collaborative drug therapy management protocols are defined and written agreements between pharmacists and providers that allow pharmacists to optimize medication therapy management for individual patients. Under these protocols, pharmacists have prescriptive authority and may initiate, adjust, continue, monitor, and/or discontinue medication therapies.1

Protocols such as these have expanded the pharmacist’s role, particularly in the ambulatory setting. These protocols have led to significant improvements in healthcare outcomes for patients with chronic diseases, such as diabetes, hypertension, dyslipidemia, and anticoagulation disorders.2 However, barriers to protocol implementation exist, such as having a poor understanding of the roles and responsibilities of the pharmacist, territoriality, or a lack of administrative support.3 These barriers may adversely affect the success of protocol implementation.

To overcome these barriers, it is imperative that providers receive effective communication and education about newly implemented collaborative drug therapy management protocols. Assessment of the level of pro-
KEY POINTS

- Collaborative drug therapy management protocols have significantly improved healthcare outcomes for patients with chronic diseases, such as diabetes.
- This single-center, prospective study examined the use of collaborative drug therapy management protocols for type 2 diabetes and assessed pharmacist and provider satisfaction.
- In a satisfaction survey of 24 providers or clinical pharmacists, 88% had favorable responses toward the protocol and its effect on access to and quality of care.
- Most (92%) of the providers were able to spend extra time with patients as a result of using a protocol, and 92% said it was easy to refer patients per the protocol.
- In all, 96% of the providers approved of the protocol-driven services, and 67% of the pharmacists were satisfied with how they managed patients with type 2 diabetes using the protocol.
- Provider report cards can increase the number of appropriate patient referrals to pharmacy for type 2 diabetes protocol management in the ambulatory care setting.
- Pharmacist-led protocols can allow providers to spend more time with patients to manage additional acute and chronic disease states.
- Future studies are needed to assess patient satisfaction with pharmacist-led collaborative drug therapy management protocols.

Pharmacist and provider satisfaction with collaborative drug therapy management protocols may also identify barriers to implementation and other factors that may affect the success of the protocol’s execution.

In a recent pilot study by Hansen and colleagues that had the primary end point of measuring the levels of patient and provider satisfaction with a pharmacist-led drug therapy program for oncology-based symptom management, 11 of 12 patients had favorable responses regarding satisfaction with the quality of services provided by pharmacists.4 Similarly, all the oncologists surveyed (N = 5) strongly supported the continuation of these pharmacist-led services.4 Although only a small number of participants were included in that study, other studies have also shown increased provider and patient satisfaction scores when pharmacists prescribe as part of a collaborative drug therapy agreement.5-8

The results of the pilot study by Hansen and colleagues demonstrated that patients and providers displayed favorable responses to the services provided by pharmacists over a short time.4 Although the investigators indicated that the drug therapy program was expected to grow and expand its pharmacy services in light of the study’s results, they did not discuss how the results may affect changes to the protocol or how they may influence the implementation process of future protocols.4

To assess this gap in the literature regarding protocol implementation, we studied the implementation process of a new pharmacist-led type 2 diabetes collaborative drug therapy management protocol at our center. The objectives of our study were to determine the preferred method of educating providers about the protocol, to assess provider and pharmacist satisfaction with the implementation of the protocol, and to characterize the population referred to pharmacists during the study time frame.

Methods

This was a single-center, prospective cohort study of providers and pharmacists who were practicing within a pharmacist-led type 2 diabetes collaborative drug therapy management protocol. The 4 ambulatory care clinics that participated in the study were all part of an integrated healthcare system affiliated with an urban, underserved, nonprofit, safety-net hospital. The study was approved by the Colorado Multiple Institutional Review Board.

Provider groups at each clinic were educated about the protocol in 1 of 2 ways. Providers at 2 primary care clinics received education about the protocol at a provider meeting. Providers at 2 other primary care clinics received a personalized provider report card. The personalized provider report card identified patients within the provider’s panel who met the criteria for pharmacist referral under the protocol (Table 1).

