A Quality Improvement Program to Reduce Potential Overtreatment of Diabetes Among Veterans at High Risk of Hypoglycemia

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ABSTRACT

Background. Intensive glycemic control confers increased risk of hypoglycemia and little benefit among older individuals with diabetes. The aim of this quality improvement project was to reduce the number of patients treated to A1C levels that might confer greater risk than benefit (i.e., potential overtreatment) in the VA New England Healthcare System.

Methods. A provider report and clinical reminder were created to identify potentially overtreated patients and prompt clinicians to consider treatment de-intensification. Potentially overtreated patients were defined as those on insulin or a sulfonylurea whose most recent A1C was <7.0% and who were >74 years of age or diagnosed with dementia or cognitive impairment. The numbers of patients screened and whose treatment was de-intensified using the clinical reminder were counted from January to December 2014. The number of high-risk veterans at baseline was compared with that 6 and 18 months after implementation using *t* tests.

Results. A total of 2,830 patients were screened using the clinical reminder; 9.6% had their glycemic treatment de-intensified. Among the 261 patients reporting hypoglycemia, 37% had their treatment de-intensified. Higher percentages of patients had treatment de-intensified when reported symptoms were more severe. The monthly average in the high-risk cohort declined from baseline by 18% at 6 months and by 22% at 18 months (both $P < 0.005$).

Conclusions. A clinical reminder helps clinicians identify and reduce the number of potentially overtreated patients. The large number of screened patients whose treatment was not de-intensified suggests that a clinical reminder should be combined with provider education, national guidelines, and performance measures aligned in the interest of reducing potential overtreatment.

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Among older individuals with diabetes, intensive glucose control may lead to greater harm than benefit. Although large clinical trials have consistently shown that reducing A1C prevents microvascular complications (e.g., retinopathy and nephropathy) over time, short-term benefits of intensive glucose control in older patients with a longer duration of diabetes have yet to be demonstrated (1–4). The major risk of intensive glucose control among older individuals is hypoglycemia. Hypoglycemia risk is greatest with insulin and sulfonylureas and is increased by other conditions common among older individuals, including dementia, cognitive impairment, and chronic kidney disease (5–7).

Treatment-associated hypoglycemia is the second most common medication-related adverse event (8) and results in ~25,000 emergency

department visits and 11,000 hospitalizations yearly among individuals >65 years of age (9). Among older patients, hypoglycemia now exceeds hyperglycemia as a cause for hospitalizations (10). Severe hypoglycemia (i.e., abnormally low blood glucose requiring the assistance of another person) is associated with seizures and coma, but even mild hypoglycemia causes troubling symptoms such as anxiety, palpitations, and confusion. Individuals who have experienced repeated or severe hypoglycemia may withdraw from daily activities such as driving and exercise to avoid hypoglycemia and its consequences (11). This in turn can lead to depression and reduced quality of life (12). Recent guidelines and performance measures support less intensive A1C goals for older patients with diabetes (13–15), but a substantial number of older patients with diabetes are still potentially overtreated to A1C levels that likely confer greater risk than benefit (16).

Potential overtreatment of diabetes is an important issue in the Veterans Health Administration (VHA). At least 24% of veterans served by VHA have diabetes (17). A cross-sectional study of VHA patients indicated that 50% of older patients taking insulin or sulfonylureas are potentially overtreated (18). A similar proportion of older veterans with diabetes and dementia are treated to an A1C <7% (19). Despite the accumulating evidence of the negative consequences of overtreatment, providers are reluctant to de-intensify glycemic therapy. For example, one VHA study found that neither low A1C values nor limited patient life expectancy were strongly associated with de-intensification of therapy for older patients (16).

Recently, the VHA has focused on hypoglycemia safety, building on the American Board of Internal Medicine Foundation's Choosing Wisely initiative. Choosing Wisely focuses on "advancing a national dialogue on avoiding wasteful or unnecessary medical tests, treatments, and procedures" (20). As part of this effort, a VHA Choosing Wisely Task Force prioritized reducing the number of patients with diabetes who were potentially overtreated and therefore at high risk for hypoglycemia (the Hypoglycemia Safety Initiative). Concurrently, the Veterans Affairs (VA) New England Healthcare System (VANEHS) pursued a quality improvement (QI) initiative to reduce potential overtreatment in diabetes. The aim of this article is to share the methodology and outcomes from implementation of a risk reduction program to reduce the number of older patients potentially overtreated for diabetes.

