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Quality Improvement in Diabetes Care: A Review of Initiatives and Outcomes in the T1D Exchange Quality Improvement Collaborative

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Despite immense strides in therapeutic advances, clinical outcomes continue to be less than ideal for people with type 1 diabetes. This discrepancy has prompted an outpouring of quality improvement (QI) initiatives to address the medical, psychosocial, and health equity challenges that complicate ideal type 1 diabetes care and outcomes. This article reviews a framework for QI in diabetes care that guided the development of the T1D Exchange Quality Improvement Collaborative to improve care delivery and health outcomes in type 1 diabetes. Evaluation of the methodology, outcomes, and knowledge gained from these initiatives will highlight the importance of continued QI initiatives in diabetes care.

Type 1 diabetes is characterized by immune-mediated depletion of pancreatic β -cells, resulting in lifelong dependence on insulin. Among the U.S. population, an estimated 187,000 youths and 1.4 million adults have type 1 diabetes (1). This prevalence is further intensified by the impact of the burden of disease as related to its complications, excess mortality, and challenges in access and affordability of insulin (2). The life expectancy for individuals with type 1 diabetes is estimated to be 3.6 years less than the general population (3).

Since the Diabetes Control and Complications Trial provided irrefutable evidence for the benefit of optimal

glycemic control in mitigating risks of long-term micro- and macrovascular complications (4–8), many important advances in diabetes therapy have been made. However, youths and adults with type 1 diabetes continue to struggle to meet the glycemic targets outlined by the American Diabetes Association (ADA) (9,10), with just 17% of youths in the T1D Exchange clinic registry achieving an A1C <7.5% and 21% of adults having an A1C <7.0% between 2016 and 2018 (11). Even more concerning, the adjusted mean A1C increased by 0.6% from 2010–2012 to 2016–2018 (11).

The discrepancy between therapeutic innovations and clinical outcomes is likely the result of ongoing gaps in care delivery, psychosocial needs, self-management, health system design, and equity of care. A 2016 meta-analysis (12) highlighted a lack of high-quality, well-designed interventions to improve clinical and psychosocial outcomes in type 1 diabetes. The awareness of this incongruence in care advancement and patient outcomes has prompted a surge of quality improvement (QI) initiatives to address the medical challenges, as well as the equally significant psychosocial aspects of type 1 diabetes, including diabetes distress, depression, anxiety, disordered eating behaviors, and diabetes-related family conflict (13).

QI methods are systematic and continuous actions that lead to measurable improvement in health care services

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and the health status of targeted patient groups (14). In turn, the implementation of QI methodologies provides reliable application of evidence-based care. In this review, we discuss QI projects in the United States that have been implemented to improve care delivery and health outcomes in type 1 diabetes. Evaluation of the methodology and knowledge gained from these initiatives will highlight the importance of continued QI initiatives in diabetes care, which will ultimately improve clinical outcomes, reduce psychosocial burden, and improve health-related quality of life.

A Framework for QI in Diabetes Care

Two decades ago, the development of the Chronic Care Model (CCM) outlined a systematic approach to improving health care delivery (15). The CCM emphasizes regular, patient-centered interactions between individuals and their health care team. It focuses on improving psychosocial support and leveraging information technology to redesign health systems for better care delivery. The model emphasizes four main categories of interventions: 1) self-management support, 2) delivery system design, 3) decision support, and 4) clinical information systems (Figure 1) (16). When integrated, these elements produce better interactions between patients and care teams (17).

The Institute for Healthcare Improvement (IHI) Breakthrough Series Collaborative further developed the CCM by developing strategies to serially test and adapt QI interventions to generate a change in outcomes. IHI expanded on this concept by promoting a Triple Aim initiative to improve population health, reduce health

care costs, and improve patient satisfaction (18). IHI's Breakthrough Series provided a framework for collaborative improvement that catalyzed the emergence of partnerships worldwide to apply QI methodologies to the diabetes population (19–21). Groups such as the Diabetes Quality Improvement Program have applied the IHI Triple Aim model to focus on improving care delivery, as measured by A1C and end-organ complications (22,23).

The Institute of Medicine (IOM) cultivated improvement science further to the development of a Learning Health System model (24). In this model, patients and families are key members of the health care team, which promotes ideal, patient-centered care. The Collaborative Chronic Care Network is an example of a learning health system that was originally focused on inflammatory bowel disease and cystic fibrosis and has served as a model for QI initiatives in type 1 diabetes (25).

