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Cover Letter

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Abstract

Background and Purpose: This evidence-based project conducted a practice change in a primary care setting to improve provider adherence in monitoring, treating and documenting LDL-C management for adults with type 2 diabetes.

Methods: The project was conducted over 8 weeks. A clinical support tool, the Diabetic LDL Protocol, was developed for the clinic to implement into practice. The providers were instructed to use the tool during each encounter with an adult diabetic patient. Pre- and post-implementation data were abstracted from the electronic health records of 41 patients with type 2 diabetes during the implementation period.

Conclusions: The providers' adherence rate for use of the Diabetic LDL Protocol peaked at 6 weeks post-implementation and declined steadily by 8 weeks. The tool was only used during 29% of the applicable patient visits. Communication issues during implementation of the protocol and electronic health record system restrictions were contributing factors to poor adherence.

Implications for Practice: The use of a clinical support tool may promote adherence to guidelines for diabetic patients in primary care. Integrating the tool into the workflow of a primary care practice and encouraging use of the tool are the major challenges of successful implementation. Further research is necessary to investigate strategies that can overcome clinical inertia and increase provider willingness to comply with new electronic protocols.

Introduction to the Problem

Diabetic patients have an increased risk for cardiovascular disease, with a mortality rate from cardiac disease two to four times higher than individuals without diabetes (Nesto, 2008; Sperl-Hillen et al., 2010). The management of low-density lipoprotein cholesterol (LDL-C) in diabetic patients is a critical component in decreasing cardiovascular disease and mortality for this high-risk population (Nesto, 2008; Sperl-Hillen et al., 2010). In general, primary care providers are not meeting national standards for target LDL-C levels for their diabetic patients (Casagrande, Fradkin Saydah, Rust, & Cowie, 2013; Davidson, 2009; Nesto, 2008; Sperl-Hillen et al., 2010).

Strong evidence indicates that a reduction in LDL-C level results in a proportionate reduction in cardiovascular disease and mortality (Cholesterol Treatment Trialists & Collaborators, 2005, 2008; Shepherd et al., 2006). Studies have estimated that each 1.8mg/dL decrease in LDL-C level reduces the risk of a cardiovascular event by 1% (Katcher, Hill, Lanford, Yoo, & Kris-Etherton, 2009). Primary care providers have a variety of treatment options to assist with LDL-C reduction, including prescribing medications, offering dietary recommendations, and encouraging healthy lifestyle changes (Katcher et al., 2009; National Institute of Health, 2002). Unfortunately, in a busy practice setting, the opportunity to address LDL-C levels is often missed.

Prior Research on Diabetic Clinical Support Tools

LDL-C guidelines have existed for years, yet clinicians still have difficulty meeting these goals for their patients (Sperl-Hillen et al., 2010). Common healthcare specific reasons cited as barriers to implementation of these guidelines are clinician inertia and outdated paper patient health records; *clinical inertia* refers to the failure of a provider to intensify a therapy when a patient is not meeting clinical goals (Sperl-Hillen et al., 2010). Transitioning from a paper chart system to an electronic health record (EHR) has been associated with improved glycemic and cholesterol control for diabetic patients (Cebul, Love, Jain, & Hebert, 2011; Reed et al, 2012). However, simply implementing the EHR may not be enough to make needed changes. The tools and decision support that are imbedded in the EHR likely make the biggest impact in clinician behavior and patient outcomes (Bell et al., 2010; Cebul et al., 2011; O'Connor et al., 2011; Roshanov et al., 2011; Samal, Linder, Lipsitz, & Hicks, 2011; Sperl-Hillen et al., 2010; Weber, Bloom, Pierdon, & Wood, 2007).

With advances in technology, one common solution is the use of the diabetic clinical support tools integrated into the EHR (Cebul et al., 2011; Reed et al., 2012; Sperl-Hillen, et al., 2010). The use of these support tools has demonstrated successful improvements in the use of guidelines in primary care settings (Bell et al., 2010). Furthermore, the use of diabetic clinical support tools has demonstrated increased test rates for intermediate outcomes for diabetic patients including Hemoglobin A1c, LDL-C levels, and blood pressure (O'Connor et al., 2011; Reed et al., 2012; Roshanov et al., 2011; Samal et al., 2011; Sperl-Hillen et al., 2010; Weber et al., 2007.