**Table 1 Example of a Personalized Provider Report Card**

<table>
<thead>
<tr>
<th>Medical record number</th>
<th>Patient name</th>
<th>Next appointment</th>
<th>Last A1c level, %</th>
<th>Date of last A1c measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AAA</td>
<td>9.0</td>
<td>1/4/2017</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>BBB</td>
<td>1/31/2017</td>
<td>9.2</td>
<td>7/15/2016</td>
</tr>
<tr>
<td>3</td>
<td>CCC</td>
<td>10.3</td>
<td>3/18/2016</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>DDD</td>
<td>2/20/2017</td>
<td>10.7</td>
<td>12/22/2016</td>
</tr>
<tr>
<td>5</td>
<td>EEE</td>
<td>10.8</td>
<td>12/2/2016</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>FFF</td>
<td>11.9</td>
<td>1/14/2016</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>GGG</td>
<td>12.7</td>
<td>11/3/2016</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>HHH</td>
<td>13.0</td>
<td>9/12/2016</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>III</td>
<td>15.4</td>
<td>1/25/2016</td>
<td></td>
</tr>
</tbody>
</table>

A1c indicates glycated hemoglobin.
Patients with a glycated hemoglobin (A₁c) of >9% qualified for pharmacy management of type 2 diabetes per the protocol. Providers at all 4 primary care clinics also received education via e-mail about the protocol.

After implementation of the protocol, the number of patients referred per protocol was tracked for 2 months. The number of referrals was stratified by clinic and by method of provider education regarding the protocol.

The levels of provider and pharmacist satisfaction with the protocol were assessed via an anonymous online survey. Before the survey, a statement was included indicating that participants who agreed to complete the survey also provided informed consent to participate in the study. “Strongly agree” and “somewhat agree” were considered favorable responses. Surveys were administered via SurveyMonkey and were e-mailed out approximately 2 months after the implementation of the protocol. The survey responses were reported using descriptive statistics.

The demographics for the patients who were referred were collected via chart review and were reported using descriptive statistics.

Results

Over the 2-month study period, a total of 54 patients with type 2 diabetes were referred for pharmacist management per protocol. Of the 54 patients, 48 (89%) were referred by providers who received a personalized provider report card (Figure 1).

Patient demographics and characteristics are summarized in Table 2. The majority of patients referred were Hispanic (63%), followed by African American (16.7%) and Caucasian (14.8%). The distribution of male and female patients referred was even.

The mean A₁c level of referred patients was 10.7% (standard deviation, ± 1.7%). At the time of referral, 75.9% and 81.5% of patients, respectively, were receiving therapy for dyslipidemia and hypertension. In addition, many patients had co-existing conditions, including chronic kidney disease (9.3%), atherosclerotic cardiovascular disease (13%), retinopathy (13%), neuropathy (38.9%), and/or nephropathy (35.2%).

Table 2: Baseline Characteristics of Patients Referred to a Pharmacist

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients (N = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>27 (50)</td>
</tr>
<tr>
<td>Female, N (%)</td>
<td>27 (50)</td>
</tr>
<tr>
<td>Mean (± SD) age, yr</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58 (± 10.2)</td>
</tr>
<tr>
<td>Female</td>
<td>52 (± 9.6)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic, N (%)</td>
<td>34 (63)</td>
</tr>
<tr>
<td>African American, N (%)</td>
<td>9 (16.7)</td>
</tr>
<tr>
<td>Caucasian, N (%)</td>
<td>8 (14.8)</td>
</tr>
<tr>
<td>Other, N (%)</td>
<td>3 (5.5)</td>
</tr>
<tr>
<td>Mean (± SD) baseline A₁c concentration, %</td>
<td>10.7 (± 1.7)</td>
</tr>
<tr>
<td>Mean (± SD) estimated glucose, mg/dL*</td>
<td>259 (± 40.6)</td>
</tr>
<tr>
<td>Mean (± SD) weight, kg</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>96.1 (± 21.7)</td>
</tr>
<tr>
<td>Female</td>
<td>81.9 (± 16.9)</td>
</tr>
<tr>
<td>Concomitant therapies</td>
<td></td>
</tr>
<tr>
<td>Hypertension, N (%)</td>
<td>44 (81.5)</td>
</tr>
<tr>
<td>Dyslipidemia, N (%)</td>
<td>41 (75.9)</td>
</tr>
<tr>
<td>Co-existing conditions</td>
<td></td>
</tr>
<tr>
<td>Neuropathy, N (%)</td>
<td>21 (38.9)</td>
</tr>
<tr>
<td>Nephropathy, N (%)</td>
<td>19 (35.2)</td>
</tr>
<tr>
<td>Retinopathy, N (%)</td>
<td>7 (13)</td>
</tr>
<tr>
<td>Atherosclerotic cardiovascular disease, N (%)</td>
<td>7 (13)</td>
</tr>
<tr>
<td>Chronic kidney disease, N (%)</td>
<td>5 (9.3)</td>
</tr>
</tbody>
</table>

