Improving Diabetes Control Using Lean Six Sigma Quality Improvement in an Endocrine Clinic in a Large Accountable Care Organization

Usha Kollipara,[1] Mario Rivera-Bernuy,[2] Joseph Putra,[1] Jessica Burks,[1] Amber Meyer,[2] Shayla Ferguson,[2] Carolyn Nelson,[2] Jackie Mutz,[1] Sasan Mirfakhraee,[2] Puneet Bajaj,[1] Asra Kermani,[2] Jason S. Fish,[1] and Sadia Ali[2]

This article describes a quality improvement project to reduce the number of patients with diabetes who have poor glycemic control in a large tertiary care endocrinology clinic. The project used the Lean Six Sigma Define-Measure-Analyze-Improve-Control process improvement methodology to develop clinic workflow processes for obtaining A1C measurements in a timely manner to facilitate interventions to improve glycemic control. The percentage of patients with poorly controlled diabetes (A1C >9.0% or missing value in the past 12 months) significantly improved from 26.4% at baseline to 16% (P <0.001), and the proportion of patients with an A1C test within 3–6 months of an appointment improved from 76 to 92%.

Diabetes is a leading cause of death and disability. Clinical trials show that improved glycemic control, as evidenced by reduced A1C, correlates with a reduction in developing diabetes complications (1). There are many barriers for improving glycemic control in clinical practice, including failure to follow clinical guidelines for monitoring diabetes and therapeutic inertia (2,3).

Patients who have their A1C tested less frequently than every 6 months tend to have poorer glycemic control (4). The American Diabetes Association recommends A1C testing quarterly in patients whose therapy has changed or who are not meeting glycemic goals and at least twice yearly in those who are meeting treatment goals (5).

Various quality improvement (QI) methodologies are being used in health care, including in the diabetes care arena (6–8). These tools include the Lean Six Sigma Define-Measure-Analyze-Improve-Control (DMAIC) methodology, Plan/Do/Study/Act cycles, and performance benchmarking. Lean Six Sigma QI tools have been widely used in non–health care industries (9). Their use in health care is increasing, and previous applications have included improvement of care quality in a hospital setting, prescription errors, and waste control (10,11). Kutz et al. (12) used Lean Six Sigma methodology to demonstrate that standardization of accepted care practices for patients with diabetes improved compliance with diabetes care bundle completion and patient outcomes in a primary care setting.

Our clinic is part of a large accountable care organization (ACO) serviced by a population health services company, with performance goals and payments tied to quality measures. The 2018 Centers for Medicare & Medicaid Services (CMS) Shared Savings Program for the ACO included poor control of diabetes as a performance measure (13). Hence, a reliable method for improving poor control of diabetes became imperative.

The aim of our project was to design and implement best practices to reduce the percentage of patients with poor glycemic control defined as an A1C >9.0% (or missing value), from 26.4% in May 2018 to 22.0% by December 2019.

Design and Methods

We applied the Lean Six Sigma DMAIC process improvement methodology for development and implementation of our QI initiative to improve glycemic control

[1]Southwestern Health Resources, Dallas, TX; [2]University of Texas Southwestern Medical Center, Dallas, TX

Corresponding author: Sadia Ali, sadia.ali@utsouthwestern.edu

U.K. and M.R.-B. are co-first authors and contributed equally to the manuscript.

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(A1C) in patients with diabetes seen in the endocrinology clinic at the University of Texas Southwestern Medical Center in Dallas, which is a large multispecialty clinic. Our participants included all patients seen in the clinic for diabetes management. In the absence of an industry standard for QI methodology, we elected to use the DMAIC methodology because we believed it was a good choice for process-oriented projects. We have successfully used this methodology in the past for various QI projects, and it is one of the QI methodologies currently in use in our institution. The steps of the process are described below.

Define

A clearly defined project charter that included the project aim, list of stakeholders, and timeline for deliverables was developed and approved by the leadership team before implementation. Project team members included all clinical staff, including medical office assistants, nurses, information resources representatives, clinical workflow analysts, process improvement personnel, clinic management, and medical providers. All team members were involved in the planning, development, and implementation of the process improvement steps. The university's institutional review board determined that this QI project was exempt from review.

