Efficacy of Patient Aligned Care Team Pharmacist Services in Reaching Diabetes and Hyperlipidemia Treatment Goals

Jaymee L. Gaspar, PharmD; Megan E. Dahlke, PharmD, BCACP; and Barbara Kasper, PharmD, BCACP

The services provided by clinical pharmacy specialists can improve low-density lipoprotein cholesterol and hemoglobin A_{1c} levels in the veterans enrolled in a disease management clinic.

According to the CDC, diabetes mellitus (DM) and hyperlipidemia have been distinguished as major contributors to death and disability among adults within the U.S. Although these diseases may often escape a directly malignant etiology, the complications of these metabolic disorders are correlated with long-term disability. Uncontrolled diabetes contributes to 5 major complications in U.S. adults, including myocardial infarction, cerebral vascular accident, lower extremity amputation, renal failure, and hyperglycemic crisis. Hyperlipidemia is another major risk factor listed for advancing heart disease and ischemic stroke. Medical and preventive care are effective means for declining complication rates, but these chronic diseases continue to increase in frequency.[1,2]

The prevalence of DM and hyperlipidemia among U.S. veterans is uniquely higher than that of the general population. About 9.3% of the U.S. population has been diagnosed with diabetes compared with almost 25% of veterans receiving care through the VHA.[3,4] According to the 2012 National Ambulatory Medical Care Survey, 15.2% of patients receiving nonfederal care had a hyperlipidemia diagnosis compared with > 20% of the U.S. veteran population.[5,6]

PATIENT-CENTERED CARE

A key initiative of the VHA Office of Patient Care Services in providing coordinated health care is the patient aligned care team (PACT). The PACT model seeks to provide communicative patient-centered care and involves primary care providers (PCPs) as well as other clinical and nonclinical affiliates.[7] These team members often include a PCP, a registered and licensed practical nurse, a dietitian, a social worker, clerical support, and a clinical pharmacy specialist (CPS). Each professional uses his or her unique specialty to provide evidence-based care to the veteran. Clinical pharmacy specialist integration into the PACT model is one way to provide greater continuity of care for patients and more comprehensive treatment of chronic diseases. Given the need for regular medication titration, these patients may require a greater allocation of time and resources than PCPs can feasibly give. For this reason, CPSs were integrated into PACTs to allow for focused management of chronic conditions.

Most PACT CPSs at the VA Illiana Health Care System (VAIHCS) have advanced residency training and/or board certification, making them proficient in patient communication, drug knowledge, pharmacology, and therapeutics. Within the VHA, CPSs practice as midlevel providers with a scope of practice. This scope grants them the ability to clinically assess drug therapy, order and evaluate laboratory data, prescribe pertinent medications to treat the disease within the scope,

Dr. Gaspar is a clinical pharmacy specialist at the VA Northern Indiana Health Care System in Marion. **Dr. Dahlke** is a clinical inpatient pharmacist at the Iowa City VA Health Care System, a former clinical pharmacy specialist of the VA Illiana Health Care System in Peoria, Illinois, and an adjunct faculty member for the University of Iowa College of Pharmacy in Iowa City. **Dr. Kasper** is a clinical assistant professor at the University of Missouri-Kansas City School of Pharmacy and a former VA Illiana Residency Program director and clinical pharmacy specialist.

and order consults with other professionals of the PACT team.[8]

Research Studies
Several studies have revealed that pharmacist-driven outpatient interventions for patients with dyslipidemia have significantly reduced low-density lipoprotein cholesterol (LDL-C).[9-14] Mazzolini and colleagues found that VHA pharmacist intervention produced a mean LDL-C reduction of 24.5 mg/dL and increased the percentage of patients reaching their LDL-C goal from 36.8% to 64.3%.[9] Similarly, at another VHA facility, telephone interventions with patients were also effective in reducing veterans' LDL-C levels. Fabbio and colleagues found a mean LDL-C reduction of 44.3 mg/dL when performing retrospective chart reviews of pharmacist interventions.[10] Other pharmacist-driven LDL-C outcomes were also positive compared with that of usual care by PCPs, showing mean LDL-C reductions of 10.7 mg/dL and 10.4 mg/dL.[11,12] All these studies showed positive impacts on outcomes for patients with dyslipidemia. Additionally, these types of interventions have been shown to maintain both patient and PCP satisfaction.[15]

