0%	7	4	6	12	10	4	3	1	<1

Data are expressed as percentage.

[a] A total of 662 participants were missing an HbA1c recorded within 6 months before enrollment.

ulation-based and participation in the cohort is predicated on being followed by an endocrinologist. We expect that this has a greater effect on the representativeness of the adult cohort than the pediatric cohort because it is our belief that pediatric patients with T1D are more likely to be regularly cared for by an endocrinologist than are adult patients with T1D. Although there is potential selection bias of the sample within each clinic, it should be noted that whereas only one fourth of patients at the clinics are included in the registry, the weighted distribution of characteristics such as race/ethnicity, insurance status, and pump use were fairly similar between those enrolled and the total patient population of the clinics. Additionally, less than 3% of patients who were approached declined participation in the registry.

Because the cohort is not population-based, estimated frequencies and prevalences of various factors could be overestimates or underestimates. This has pertinence for certain factors from a broad public health perspective but is less likely to affect the interpretation of associations between one variable and another. Thus, the greatest value of this database is likely to be in assessing the relationship between patient characteristics and diabetes management factors with outcomes and in generating hypotheses that can then be tested under more rigorous conditions.

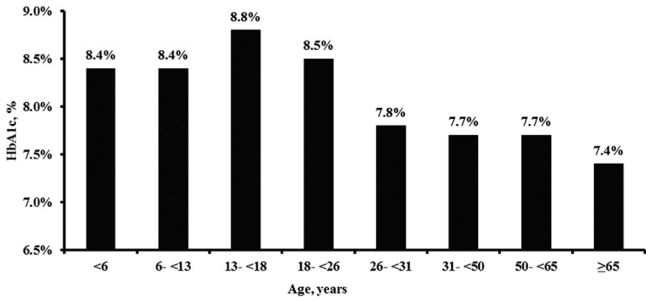

FIG. 3. Mean HbA1c by age group. Each bar represents the mean HbA1c for participants in the corresponding age group. Means were calculated using the most recent HbA1c value, obtained within 6 months of enrollment. An HbA1c within 6 months of the enrollment visit date was missing for 662 participants.

Although the cohort is not population-based, pediatric participant characteristics generally are similar to those of participants in the SEARCH for Diabetes in Youth Study (SEARCH), a study of individuals less than 20 yr old with diabetes in six areas of the United States that began in 2001. Comparing characteristics of the T1D Exchange participants less than 20 yr old with SEARCH (excluding those with < 1 yr diabetes duration) shows similarities in age (both with mean age 13 yr), female gender (48 *vs.* 50%), race-ethnicity distribution (non-Hispanic white, 78 *vs.* 75%; African-American, 6 *vs.* 7%; Hispanic, 10 *vs.* 12%), age of diagnosis (mean age, 6.9 *vs.* 7.8 yr), annual income of at least $50,000 (69 *vs.* 63%), private insurance (72 *vs.* 80%), body mass index z-score (mean of 0.64 *vs.* 0.63), and HbA1c levels (both with a mean HbA1c level of 8.5%). It should be noted that in SEARCH, HbA1c levels were available for only about 40% of the cohort—those who were sufficiently motivated to return for a research visit and blood draw. Interestingly, pump use is substantially higher in the T1D Exchange cohort than the SEARCH cohort with duration greater than 1 yr (52 *vs.* 22%), which could reflect an increase in the use of pumps since SEARCH was initiated or differences in health care provider preferences (5). Comparison of the T1D Ex-

TABLE 3. Frequency of renal disease and retinopathy treatment by diabetes duration

