Assessing the impact of community pharmacist on diabetes knowledge, hemoglobin A1c, and cholesterol in patients with prediabetes and patients with diabetes

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Final Report

BACKGROUND:

The Center for Disease Control (CDC) reports crude estimates of 34.2 million people of all ages in the United States had diabetes in 2018. The CDC also reports that 7.2 million people were living with undiagnosed diabetes and estimate that 88 million people are at an increased risk of being diagnosed with diabetes in 2018.[1] Pharmacologic agents have been the front runner for managing this disease state; however, recently more focus has been placed on patient education about the disease state and how to live a healthy lifestyle. In a 2014 study, patients who received diabetes self-management education (DSME) had a 23.5% reduction in mean A1c.[2] An inpatient study showed a reduction in 30-day readmission rate from 16% to 11% of patients who had received inpatient diabetes education versus those who had not.[3] This reduction lowers the cost of healthcare and prompts healthcare professionals to provide chronic disease education. There have been many studies proving DSME is effective in improving Body Mass Index (BMI), waist circumference, and various lab values, there have been few studies that have evaluate diabetes knowledge retention post diabetes education.

With the role of the community pharmacist constantly advancing and patients presenting to their pharmacist an average of thirty-five times per year, the opportunity to educate patients and improve their quality of life is unique for pharmacists.[4] Poole's Pharmacy provides personalized diabetes education and CLIA-Waived Point of Care (POC) testing to patients at risk of developing diabetes and diabetic patients. The Diabetes Knowledge Test 2 (DKT2), recently validated by the University of Michigan, is utilized to evaluate and quantify patient knowledge.[5] The investigators of this study wish to evaluate the impact of pharmacist-led patient education on patient knowledge retention, hemoglobin A1c, lipid profile, and BMI.

PRIMARY OBJECTIVE:

- To evaluate the effect of community-based diabetes education on patient's diabetes self-care knowledge and hemoglobin A1c in patients with prediabetes and diabetes after 3 months

SECONDARY OBJECTIVES:

- To evaluate the effect of community-based diabetes education on patient's diabetes self-care knowledge and hemoglobin A1c in diabetic and prediabetic patients after 6 months and 9 months
- To evaluate the impact of community-based diabetes education on cholesterol, BMI and waist circumference after 3 months, 6 months and 9 months
- To assess the length of counselling required in each intervention group
- To assess the changes in antidiabetic agents during the study and their impact on patient outcomes

METHODS:

Study Design

- Prospective cohort study of diabetic and prediabetic patients at Poole's Pharmacy.
- Two cohort design:

    - Intervention 1: Prediabetes diagnosis
        - Defined by presence of diagnosis in the chart or diagnosis using the CDC prediabetes screening tool
    - Intervention 2: Diabetes diagnosis
        - Defined by presence of diagnosis or presence of antidiabetic agents in the MAR
- DKT2 administration at pre-education, post-education, 3 months, 6 months, and 9 months
- Date range: August 2020 – June 2021
- Data Source: Quickscript ® Medication Administration Record (MAR), Dispill ® medication compliance packing system

Procedure

Day 1: Patients will sign the informed consent document and then be tested using the DKT2 for baseline knowledge. The patient will be educated using a brief standardized education tool. Once the patient is educated, the patient will be weighed, measured, and the BMI will be calculated. Post-measurement, the patient's hemoglobin A1c and Cholesterol (TC, HDL, LDL, and TG) will be obtained using point of care (POC) testing devices. The DKT2 will be used again to assess their post-education knowledge.

Month 3 (day 84): Repeat POC testing, BMI, and waist circumference measurements. Administer DKT2 and document.

Month 6 (day 168): Repeat POC testing, BMI, and waist circumference measurements. Administer DKT2 and document.

Month 9 (day 252): Repeat POC testing, BMI, and waist circumference measurements. Administer DKT2 and document.

Throughout the 9 months: adherence to statin therapy will be assessed and changes in antihyperglycemic agents will be documented.

With consent the patient's primary care physician will be notified of involvement and progress throughout the study.

Informed Consent

- Researchers and patients will obtain written and verbal informed consent before the patient is eligible to participate in this study.

Risk of Participation

- The various point of care tests requires a finger stick which may be associated with discomfort. If the patient is uncomfortable with the finger stick and blood draw required for point of care testing, the study subject may verbally withdraw at any time during testing process.