Clinical pharmacist interventions in the primary care setting have shown positive impacts in DM control with hemoglobin A_{1c} (A_{1c}) reductions by as much as 1.3% to 3.4%.[16-19] The highest A_{1c} reductions were evident when pharmacists had the ability to prescribe medications or work in a collaborative practice model with PCPs.[16-18] Independent practice and the ability to prescribe medications have been shown to have more impact than recommendations to physicians alone. Recommendation letters from pharmacists did not produce a significant reduction of A_{1c} in one physician group compared with another physician group not receiving DM management recommendations.[20]

Given the increased prevalence of chronic diseases in the veteran population and the literature to support the value of CPSs as provider extenders, the focus of this analysis was to determine the potential benefit of CPS services to the PACT.

The primary objectives of this analysis were to determine the true impact of PACT CPSs on LDL-C and A_{1c} in the veterans enrolled in VAIHCS Disease State Management (DSM) clinics. If positive impacts were revealed, this study would support expansion of CPS services to include additional staff and the management of additional diseases.
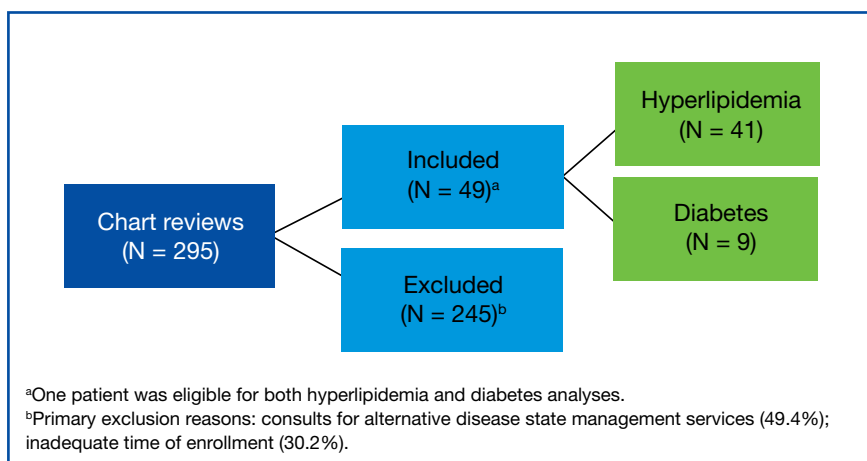
METHODS
This analysis was a retrospective chart review approved by the VA Illiana Publication and Presentation Committee as a quality improvement (QI) project. Data were collected through the VistA electronic medical record. Subject data were analyzed in a multicenter fashion. A total of 5 sites within VAIHCS were included for review. The study subjects acted as their own controls and were distributed proportionally by volume of DSM visits at each VAIHCS location.

The primary objectives of this QI analysis were to determine the efficacy of PACT CPSs in reducing LDL-C and/or A_{1c} levels in veterans enrolled in VAIHCS DSM clinics. The primary endpoints of this study were change from baseline LDL-C to first LDL-C drawn between 6 and 9 months and change from baseline A_{1c} to first A_{1c} drawn between 9 and 12 months after enrollment in DSM clinics.

The secondary objectives of this QI analysis were to determine the efficacy of PACT CPSs in improving high-density lipoprotein cholesterol (HDL-C), triglycerides (TGs), and total cholesterol (TC) levels in veterans enrolled in DSM clinics. The secondary hyperlipidemia endpoints were the change from baseline HDL-C, TG, and TC to first blood work results and percentage of patients who achieved National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP III) LDL-C goal between 6 and 9 months after clinic enrollment.[21] The secondary DM endpoint was the percentage of patients who achieved the recommended American Diabetes Association A_{1c} goal between 9 and 12 months after enrollment. Mean percentage reduction of primary and relevant secondary endpoints were determined for each study subject.

Subjects selected for inclusion within this analysis were U.S.

Table 1. Subjects Meeting LDL-C Goal

LDL-C Goal, mg/dL	No. of Subjects	No. Meeting Goal Posttreatment
< 70	3	0
< 100	33	11
< 130	5	4
Total	41	15

Abbreviation: LDL-C, low-density lipoprotein cholesterol.

