



Vanderbilt Health Affiliated Network Statin Outreach Service

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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 the design and implementation of a pharmacist-led program to improve rates of statin use among appropriate patients in high-risk populations.

Describe your practice setting and location.

The Vanderbilt Health Affiliated Network (VHAN) is a collaborative alliance of physicians, health systems, and employers driving a new level of clinical innovation and teamwork to enhance patient care, contain costs, and improve the health of communities in Tennessee and surrounding states. The network includes more than 5,000 clinicians, 60 hospitals, 12 health systems, and hundreds of physician practices and clinics who work together to strengthen communities and improve quality of life across the Southeast through better health. The statin outreach service was piloted in one VHAN practice, the Vanderbilt Medical Group, a large primary care group at

Vanderbilt University Medical Center (VUMC). VUMC is a tertiary care academic center. VUMC primary care providers (PCPs) are located in several practice locations, and one location was chosen to pilot this intervention. The PCPs included internal medicine residents and attending physicians. Before this project, there was no clinical pharmacy presence in this practice.

Describe the specific quality gap addressed through the initiative.

Statin medications are lipid-lowering drugs that also reduce the risk of cardiovascular events such as heart attacks and strokes. Given the strong evidence for cardiovascular risk reduction in patients with diabetes or preexisting heart disease, many major medical societies recommend administering statins in these groups as a standard of care (1,2). Thus, prescription of and adherence to statins is a commonly tracked quality measure, including for the Centers for Medicare & Medicaid Services (3).

Despite the demonstrated efficacy and safety of these agents and evidence-based recommendations for their use, statins are both under-prescribed and underutilized in practice. Even with appropriate prescribing, research has shown that half of patients stop taking their prescribed statin within the first year (4), often because of presumed adverse effects or poor understanding of why or how to take statins. Other studies have shown that pharmacist-led treatment interventions can improve rates of appropriate patients taking statins (5–7). Building on the work of Lowrie et al. (5), we designed and implemented a program utilizing clinical pharmacists to improve the rates of statin use in high-risk populations. This intervention is unique in using a population health team to identify patients, then providing support to PCPs to improve the measure of statin use.

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This article contains supplementary material online at <https://doi.org/10.2337/figshare.12149748>.

<https://doi.org/10.2337/cd19-0099>

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

Patients were included if they had seen a VUMC PCP, were 40–75 years of age, had type 2 diabetes and/or atherosclerotic cardiovascular disease (ASCVD), and had not filled any statin prescription in the past 6 months. Exclusion criteria included pregnancy or breastfeeding, documented true statin allergy, and hemodialysis. These criteria yielded a group of 19 patients identified through review of medical and prescription claims data.

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

Among patients with indications for statin therapy, 19 patients identified for initial intervention and 38 control patients did not appear to have any filled statin prescriptions within the previous 6 months, resulting in inclusion. The average age in both groups was 55 ± 7 years, and 7 of the 19 patients in the intervention group (37%) were male. In the control group, 9 of 38 (24%) were male. Calculated 10-year ASCVD risk ranged from 3.2 to 29%, with a median of 15% and interquartile range of 7.6–17.7%. Although all patients in both groups had a diagnosis of diabetes, the majority (55 of 57) did not have known established ASCVD.

What was the time frame from initiation of your quality improvement (QI) initiative to its completion?

The intervention period was conducted over ~6 weeks in February and March 2018. The post-intervention analysis was at least 12 months after the intervention for all patients.

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

Two clinical pharmacists, an endocrinologist, and an operational leader with a nursing background designed the intervention. One clinical pharmacist served as project leader. He did the majority of patient outreach, and communicated with PCPs and coordinated with an assistant pharmacy technician. He was selected as the leader because of his experience as a clinical pharmacist and willingness to communicate with PCPs about this new way of working together.

A few members of the primary care practice served as key contacts for us. They were supportive of the new approach

and facilitated introduction of the program to their colleagues. The program was introduced to the group via practice meetings and e-mail before its initiation. The key contacts helped us determine that the PCPs would accept an opt-out approach. Accordingly, PCPs with patients identified in this group were provided a list of patients and were permitted to decline intervention for individual patients.

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

Using claims-based data to proactively reach out to patients with gaps in quality measures was not a new practice at our institution. However, combining medical and pharmacy claims to better target appropriate patients and involving a pharmacist to assist PCPs in closing specific medication gaps was novel here.

Before this project, clinical pharmacists supported patient care as part of a peripheral support team. They provided medication management for patients engaged with a care coordination team of nurses and social workers. Within this project, the clinical pharmacist engaged directly with PCPs. Given space and scheduling constraints at the clinic, the pharmacist worked from a central location, and most contacts were by telephone. He did have the opportunity to come and see patients in the clinic if this was desired. The pharmacist spent ~4 hours/week engaged in this work over a period of 6 weeks, including time spent in chart review, communicating with providers, and communicating with patients.