*Unable to report in 2 patients because of elevated levels. A₁c indicates glycated hemoglobin; BMI, body mass index; SD, standard deviation.
sponded favorably regarding the overall satisfaction with services provided by pharmacists per the protocol.

All pharmacists responded favorably to the question inquiring if they felt they were “practicing at the top of their professional license” under the protocol (Figure 3). Typically, practicing at the top of one’s license implies that the pharmacist is allowed to perform medical and cognitive services, for which few pharmacists are qualified.

Half of the pharmacists who responded to the survey somewhat disagreed that they received more referrals per month on average since the implementation of a protocol, and half were undecided about whether the protocol strengthened their relationships with the providers at their clinic. Of the 6 pharmacists who responded to the survey, 4 (67%) responded favorably pertaining to the ease of protocol implementation and to the overall satisfaction with the role they have played in managing patients with type 2 diabetes per the protocol (Figure 3).

Providers who personalized the report card referred more patients than providers who did not receive the report card. Nearly all the providers were satisfied with the protocol-driven services, and the majority of pharmacists were satisfied with their role in managing patients with type 2 diabetes per the protocol.

Of note, several differences among the clinics included in the study are significant. The clinic that received the fewest referrals (4%) is the largest internal medicine clinic in the health system and has the most (2.2) pharmacist full-time equivalents. Before the implementation of the protocol, this clinic was undergoing major leadership and provider transitions, including the transfer of approximately 50% of its providers to a newly opened clinic and hiring new providers to fill their ensuing vacancies. Thus, the changes at this clinic might have affected the number of patients referred.

Another clinic that received very few (7%) referrals has had an established nurse-led insulin titration program in place since 2007. This may have reduced the need (or perceived need) to refer patients to the pharmacist for management. The clinic that received the largest number of referrals (46%) is the clinic with the longest established clinical pharmacy services.

The clinic with the second largest number of referrals (43%) is the only family medicine clinic among the 4 clinics included in the study. It is also the newest clinic and has therefore been providing clinical pharmacy services for the shortest amount of time; however, the pharmacist hired into the newest clinic was well-known to providers across the system.

Of note, the clinics that had more resources dedicated to managing patients with type 2 diabetes (i.e., full-time equivalent pharmacists and nurses) received the fewest referrals. The clinics that had pharmacists staffed.
ing for the longest and shortest amounts of time received more referrals.

**Discussion**

Given the differences in clinic cultures and dynamics, we cannot draw conclusions regarding the number of patient referrals based on specific clinic characteristics. Although potentially more patients could have been referred for type 2 diabetes management at the clinics that received education about the protocol via a provider meeting, in our study, providers who received personalized provider report cards referred the vast majority of patients. Overtly identifying patients who met the referral criteria streamlined the process for providers to promptly refer patients versus expecting providers to recall referral criteria during patient visits.