Figure 1. Retrospective Chart Distribution

aOne patient was eligible for both hyperlipidemia and diabetes analyses.
bPrimary exclusion reasons: consults for alternative disease state management services (49.4%); inadequate time of enrollment (30.2%).

veterans aged 18 to 75 years who were enrolled in DSM clinics for hyperlipidemia or type 2 DM (T2DM) between September 1, 2011, and September 1, 2013. These subjects did not meet VA performance measures for hyperlipidemia or T2DM at baseline. The key focus of these measures was to include disease prevention and management of diagnosed disease by clinical practice guideline standards. To be included in the analysis, subjects were required to attend DSM clinic appointments for a minimum of 3 months for hyperlipidemia or 6 months for T2DM.

Subjects were excluded from this study if they were nonadherent to clinic visits (defined as missing > 50% of their appointments), were discharged from the clinic due to nonadherence to drug therapy and/or lifestyle interventions, met LDL-C or A_{1c} goals prior to the laboratory collection interval, or had a baseline LDL-C of < 110 mg/dL or baseline A_{1c} of < 8%. Subjects were also excluded if they failed to receive any antihyperlipidemic or antidiabetic agents through the course of their enrollment.

Statistics were derived by averaging the percentage change of laboratory parameters per subject. The time frame used was from baseline to the time of primary and secondary endpoint collection. Due to the QI nature of this analysis, power was not targeted for attainment. A randomized sample of 49 subjects was pulled from the population for complete analysis, which was determined by using a random number generator and analyzing corresponding alphabetized patient charts.

RESULTS

Two hundred ninety-five charts were reviewed to yield 49 subjects eligible for the analysis (Figure 1). One subject was eligible for both hyperlipidemia and T2DM. The primary reasons for exclusion were consults for DSM services not related to T2DM or hyperlipidemia (49.4%) and inadequate time of enrollment (30.2%). Less than 10% of exclusions were due to baseline LDL-C < 110 mg/dL or A_{1c} < 8%, unavailable blood work within the collection interval, nonadherence to clinic visits or medications, or other reasons.

Hyperlipidemia

Means and ranges for LDL-C, TG, and TC were all significantly reduced from baseline (Figure 2). The primary endpoint for hyperlipidemia included a 25.1% reduction in mean LDL-C (95% CI, 0.173-0.327). Secondary endpoints included a 12.9% reduction in mean TG from baseline (95% CI, 0.017-0.241) and a 22.5% reduction in mean TC from baseline (95% CI, 0.174-0.276). A 2.1% increase in mean HDL-C was considered nonsignificant (95% CI, -0.082 to -0.042). The percentage of subjects meeting LDL-C goal between 6 and 9 months after enrollment was 36.7% (Table 1).

Twenty-six subjects (63.4%) did not reach their LDL-C goal between 6 and 9 months after clinic enrollment. Of these subjects, an additional analysis was performed to determine potential contributing factors. Eleven of these subjects received moderate- to high-intensity statin therapy, 2 received low-intensity statin therapy, and 3 (without documented statin intolerance) received no statin therapy. Seven subjects had statin intolerance documented in their charts at baseline or during treatment in DSM clinics. Three subjects had documented nonadherence. Subjects receiving no statin therapy due to intolerance or other reasons were prescribed fibrates, cholestyramine, psyllium, or therapeutic lifestyle changes.

Diabetes

Mean A_{1c} and A_{1c} range resulted in a significant reduction from baseline (Figure 3). The primary endpoint for T2DM included a 3.1% reduction in mean A_{1c} (95% CI, 1.45-5.52). The percentage meeting A_{1c} goal between 9 and 12 months after enrollment was 44.4% (Table 2).

DISCUSSION

The results of this analysis suggest a positive impact of CPSs on the care of veterans within VAIHCS,

consistent with previous literature. The strengths of this study include a true measure of pharmacist intervention via an extended length of enrollment and regular CPS follow-up visits. Additionally, this was a multicenter design across numerous sites within VAIHCS. The variety of sites showed the impact of differing prescribing practice or consulting habits among CPSs and their associated PACT providers. Subjects were analyzed only if they received a prescription for antihyperlipidemic or antidiabetic medications. This exclusion allowed the analysis to focus on CPS medication adjustment skills.

