

## **APhA 2019 Foundation Incentive Grant Report**

**Title:** Impact on glycemic control in patients with Type 2 Diabetes using student-run teleinsulin programs in medically underserved communities in rural Mississippi

**Incentive Grant Category:** Residents and their Preceptors

### **Project Description:**

Type 2 Diabetes Mellitus (T2DM) is one of the most prevalent and serious chronic health conditions in the United States. According to the Centers for Disease Control and Prevention (CDC), 30.3 million people in the United States have diabetes, with approximately 7.2 million people possibly undiagnosed and unaware of their condition<sup>1</sup>. The management often requires continued medical care by both physicians and pharmacists in order to prevent secondary complications, including microvascular and macrovascular complications leading to hospitalizations and death.

Insulin is commonly prescribed to patients whose T2DM is unable to be controlled with conventional therapy. Therapy requires frequent reporting of self-monitoring blood glucose concentrations (SMBG) for dose titration by a provider. These concentration levels are typically reported in person, requiring frequent visits to the provider in order for titration to occur. This can be burdensome for patients, as they are required to arrange for changes in work schedules, childcare, or transportation. Insulin dose titration may also be difficult during limited in-person clinic appointments if patients are not adequately counseled when insulin concentrations are changed and providers are unaware of patient at-home maintenance regimens and/or blood glucose monitoring.

The state of Mississippi has an estimated population of 2.9 million residents. Of the 82 counties across this state, 65 counties are considered to be rural, indicating that a majority of residents live in rural areas<sup>2</sup>. Despite the decline in diabetes-related mortality across the United States, the South continues to have the largest gap in mortality rate associated with diabetes when comparing metropolitan versus rural areas<sup>3</sup>. According to the Mississippi Department of Health, diabetes mellitus is the 6<sup>th</sup> leading cause of death in the state but accounts for the third most costly chronic condition<sup>4</sup>. More specifically, in Yazoo county 18.2% of patients reported being diagnosed with diabetes mellitus compared to the state average of 13%. In 2015, 34.2% of residents in Yazoo county were below the poverty level compared to a state average of 22.1%. The patient to primary care provider ratio in Yazoo County at that time was 5,477 to 1. Also in 2015, the Annual Mississippi Health Disparities and Inequalities Report cited that among adult Mississippians, diabetes prevalence significantly decreases as annual household income increases<sup>5</sup>. When considering a community's health equity, this extent of poverty in addition to inaccessibility to healthcare may often result in high morbidity and mortality rates and increased healthcare costs and resource utilization.

Despite a growing number of health disparities improvement initiatives and awareness for rural and urban communities, pharmacists and student pharmacists continue to have room for additional impact on communities with limited access to healthcare. Telemedicine interventions delivered by pharmacists and student pharmacists can provide support in diabetes self-management for patients in areas that are medically underserved. In 2019, 31 of the 64 rural hospitals in Mississippi were at risk of closing<sup>7</sup>. Many patients are unable to attend frequent appointments for titration due to limitations

of transportation or healthcare providers, leading to the perpetuation of unattained diabetes therapeutic goals. In instances where patients are enrolled in telemonitoring for at least 6 months, research has shown significant reduction in hemoglobin A1c (HbA1c) levels and has demonstrated more effective care than usual in-person management of diabetes<sup>6</sup>. Furthermore, studies have shown that patients who participate in a telephone-delivered intervention program for diabetes support were more likely to reach their optimal insulin dose in addition to improving their glycemic control<sup>8</sup>.

The aim of this study is to determine if a student-run teleinsulin program can have a positive impact on glycemic control in patients with T2DM in medically underserved communities of Mississippi.

### **Project Objectives:**

To evaluate the change in HbA1c and change in patient-reported self-monitoring of blood glucose (SMBG) of patients in a federally qualified health center using a student-run teleinsulin program. In addition, the study aimed to evaluate the comfort and confidence of pre-clinical pharmacy students trained in utilizing an insulin algorithm and protocol for a new teleinsulin service.