The problem lies in the actual improvement of these values. Past studies indicated that most clinical support tools merely improve monitoring of these outcomes and do not lead to improved patient outcomes (Sperl-Hillen et al., 2010). Therefore, if the goal is to meet national guidelines for a given outcome, the practice change must not only encourage a provider to obtain lab values or perform testing but also to implement an appropriate intervention. According to Sperl-Hillen et al. (2010), the most successful diabetic support tools overcome clinical inertia and encourage the provider to prescribe more aggressive pharmacological and lifestyle interventions.

In a study by Sperl-Hillen et al. (2010), the Diabetes Wizard EHR clinical decision support tool was implemented as a randomized trial that included 41 primary care providers and 2556 diabetic patients at 11 primary care clinics. Six clinics were randomly chosen to implement the tool, while the other clinics served as controls. The intent of the intervention was to change provider behavior through the use of clinical support tools to ultimately improve HbA1c, blood pressure, and LDL-C levels in type 2 diabetics. Results showed that the intervention group used the Diabetes Wizard 62.6% of the time for adult diabetic patients, indicating that the tool was

successful in changing provider behavior. Data analysis indicated that the Diabetes Wizard resulted in significantly improved Hb A1C and systolic blood pressure, but no significant change in LDL-C levels occurred compared to the control group. The physicians reported high satisfaction with the use of the tool.

Methods

This study was conducted using a pre- and post-implementation design. A baseline review of 87 medical records was conducted to obtain a collective overall baseline adherence rate for the providers. Post-implementation data were collected to monitor adherence rates over the 8-week implementation period for each provider individually and collectively as group. Post-implementation data included adherence information from a total of 41 patient encounters. The providers received a survey at four-weeks post implementation to assess their satisfaction with the Diabetic LDL Protocol and office workflow.

Study Setting and Sampling

The study was conducted in a family-owned primary care clinic that serves approximately 6400 patients in the Tualatin Valley of Oregon. The clinic offers comprehensive care to individuals and families at two locations; and services include routine care, physicals, vaccinations, respiratory care, back and neck pain, personal injury and worker's compensation, diabetes care and education, healthy heart care, women's health, and in-house x-ray and blood work. Providers include two doctors of osteopathic medicine (DOs), two family nurse practitioners (FNPs), one physician's assistant (PA), and multiple medical assistants (MAs). Medical records of each patient 18 years or older with a hemoglobin A1C greater than 6% and an LDL-C level greater than 100 mg/dL who had had an office visit with a provider at the clinic within the 8-week implementation time frame were included in the data-collection process.

Data Collection

Provider-specific data were collected to determine adherence rates for each individual primary care provider and then as a group. The following data were collected during the implementation period: frequency of use of the Diabetic LDL Protocol, percent of patients with current LDL-C levels (within the last year), percent of patients with a prescription for a lipid-lowering medication, and percent of patients with appropriate ICD-9 or ICD-10 codes for hyperlipidemia accurately documented in the EHR problem list.

Implementation Materials

An evidence-based electronic clinical decision support tool, the Diabetic LDL Protocol (see Figure 1) was designed and implemented into the EHR at the center. Providers were given copies of the office workflow diagram, which detailed when and how to use the Diabetic LDL Protocol in practice. The MAs were asked to scrub the chart of each patient being seen in the clinic at the start of the day, then to mark on the clinic's visit summary sheet if the patient was a diabetic, 18 years or older with a hemoglobin A1C greater than 6% and LDL-C level greater than 100 mg/dL. The provider was to then complete the Diabetic LDL Protocol during the clinical encounter. Patient education handouts on lifestyle and dietary modifications were given to the clinic for replication and distribution to patients. These documents served as a reminder for the providers to follow current evidence-based practice in the management and monitoring of LDL-C values in diabetic patients.