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

This was a new workflow that altered the process of care delivery substantially. The intervention was designed to change the process of care delivery to ease the workload of providers and assist them in starting statins for appropriate patients.

Once eligible patients were identified, providers were engaged before patient outreach. Our pharmacist then owned the patient care process, reaching out to patients by telephone rather than waiting until patients returned for an office visit. An analyst reviewed claims data and provided the pharmacist with a list of potentially eligible patients. Subsequently, appropriateness for statin therapy was determined via chart review. This process included reviewing medical history, past laboratory test results, and medication history. Review of patients' medication history

included a full review of all medications with a focus on previous use of any statins, side effects, potentially interacting drugs, and any other possible barriers to statin use.

During the chart review process, one patient was excluded for well-documented statin intolerance. The remaining eligible patients ($n = 18$) were further stratified using an algorithm derived from guidelines (2) to determine each patient's 10-year risk of a cardiac event along with the corresponding appropriate intensity of statin therapy (Supplementary Materials).

The PCP for each eligible patient was then notified via electronic medical record (EMR) with details regarding why the patient was identified. The pharmacist requested permission to engage with the patient on behalf of the practice to help address this gap in care. The PCP was permitted to decline the intervention for specific patients. In the event that other treating specialists needed to be consulted per the PCP (e.g., a hepatologist), a similar message was sent to the specialist for sign off on consideration of statin therapy.

After review by all pertinent providers, the clinical pharmacist then reached out to identified patients via telephone to discuss cardiovascular risk reduction strategies and statin therapy. If a patient did not answer, the pharmacist left a detailed message giving his name and role. Second and third calls were made after 1 and 2 weeks, respectively, as needed, with messages left if possible. If the calls went unreturned, letters detailing the nature of the calls, along with information detailing the indication and purpose of statins, were sent to patients at their mailing addresses.

When a patient was reached by phone, the pharmacist introduced the idea of a clinical pharmacist working on behalf of the patient's PCP as part of the care team. The pharmacist did not have a specific script but did have talking points. Talking points included explaining that this free service was new to the clinic and that it was designed to ensure that patients' needs were met regarding their medications. The pharmacist explained that this service was designed to focus on strategies to help prevent potential complications of diabetes or the recurrence of coronary events in patients with clinical ASCVD. The patient was counseled that diabetes and other risk factors increase risks of heart attack and stroke.

The pharmacist then discussed the patient's various risk factors for a cardiac event and discussed strategies for addressing those, including providing smoking cessation counseling if needed. Finally, the pharmacist counseled

the patient on the role of statin therapy in ASCVD risk reduction, including indication, risks, benefits, adverse effects, monitoring, and what to expect with or without statin therapy. The pharmacist explained the novel process of facilitating statin initiation without the need for an office visit with the patient's provider.

For patients amenable to starting statin therapy after the phone call, the pharmacist then sent a detailed description of the discussion along with an assessment and recommendations, to the PCP via the EMR. The pharmacist coordinated the initiation of statin therapy with the PCP by pending the medication order for cosignature, along with laboratory orders that might be needed before statin initiation. Most patients received atorvastatin, which was selected given its classification as both a moderate- and high-intensity statin depending on the dose. Several patients were open to the idea of statin therapy but preferred to discuss this with their PCP. In those instances, appointments were scheduled with the PCP so statin therapy could be addressed. Regardless of their final decision, all patients received detailed information about statin therapy. The pending of protocol-driven orders by pharmacists was a new process in this practice, which previously relied on prescribing by providers without the assistance of other team members.

Once statin therapy was initiated, the patient was contacted again via telephone 2 weeks later to assess for adverse effects, tolerability, and adherence to the prescribed medication. The pharmacist once again used the intervention algorithm (Supplementary Materials) to assess and evaluate for any adverse effects, especially statin intolerance. If the statin was well tolerated, the patient was then contacted in 4–12 weeks to repeat a fasting lipid panel to assess for adherence. This follow-up laboratory surveillance was often obtained in conjunction with a PCP office visit.

If there were any symptoms suggesting possible intolerance, the pharmacist followed the algorithm to thoroughly evaluate the issue. The algorithm was designed to try dose reduction before changing to a different statin or discontinuing therapy altogether. The protocol was specifically designed to exhaust statin therapy before considering alternative medications. With any change to drug therapy, the patient was contacted within 2 weeks for reassessment.

If the patient's repeat fasting lipid panel reflected the expected percentage reduction in LDL cholesterol, the patient was instructed to continue taking the same dose of the same statin. If the LDL cholesterol reduction was less

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than expected, the patient was counseled on adherence and, if there were no issues, instructed to increase the dose of statin therapy and repeat the process.

