Evaluating the Quality of Comprehensive Cardiometabolic Care for Patients With Type 2 Diabetes in the U.S.: The Diabetes Collaborative Registry

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The prevalence of diabetes continues to escalate (1,2) with profound impact on complications and mortality (3–5). Evidence-based guidelines (6–9) and performance measures have been developed (10–12). However, there is currently no sustainable nationwide mechanism by which to *1*) systematically evaluate and track the quality of care in primary and specialty settings or *2*) evaluate the real-world treatment strategies and their effects on health outcomes. Over the past two decades, quality-oriented registries in cardiovascular disease have pioneered mechanisms of quality assessment, benchmarking, and feedback to individual providers and institutions, and there is evidence that such initiatives can translate into improved quality of care and patient outcomes (13–17). In an effort to extend these efforts to diabetes and cardiometabolic care, the Diabetes Collaborative Registry (DCR) was formed in 2014 by the American College of Cardiology, the American Diabetes Association, the American College of Physicians, the American Association of Clinical Endocrinologists, and the Joslin Diabetes Center. The DCR is a real-world, quality-oriented registry covering the spectrum from primary to specialty outpatient care in the U.S., thereby permitting evaluations of multidisciplinary diabetes care across the spectrum of the disease process (from diagnosis to complications) and the relationship between treatment patterns and health outcomes.

ROLE OF THE DCR IN IMPROVING CARE

Despite evidence-based guidelines for treating patients with diabetes (1,7,9,18,19), a divide exists between the recommendations and their practical application (20). The DCR seeks to fill this void through collecting data on a national level, allowing for regular feedback and benchmarking that we envision will result in rapid-cycle quality improvement efforts. Through measuring adherence to clinical guidelines, quantifying local performance, and reporting these data with national benchmarks to individual sites and practitioners, we expect these data will spur site-driven quality improvement efforts. In addition, we hope that connecting primary care and specialty practices to a diabetes care network will promote integrated team-based care, comprehensive disease management, efforts focused on health promotion and complication prevention, and a more population-based health focus.

Beyond local quality efforts, research efforts within the DCR may allow for an enhanced understanding of disease progression, generate new insights into management patterns, and highlight opportunities for care improvement. Observational research in these longitudinal data sets can be powerful—identifying local, regional, and national gaps in care; evaluating and comparing the application and effectiveness of different treatment strategies; and exploring predictors of outcomes (treatment, patient, provider, and system-related). These insights can inform future clinical trials, examine the

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usefulness and validity of existing guidelines, inform the creation of new guidelines, and, ultimately, transform the care that we provide.

INITIAL SITES AND PATIENTS

U.S. outpatient practices were invited to participate in the DCR through a public website (www.thediabetesregistry.org) and through partnering societies who established practice recruitment targets and promoted enrollment to their member physicians and/or affiliate clinics. In addition, several electronic health record vendors used DCR-supplied materials to encourage registry participation among their outpatient customers as a mechanism for meeting certain federal Electronic Health Record (EHR) Incentive Programs ("Meaningful Use") requirements. Cardiology and multispecialty practices currently in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) PINNACLE program were targeted as initial sites for the DCR because of existing information technology platforms. However, to better understand the care of patients with diabetes across the wider spectrum of providers, primary care, cardiology, endocrinology, and multispecialty practices have been actively recruited. As of late 2015, 299 practice entities enrolled in the DCR, covering 46 states across the U.S. and representing 4,256 practitioners. Eighty-five percent of the sites represented in this initial recruitment effort are cardiology practices, 32% are primary care, and 1% are endocrinology (some sites are multispecialty, thereby creating overlap). Practices are distributed across the U.S. with 49% in the South, 20% in the Midwest, 16% in the West, and 15% in the Northeast.

Participating practices submit data either through an automated system integration solution that periodically extracts relevant data elements from EHRs or through manual submission in a web-based data collection form (a small minority of sites). All protected health information is de-identified at the time of data extraction (or manual entry) and stored in a secure facility in a manner compliant with Health Insurance Portability and Accountability Act regulations. Because registry participation requires no data collection beyond that of routine clinical care and poses no additional risks to clinical providers or their patients, a waiver of written informed consent and authorization for this study was granted by Chesapeake Research Review, Inc.