We cannot conclude that clinic characteristics versus provider report cards drove referrals, but it is likely that each contributed to the difference in referral numbers. Nevertheless, because 89% of patients were referred by providers who received the report card, the outcomes of this study will lead to an increase in the utilization of report cards for providers when implementing future collaborative drug therapy management protocols within our organization. Provider report cards may also be used for ongoing protocol referral management to inform providers of new patients who qualify for pharmacy referral.

In addition to increasing patient referral numbers for the pharmacy management of diabetes, the utilization of provider report cards may also positively affect healthcare outcomes and reduce healthcare costs. For example, several studies have shown reductions in the risks for diabetes-related hospitalizations, healthcare costs, and A1c for patients enrolled in pharmacist-led diabetes programs.1,9-12 Therefore, the more patients enrolled in these programs, the more potential there is to improve healthcare outcomes and drive down costs associated with diabetes.

In 2012, the economic costs of diabetes alone in the United States was $245 billion compared with $202 billion in 2007, of which $76 billion is attributed to diabetes-associated inpatient care.13 Considering the economic burden of diagnosed diabetes on society, pharmacist-led chronic disease management programs may ultimately incentivize payers to reimburse pharmacists for their services.

Because we investigated the real-time implementation of a new collaborative drug therapy management protocol, the study has practical applications for other institutions that are seeking to evaluate the implementation process of collaborative drug therapy management protocols within their clinics. In addition, the protocol was implemented within a heterogeneous mix of 3 internal medicine clinics and 1 family medicine clinic with attending, resident, and mid-level providers.

The variety of clinic and provider types included in the study allows the results to be applicable to several ambulatory care settings. Given the high survey response rate, the feedback that was received can be used to help facilitate discussion with providers and pharmacists about ways to make the referral process of future collaborative drug therapy management protocols more efficient and straightforward.

**Limitations**

This study has several limitations. This study was conducted over a 2-month period. A longer study duration might have yielded different numbers of referrals and survey responses given that providers and pharmacists would have had more time to familiarize themselves with the protocol. A larger number of providers and pharmacists surveyed may have produced different survey responses.

Another limitation is that pharmacists were already co-managing patients with type 2 diabetes in collaboration with providers before the implementation of a protocol. However, during that time, no formalized method was available that allowed providers to refer patients for pharmacist-led type 2 diabetes management.

Furthermore, the protocol allowed pharmacists to manage patients without having to obtain a provider co-signature on laboratory orders or on medication changes. To comply with state regulations, pharmacists can only manage a patient’s medication therapy per protocol if there is a patient-specific referral order documented in the medical record. However, providers continued to refer patients outside this process, which prevented those referrals from being counted in our study, because a formal referral order was not placed.

In addition, an electronic referral order was not created at the time of the implementation of the protocol, and instead, providers had to document and sign an encounter, result, or telephone note in the patient’s medical record indicating that they were referring the patient to a pharmacist for type 2 diabetes protocol management. This referral process takes more time and effort than entering an electronic referral order, which might have led to referrals being missed or delayed.

As described, the clinics differed from one another in several aspects. It is unknown whether these differences were more or less influential in affecting the number of referrals.

Finally, we did not assess patient healthcare outcomes (eg, change in A1c), given the relatively short study time period. We acknowledge that assessing patient health-
care outcomes could enhance the utility of creating additional pharmacist-managed disease state programs to improve disease control and reduce healthcare costs.

Conclusions
Our study results suggest that a personalized provider report card can be utilized in the ambulatory care setting to increase the number of appropriate patient referrals to pharmacy for type 2 diabetes protocol management. Moreover, pharmacist-led protocols can allow providers to spend additional time with patients to manage other acute and chronic disease states.

Because several studies have shown a reduction in healthcare costs associated with type 2 diabetes and an improvement in A1c levels for patients enrolled in pharmacist-managed diabetes programs, it is imperative to determine the preferred method of implementing collaborative drug therapy management protocols to increase the number of patients referred for pharmacy services. Optimizing the ability of pharmacists to manage more patients with chronic diseases via collaborative drug therapy management protocols has the potential to affect healthcare outcomes positively.