Most interactions between a patient and the pharmacist were via telephone, independent of an office visit with a provider, unless the patient requested an in-person visit or communication via electronic messaging. All interactions among the pharmacist, the patient, and PCP were documented in a shared EMR and sent to the PCP to keep him or her informed throughout the process.

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

After a minimum of 12 months after the intervention date, we conducted a post-intervention analysis. During the analysis, we again evaluated for claims on filled statin prescriptions 6 months before the baseline date (pre-intervention) and 6 months after (post-intervention). The baseline date was the date of outreach to the intervention group, and the latest date in that cohort was used as a baseline date for all patients in the comparison group. At that analysis, 1 of the 19 intervention patients and 2 of the 38 patients in the comparison group were found to have a claim for at least one filled statin prescription in the pre-intervention time frame. This was likely because of a lag of availability of claims data (known to be up to 2 months with this data source), resulting in new data being found when the analysis was rerun at a later date. We used an intention-to-treat (ITT) approach to our analysis, retaining these patients as well as any who could not be reached in the intervention group. We do not believe this lag in claims affected our post-intervention data because the analysis was done at >12 months after the last patient enrollment.

Following ITT principles, 7 of the 19 patients in the intervention group (36.8%) were adherent to statin therapy based on having at least one filled prescription. This result compared with 5.3% of that group before the intervention.

For the control group, who were not contacted by the pharmacist, we also measured adherence to statin based on at least one filled prescription claim in the 6 months after the baseline date. In that group, 7 of 38 patients (18.4%) had filled a statin prescription at least once at follow-up. Although this finding provides some comparison of intervention versus natural history, it is also possible that the PCPs may have been more likely to address the need for statins in all patients with an indication as a result of this work occurring within the practice.

In the intervention group, the preintervention mean LDL cholesterol level was 104 ± 26 mg/dL. Among patients in the intervention group with at least one claim for a statin after the intervention, the postintervention LDL cholesterol level was 85 ± 16 mg/dL, suggesting that this group was indeed taking a statin. The relatively low baseline mean LDL cholesterol level in the intervention group is not surprising because the indication for inclusion was irrespective of lipid levels. Using ITT analysis, lipid measurements in the intervention group as a whole before and after therapy were not significantly changed; the postintervention mean LDL cholesterol level for all members of the group was 96 ± 31 mg/dL.

Reasons for ongoing nonadherence in the intervention group included patients declining a new medication (three patients), true statin intolerance uncovered (one patient), and team unable to reach patients (two patients). In two additional cases, the PCP deferred statin therapy because diabetes was the patient's sole cardiovascular risk factor or the patient had relatively low LDL cholesterol, and the PCP expressed a desire to prioritize other medications in patients who were reluctant to take any medications. In four additional patients, the reasons for nonadherence (lack of filled claims) after the intervention are unknown.

What are your next steps?

Similar methods are being applied to other clinical problems in our network. We are now more efficiently using claims-based methods of patient identification to ensure that our efforts are addressing the correct patients. We adopted several of the lessons we learned in contacting patients and engaging providers to work with patients with uncontrolled diabetes and patients recently discharged from an acute care setting.

The pharmacist's work and collaboration with the providers on the care team have also led to substantial growth of clinical pharmacy services. Because of demand for more help in managing patients with complex chronic conditions, the pharmacy team hired more pharmacists and pharmacy technicians.

What lessons did you learn through your QI process that you would like to share with others?

We found this new method of working together for patient care to be well accepted in the primary care practice, and we believe that up-front communication facilitated this acceptance. The program was introduced through multiple communication channels and with the support of

early adopters from the practice, who acted as champions. Patients seemed receptive to the fact that a pharmacist was working on behalf of the primary care practice, rather than on behalf of a health plan or other entity not really known to them. Additionally, communicating through the EMR was perceived as more beneficial than other programs in which faxes may be sent to indicate a care gap.

Although reasons for lack of statin therapy at baseline were not always apparent from chart review, the majority of patients in our program lacked established ASCVD, and some had very low calculated ASCVD risk scores. This finding, along with feedback in some cases that PCPs felt they needed to prioritize other medications when diabetes was the only ASCVD risk factor, gave us the impression that statin prescriptions or counseling on their importance were sometimes omitted because of competing priorities. We found that a pharmacist was able to help fill this gap with proactive outreach and counseling on behalf of the practice.

DUALITY OF INTEREST

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

AUTHOR CONTRIBUTIONS

C.T. designed the intervention, performed the clinical intervention, collected data, and wrote the manuscript. E.B.N. designed the intervention and reviewed/edited the manuscript. K.D. performed abstraction of claims data and reviewed/edited the manuscript. D.S. designed the intervention and reviewed/edited the manuscript. M.L.G. designed the intervention, analyzed data, and wrote the manuscript. M.L.G. 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 intervention description and reported outcomes.

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