LIMITATIONS

This analysis is limited by its retrospective design and the reliance on chart reviews to collect data. As a retrospective analysis, a direct causality between CPS intervention and change in endpoints cannot be determined. Retrospective chart reviews are also subject to both bias and influence from confounding variables

Table 2. Subjects Meeting A_{1c} Goal

A_{1c} Goal, %	No. of Subjects	No. of Subjects Meeting Goal Posttreatment
< 8	1	0
< 7	8	4
Total	9	4

due to inability to establish blinding. One confounding variable not assessed was the impact of ancillary PACT members on subject outcomes. Therapeutic lifestyle changes implemented by registered dietitians could have confounded A_{1c} and lipid profile improvements throughout the course of the analysis.

A specific limitation for hyperlipidemia included an early exclusion for meeting LDL-C goal before 3 months. After the completion of several chart reviews, it was determined that many of these patients required rapid or minimal medication adjustment to meet their therapeutic goals. The major limitation for T2DM included a small sample size.

This limitation was partially due to the establishment of hyperlipidemia services before T2DM services within VAIHCS DSM clinics. Due to earlier establishment, hyperlipidemia management was better recognized, and consults for this disease were more prevalent. Sample size was also limited for T2DM due to the nature of the chart review and the original data attainment. The review of both diseases was limited due to some subjects not acquiring laboratory values within the predefined collection periods. In some cases, useful data outside the collection interval could not be used.

Although CPSs produced significant reductions in LDL-C, TG, and

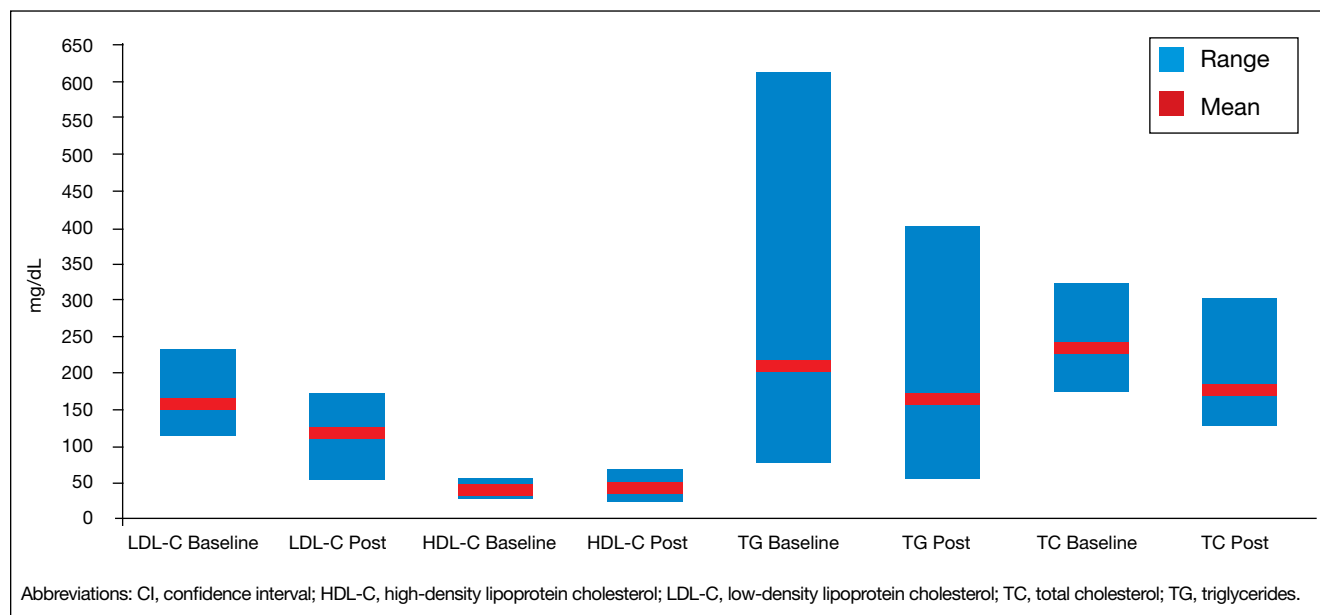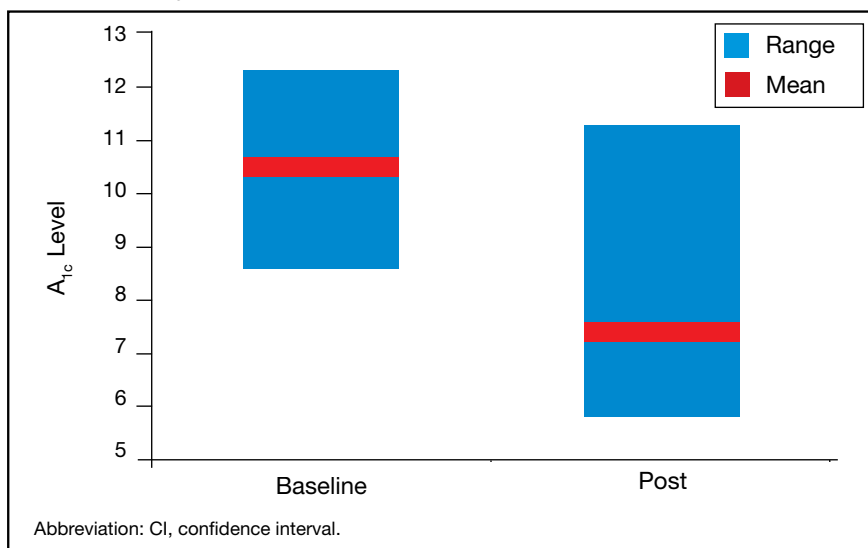## Figure 2. Hyperlipidemia Change From Baseline