Initially, these models provided the context for the development of diabetes QI initiatives, primarily in the realm of type 2 diabetes. Initial diabetes-related interventions included implementation of multidisciplinary teams, formation of patient registries, better dissemination of information, continuation of QI work, and development of patient education initiatives (26,27). The framework provided by the CCM, IHI, and IOM, and the experience of type 2 diabetes QI interventions, were instrumental in applying improvement science to type 1 diabetes care. This effort has included the identifying metrics to measure processes and outcomes, developing QI interventions, and using Plan-Do-Study-Act (PDSA) cycles to analyze the success of the interventions for possible full implementation or to develop another change cycle (28). The focus on improved population health also prompted the development of large clinical registries to promote shared communication among health systems (29).

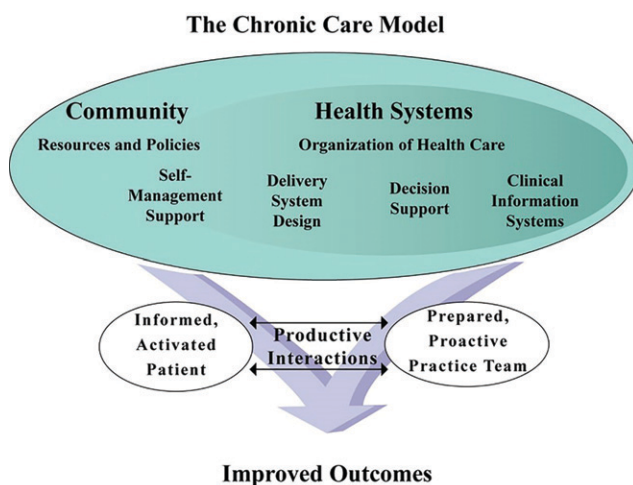


FIGURE 1 The Chronic Care Model. Developed by the MacColl Institute. ©ACP-ASIM Journals and Books (16).

T1D Exchange Quality Improvement Collaborative

Quality improvement collaboratives (QICs) enable an organized, multifaceted, multidisciplinary approach that includes teams from multiple health care institutions uniting together to develop, apply, and disseminate QI initiatives for a given health care topic. QICs are supported by faculty experts in the given topic area who identify best clinical practices and facilitate implementation strategies to improve care. Teams apply QI methods locally, undertake rapid PDSA cycles to understand

tests of change, and share data, novel interventions, and lessons learned with QIC partner institutions. Ideally, this process results in more effective implementation and spread of QI interventions and allows benchmarking of local progress to other sites. In a recent systematic review (30), QICs were reported as yielding significant improvements in target clinical processes and outcomes across hospital-based and ambulatory settings. The QIC model for shared learning, reporting, and benchmarking outcomes in QI interventions prompted the development of the T1D Exchange Quality Improvement Collaborative (T1DX-QI), which focuses on type 1 diabetes.

In brainstorming the design of the T1DX-QI, Corathers et al. (29) proposed a learning health system based on the aforementioned improvement science principles. They developed a key driver diagram that focused on improving glycemic control, reducing severe hypoglycemic events, improving health-related quality of life, and decreasing the psychosocial burden of diabetes (Figure 2) (29). To achieve these aims, the T1DX-QI initially concentrated on drivers such as self-management, integration of technologies, and patient-centered care (29). Furthermore, they emphasized the need for future models that are cooperative—not only among patients, families, and the health care team, but also among health systems, with encouraged sharing of information and collaboration.

In developing the T1DX-QI, a multidisciplinary team consisting of patients, family members, clinicians, informaticians, computer scientists, software engineers,

educators, and experts in community integration and business was formed to coproduce an optimal type 1 diabetes care process model for improved health outcomes (31,32). Ethnographic interviews were conducted at two large health systems with a diverse group of participants, which included people with type 1 diabetes, caregivers, physicians, nurse educators, social workers, dietitians, and health care administrators with an interest in diabetes, to characterize the barriers that patients and families commonly encounter (31). The team also used extensive medical literature queries and invited expert guidance. These various explorations revealed that the current system of diabetes care was failing in multiple aspects: cost, psychosocial support, reliability, and translatability (31). Subsequently, with the additional insight of patient- and family-specific barriers from the interviews, the team developed 84 intervention ideas. These were narrowed down using an impact-effort matrix to rank the interventions based on their perceived impact and feasibility, which resulted in a robust set of ideas with potential for having breakthrough impact on research, care delivery, and health outcomes in type 1 diabetes.