Methods

Context

This QI project was conducted across the VANEHS. The goal was to reduce the number of potentially overtreated veterans with diabetes by encouraging primary care providers (PCPs) to reevaluate their use of diabetes medications among patients potentially overtreated and at high risk for hypoglycemia. This work met criteria for operational improvement and was exempt from institutional review board review.

Eight VA medical centers participated in the initiative between July 2013 and December 2014. The project engaged participants from throughout the organization, including clinical leaders (for direction and sponsorship), informatics specialists (for technical implementation of reports and the clinical reminder in the electronic medical record [EMR] system), and systems engineers (for project management, data analysis, and implementation expertise). A PCP at each of two pilot sites (Boston, Mass., and White River Junction, Vt.) advised on development of the QI initiative, provided feedback on usability and usefulness of the tools as they evolved, and served as a local champion for the project.

Intervention

There were three major stages of designing and implementing the intervention: *1*) identifying potentially overtreated patients, *2*) designing the Hypoglycemia Risk Reduction report, and *3*) designing and spreading the Hypoglycemia Risk Reduction clinical reminder.

Identifying Potentially Overtreated Patients at High Risk for Hypoglycemia

Potentially overtreated patients were defined as those who were on insulin or a sulfonylurea whose most recent A1C was <7.0% and who were also >74 years of age or diagnosed with dementia or cognitive impairment (18). These criteria were based on research by Feil et al. (7). In fiscal year 2013, ~220,000 veterans were enrolled in primary care in the VANEHS. In July 2013, 2,513 veterans met the criteria for inclusion in the potentially overtreated cohort. Data were drawn from the Corporate Data Warehouse, a large VA dataset that provides clinical and administrative data for VA analytical purposes.

Designing the Hypoglycemia Risk Reduction Report

A Hypoglycemia Risk Reduction report was developed by VANEHS Clinical Informatics for use with VANEHS patients, based on a similar report developed by the VA Great Lakes Healthcare System (VAGLHS). The report was provider-specific and contained information for each potentially overtreated patient cared for by that provider, including name, age, most recent A1C value and date, and all diabetes medications prescribed with dosing instructions. PCPs at the two pilot sites received a report relevant to their panel of patients. A sample report is displayed in Table 1.

Designing and Spreading the Clinical Reminder

Clinical reminders are alerts in patients' EMRs that prompt and guide clinicians in providing or scheduling preventive care and clin-

TABLE 1. Hypoglycemia Risk Reduction Sample Report

Name	Age (years)	A1C Result (%)	A1C Date	Diabetes Medication	Sig	Long Sig
VA Boston Healthcare System						
Dr. Smith						
Mr. A	76	5.0	1/7/15	Glyburide 2.5-mg tablet	2.5 QD	Take one tablet by mouth every day for diabetes
Mr. B	81	6.0	1/1/15	Glipizide 5-mg tablet	2.5 BID	Take one-half tablet by mouth twice a day for diabetes
				Metformin HCl 500 mg tablet	500 QD	Take one tablet by mouth every day for diabetes

BID, twice daily; QD, daily; Sig, label instructions.

ical interventions in a timely manner. The VANEHS Hypoglycemia Risk Reduction clinical reminder was based on a reminder used by VAGLHS to identify and address potential overtreatment. The VANEHS reminder was first implemented at the two pilot sites from October 2013 through December 2013 and then implemented at all eight VANEHS medical centers in January 2014.

The clinical reminder alerts providers at the time of routine care visits when a patient may be potentially overtreated. The reminder then leads the provider and patient through a series of questions to help assess the occurrence of hypoglycemia, as follows:

- In the past few months, how often did the veteran/caregiver report that the veteran had a low blood glucose level? If the answer is >0, then ask:
  - In the past few months, how often did the veteran/caregiver report that the veteran had blood glucose low enough to fear passing out? If the answer is >0, then ask:
    - Did the veteran/caregiver report that the veteran passed out or fell due to low blood glucose?
    - Did the veteran/caregiver report that the veteran required a visit to the emergency department or hospital because of low blood glucose?

Based on the results of these questions, the provider decides whether to de-intensify therapy and registers this decision by checking one of two boxes indicating either "No change in glycemic management at this time" or "Relax glycemic treatment." Additional guidelines for making this decision are available from the VA/Department of Defense Management of Diabetes Mellitus Clinical Practice Guideline (13). The link to this document was made available to providers in an informational email message sent out before implementation of the clinical reminder.