	All		Diagnosis age <18 yr		Diagnosis age ≥18 yr	
	n	n (%)	n	n (%)	n	n (%)
Renal disease[a]	19,139	1,605 (8%)	15,345	1,146 (7%)	3,794	459 (12%)
Duration of T1D (yr)						
<10	9,962	387 (4%)	8,759	318 (4%)	1,203	69 (6%)
10 to <20	4,978	387 (8%)	3,910	292 (7%)	1,068	95 (9%)
20 to <30	1,980	287 (14%)	1,153	157 (14%)	827	130 (16%)
30 to <40	1,250	266 (21%)	800	179 (22%)	450	87 (19%)
40 to <50	731	208 (28%)	527	143 (27%)	204	65 (32%)
≥50	238	70 (29%)	196	57 (29%)	42	13 (31%)
Retinopathy treatment[b]	20,620	1,186 (6%)	17,273	760 (4%)	3,347	426 (13%)
Duration of T1D (yr)						
<10	12,657	31 (<1%)	11,511	12 (<1%)	1,146	19 (2%)
10 to <20	4,331	92 (2%)	3,448	50 (1%)	883	42 (5%)
20 to <30	1,700	259 (15%)	992	136 (14%)	708	123 (17%)
30 to <40	1,078	389 (36%)	689	249 (36%)	389	140 (36%)
40 to <50	647	311 (48%)	462	230 (50%)	185	81 (44%)
≥50	207	104 (50%)	171	83 (49%)	36	21 (58%)

[a] Includes microalbuminuria, macroalbuminuria, glomerular filtration rate <60 ml/min, renal failure, receiving dialysis, or post-kidney transplant. Data were not available for 6,694 due to unknown renal status or missing diabetes duration data.

[b] From medical chart review, defined as the participant ever having been treated for diabetic retinopathy in either eye (including laser, injections into the eye, and vitrectomy). Data were not available for 5,213 due to unknown retinopathy status or missing diabetes duration data.

change adult cohort with adult population-based cohorts in the United States is difficult because a distinction is generally not made between T1D and type 2 diabetes. As a result, the T1D Exchange registry data are particularly valuable for the information they provide about adults with T1D.

In a registry dataset such as this, there will be some errors that go undetected even with extensive validity checks. This is particularly a concern when the number of subjects in a subset is small either because the characteristic is rare or a variable has been divided into multiple categories. In such circumstances, a small number of errors can give an erroneous view of the data. Fortunately, for the vast majority of analyses, a small number of errors will have no impact because the number represents a very small percentage of the overall data.

Consistent with other registry studies (1, 2) and recent randomized clinical trials of diabetes technology (6), HbA1c levels were higher in adolescents and young adults than in older or younger patients. However, it is noteworthy that in all age groups only a minority of participants had an HbA1c level at their most recent visit meeting age-specific goals of less than 7.0% for adults established by the ADA (3) and less than 7.5% for children and adolescents established by the ISPAD (4). Factors associated with lower HbA1c levels will be analyzed in greater detail in future manuscripts. It is also disappointing to see that so few patients are downloading and reviewing blood glucose monitoring data on a regular basis, although regular adjustments of insulin doses in response to elevations in blood glucose levels are critically important to maintain optimal glycemic control. Use of continuous glucose monitoring is relatively infrequent, particularly in the pediatric cohort. As expected, the frequency of microvascular diabetic complications is strongly related to the duration of T1D.

While the initial baseline data are very informative, key data elements will be updated annually to provide longitudinal data, and new modules will be added that address specific objectives in greater detail. Moreover, we envision the registry as only one aspect of the clinic network's research potential. The network of 67 centers and a central coordinating center provides the framework for clinical and translational research protocols of practical clinical relevance that are aimed at promoting better care of patients with T1D, studies that could be supported by the Helmsley Charitable Trust, the National Institutes of Health, the Juvenile Diabetes Research Foundation, the ADA, other foundations, or industry. 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 T1D, has positive implications regarding potential collaborations with industry to promote future phase 3 or 4 randomized clinical trials in T1D. In addition, the network has potential to identify patients for studies rapidly because about 75% of the clinic registry participants have provided an e-mail address to inform them of studies for which they might be eligible.

The clinic registry, the first initiative of the T1D Exchange project, provides a database of important infor-

mation on individuals with T1D in the United States. In this paper, we have been able to provide just an overview of the data that have been collected. The rich dataset of the registry provides an opportunity to address numerous issues of relevance to clinicians and patients, including assessments of associations between patient characteristics and diabetes management factors with outcomes, that hopefully will lead to improvements in diabetes management and outcomes to improve the lives of individuals with T1D.