Abbreviations: CI, confidence interval; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides.

Figure 3. A_{1c} Change From Baseline (95% CI, 1.45-5.52)

Abbreviation: CI, confidence interval.

CONCLUSION
Pharmacists were able to produce significant improvements in LDL-C and A_{1c} profiles despite the confounding factors mentioned previously. With further analysis, VAIHCS may demonstrate efficacy in other CPS services and have greater potential to expand its services. ●

Author disclosures
The authors report no actual or potential conflicts of interest with regard to this article.

Disclaimer
This quality improvement analysis was performed to improve patient care at the VAIHCS, Danville, IL. It was reviewed by the VHA education department, privacy officer, information security officer, and VAIHCS leadership and was determined to meet guidelines for non-research, which is exempt from IRB review. As a quality improvement project, these data are not generalizable.

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TC, their ability to provide more impactful results was likely limited due to enrollment for statin intolerance. Some studies indicated the incidence of statin intolerance to be about 5% to 10% of the general population.[22] However, in this analysis, 17.1% of patients who did not meet LDL-C goal had some history of or current statin intolerance. Despite this high degree of intolerance, CPS management was still able to effectively improve lipid profiles but to a less significant degree.

A final point to consider is the design of the analysis before the release of the American College of Cardiology/American Heart Association (ACC/AHA) 2013 cholesterol guidelines.[23] Target LDL-C reduction is no longer considered the most appropriate management technique for reducing the risk of atherosclerotic cardiovascular disease (ASCVD). However, the hyperlipidemia endpoints in this analysis were directly related to NCEP-ATP III recommendations. The current guidelines focus on the intensity of statin therapy for patients with ASCVD or elevated risk for ASCVD. With the release of this new guideline, a poststudy analysis was completed to apply the new information to previous practice in VAIHCS DSM clinics. Many subjects were already meeting their statin intensity goal without further intervention. In fact, 46.3% of subjects were meeting their goal at the time of primary endpoint collection. Between the release of the new clinical guideline and February 2014, another 14.6% of subjects had changed therapy and were meeting their statin-intensity goal, with or without pharmacist intervention. Another 17.1% of patients had statin intolerance that may have limited their ability to reach their statin-intensity goal. The remaining 22% of subjects (without statin intolerance) did not have any adjustments in hyperlipidemia profiles since the release of the updated guideline; these patients were scheduled to be contacted as a result of this analysis. Further review of patients meeting LDL-C goal at primary endpoint collection would also be beneficial to ensure appropriate management per current ACC/AHA 2013 guidelines.

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