Outcome Measures

Two key measures were selected to quantify the impact of the QI initiative on process outcomes in post-hoc analyses. Systems engineers led the improvement team in identifying, collecting, and analyzing this information. The measures were:

- Number of potentially overtreated veterans whose treatment was de-intensified using the clinical reminder
- Number of veterans potentially overtreated at baseline and 6 and 18 months after implementation

For the first measure, the total number of unique veterans who were screened with the reminder from January 2014 through December 2014 was counted. The overall percentage of screened veterans whose glycemic therapy was de-intensified was calculated. For each group with a positive response to a question about hypoglycemia occurrence and severity in the clinical reminder, the percentage whose treatment was de-intensified was calculated.

For the second measure, baseline data about the number of potentially overtreated veterans was calculated as a monthly average based on data from July 2013 through September 2013. The reminder was implemented across all VANEHS sites in January 2014. Follow-up data on the number of potentially overtreated veterans was collected 6 months after implementation of the clinical reminder from July 2014 through September 2014, and 18 months after implementation from July 2015 through September 2015. The monthly average for each follow-up period was calculated. Before-and-after comparisons of baseline with each post-intervention period were performed using *t* tests.

We assessed secular trends in the frequency of potential overtreatment among veterans not targeted by the intervention by measuring the percentage of patients who met the same clinical criteria as the intervention cohort but were 65–74 years of age.

Results

From January 2014 through December 2014, 2,830 unique veterans were screened using the clinical reminder. The average A1C for all veterans screened was 6.4%. Overall, glycemic therapy was de-intensified for

TABLE 2. Responses to Screening Questions, Average A1C Values, and Therapy De-Intensification Among 2,830 Screened Veterans

Screening Question	Screened Patients Reporting "Yes" (*n* [%])	Average A1C Before Screening (% ± SD)	Patients Reporting "Yes" for Whom Therapy was De-Intensified (*n* [%])
Reported low blood glucose	261 (9.2)	6.49 ± 0.72	96 (37)
Reported blood glucose low enough that patient feared fainting or passing out	78 (3)	6.57 ± 0.82	40 (51)
Reported fainting or passing out because of low blood glucose	12 (0.4)	6.59 ± 1.04	10 (83)
Reported visiting the emergency department or hospital because of low blood glucose	13 (0.5)	6.65 ± 0.93	8 (62)

272 (9.6%) of the veterans screened. There were 261 veterans who reported having had low blood glucose (Table 2), and 78 of those reported fear of fainting or passing out. Of the 78 who reported fear of fainting or passing out, 12 reported having fainted or passed out because of low blood glucose, and 13 reported having visited the emergency department or hospital because of low blood glucose. Of those veterans who reported having had low blood glucose, 96 (37%) had their glycemic therapy de-intensified. Higher percentages of patients had treatment de-intensified when screening questions revealed fainting or emergency room or hospital visits because of low glucose. Among the 2,569 veterans who reported no low blood glucose, the average A1C was 6.44 ± 0.49%, and 7% of these individuals had their treatment de-intensified.

Before implementing the clinical reminder, 2,465 veterans per month on average met criteria for potential overtreatment. Six months after implementation, this declined to a monthly average of 2,014 veterans (before vs. 6 months after implementation –18%, P <0.005). By 18 months after implementation, the monthly average number of veterans in the potentially overtreated cohort was 1,924 (before vs. after implementation –22%, P <0.005). In comparison, we evaluated the frequency of potential overtreatment among veterans aged 65–74 years with similar clinical criteria who were not targeted by the intervention. The frequency of potential overtreatment in this group increased from 29% at baseline to 36% at both 6 and 18 months.

Discussion

In this QI initiative to reduce the number of older patients at high risk for hypoglycemia resulting from potential overtreatment, PCPs' use of a computerized clinical reminder was associated with treatment de-intensification. De-intensification was more common among patients who reported more severe symptoms or effects from hypoglycemia in the screening questions. Over time, there was a significant reduction in the number of patients in the potentially overtreated cohort. This reduction persisted 18 months after implementation of the clinical reminder.

A large number of patients who were identified as potentially overtreated and screened using the clinical reminder had no subsequent action taken with regard to de-intensification of therapy. Most of the de-intensification that occurred was reactive (i.e., triggered in response to hypoglycemia symptoms). A recent report suggests that many PCPs overestimate the benefits of tight glucose control in older adults and have concerns about the impact of relaxing A1C goals on their practice performance measures (21). Indeed, many quality metrics continue to align performance with lower A1C levels without regard to patients' age or comorbid conditions. Although the clinical reminder could be improved to encourage more careful scrutiny of patients without symptoms (i.e., proactive de-intensification) and possibly further reduce the size of the potentially overtreated cohort, the impact of a clinical reminder may be most effective if combined with provider education, national guidelines, and performance measures with the common goal of reducing potential overtreatment. In all cases, however, the reminder should serve as a cue to perform individual assessments in potentially high-risk patients rather than a directive to de-intensify treatment.