Procedures

This study was approved by the University of Portland (Oregon)'s institutional review board. Participation in the project was voluntary and all subjects signed an informed consent. Project authors signed confidentiality agreements at the clinic to ensure patient confidentially and protection of personal health information. All information collected was de-identified and anonymous.

Prior to their implementation of the Diabetic LDL Protocol, the clinic providers attended a 60-minute educational session. Information regarding the importance of LDL-C management in diabetics and the intent and use of the Diabetic LDL Protocol were discussed. The staff members were instructed on the workflow changes that would be necessary to implement the new protocol, and providers received education on lifestyle and dietary approaches to lowering lipid levels. Providers were also encouraged to ask questions and propose changes to the office workflow and Diabetic LDL Protocol. Emails, meetings, and a formal presentation were used to ensure that instructions were provided and expectations were established for implementation. A target LDL-C goal was agreed upon and set at less than 100mg/dL for patients with a hemoglobin A1c greater than 6%.

Data were collected from the EHR of patients who met inclusion criteria prior to implementation. The Diabetic LDL Protocol was then implemented over an eight-week period of time. After four weeks, six weeks, and eight weeks post-implementation, the EHR of eligible patients were reviewed.

Data Analysis

Frequencies were used to determine differences between pre- and post-implementation rates of the percent of patients with current LDL-C levels (within the last year), percent of

patients with a prescription for a lipid-lowering medication, and percent of patients with appropriate ICD-9 or ICD-10 codes for hyperlipidemia accurately documented in the EHR problem list. Provider adherence to use of the Diabetic LDL Protocol was assessed by determining frequency of use over the implementation period.

Results

Sample Characteristics

Eighty-seven medical records were reviewed prior to implementation. Among these patients, 47 (54%) had a LDL-C level documented within the last 12 months, 42 (48%) were prescribed a lipid-lowering medication, and 69 (79%) had an appropriate ICD- 9 code documented related to their elevated LDL-C level. Care was provided by five providers: two DOs, two NPs, one PA and their five MAs.

Use of Diabetic LDL Protocol

At four weeks post-implementation, there had been 12 patient encounters that met the requirements for use of the Diabetic LDL Protocol; however, none of the providers had used the protocol during these encounters. Between weeks four and six, 20 patient encounters met the requirements for use of the Diabetic LDL Protocol and it was used during 11 (55%) of these patient encounters. Among these patients, 14 (70%) had a LDL-C level documented within the last 12 months, 12 (60%) were prescribed a lipid-lowering medication, and 16 (80%) had an appropriate ICD- 9 code documented related to their elevated LDL-C level. At eight weeks post-implementation, there had been 9 additional patient encounters and the Diabetic LDL Protocol was used during only one (11%) of these patient encounters. Among these patients, 5 (56%) had a LDL-C level documented within the last 12 months, 8 (89%) were prescribed a lipid-lowering

medication, and 9 (100%) had an appropriate ICD- 9 code documented related to their elevated LDL-C level.

At eight weeks post-implementation, a total of 41 patient encounters had met the requirements for use of the Diabetic LDL Protocol, and the protocol was used during 12 (29%) of them. Among these 41 patients, 28 (68%) had a LDL-C level documented within the last 12 months, 27 (66%) were prescribed a lipid-lowering medication, and 35 (85%) had an appropriate ICD- 9 code documented related to their elevated LDL-C level (see Table 1).

Table 1

Pre- and Post-Implementation Results of Outcome Measures

Category	Frequency	Percent
Pre-implementation (n= 87)		
LDL-C[a] <12 months	47	54
Medication	42	48
ICD-9[b]	69	79
Post-implementation (4 weeks; n= 12)		
Protocol used	0	0
LDL-C <12 months	9	75
Medication	7	58
ICD-9	10	83
Post-implementation (6 weeks; n=20)		
Protocol used	11	55
LDL-C <12 months	14	70
Medication	12	60
ICD-9	16	80
Post-implementation (8 weeks; n=9)		
Protocol used	1	11
LDL-C <12 months	5	56
Medication	8	89
ICD-9	9	100

[a]LDL-C = low-density lipoprotein cholesterol
[b]ICD-9 = international classification of diseases, 9th rev.

