Increasing Vitamin B12 Screening Among Patients With Type 2 Diabetes on Long-Term Metformin Therapy

Elijah P. Mays, Jr.

Quality Improvement Success Stories are published by the American Diabetes Association in collaboration with the American College of Physicians and the National Diabetes Education Program. This series is intended to highlight best practices and strategies from programs and clinics that have successfully improved the quality of care for people with diabetes or related conditions. Each article in the series is reviewed and follows a standard format developed by the editors of Clinical Diabetes. The following article describes an initiative designed to increase vitamin B12 screening in patients with type 2 diabetes on long-term metformin therapy at a free clinic in the southeastern United States.

Describe your practice setting and location.

The setting for this project was a free clinic that serves an underserved and underprivileged community in the southeastern United States. The patient population is 80% Hispanic and 20% African American and Caucasian. The clinic also serves the community by doubling as a food bank and clothing center. Clinician staffing at the clinic included three physicians, two family nurse practitioners (FNPs), one physician assistant (PA), and a mixture of nurse practitioner (NP) and PA students. The students rotated through the clinic for one semester or multiple semesters as they progressed through their graduate program’s plan of study.

Describe the specific quality gap addressed through the initiative.

This project focused on increasing vitamin B12 screening in patients with type 2 diabetes who have been prescribed metformin for >2 years. This type of screening is important because long-term use of metformin is known to cause vitamin B12 deficiency as a result of its effect in altering the membrane potential in the small bowel (1).

The process by which this deficiency develops is as follows. Vitamin B12 is derived primarily from consumed animal proteins. Upon digestion of these proteins, gastric parietal cells produce intrinsic factor (IF), which attaches to the vitamin B12 and assists in its transport through the small bowel. In the small bowel, specifically the terminal ileum, vitamin B12 and IF are cleaved from each other. In the terminal ileum, calcium plays a vital role in assisting in the transportation and storage of vitamin B12 in the liver. Long-term metformin use impairs the ability of calcium to carry out this role, thus leading to vitamin B12 deficiency in people with type 2 diabetes (2).

This quality improvement (QI) project was chosen because the American Diabetes Association’s guidelines recommend annual vitamin B12 screening for people with type 2 diabetes who are prescribed metformin (1). Review of the electronic health record (EHR) for >100 patients with type 2 diabetes revealed that this recommendation was not being carried out routinely and consistently at the clinic.

How did you identify this quality gap? In other words, where did you get your baseline data?

Baseline data came from a random EHR audit of the records of patients with type 2 diabetes to identify how
many had not received a vitamin B12 screening despite being prescribed metformin.

**Summarize the initial data for your practice (before the improvement initiative).**

Of the patients with type 2 diabetes who were included in the EHR audit, 68% had not been screened for vitamin B12 deficiency despite taking metformin for >2 years. During an initial data collection period from 1 February to 30 June 2019, 213 patients with type 2 diabetes who had been prescribed metformin for >2 years were seen, including 100 males and 113 females. Inclusion criteria for data collection were age ≥18 years, diagnosis of type 2 diabetes or prediabetes, and taking metformin for >2 years. There was no difference in vitamin B12 screening rates between males and females.

**What was the time frame from initiation of your QI initiative to its completion?**

This was a 4-month QI initiative beginning in February 2020 and ending in June 2020.

**Describe your core QI team. Who served as project leader, and why was this person selected? Who else served on the team?**

The QI project was undertaken as part of a doctoral program, with the author, then a candidate for a doctorate in nursing practice degree, serving as project leader. Doctoral program faculty served as core QI members and provided guidance and feedback. The clinic's two FNPs assisted with fine-tuning the process, serving as “eyes on the ground” and consistently relaying information to the project leader. Due to unforeseen circumstances surrounding the coronavirus disease 2019 (COVID-19) pandemic, NP and PA students were not allowed in the clinic; therefore, the project leader was the only person responsible for alerting providers about vitamin B12 screening for patients with type 2 diabetes. The project leader therefore reviewed patients' charts the day before their visits, alerted the providers about those in need of a vitamin B12 screening, reviewed the screening results, and notified providers of those who were deficient or borderline deficient in vitamin B12.