Measure

A detailed map of the current clinic workflow was created based on observations and input from various clinic members. This map included all processes around patients' appointments, including pre-visit planning, reminder calls to patients, placement of laboratory orders before and after appointments, referrals for diabetes self-management education, and discharge processes.

The endocrinology clinic's diabetes registry was used to measure and track variables for this project. The ambulatory clinics have been using registries for chronic disease since 2016 for their decision support tools and health maintenance alerts. The diabetes registry includes all patients who have diabetes on their problem list and visit diagnosis. A customized report was available from the registry for relevant screenings and diagnostic values.

We used the National Quality Forum definition for measuring poor diabetes control in line with our institution's quality measure definitions. This measure is defined by CMS as the percentage of patients 18–75 years of age with diabetes who had an A1C >9.0% or missing value during the measurement period. Although the measure applies to adults 18–75 years of age, the QI process was applied to all patients with diabetes who were seen in the clinic regardless of age.

Analyze

Before initiating this project, A1C tests were ordered as needed, and external A1C values were not being reported in analyzable data fields. The team believed these factors contributed to inconsistent capturing of A1C values.

A brainstorming session was conducted with the clinic nursing staff and providers to gain insight into the barriers patients frequently encountered with regard to compliance with diabetes treatment. Issues around self-management such as diet, medications, and lack of resources came up frequently and consistently. Other issues included access to appointments, psychosocial problems, issues related to glucose meters, and patient-specific factors such as language barriers and vision deficits. All issues noted by team members were grouped into categories under a cause-and-effect "fishbone diagram."

Because the brainstorming was subjective, we also conducted a random audit of 125 charts (~5% of the population). Half of the sample population was from the subgroup with an A1C >9.0% (poor control), and the other half was from the subgroup with an A1C <9.0% (in control). The sample size was chosen based on the principles of the central limit theorem, under which a sample size ≥30 is considered sufficient to represent a study population.

Provider assessment from the last available chart note was used as a basis for determining trends. Frequency of A1C testing was obtained from discrete laboratory results, and diabetes self-management education status was determined from completed education visits recorded in the electronic health record (EHR). Patient appointment status, including whether a patient had a next scheduled appointment, and average time between appointments was determined using the diabetes registry.

Our chart review of the 5% random sample showed that the group with an A1C >9.0% included a high number of patients with at least one comorbid condition who were more likely to not schedule appointments at the time of discharge from a clinic visit, who frequently canceled existing appointments, and who reported barriers to compliance and had a high degree of difficulty with self-management. Further analysis from the diabetes registry of patients with poor glycemic control showed that the average number of days between appointments was 169, and ~50% of these patients did not have a scheduled next visit at the time of discharge from their most recent clinic