HIPAA

- There is a minimal risk to the privacy of patients due to the design of the study. Protected health information will only be used to identify and select patients. The data will be recorded and stored in a database that will remain accessible only to study

personnel. Patient data will be password-protected and stored electronically. Identification of patients for this study is only possible with this waiver.

Benefits to Future Subjects of Science

- Results will inform providers and patients with patient outcomes associated with pharmacist involvement in the community
- Results may provide validation for further pharmacist involvement in diabetes patient education
- Results will provide insight on the impact of diabetes education in the community pharmacy setting

PATIENT POPULATION:

Study Subjects

- Consenting type 2 diabetic patients and prediabetic patients who fill all of their diabetic and antihyperlipidemic medications at Poole's Pharmacy will be considered for inclusion in this study.

Inclusion Criteria

- Age ≥ 18 years old
- Diagnosis of type II diabetes mellitus or
- Diagnosis of prediabetes or positive risk of prediabetes using the CDC screening test
- Patients must fill all antidiabetic and antihyperlipidemic agents at Poole's Pharmacy

Exclusion Criteria

- Pregnancy
- Severe discomfort to point of care testing
- Diagnosis of type 1 diabetes mellitus
- Not able to comprehend or speak English well enough to participate in counselling

Sample

- A report of diabetic patients who meet inclusion criteria and no exclusion criteria will be generated from Cost Effective, the pharmacy dispensing software. Patients without a formal type 2 diabetes diagnosis will be asked to voluntarily complete the CDC Prediabetes Screening Tool for inclusion.

DATA COLLECTION:

Data will be collected using CLIA-waived Point of Care testing and chart review using the patient's MAR. Data to be collect will include the following:

- Background demographics, including age, sex, weight, and race
- Hemoglobin A1c measured at the pharmacy using A1C Now®
- Total cholesterol, HDL, LDL, Triglycerides, and Blood glucose measured at the pharmacy using the CardioChek Plus®
- Weight, waist circumference, and BMI
- Patient's diabetes knowledge using the DKT2

- Use of antidiabetic agents on the patient's MAR
- Adherence to antihyperlipidemic agents

Primary Outcomes

- Change in baseline knowledge assessment and hemoglobin A1c measured at 3 months

Secondary Outcomes

- Change in baseline knowledge and hemoglobin A1c at 6 months and 9 months
- Change in cholesterol, BMI and waist circumference at 3 months, 6 months, 9 months
- Compare average length of patient counseling in minutes for each intervention
- Number of changes in antidiabetic regimen
- Adherence to antihyperlipidemic agent

DATA ANALYSIS:

- Descriptive and statistical analyses will be used to compare the two groups

CONFIDENTIALITY:

- All information will be compliant with the Health Insurance Portability and Accountability Act (HIPAA). Due to the study design, there is minimal risk to the privacy of patients included in this study. Only data pertinent to the study objectives and outcomes will be collected. Protected health information will only be used to identify patients using the medical record number or financial identification number. To maintain patient confidentiality, patients will be assigned a unique code that will be used on all study documents. Unique codes will be used to de-identify patient information before it is entered into the database for analysis. These codes and all data will be stored electronically, encrypted, password protected, and only accessible to study personnel. All patient identifiers will be removed prior to analysis by a statistician. All data and electronic files will be shredded or deleted three years after publication.

RESULTS:

- Results of this study are currently in progress. All of our pharmacy staff is now fully vaccinated, and a majority of our patients are as well. Due to this, our pharmacy managers are now comfortable to begin implementing this service. The supplies have been purchased with the grant monies, and the fine details are being planned right now, such as dates the service will be offered and the location. The pharmacy has started screening patients and enrollment into the service is currently underway.

ADDENDUM:

- We are scheduled to begin data collection later this month. Poole's pharmacy has been able to assist in providing affordable medical care and medications along with a volunteer physician at a local indigent health clinic. Since COVID-19 restrictions have been relaxed in our area, Poole's Pharmacy is now scheduled on June 22, 2021 for face-to-face visits with the patients to provide the services for which the grant was requested. APhA's Community Pharmacy Foundation Incentive Grant made this

additional service a possibility for the pharmacy. Due to the restrictions imposed with the COVID-19 pandemic we were unable to begin offering this service as originally planned. We are excited to finally have the opportunity to begin our project. Poole's Pharmacy anticipates that this will be an ongoing community service offering.

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