**Describe the structural changes you made to your practice through this initiative.**

The project leader and the two FNPs determined that the NP and PA students would be responsible for reviewing patients' charts before their clinic visits. The students were oriented to the process and informed of this responsibility on their first clinical day. The clinic instituted a daily morning huddle, typically lasting 25–30 minutes, at the start of each day. Pertinent information was discussed about all patients on the panel for the day, including any transportation issues, details from their last visit, their laboratory results, medications, and so forth. The students presented the patients and alerted the clinicians about which patients with type 2 diabetes on metformin therapy needed a vitamin B12 screening. The students also reviewed and notified providers of the results of A1C and renal function tests, eye exams, and other routine assessments. Implementing a morning huddle facilitated effective communication between students and providers and helped to set the tone and expectations for each day.

**Describe the most important changes you made to your process of care delivery.**

At the time the project was implemented, the clinic's EHR system did not have the capability of alerting providers. Therefore, the lead author implemented a manual alert process through which the NP and PA students communicated with providers about patients' needs both during the morning huddle and before each patient was seen. The switch to a new EHR system a few weeks after the project started (in March 2020) was an important process change because it added the capability of sending notes or alert reminders to providers electronically when a patient chart was accessed. However, even after the new EHR system was in place, providers were still notified during morning huddle of any patient needs.

Throughout the project, both the students and the clinical staff were still becoming familiar with the new EHR system and learning its capabilities. In addition, everyone was navigating ever-changing clinic operations in response to the COVID-19 pandemic.

**Summarize your final outcome data (at the end of the improvement initiative) and how it compared with your baseline data.**

Initially, the rate of vitamin B12 screening for February and March 2020 exceeded the rate for the same months of 2019. However, in April 2020, the screenings decreased by 49%. This decrease was likely caused by COVID-19-related disruptions to clinic workflows. However, vitamin B12 screenings steadily increased to 64% in May 2020 and 69% in June 2020.
as patients began to return to the clinic for in-person visits (Supplementary Figure S1).

What are your next steps?
The clinic will continue to have morning huddles, as clinical staff agreed that they have improved communication and serve a useful purpose in training NP and PA students how to properly present patients.

What lessons did you learn through your QI process that you would like to share with others?
As project leader, the author learned that QI initiatives can be challenging. There are multiple moving parts in the QI process, and the author had to learn to trust others to do their part. Being flexible, attentive, and thorough when communicating was key to a successful project. Also, meeting with clinicians via Zoom or similar digital platforms when in-person meetings were not possible was very helpful for discussing what was working well and what could be improved. Upon the completion of the QI project, the author had a deeper appreciation for the leadership and commitment it takes to implement such an initiative in a clinic or other health care facility.

One tremendous hurdle was trying to manage the project during the initial shutdown caused by the COVID-19 pandemic. Because the students were no longer allowed at the clinic and most patients were using telehealth visits, the project leader had to coordinate and have constant communication with the front office staff to keep the project on track. From coordinating digital meeting times with providers, to reviewing charts, to notifying providers and following up on vitamin B12 screening results, the entire process was made more challenging by the pandemic.

Overall, the rate of vitamin B12 screening did not improve (Supplementary Figure S2), most likely because students, clinicians, and staff were all trying to navigate the new clinic normal amid the pandemic. At the start of the project (February and March 2020), the screening rate far exceeded that of the same period of the previous year; however, the COVID-19 shutdown had a significant negative impact on screenings in April 2020, when the shutdown occurred and telehealth visits began. Still, the screenings steadily increased in May 2020 and still more in June 2020, as patients began to resume in-person visits, suggesting that the new emphasis on vitamin B12 screening could have a positive long-term impact post-pandemic.

The author did not identify any previous studies of vitamin B12 screening rates in patients using metformin in a clinic or other medical facility setting. Likewise, no studies were identified comparing a clinic’s year-to-year vitamin B12 screening rates in people with type 2 diabetes and taking metformin.

ACKNOWLEDGMENTS
The author thanks Drs. Natalia Davila, Cathy Durham, Sharon Kozachik, Angela Stanley, Martha Sylvia, and Emily Johnson for their assistance, guidance, and expertise throughout this QI project.

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

GUARANTOR STATEMENT
As the sole author of this article, E.P.M. is the guarantor of this work and, as such, had full access to all the data reported and takes responsibility for the integrity of the data and the accuracy of the data analysis.

REFERENCES