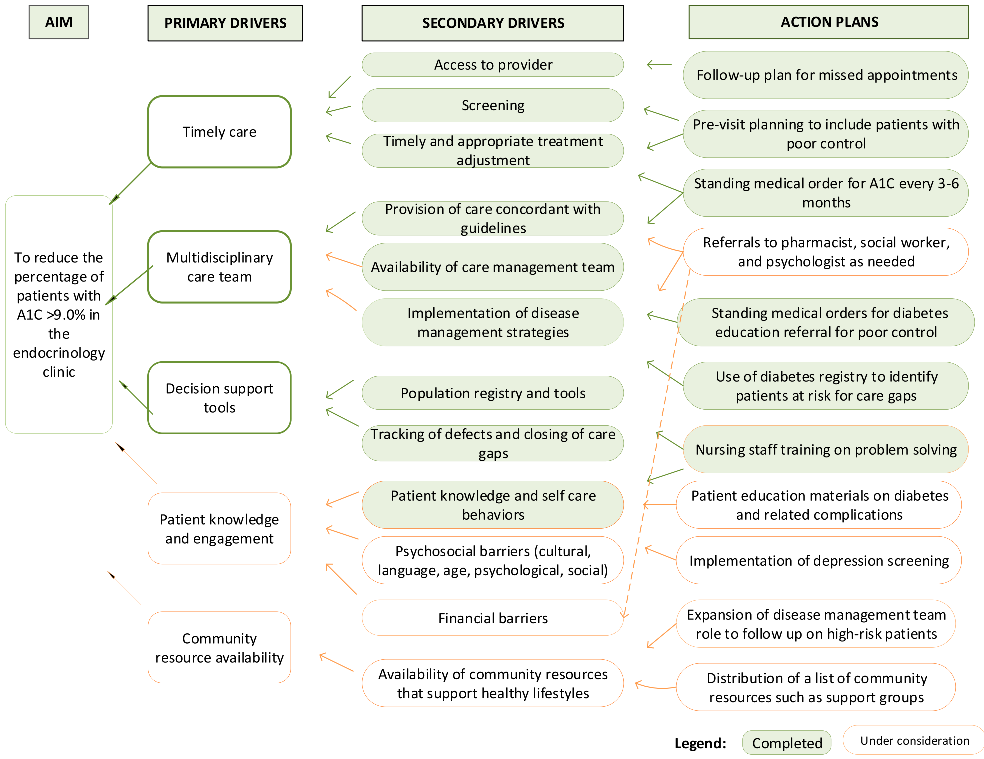

FIGURE 1 Identification of change drivers and development of potential action plans.

appointment. Based on the sample and population analyses, as well as input from all stakeholders, key drivers that affect change and potential action plans were developed and are summarized in Figure 1.

Improve

Given the gaps in availability of recent A1C values, it was deemed necessary to verify a recent A1C value before visits. Pre-visit planning for all upcoming diabetes management appointments was expanded to include verification that the last A1C value was within 3 months of each appointment. A standing medical order protocol was developed to authorize a qualified clinic nurse to place an order for A1C testing on behalf of the provider if there was no value available within the previous 3 months in the EHR based on manual chart review.

A similar standing medical order was developed to initiate a diabetes education referral when a patient's last A1C was >9.0% and there was no pending or completed education in the past 12 months. A follow-up plan was developed for missed appointments, which included informing patients of the self-scheduling process and mailing letters to patients asking them to reschedule missed appointments.

Control

During the control phase, we conducted biweekly audits of 10 sample charts and communicated feedback to the clinic staff with the percentage of patients who were either missing an A1C test result or in poor glycemic control (A1C >9.0%). The diabetes registry and a newly created diabetes quality measure dashboard with provider-level performance details were shared with the clinic to review their performance.

Results

At baseline, 26.4% of the diabetes patient population was in poor glycemic control, defined as A1C >9.0% or missing A1C value in the 12 months before their visit. These data were extracted from the clinic's diabetes registry.

Data were reanalyzed at multiple points in time after implementation of new improvement processes in the clinic starting in January 2019. A total of 3,304 patients had one or more visits for diabetes management to the endocrinology clinic between 1 January 2019 and 31 December 2019. Baseline patient characteristics included a mean age of 56 years and average A1C of 7.6%, with 68% of patients having a blood pressure <140/90 mmHg and 56% having an LDL cholesterol level <100 mg/dL (Table 1).

We compared our metric for diabetes poor control at the end of the study to our baseline. The results showed a decrease in the number of patients with an A1C >9.0% from 16.53 to 12.89% (P <0.001). Patients with a missing A1C value decreased from 9.93 to 3.03% (P <0.001).

TABLE 1 Demographics and Population Characteristics at Baseline and End of Project

