Introduction

According to the American Diabetes Association, "one in every seven healthcare dollars is spent directly treating diabetes and its complications," making it the most expensive chronic disease in the United States.¹ Such complications can include vaccine-preventable illnesses as well as atherosclerotic cardiovascular disease (ASCVD), which is the leading cause of morbidity and mortality in patients with diabetes.² To help prevent cardiovascular events from occurring and to minimize risk factors, the ADA recommends pharmacological therapies such as ACE inhibitors, ARBs, calcium channel blockers, thiazides, statins, and aspirin depending on age and past medical history. Recent updates in the 2018 ADA guidelines have added specific recommendations that patients who have ASCVD and type 2 diabetes should be placed on agents indicated to reduce the risk of risk of major adverse cardiac events, which include Victoza[®] (liraglutide) and Jardiance[®] (empagliflozin).² Despite these evidence-based recommendations from the ADA, the rates of patients with diabetes that should be on recommended blood pressure agents, statins, antiplatelet, and cardiovascular mortality reduction agents is suboptimal. Previous studies have demonstrated how community pharmacists have been able to create significant gap closures in statin³ and aspirin therapy⁴ in diabetes patients through pharmacist-to-provider interventions.

In the 2015 National Health Interview Survey, from the adults 18 years of age with diagnosed diabetes, only 61.6% had an influenza vaccine in the past year, 52.6% had a pneumococcal vaccine, and 17.1% had the 3-dose vaccination schedule for hepatitis B completed.⁵ Community pharmacists are in a key position to recognize diabetic patients who may be not be up to date with recommended vaccinations. Individuals with diabetes are at a heightened risk for Hepatitis B infection. Additionally, patients with diabetes are more likely to suffer complications from influenza and pneumococcal disease, if contracted.⁶ In Massachusetts, pharmacists can access the Massachusetts Immunization Information System (MIIS) and check an individual's immunizations records. As vaccine advocates, community pharmacists can provide ACIP recommended vaccinations to patients with diabetes which include vaccinations for Hepatitis B, pneumococcal disease, influenza, tetanus-diphtheria-pertussis, and zoster.

The primary objective of the study was to evaluate how a community pharmacist can optimize a patient's diabetes care by ensuring that they are on the appropriate agents to minimize their cardiovascular disease risk and ensuring that they are up to date with vaccinations in accordance with 2018 American Diabetes Association (ADA) guidelines. The secondary objective was to identify potential adherence barriers to oral diabetes medications and suggest methods to minimize this in patients who confirm non-adherence. Finally, the impact of pharmacist-driven services for diabetes management was assessed through a patient satisfaction survey.

Methods

<u>Study Design</u>: The protocol for this prospective, single-center study within a chain community pharmacy was approved by the University Institutional Review Board. The resident identified participants for study inclusion during the drug utilization review (DUR) process. Participants who were \geq 40 years of age with an active prescription for \geq 2 diabetes medications and with inferred diagnosis of diabetes based upon medications prescribed were deemed as eligible for study inclusion. Exclusion criteria included patients

<18 years of age, patients who are unable to speak or understand English, and women with gestational diabetes.

After participants were identified for study inclusion, a medication gap analysis was conducted to determine missing cardiovascular risk reduction agents. Medications evaluated were aspirin, blood pressure medications, statins, and agents such as Jardiance and Victoza, which have been shown to reduce the incidence of cardiovascular events in patients with T2DM and on metformin.² Immunization history was also documented by reviewing the state immunization registry, specifically noting missing vaccinations per Advisory Committee on Immunization Practices (ACIP) recommendations.

Upon pick up, the pharmacist obtained informed consent for study participation. Communication regarding study recruitment with the patient was done primarily by the pharmacy resident or by trained APPE students. For patients that were not able to participate at the time of question, the resident pharmacist followed up with a phone call a week later. Once consent was obtained, the pharmacist educated the patient on their current and missing therapies, faxed recommendations to their PCP, and administered missing immunizations. A summary of the recommendations was also provided to the patient to take to their next PCP appointment. For those patients in which non-adherence was mentioned during consultation, the pharmacist questioned the reason for non-adherence and then provided potential solutions. Before the consultation was finished, the pharmacist asked the participant to fill out a survey assessing the patients' satisfaction in regards to the pharmacist's role.