### **Methods:**

#### *Study Design*

This study was approved by the University of Mississippi Institutional Review Board. Third- and fourth-year student pharmacists from the University of Mississippi School of Pharmacy were recruited for participation in this volunteer research opportunity. Participating students underwent three, 1-1.5 hour training sessions that included lessons on communication, glycemic goals according to the American Diabetes Association, insulin products, insulin titration protocols, and diet/exercise/lifestyle modification recommendations according to the American Diabetes Association. All recruited patients were identified within the G.A. Carmichael Family Health Center, a federally qualified health center located in central Mississippi. Patients were recruited for this study by their in-clinic primary care provider or by the pharmacist, if they met all of the following inclusion criteria: clinical diagnosis of type 2 diabetes mellitus, HbA1c greater than or equal to 9% within 30 days of recruitment, a current prescription for insulin or need for insulin initiation, ability to understand English, and at least 18 years of age. In an effort to recruit more patients, the inclusion criteria during the extended study period was expanded to include patients with a HbA1c greater than or equal to 7% within 60 days of recruitment. Patients were excluded if they did not have access to a telephone and were currently being managed for diabetes by an outside provider (defined as a healthcare provider outside the G.A. Carmichael Family Health Center).

Pharmacists within this clinic serve patients under a collaborative practice agreement that allowed for the initiation, titration, and discontinuation of treatments related to the care of the patient's diabetes diagnosis. Students participating in this study worked under the direct supervision of the pharmacist and under approved protocol for the service. Supervising pharmacists were faculty members of the University of Mississippi whose primary clinical practice site was the G.A. Carmichael Family Health Center. These supervising pharmacists worked under a collaborative practice agreement and had a pre-existing relationship with the staff, providers, and patients at this site.

Prior to patient recruitment, 3<sup>rd</sup> and 4<sup>th</sup> year student-pharmacists completed student surveys and were trained by the primary investigator on patient communication, appropriate documentation, and insulin titration according to the provided algorithm. Each student received a manual with protocol flowchart, insulin titration algorithm, insulin titration script, and data collection tool. Per the inclusion criteria, baseline HbA1c was documented within 60 days prior to study enrollment. The first cohort of student pharmacists (2018-2019) shared a patient pool to contact for teleinsulin management. These students would conduct these teleinsulin calls outside of their regular classroom hours on a personal time availability basis. The second cohort of student pharmacists (2019-2020) were assigned specific patients as patients were enrolled and consented to the project. These students performed appointment-based weekly teleinsulin calls in order to perform insulin titration as needed. These patients were thereby only contacted by their assigned student pharmacist, and would thus be able to create a patient-provider relationship much similar to that developed in a typical clinic scenario.

Based on referral by a primary care provider, patients were contacted by a pharmacy student to be recruited for inclusion into the study. Patients were given the option to give verbal consent over the telephone or could come into the clinic to sign a consent form. Patients were then instructed to record their daily SMBG values for a follow-up call within one week. Patients were contacted weekly by a pharmacy student for insulin titration according to an algorithm and protocol. If the patient demonstrated two consecutive weeks of SMBG within goal range, the calls were then reduced to monthly follow-up calls. At the 90-day mark, patients were asked to return to the clinic to draw a new HbA1c.

#### *Data Analysis*

This intention-to-treat analysis was conducted using student's t-test in order to evaluate the change in HbA1c at 3 months compared to baseline, as well as the change in average patient-reported SMBG at baseline and the 3-month mark. Descriptive statistics were used to highlight trends in baseline patient characteristics and trends in surveys.

Investigators determined that in order to detect an effect size of 15% relative reduction in HbA1c from baseline, a sample size of 700 patients would be needed. Therefore, investigators predicted that power would not be reached. Despite the prediction that power would be unattainable in this investigation, investigators proceeded with this service with the understanding that it was a pilot study without a control group, primarily intended as a proof of concept service for further service development and implementation at this federally qualified health center.

## **Results:**

### *Patients*

A total of 20 out of 22 patients referred to the teleinsulin service agreed to participate in the study. A majority of the participants were female (65%) and were greater than 60 years old. Almost all patients in this pilot study were African American (95%), a majority were uninsured (55%) and a majority were on a basal-bolus insulin regimen (55%). Almost all patients were taking other oral medications for diabetes at the time of the

study. Six patients were lost to follow-up and 2 patients obtained consistently controlled blood glucose averages and were thus graduated from the service.

At baseline the average cohort HbA1c was 11.07%. At the 3-month mark, there was a relative reduction of 9.4% and the absolute reduction was 1.67% ( $p < 0.0001$ ).