	Baseline (May 2018)	End of Project (December 2019)	*P*
Total patients per quality measure, *n*	2,559	3,304	–
Male	1,257 (49.12)	1,544 (46.73)	0.63
Female	1,302 (50.88)	1,760 (53.27)	0.08
Mean age, years	56.31	56.8	0.158
Median age, years	59	59	–
Type of diabetes			
Type 1	411 (16.06)	445 (13.47)	0.006
Type 2	1,842 (71.98)	2,278 (68.95)	0.011
Other*	306 (11.96)	581 (17.58)	<0.001
≥1 A1C value in past 12 months	2,305 (90.07)	3,204 (96.97)	<0.001
A1C ≤9% in past 12 months	1,882 (73.54)	2,778 (84.08)	<0.001
A1C >9% in last 12 months	423 (16.53)	426 (12.89)	<0.001
Missing A1C in last 12 months	254 (9.93)	100 (3.03)	<0.001
Mean A1C at population level, %	7.6	7.41	<0.001
LDL cholesterol <100 mg/dL in past 12 months	1,443 (56.39)	1,867 (56.51)	0.97
Mean LDL cholesterol, mg/dL	83.12	82.33	0.3
On statin	1,804 (70.50)	2,286 (69.19)	0.25
Blood pressure <140/90 mmHg in past 12 months	1,727 (67.49)	2,372 (71.79)	<0.001
UACR in past 12 months	1,258 (49.16)	1,845 (55.84)	0.892
UACR <30 mg/g	884 (34.54)	1,249 (37.80)	0.12
A1C <7%, blood pressure <140/90 mmHg, and LDL cholesterol <130 mg/dL	648 (25.32)	1,023 (30.96)	<0.001
Current retinopathy screening	1,651 (64.52)	2,348 (71.07)	<0.001

Data are *n* (%) unless otherwise noted. Quality measure definition: patients were aged 18–75 years and had at least one visit in the past 12 months for diabetes management. *Nonspecified type of diabetes included drug-induced hyperglycemia, exocrine pancreas dysfunction, and genetic syndromes. UACR, urine albumin-to-creatinine ratio.

Mean last A1C was 7.6% at baseline and 7.41% at the end of the study (*P* <0.01). On subset analysis, the improvement in A1C was prominent in patients with poor glycemic control (A1C >9.0%), with an average improvement of 1.9%.

We observed a 30% increase in our clinic population during the study period, which was the result of an increase in clinic volume over time. This increase was mainly observed in patients with type 2 diabetes or other diabetes categories, which the investigators attributed to our clinic receiving a higher number of referrals for cystic fibrosis–related diabetes, steroid-induced diabetes from the oncology clinic, and post-transplant diabetes, as part of a large tertiary care academic center.

Further analysis showed significant improvement by the end of the study in blood pressure control <140/90 mmHg (71.79 vs. 67.49%, *P* <0.001) and in diabetic retinopathy screenings (71.07 vs. 64.52%, *P* <0.001). The improvements in blood pressure and diabetic retinopathy screenings were the result of simultaneous process improvement projects in the clinic. There was no statistically significant difference in the percentage of patients with an LDL cholesterol <100 mg/dL or the number of patients on statins from baseline to end of the study. The percentage of patients who met all diabetes composite measures (blood pressure <140/90 mmHg, A1C <7%, and LDL cholesterol <130 mg/dL) improved from 25.32 to 30.96% (*P* <0.01).

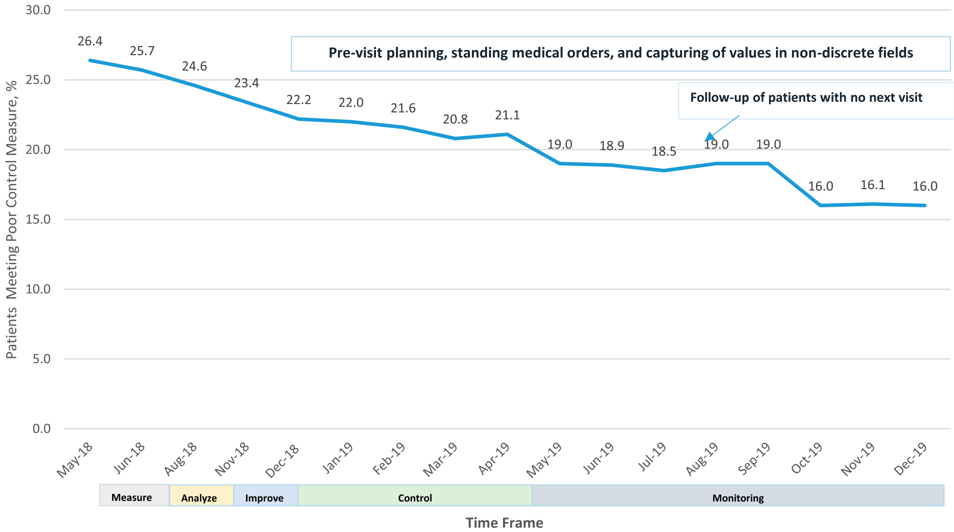

FIGURE 2 Percentage of patients meeting diabetes poor control measure.