As a multicenter initiative, the T1DX-QI aims to accelerate QI interventions to improve the care of people with type 1 diabetes through shared learning and continuous review of best practices. At the launch of the collaborative, 10 large U.S. diabetes centers participated, including seven pediatric clinics and three adult clinics collectively serving >24,000 patients with type 1 diabetes (31). The initial clinics were selected based on their baseline QI capacity, number and expertise of patients

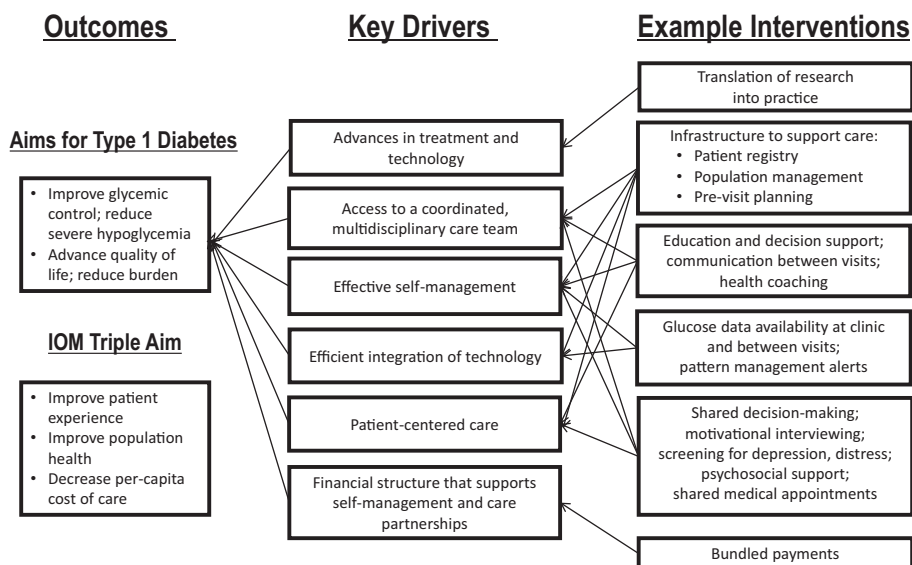


FIGURE 2 Key driver diagram for type 1 diabetes (29).

or family members in improvement processes, and information technology landscape. Clinic personnel from each site received formal QI training and were then regularly evaluated with an adapted Quality Improvement Organizational Readiness Assessment that reviewed specific QI domains, including team structure, foundation, capacity or proficiency, and success (31). This tool uses a simple “yes”/“no” scoring system, which allowed the staff to determine which of the aforementioned domains are insufficient and subsequently provide resources to strengthen the targeted areas. Within 6 months of training, 80% of clinics achieved scores of $\geq 75\%$ on the readiness assessment. Teams were structured to include a clinical champion, a QI coordinator, a senior department leader, a data analyst, and a patient/family representative. Collaboration among all clinic sites (virtually, in-person, and via electronic database) and formation of patient/parent advisory boards were encouraged to allow for continued sharing of data and ideas (31).

Focused Interventions in Type 1 Diabetes Care

With the maturation of the T1DX-QI, multiple QI interventions in diabetes care have been deployed and evaluated across several areas. The bulk of these QI initiatives have focused on three key areas: care delivery, self-management, and psychosocial support.

Care Delivery

Improving the delivery of diabetes care includes a focus on risk-stratification tools, pre-visit planning, access to care, and a multidisciplinary team approach to care. An example of improvement science to enhance diabetes care delivery was the development of the Type 1 Diabetes Care Index (T1DCI) (33), a metric developed by Nationwide Children’s Hospital (NCH) to aggregate missed opportunities to deliver elements of optimal diabetes care based on ADA (9) and International Society for Pediatric and Adolescent Diabetes (34) guidelines. NCH used the T1DCI metric to identify gaps in care and focus QI efforts. Implementation of the T1DCI guided QI interventions in processes for care delivery, which led to a 26% improvement in T1DCI scores over 12 months at NCH (33). The same QI team at NCH also created the Type 1 Diabetes Composite Score (T1DCS) as a clinical indicator that goes beyond A1C to comprehensively reflect patient status. The T1DCS aggregates nine outcome measures from the electronic health record (EHR) associated with optimal diabetes care and assigns a score for each patient, with higher scores

reflecting better management and outcomes. In using the T1DCS to direct QI and clinical care, the NCH team observed a right shift in scores, indicating improved clinical outcomes and compliance with guidelines (35).