Patients eligible for enrollment in the DCR include those with a diagnosis of diabetes as identified through ICD-9/10 diagnostic codes. Data transfer from practices to the analytic center began in 2015 with data collected on 979,175 patients encompassing 4,059,690 unique clinical visits. Demographic and clinical characteristics of the patients with type 2 diabetes in the initial cohort are shown in Table 1.

POTENTIAL CHALLENGES WITHIN THE DCR

Collection of standardized and usable data on such a large scale and across so many different types of practices can pose significant challenges. Although automated system integration with EHR has clear benefits in terms of user burden, there are limitations to its use (21). Certain data elements (e.g., race, outside laboratory values) may not be systematically captured or readily extractable in various EHRs or are not captured with enough granularity (e.g., daily insulin dose, diabetes type and duration). Furthermore, despite extensive data checks, the accuracy of some data can be difficult to determine without validation (e.g., comorbidities), which may impart an unmeasured bias. However, because of the large number of observations, these data-related issues often are less critical to the overall conclusions but should be recognized as potential limitations in future studies. Another important challenge is the participation of a diverse group of practices. For example, the high proportion of white participants registered thus far underscores the importance of recruiting sites with more racial heterogeneity. Although efforts will be made to be as

Table 1—Baseline characteristics of initial patients enrolled in the DCR

	Patients (n = 902,772)
Age, years	67.9 ± 12.6
Male sex	54.6
Race (n = 625,887)	
White	85.1
Black	11.8
Other	3.0
Hispanic or Latino ethnicity	5.5
Insurance (n = 542,792)	
Private	85.9
Medicare	12.0
Medicaid	0.2
None	1.1
Other	0.7
Hypertension	87.1
Systolic blood pressure, mmHg	129.7 ± 18.1
Diastolic blood pressure, mmHg	73.7 ± 11.3
Dyslipidemia	79.8
Coronary artery disease	58.0
Prior myocardial infarction	15.7
Prior coronary bypass graft surgery	12.3
Heart failure	26.6
Peripheral arterial disease	15.7
Prior stroke	10.0
Atrial fibrillation/flutter	24.1
Tobacco use	
Never	47.8
Current	15.2
Quit within past 12 months	1.1
Quit more than 12 months ago	35.9
HbA_{1c}, % (mmol/mol) (n = 303,737)	9.0 ± 4.1 (75 ± 21)

Data are percent or mean ± SD.

inclusive as possible in site recruitment, this will always be a potential concern and should be acknowledged in future studies using data from the DCR.

CONCLUSIONS

The DCR is the first large-scale, nationwide, multidisciplinary quality assessment and improvement initiative formed by partner organizations across the primary and specialty care continuum and dedicated to improving and transforming the future of diabetes care in the U.S. Over time, it is anticipated that the DCR will result in a better understanding of management patterns, highlight opportunities for improvement, provide a mechanism for insightful research to guide future care, and ultimately improve outcomes.

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Duality of Interest. D.K.M. has received honoraria for trial leadership from Boehringer Ingelheim, Janssen Research & Development, LLC, Merck Sharp & Dohme, Eli Lilly, Novo Nordisk, GlaxoSmithKline, Takeda, AstraZeneca, and Lexicon and honoraria for consultancy from Janssen Research & Development, LLC, Sanofi, Merck Sharp & Dohme, Novo Nordisk, and Regeneron. D.E. has received honoraria for consultancy from Eli Lilly, Novo Nordisk, Sanofi, AstraZeneca, Janssen, Takeda, and Halozyme and clinical research honoraria from Novartis, Eli Lilly, Novo Nordisk, Mylan, Janssen, Bristol-Myers Squibb, and Eisai; has been a speaker for Takeda; and holds equity in Halozyme. N.H. and P.F. are employees of and hold equity in AstraZeneca. J.J.S. is an employee of AstraZeneca and a prior employee of Bristol-Myers Squibb. M.K. has received research grants from AstraZeneca, Gilead Sciences, Genentech, and Sanofi; other research support from AstraZeneca, Gilead Sciences, Amgen, and ZS Pharma; consulting honoraria from AstraZeneca, Sanofi, Eli Lilly, GlaxoSmithKline, Boehringer Ingelheim, Takeda, Glytec, Amgen, and ZS Pharma; and speaker's bureau fees from Amgen. No other potential conflicts of interest relevant to this article were reported.

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