At the end of 12 months of the control phase, the newly created processes were determined to be stable (Figure 2). The percentage of patients with poor control of diabetes (A1C >9.0% or missing value) decreased from 26.46 to 16.0% (P <0.01) over 20 months.

The proportion of patients with an A1C test within 3–6 months before an appointment improved from a baseline of 76% (lower control limit [LCL] 70%, upper control limit [UCL] 94%) to 92% (LCL 88%, UCL 93%). The improvement was noticeable within 1 month of implementing the new processes and was sustained over time. The mean in the control chart had an absolute improvement of 15.5%. The variation from the mean decreased from 25% at baseline to 6% at the end of the control phase (Figure 3).

Discussion

In this study, we used Lean Six Sigma DMAIC QI tools to improve glycemic control in patients with diabetes who were seen at a tertiary care endocrinology clinic. We were successful in decreasing the percentage of patients with poor glycemic control (defined as A1C >9.0%) from a baseline of 26.4% in May 2018 to 16% by the end of December 2019.

After identifying care gaps, we introduced multiple interventions, including pre-visit planning, standing medical orders for A1C testing and diabetes education referral, and follow-up of missed clinic appointments. Standing medical orders empowered the clinic staff to order A1C testing and to refer patients for diabetes

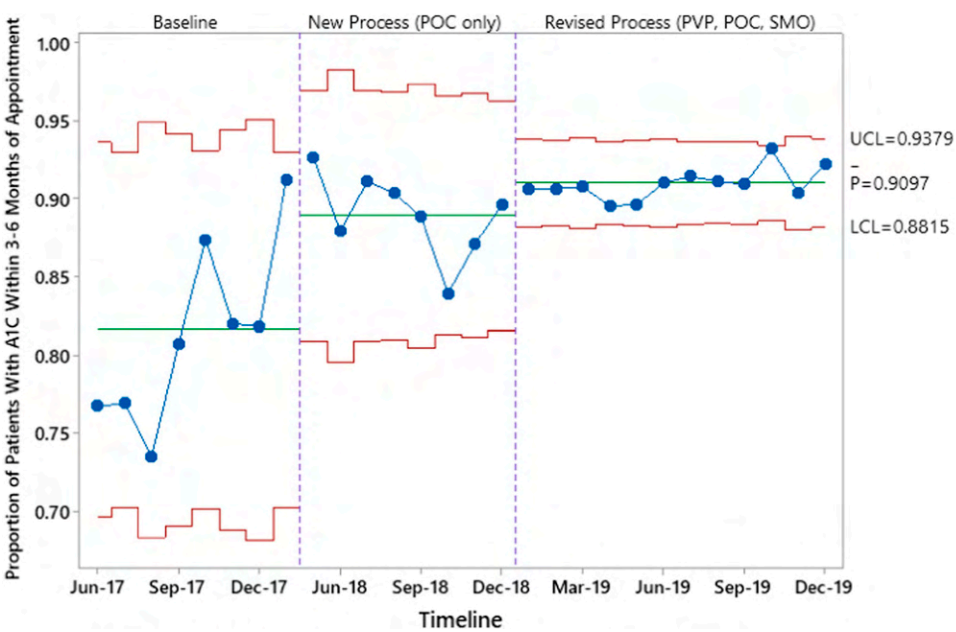

FIGURE 3 Proportion of patients with A1C testing within 3–6 months before an appointment. Sigma Z = 2.34923, 1.94601, 0.846439. POC, point of care; PVP, pre-visit planning; SMO, standing medical order.

self-management education classes to help achieve our goal.