A pre-visit planning work group involving five T1DX-QI clinics improved information collection by 91%, including asking patients/families about their needs and goals, reviewing appropriate screening tests, and ensuring that refills were completed (31). High-risk patients, which T1DX-QI defines as those having two A1C values $>9\%$ in the preceding 12 months, have an increased risk of acute and long-term complications. In a QI project to reduce the proportion of patients who fell into the high-risk category, 10 centers deployed multiple PDSA cycles, resulting in a decrease of 3 percentage points, from a baseline of 40% to 37%, over a 15-month period (36). Pediatric and adult clinics co-developed the project design to support patient needs based on five key driver interventions: 1) glucose monitoring, 2) insulin management, 3) patient-centered care, 4) access to clinical care, and 5) psychosocial care. Successful interventions included using a patient navigator to reach out to families between visits, increasing depression screening, developing classes to encourage patients to be quicker to accept continuous glucose monitoring (CGM), and addressing social determinants of health (SDOH). In an effort to assess patients at risk for an acute complication, one T1DX-QI clinic developed an EHR-based, automated tool to stratify risk of DKA (unpublished data, Texas Children’s Hospital). This provider-facing tool correctly determined risk in 75% of patients based on subsequent DKA outcomes. QI and clinical interventions to prevent DKA for those at high risk are currently underway.

Self-Management

Effective patient self-management strategies have been associated with improved glycemic control (37–40). One T1DX-QI center developed a score based on six diabetes self-management habits, including checking glucose ≥ 4 times/day or using CGM, administering three or more insulin boluses daily, using an insulin pump, administering bolus insulin doses before meals, reviewing diabetes data between visits, and changing insulin doses between visits. A total habit score was created by summing all six habits based on EHR documentation. A1C was lower for patients performing the self-management habits, with a reduction of 0.7% percentage points in per 1-unit increase in habit score (41). These metrics will be adopted by multiple T1DX-QI centers to support

interventions to improve diabetes self-management and glycemic outcomes.

Use of diabetes devices, including CGM systems and insulin pumps, has the potential for improving glycemic control and improving quality of life. Ten clinics in the T1DX-QI participated in a project aimed at increasing CGM use in patients aged 12–26 years. Eight of 10 centers saw improved CGM uptake, with an overall 12% increase of CGM use, from a baseline of 36% to 48%, over a 20-month period across the entire T1DX-QI cohort (42). Initiatives to improve CGM use included investing in new staff roles to support CGM uptake and creating patient navigator positions dedicated to helping patients navigate insurance coverage, industry forms, and CGM training sessions. In another collaborative project focused on diabetes devices, five T1DX-QI sites deployed QI interventions to expand insulin pump use, with a 10% overall increase from a baseline of 46 to 56% for the entire cohort (43). Successful interventions to expand pump use included redesigning clinic workflows, developing mobile technology classes, and coaching patients to take insulin before meals.

Psychosocial Support

Psychosocial stresses such as family conflict, underlying mood disorders, and diabetes distress contribute to poor health outcomes in patients with type 1 diabetes. In adolescents with type 1 diabetes, negative mood and feelings of ineffectiveness have been closely correlated with decreased frequency of blood glucose monitoring and higher A1C (44).

In a QI project to expand depression screening, six T1DX-QI centers developed initiatives to increase consistent referral and screening and to increase psychosocial resources with the use of health information technology (45). By implementing bimonthly calls and three learning sessions focused on depression screening, they saw an increase in screening of >60%, from a baseline of 10% to 71% across all sites. Notably, 7.8% of patients across all sites had a positive depression screen, thus allowing further evaluation and treatment. Comparison of psychosocial screening scores across sites is limited by the use of different instruments and cut-off scores to define a positive screen, so the T1DX-QI is moving toward standardizing depression screening across sites, which might enable such analyses.