### *Students*

Students recruited for this research study included third and fourth-year pharmacy students at the University of Mississippi School of Pharmacy. Of the 216 students that were contacted through email during the first cohort recruitment (2018-2019), 6 third-year pharmacy students volunteered to participate in the study. During the extended enrollment period (2019-2020), 11 additional third-year students participated in the study. All participating students were in the didactic portion of their curriculum and did not have any formal clinical pharmacy experiential training. Between both student cohorts, a total of 12 out of 17 students completed a pre- and post-experience survey to assess self-reported clinical confidence in an insulin titration program.

Students identified their agreement with statements on a Likert scale to express their confidence in knowledge of diabetes management and comfort in utilizing an insulin algorithm and protocol for telemedicine management. When comparing these statements at baseline and post-experience, all students felt more confident in their knowledge of diabetes recommendations and guidelines, diabetes pharmacology, insulin titration, and the ability to follow a protocol for insulin management.

## **Discussion:**

As the incidence and prevalence of diabetes continues to grow in the United States, the opportunities for telemedicine and insulin titration services from pharmacists and student pharmacists become increasingly important. Key factors that limit patients from access to care in many rural communities include limited transportation, health insurance status, and the stigma associated with receiving care<sup>7,8</sup>. By providing telemedicine services, healthcare providers are able to care for patients more readily at a time and “place” that is convenient for the patient. Furthermore, teleinsulin services in rural communities allow for tighter glycemic control by allowing for quicker follow-up for diabetic monitoring.

### *Strengths*

The strengths of this study included a structured and intensive training process for the pharmacy students based on guidelines from the American Diabetes Association Standards of Medical Care. The study allowed for enhanced access to care that filled a void within this specific federally qualified health center as patients’ access to transportation is often a barrier. Additionally, the expansion of pharmacy services created a need for more dedicated time from the pharmacy team, which led to the development of a permanent learning experience for pharmacy residents. Lastly, it allowed for a novel use of resources as pharmacy students are often underutilized in the clinical setting.

### *Limitations*

The limitations of this study included the lack of control group and the inherent reliance on the patients for recall in self-monitoring blood glucose values. The lack of control group within this study was largely due to limitations in time and resources. As this project was designed to be a proof-of-concept service, a control group was deemed less

crucial in the development of this service. Since the pharmacy team relied on the patient to accurately check SMBG values and record in a journal at home for follow-up and titration over the telephone, patients that failed to record values could not receive titrations on time. Pharmacy team members were limited in their recommendations due to formulary limitations as a majority of the participants were uninsured and cash-paying patients. Due to the inherent advantages of a telemedicine service for transportation-limited patients, having patients return to the clinic for HbA1c and other lab checks also proved to be difficult as they continued to have transportation issues for these services. Additionally, the beginning of the COVID-19 pandemic could have interrupted patients' ability to be reached by phone, access medications, and capture timely hemoglobin A1c's. Furthermore, due to the small sample size and unique patient population in this rural community, this study demonstrates limited external validity.

**Conclusion:**

This study of implementation of a student-run, teleinsulin program in a federally qualified health center identified key opportunities and barriers to this new service. The structured training program not only allowed the students to feel more confident in their ability to management teleinsulin patients despite their limited clinical skills, but the service also demonstrated the potential for clinical benefit in patients that benefited from the extra attention and convenience that telemedicine provides.

**Timetable:**

November 2018	Data collection begins
April 2020	Data collection ends
October 2020	Submitted manuscript to JAPhA

**Evaluation Strategy:**

Research project progress was evaluated by peer pharmacy residents and residency research mentors/advisors on a biweekly basis. PGY-1 Community Pharmacy Residents participated in a structured Research Project Development Program. As part of this program, residents were required to present their topics to a panel of advisors and mentors for evaluation and approval. Progress status update meetings were also documented through PharmAcademic and quarterly progress reports with the residency program director.

Areas of evaluation included IRB protocol compliance via a protocol checklist, manuscript draft review, resolution steps, and identification of professional presentation opportunities which included poster presentations at the 2018 ASHP Midyear Clinical Meeting, and 2019 ASHP Midyear Clinical Meeting.

**Budget: \$1000**

Category	Specific Items	Budget	Actual Amount Spent
Glucose Log Books	Bound books for patients to record SMBG levels	500.00	0.00
Glucose Test Strips	Test strips for “emergency” supply in patients who cannot afford additional testing based on needs of study	500.00	1000.00

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