These interventions reduced our percentage of patients with missing A1C values, provided timely A1C values to inform clinicians' treatment interventions, and increased utilization of diabetes self-management education services. The mean reduction in A1C achieved at an individual level by the end of the study was significant and comparable to the reduction described in other various studies (6). Furman et al. (8) recently demonstrated a similar improvement in the proportion of patients with an A1C >9.0% from 13 to 11%, with a 2.1% improvement of population mean A1C in a large primary care setting.

We also observed improvements in retinopathy screening status and blood pressure control resulting from simultaneous process improvement efforts, and our improvements were comparable to those described in the literature (6,7). No significant changes were observed in LDL cholesterol control, statin use, or microalbuminuria. The proportion of patients with microalbumin testing within the past 12 months increased; however, this change was not statistically significant.

Poor glycemic control is associated with increased health care costs. Preventive strategies to improve glycemic control in people with diabetes could reduce the economic impact associated with the disease. In a large cross-sectional study of health care utilization, poor glycemic control was directly related to higher total health care, hospitalization, and medication costs (14). Patients with poor control had a higher probability of hospitalization than those with good control and a greater average cost when hospitalization occurred. Health care costs increased by 18% with very poor glycemic control (A1C >10.0%) and 23% in poor control (A1C >8.0 and <10.0%) (14). Furthermore, improvement in A1C indicative of poor control (>9.0%) was found to be associated with an annual average 2% reduction in hospitalization days leading to a substantial reduction in tertiary costs in a time series study with quality indicators (15).

We feel having a robust EHR was one of the tools contributing to our success with the QI project. A robust EHR can help hospitals perform better QI projects in the future. However, an approach similar to ours can be undertaken at any community primary care clinic, with adjustments based on available resources. A simple registry can be created from a clinic's existing EHR using database tools. Standing medical orders for A1C and diabetes education referral can be created and implemented in any primary care clinic. The key is to create a sustainable process with input from all stakeholders and to monitor the process over time.

The QI activities reported here are part of a bigger population health focus in our ACO. We carried out this project as a pilot at an individual clinic site. However, as part of a large population health services company, our focus is to improve the health of our patient population by leveraging EHR tools, coupled with process improvement, for better clinical outcomes. These positive results and successful experiences in our clinic are being shared across the network for feasibility of scaling the processes at a network level to improve population health. Similar QI projects are being conducted at other sites within the Southwestern Health Resources network.

Strengths and Limitations

In addition to having a robust EHR, we attribute the success of our study to the active involvement and engagement of team members at all stages of the project. We implemented a standardized process using standing medical orders, which empowered the clinic staff to place orders for A1C testing and diabetes education referral and to better coordinate the care of our patients. This improved care coordination led to a robust improvement in A1C.

There were some limitations to our project. Our diabetes clinic is a large academic referral center. Therefore, we encounter more patients with type 1 diabetes (13%) and secondary diabetes from other medical conditions or medications, as well as more advanced complications (17%). This population may not be representative of the usual proportion of type 1 diabetes at primary care centers, which is reported to be from 2 to 6% (7). Additionally, the proportion of patients with different types of diabetes differed at the beginning and end of study. This difference was statistically significant and may have altered the internal validity of our results. A likely explanation for our increased number of patients with other types of diabetes is the high level of referrals we receive as a tertiary care referral center for potentially sicker patients with new-onset diabetes resulting from chemotherapy, immunotherapy, or pancreatectomy.

Conclusion

The use of Lean Six Sigma DMAIC QI tools was an effective method to improve the quality of diabetes care in our clinic setting. The magnitude of improvement was comparable to other published QI work (6,7). These strategies can be applied for other clinical QI projects. Further studies on the application of these strategies to telehealth services are plausible to ensure uninterrupted diabetes care when face-to-face visits are limited.

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No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

U.K. and S.A. conceived the QI idea, developed the theory and processes, implemented the project, and wrote the manuscript. M.R.-B., C.N., and S.M. participated as providers in the project and contributed to the manuscript. J.P. verified the data and analytical methods and contributed to the manuscript. J.B., A.M., and S.F. implemented the project, collected the data, and contributed to the manuscript. J.M., P.B., A.K., and J.S.F. provided guidance and mentorship as population health and quality experts throughout the project and contributed to the manuscript. U.K. and S.A. are the guarantors of this work and, as such, had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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