Potential overtreatment in diabetes may serve as an ideal example of a clinical problem well-suited to QI in the form of an EMR clinical reminder. Acceptability and uptake of clinical reminders are based in part on their perceived utility and usability (22). This reminder integrates multiple clinical characteristics to enable rapid identification of potentially overtreated patients. This renders the reminder useful for complex assessments. This also benefits PCPs who might not otherwise have time to individually evaluate patients for their level of risk. The clinical reminder was also designed to be readily usable and quick to complete. Taking action in response to the assessment findings (e.g., decreasing or stopping medica-

tions) could be done while discussing changes with patients and caregivers during a clinical encounter. In addition, the absolute number of patients per provider at each is relatively small, averaging 10 patients in total, which limits the burden of additional work per PCP.

The reminder was well received by PCPs, who reported that it was relevant, easy and quick to use, and well-integrated in their workflow at the point of care. Implementation of the reminder was relatively simple because the reminder was embedded in the EMR, so providers were able to address it during visits for patients who were flagged as potentially overtreated. The reminder included questions to help providers gauge the severity of hypoglycemia risk, and treatment was more commonly de-intensified among patients reporting more severe symptoms. This suggests that clinical decision-making was affected by the addition of these more detailed assessment questions.

The feedback report also identified patients who were at high risk for hypoglycemia because of a combination of clinical criteria and flagged them for further evaluation. It was anticipated that the report would be well-received by PCPs because of its simplicity. However, early in the pilot, providers conveyed their lack of enthusiasm for the stand-alone report because it was not integrated into their daily workflow, in contrast to the clinical reminder. This component of the original intervention was not pursued past the pilot stage.

Limitations

The study has several limitations. Because the project was undertaken as a QI initiative, there was not a designated control group. The initiative focused on patients who were screened with the clinical reminder. We are unable to account for the effects of events such as new guidelines or professional society position statements. Therefore, although the data suggest an association between the QI initiative and reduction in the overall population at risk, the existence of a causal relationship cannot be determined. That said, there was no decline in the frequency of potential overtreatment among slightly younger patients who were not targeted by the intervention. In addition, responses within the clinical reminder could be linked to provider actions, indicating an effect of the clinical reminder on treatment decision-making.

Criteria for inclusion in the high-risk cohort did not include some additional risk factors for hypoglycemia in potentially overtreated individuals such as chronic kidney disease (CKD), long duration of diabetes, or previous history of hypoglycemia. Of these factors, CKD is obtainable using the administrative data leveraged by the reminder. Including additional risk factors such as CKD would likely increase the size of the potentially overtreated cohort and therefore the potential impact of the reminder.

Finally, we cannot separate the impact of provider behavior from the impact of the QI initiative on the overall size of the high-risk population (21).

Areas for Future Work

There are several opportunities for strengthening the clinical reminder. Although the inclusion criteria for potentially overtreated patients already comprise several clinical characteristics, sensitivity of the criteria might be enhanced by including CKD and patient information such as emergency visits and hospitalizations with coded hypoglycemia. For patients who use glucose monitors that are reported via home telehealth systems and saved in the EMR, data could be scanned for low readings and used to identify high-risk patients. Additional clinical decision-support tools could be provided by linking to diabetes clinical practice guidelines or embedding the guidelines into the clinical reminder itself.

Nearly two-thirds of veterans reporting hypoglycemia did not have their treatment de-intensified. Providers may not de-intensify because of a determination that a specific individual is on appropriate therapy or because of clinical inertia. Future work could examine the specific reasons that providers decide against de-intensifying treatment in potentially overtreated patients. This could be explored through the addition of a question within the reminder or through qualitative work with providers that would elicit additional detail about their decision-making process.

Future studies also could explore the impact of the intervention on rates of hypoglycemia. Such a study would require validated methods for ascertaining hypoglycemia because reliance on ICD (International Classification of Diseases) codes alone is unlikely to be sufficiently sensitive.

Summary

This QI initiative employed the strength of the EMR to identify patients potentially overtreated and at high risk for hypoglycemia based on several clinical parameters and showed that prompting clinicians to ask simple questions generated a number of treatment changes. These findings suggest that a clinical reminder may be an effective means of reducing the number of patients at high risk of hypoglycemia because of overtreatment.

Disclaimer

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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Duality of Interest

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

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