<u>Statistical Analyses:</u> Data collected for the project was entered into a password-protected Microsoft excel continuously throughout the study and then analyzed. A gap analysis of the number and types of missing cardiovascular risk reductions therapy recommendations that were identified and communicated with the patients PCP was generated. Those recommendations made were further analyzed into which ones were accepted, not accepted, and received no response. Additionally, a quantitative analysis of missing vaccinations and administered vaccinations was prepared.

Results and Discussion

There were a total of 52 patients recruited for this study. Baseline characteristics of the enrolled patients are listed in Figure 1. The average age for a patient was 65 years old, with patients ranging from 45 to 88 years old. Eighty seven percent of patients were on metformin therapy, as is expected for patients with type 2 diabetes as it is first line therapy.²

In regards to the recommendations made to patients, the pharmacist made a total of 29 recommendations to healthcare providers to fill gaps in medications and vaccinations as seen in Figure 2. The most common category in which interventions were made was for aspirin initiation or reinitiation (n=10) and a particular vaccine recommendation (n=9). Of the recommendations made to PCPs, 38% were accepted, which was defined as a new prescription being sent over or verification of vaccine administration through the online immunization registry. Ten percent of recommendations were not accepted; partly due to provider requesting in person patient assessment prior to new therapy initiation or previously failure with recommended therapy. The majority of the recommendations (52%) received no response to them after multiple attempts of reaching out to the provider were made. The exact type and number of recommendations that were accepted, unaccepted, or had no response is stratified in the chart titled "Response to Pharmacist Recommendations" in Figure 2.

The quantitative analyses of missing and administered vaccinations is presented in Figure 3. Of the vaccinations that were missing in the sample population, the largest gap was found in zoster vaccines (46%) and the smallest gap was found in the Pneumococcal conjugate vaccine (8%). Overall, there were missing vaccines in each of the ACIP and ADA recommended vaccination categories for patients with diabetes. Of the gaps in vaccine history, 47% of missing immunizations were administered by the pharmacist.

The patient satisfaction surveys were met with positive attitudes towards pharmacist involvement in diabetes management, referral of the service to a friend or family member, and pharmacists' involvement in vaccinations. Of the 12 patients who admitted to non-adherence to oral diabetes medications, potential solutions to improve adherence were offering. These solutions included enrollment in an auto-refill of medications, medication synchronization, utilization of pill organizers, and/or utilization of phone alert systems.

One of the limitations to this study was that it was difficult to directly communicate recommendations to providers. Often times, messages were left with the office personnel in regards to the recommendations that were faxed over. In addition, some providers preferred to discuss these recommendations with patients at their next appointment which sometimes was every 6 months. There was also challenges with recruitment, as this study was done in a single pharmacy, in which the resident pharmacist only worked there 2 to 3 days of the week. A significant component of this study relied on immunization history, which was a limitation in some instances when patients received immunizations in another state or country and the records were not available in the Massachusetts immunization registry or with the primary care provider. Another limitation was that there was a loss to follow-up in terms of vaccinations, as some patients preferred to return to the pharmacy at another time to receive these vaccines. However, the patient did not all receive the missing vaccinations they needed to. A potential limitation to this study was that the surveys the patients were asked to complete at the end of the consultation were not anonymous. The patients were handed this survey and then directly returned it to the resident pharmacy, thus allowing for some bias in survey responses.

Conclusion

This study has shown that implementation of a pharmacist-driven service to optimize care for patients with diabetes can help fill significant gaps in medication and immunization history. Through such a service, the pharmacist has been able to provide diabetes education, administer a significant number of missing vaccinations, and communicate recommendations to patients' respective providers. Although not all recommendations received a response, the purpose of each of these recommendations was to primarily provide education and updates to patients and providers on guideline recommendations. From a patient perspective, the education and services provided by the pharmacist had a positive response. The pharmacist involvement in patients diabetes care in providing clinical services has shown how community pharmacists can expand their role beyond just dispensing to a more involved and clinical role in managing patients' diabetes. To truly evaluate the role of the community pharmacist in optimizing the care of patients with diabetes, this study needs to be executed in more than one pharmacy. In addition, such pharmacies would benefit if a tool was integrated into the pharmacy's

dispensing software that electronically screened patients and identified which gaps there were in medication therapy, to be more efficient in making recommendations. A direct line of communication from the pharmacy dispensing system to communicate these recommendations to providers would also provide more efficiency in this service.

References

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