Processes of Implementation

Providers were given a survey at four weeks post-implementation to assess their satisfaction with the pre-implementation education regarding the purpose of the Diabetic LDL Protocol and clinic workflow as well as ease of use and value in caring for diabetic patients. Providers were asked to rate their satisfaction on a Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). Open-ended questions were asked so providers could offer feedback and suggest changes moving forward. Surveys were given to the five primary care providers and their five MAs as well as the RN care manager; 64% of the surveys were returned, all anonymously.

Of the respondents, 57% indicated they were satisfied with the 60-minute education session given prior to implementation; the remaining 43% of respondents did not attend the education session. Providers expressed that they found education regarding the importance of managing LDL-C values in diabetics beneficial. One provider wanted coaching on interacting with patients regarding LDL-C values. Providers were either satisfied (43%) or neutral (43%) regarding office workflow. Feedback included increasing communication in the clinic and more involvement from the MAs in checking LDL-C values. Of the providers, 29% found the Diabetic LDL Protocol valuable in caring for diabetic patients, the other 71% were indifferent. Providers thought the Diabetic LDL Protocol reminded them to use statins in diabetics, order lipid panels if the last LDL-C value was more than 12 months earlier, and that the overall goal of the protocol was to improve the health of patients.

Discussion

There were no significant increases in LDL-C monitoring, medication management, or ICD-9 documentation in the post-implementation phase. The data reflect overall trends in LDL-C documentation, prescribing of medications, and ICD-9 code documentation for the patients during the implementation period. Since the providers may have already met these requirements prior to the encounter during the study, the values do not necessarily indicate that the use of the protocol led to changes in provider behavior. However, use of the protocol may be associated with improved LDL-C management.

Use of the Diabetic LDL Protocol peaked at 6 weeks and steadily declined by 8 weeks. These findings are consistent with previous studies, which have shown that merely using electronic alerts in the EHR does not improve patient outcomes; changes are best made when clinical support tools encourage a provider to implement the appropriate intervention (Sperl-Hillen et al., 2010).

Results of this study demonstrate that electronic alerts and inferior clinical support tools do not overcome clinical inertia in the management of LDL-C values in diabetics. Providers at the clinic were not providing care consistent with national guidelines targeting LDL-C values in diabetics both prior to and after the implementation as evidenced by failure to use the Diabetic LDL Protocol and to more aggressively treat elevated LDL-C values.

An important factor to consider when determining the potential impact of the electronic tool on patient outcomes is the capability of the clinic's EHR system. Due to restrictions within the EHR system at this clinic, the staff were unable to fully create an electronic version of the Diabetic LDL Protocol as initially designed by the project authors. The clinic was only able to create a tool that asked providers if a patient's LDL-C was greater than 100 mg/dL and, if so, to

ask if an educational handout on diet was given and if the patient was on statins. They were unable to create an algorithm that could incorporate ordering of lab values, making medication adjustments, documenting the appropriate ICD-9 code, and recommending appropriate follow-up. Since the design of the protocol was adjusted to fit the clinic's EHR capabilities and was not fully used as intended, improved compliance with the Diabetic LDL Protocol may not necessarily result in improved patient outcomes overtime.

Previous studies have demonstrated that the success to implementing practice change lies in clear communication about the purpose and process of the implementation as well as early buy-in from medical staff (O'Connor et al., 2011; Sperl-Hillen et al., 2010). The results of this study reinforce the importance of frequently communicating the purpose and process of the intervention both pre- and post-implementation. Thus, the lack of provider adherence and use of the Diabetic LDL Protocol, and a more aggressive management of LDL-C values may be contributed to insufficient communication regarding the purpose and process of implementation as evidenced by one provider stating he or she was unaware of the protocol four weeks post-implementation. Furthermore, post-implementation communication was mainly focused on the primary care providers and not the MAs, which is likely to have impacted adherence rates due to increased burden of responsibility on the primary care providers.