Acknowledgments

The authors acknowledge the patients who chose to participate in this registry and the T1D Exchange Clinic Network investigators and coordinators for their hard work and dedication.

Address all correspondence and requests for reprints to: Stephanie DuBose, M.P.H., Jaeb Center for Health Research, 15310 Amberly Drive, Suite 350, Tampa, Florida 33647. E-mail: sdubose@jaeb.org.

R.W.B. researched data, wrote the manuscript, contributed to discussion, and reviewed/edited the manuscript. W.V.T. researched data, contributed to discussion, and reviewed/edited the manuscript. R.M.B. researched data, contributed to discussion, and reviewed/edited the manuscript. K.M.M. performed statistical analysis, researched data, wrote the manuscript, and reviewed/edited the manuscript. S.N.D. performed statistical analysis, researched data, wrote the manuscript, and reviewed/edited the manuscript. C.A.H. researched data and reviewed/edited the manuscript. R.W.B. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

The T1D Exchange Clinic Network is funded through a grant provided by the Leona M. and Harry B. Helmsley Charitable Trust. The Helmsley Trust had no role in the study design; collection, analysis, and interpretation of data; writing of this report; or the decision to submit the report for publication.

These data have been presented, in part, at the 2011 International Diabetes Federation and 2012 Advanced Technologies and Treatments for Diabetes meetings.

A listing of clinical sites, investigators, and coordinators participating in the clinic registry is provided in Supplemental Appendix 1.

Disclosure Summary: K.M.M., S.N.D., and C.A.H. have nothing to declare. R.W.B.'s nonprofit employer has received consultant payments on his behalf from Sanofi and Animas and a research grant from Novo Nordisk with no personal compensation to R.W.B., R.M.B. has the following disclosures: consultant for Abbott Diabetes Care, Amylin, Bayer, Becton Dickinson, Boehringer Ingelheim, Calibra, Eli Lilly, Halozyme, Hygieia, Johnson & Johnson, Medtronic, Novo Nordisk, ResMed, Roche, Sanofi, Takeda, and Valeritas; research grants with Abbott Diabetes Care, Amylin, Bayer, Boehringer Ingelheim, Calibra, DexCom, Eli Lilly, Halozyme, Helmsley Trust, Hygieia, Intracia, Johnson & Johnson, MannKind, Medtronic, NIH, Novo Nordisk, ResMed, Roche, Sanofi, and Takeda; and stock with Merck as a family inheritance. All research and consulting payments are made to nonprofit Park Nicollet Institute, with no personal compensation to R.M.B., W.V.T. has the following financial disclosures: consultant for Novo Nordisk, Medtronic, Johnson & Johnson, Amlyin, Insuline, and UnoMedical.

References

1. **Gerstl EM, Rabl W, Rosenbauer J, Gröbe H, Hofer SE, Krause U, Holl RW** 2008 Metabolic control as reflected by HbA1c in children, adolescents and young adults with type-1 diabetes mellitus: combined longitudinal analysis including 27,035 patients from 207 centers in Germany and Austria during the last decade. Eur J Pediatr 167:447–453
2. **Mortensen HB, Hougaard P** 1997 Comparison of metabolic control in a cross-sectional study of 2,873 children and adolescents with IDDM from 18 countries. Diabetes Care 20:714–720
3. **American Diabetes Association** 2012 Standards of medical care in diabetes—2012. Diabetes Care 35(Suppl 1):S11–S63
4. **Rewers M, Pihoker C, Donaghue K, Hanas R, Swift P, Klingensmith GJ** 2009 Assessment and monitoring of glycemic control in children and adolescents with diabetes. Pediatr Diabetes 10(Suppl 12):71–81
5. **Paris CA, Imperatore G, Klingensmith G, Petitti D, Rodriguez B, Anderson AM, Schwartz ID, Standiford DA, Pihoker C** 2009 Predictors of insulin regimens and impact on outcomes in youth with type 1 diabetes: the SEARCH for Diabetes in Youth study. J Pediatr 155:183–189.e1
6. **The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group** 2008 Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 359:1464–1476