Another T1DX-QI clinic similarly aimed to address this psychosocial gap of effective recognition of underlying mood disorders to improve diabetes care delivery. This

was accomplished by expanding depression screening via updates to their health information technology to allow for automation of screening dissemination, data capture, measures of progress, and the referral process. Implementation of these initiatives resulted in a 75% improvement in screening rates using the Patient Health Questionnaire [PHQ]-2 and PHQ-9 and allowed >89% of patients with a positive screen to meet with a social worker for a targeted mental health assessment, counseling, referral to local resources, and/or safety planning before leaving the clinic (46).

Role of QI in Addressing SDOH

SDOH are conditions in the environment in which people live that affect a wide range of health and quality-of-life outcomes. Five key aspects of SDOH identified by *Healthy People 2020* include 1) economic stability, 2) education, 3) social and community context, 4) health and health care, and 5) neighborhood and built environment (47). Disparities in any of these areas can lead to inequities in health outcomes. Diabetes outcomes as measured by glycemic control and number of acute complications, use of technology, and access to care are all worse in the Non-Hispanic Black and Hispanic populations (48). The barriers for these populations may be the result of differences in language or culture, lack of financial resources, or considerable distances to access care (49). Several QI interventions aimed at reducing health inequities among patients with type 2 diabetes have been deployed in the primary care setting, and evidence suggests that some interventions can improve diabetes-related health outcomes in socially disadvantaged populations (50). In a systematic review of diabetes QI interventions, Lu et al. (49) expressed concern that QI strategies designed for the general population may not be accessible to or have the same efficacy in disadvantaged groups.

In a recent perspectives article, T1DX-QI members described how QI tools and principles can be adapted into a framework for advancing health equity. To address the literature gap on practical ways health care providers can address inequities in diabetes, the authors proposed a 10-step framework for addressing structural and systemic racism, economic disparities, and education inequities in diabetes care delivery. The framework relies on data to identify SDOH, engage an equitable project team with shared decision-making power, develop policies to expand access to care for the most vulnerable patients, and train clinic staff by naming structural racism as a driver of health inequities (48). Strategies

to incorporate this health equity framework across T1DX-QI member organizations are currently underway.

Economic Value of QI Interventions in Type 1 Diabetes

With increasingly constrained health care budgets, QI initiatives must have feasible economic value to be sustained in the long term. Emerging evidence suggests that QICs such as the T1DX-QI have potential to yield cost savings to the health care system, but more rigorous cost-effectiveness studies are needed (51). QI interventions specific to diabetes care may be cost-effective in leading to declines in health care utilization with improved glycemic control (52). This effect may not be experienced as a direct financial benefit to hospital systems or clinical practices but could have a large impact in value-based care programs.

Conclusion

Type 1 diabetes has garnered much attention in the realm of clinical research and advancement of technology in the past few decades; however, major gaps in health outcomes persist. These disparities may be the result of the mismatch between evidence and care delivery, discrepancies between the potential and reality of burden from current therapies, and racial/ethnic inequalities in access and outcomes. Only recently has diabetes-specific QI science blossomed with a global appreciation of the contributions that health systems, self-management, psychosocial burdens, and health equity have on glycemic control in patients with type 1 diabetes. A continued drive to improve health care delivery and diabetes management for people with type 1 diabetes has helped QI science in the United States progress to the ongoing and encouraging projects being carried out today. The sharing of best practices through the T1DX-QI is anticipated to continue to amplify impact and accelerate improvement in diabetes outcomes, which also has potential economic value.

Limitations of this review include the large proportion of QI work that goes unpublished and the lack of universal application of rigorous QI methodology and outcome-sharing even within robust collaborative networks such as the T1DX-QI. Given the major gaps in type 1 diabetes outcomes, continued evolution in QI methodology and focused QI interventions are essential to advance quality of life and health outcomes for people with type 1 diabetes.

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DUALITY OF INTEREST

O.E. is a compensated Health Equity Advisory Board member for Medtronic Diabetes and serves as the principal investigator for investigator-led projects sponsored by Abbott, Dexcom, Eli Lilly, Insulet, and Medtronic. J.M.L. is on the medical advisory board for GoodRx. D.J.D. is a consultant to Dexcom and Insulet. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

O.Z.B.G. and D.J.D. developed the concept for this article and wrote the manuscript. O.E. analyzed the data. All authors reviewed/edited the manuscript. O.Z.B.G., O.E., and D.J.D. are guarantors of this work and, as such, take responsibility for the integrity of the data and the accuracy of the data analysis.

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