Limitations

The limitations of this study must be considered when assessing its implications to the care of patients with diabetes. First, the study was limited to a small family-owned primary care clinic in the Tualatin Valley of Oregon, which may differ from other care settings and geographical locations. As previously mentioned, the protocol was not implemented as initially designed. Due to constraints within the EHR, the clinic's informatics department created an

alternative version of the evidence-based protocol. These changes likely impacted the quality of the electronic tool.

The small sample size is an additional limitation. Only five primary care providers practiced within the clinic during the study, and they saw a total of 41 patients who met inclusion criteria for EHR review. The small sample size and short duration of the study pose the questions of whether the Diabetic LDL Protocol will be used in the long term. Furthermore, the short duration of the study was such that patient outcomes were not tracked. It is unknown if use of the Diabetic LDL Protocol will affect changes in patient outcomes at this clinic.

Implications

Implications for Practice

The findings of this study are relevant to primary care clinical practice. Findings indicate that the use of health management tools in the EHR helps providers adhere to evidence-based recommendations regarding LDL-C management in diabetics. Unfortunately, the EHR at the clinic was unable to fully support the Diabetic LDL Protocol in its entirety, likely decreasing its ability to effect changes in patients' LDL-C values. In order for clinics to fully comply with reporting and demonstrating meaningful use of the EHR in order to receive reimbursement under the Medicare and Medicaid Electronic Health Record Incentive Program (Centers for Medicare and Medicaid Services, 2014), EHRs need to be able to support health management tools and algorithms designed to increase provider compliance with evidence-based practice. Furthermore, use of health management tools embedded in the EHR should be accompanied by periodic chart audits to determine adherence with practice recommendations and to monitor changes in patient outcomes. Data collection, even with an EHR, can be a tedious process. By embedding health management tools into the EHR in a way that automatically collects, analyzes, and provides a

breakdown of data can benefit a clinic's ability to track provider compliance and patient outcomes (Umar-Kamara & Tufts, 2013).

Implications for Research

Findings from this study have implications for future research. Longer studies should be conducted across different primary care settings and with control groups to determine provider acceptance and compliance with electronic Diabetic LDL-C support tools such as the Diabetic LDL Protocol, and to track patient outcomes. Results from future studies can help determine how to best use EHRs to improve the quality of care provided to diabetics with elevated LDL-C levels.

Conclusion

This clinic will not likely experience an improvement in patient outcomes without more aggressive medical and lifestyle management for its diabetic population. Considering the EHR limitations and the communication issues regarding the new protocol, practice change seems unlikely under the current conditions. Further attempts to change practice at this clinic will require updates to the EHR system that will enhance ease of use and will incorporate all the necessary components of LDL-C management. Improved communication methods and additional support and training will be necessary to increase provider buy-in to inspire practice change and promote sustainability.

Diabetic LDL Protocol

**** Patient Information ****

	Value	Date	Goal
LDL-C[a]	xxmg/dL/ or none on file	00/00/00	<100mg/dL

Current LDL-C lowering medication:
XYZ or none on file

Does patient have a current LDL-C value (within the past 12-months?)

- No: order fasting lipid panel
- Yes: is LDL-C greater than 100mg/dL?
  - No: no changes to therapy
  - Yes: consider lifestyle modifications and/or medication

**** Treatments to Consider ****

* Lifestyle modifications
  - Diet: TLC[b], portfolio, Mediterranean diet
  - Exercise, smoking cessation, limit alcohol consumption, weight management

* Consider ordering/increasing lipid-lowering medication with lifestyle modifications

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**** Follow-Up ****

Consider follow-up visits every 8 weeks until better LDL-C control is achieved!

How was LDL-C treatment modified?

- Lifestyle modification
- Lifestyle modification AND medication
- Medication
- No treatment given (why)

Figure 1. Diabetic LDL protocol.
[a]LDL-C = low-density lipoprotein cholesterol
[b]TLC = therapeutic lifestyle changes

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