Future studies should be conducted within the same clinic, for a longer duration, and with a greater number of patients, and should assess healthcare outcomes, such as reductions in A1c levels, hospitalizations, and emergency department visits. The studies should also assess patient satisfaction with pharmacist-led collaborative drug therapy management protocols.

Author Disclosure Statement
Dr Al-Omar, Dr Anderson, Dr Cizmic, and Dr Vlasimsky have no conflicts of interest to report.

References

STAKEHOLDER PERSPECTIVE

Collaborative Efforts Help the Avoidance of Diabetes Mismanagement

By Jack E. Fincham, PhD, RPh
Professor, Department of Pharmaceutical and Administrative Sciences, Presbyterian College School of Pharmacy, Clinton, SC

In the 5-year period from 2012 to 2017, the number of prescriptions for diabetes medications in the United States rose from 275 million to 338 million, an increase of 23%.1 The cost of diabetes mismanagement is staggering; it is estimated that 40% of all diabetes-related costs result from hospital admissions and increased lengths of stay for uncontrolled diabetes.2 In 2017, the economic estimates for the cost of diabetes in the United States alone were estimated to be $327 billion, including $237 billion in direct medical costs and $90 billion in reduced productivity.3

PROVIDERS: In their excellent study in this issue, Al-Omar and colleagues found high rates of satisfaction with provider and pharmacist satisfaction with the phar-
STAKEHOLDER PERSPECTIVE Continued

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CLINICAL

Pharmacist-led protocol for diabetes management. Results of an observational UK study utilizing the National Institute for Health and Care Excellence (NICE) guidelines to assess the adherence to all 9 key care processes for type 2 diabetes, showed an increase of meeting goals from 46% at baseline to 58% within 1 year. This rate, however, diminished a year later, suggesting that such efforts should be continued.

In a thorough review of 118 interventions, Chrvala and colleagues showed that engagement in diabetes self-management education resulted in significant decreases in hemoglobin A1c levels. In a similar analysis of multiple studies that examined the impact of pharmacist-led diabetes management protocols involving more than 5,700 patients, Pousinho and colleagues showed that these pharmacist-led efforts were very successful in improving diabetes management.

PATIENTS: The best method for controlling diabetes rests in the hands of the patient. Patients are their own best advocates, and they achieve success by working with their caregivers. The NICE Medicines Optimisation guideline provides excellent templates for the self-management of many chronic conditions, including diabetes. Berns has detailed the basic framework of this guideline, which includes an individualized documented self-management plan that is provided to patients. This involves tailoring of plans to a patient’s specific knowledge and skill set pertaining to diabetes, the benefits and risks of using the plan, incorporation of the patient’s values and preferences, and support that can be provided to patients to help them meet their individualized goals.

The burdens of the costs of diabetes and the mismanagement of therapies affect every age group. The Centers for Disease Control and Prevention (CDC) National Diabetes Statistics Report indicates that 30.3 million (9.4%) Americans have diabetes; of these people, 23.1 million are diagnosed and 7.2 million (23.8%) remain undiagnosed. The CDC further estimates that approximately 84.1 million (34%) US adults have prediabetes, of whom 23.1 million are aged ≥65 years.

PAYERS: A specific concern for aging adults is the presence of comorbid chronic diseases that can exacerbate the sequelae of poorly maintained diabetes control. The potential deterioration of kidney function is only one of these conditions that affects patients with diabetes who are aged ≥65 years. Gregg and colleagues have provided definitive explanations of the impact of diabetes over time on patients aged ≥65 years. The cost implications of diabetes treatments for the US Medicare program must also be considered. Choi and colleagues explored medication costs and their impact on Medicare Part D beneficiaries, and how out-of-pocket costs for these patients can lead to less-than-ideal adherence and persistence with drugs that are becoming more expensive.

In their article, Al-Omar and colleagues have presented how pharmacist-led diabetes management protocols can have a very positive impact on the providers who collaborate to deliver care for patients with diabetes. The real beneficiaries of this collaborative effort are the patients who receive enhanced delivery of care.