Outcomes Innovative Pharmacy Grant
Final Report

Applicant Information

Applicant Name	Wendy Mobley-Bukstein, PharmD, BCACP, CDCES, CHWC, FAPhA
Project Title	**FreeStyle Libre Pro Use for Improved Control of Blood Sugars in Patients with Diabetes**
Funding Amount	$6149.00

Final Report

- Please describe the progress made towards meeting the goals and objectives of your project. Include results or outcomes if possible.

  The overarching objective of this project is to highlight improved control of patient blood glucose through use of CGMs in the clinical literature and promote the value of its use to payors.

  We have seen throughout the pandemic that the Centers for Medicare and Medicaid have seen the value of CGM. In July 2021, the criterion for CGM coverage was changed to exclude four times a day fingerstick blood glucose testing. This change made it possible for more individuals to obtain CGMs. Due to this change, more individuals coming into the clinic have been able to be placed on a CGM with insurance covering the cost with minimal out of pocket expense (co-pay or 20% co-insurance). Thus our sample size has not yet been reached.

  In the data that we have collected thus far, it has been apparent that the use of CGM has helped us manage diabetes more efficiently and effectively in our patients. We have been able to achieve better glycemic management in our patients in a shorter time period and have successfully avoided therapeutic inertia.

  We successfully decreased average glucose by approximately 20mg/dL. The glucose variability was decreased by more than 8% and we decreased average GMI by 1%. Of note, one patient's glucose variability went from 60.3% to 44.4% during the study period. When you look at the Time-in-range data, this does not seem impressive, but recall that the changes in these numbers are occurring over a 6-week time period. In most clinical practices, an A1C would be drawn every 12 weeks. These averages are heavily skewed by individual patients who had very high glucose at the beginning of the study period and although improvement in the blood glucose ranges occurred they remained above the target range. The more impressive improvement was the average low or very low was decreased by 2.7%. This is an area of importance because this

decrease in hypoglycemia and severe hypoglycemia has a cost savings of emergency department visit, hospitalization or death attributed to it. Lastly, you can see that the high touch follow up that was being performed has been beneficial to these patients, resulting in more interactions and subsequently more frequent adjustments of their insulin dosages. Of note, there is one patient that is in contact with the clinician up to three times a day for coaching on prandial insulin dosing.

CGM Data Points	First Wear (n=5)	Second Wear (n=4)*
Average Glucose	222.6 mg/dL	200 mg/dL
Glucose Variability (%)	43.8%	35.8%
Glucose Management Index	9.05%	8.1%
Time-In-Range (TIR)	36.8%	39.75%
High/Very High Range	59%	58.75%
Low/Very Low Range	4.2%	1.5%
Number of patient interactions	28	56
Number of drug therapy interventions	27	56

*one patient is scheduled to return for second wear in the two weeks.

Additional objectives to this study include:

1. Increase blood glucose monitoring and management of diabetes
    a. Average number of scans per patient= 8/day
2. Encouraging patients to engage in the management of their diabetes by increasing the visibility of their lifestyle changes
    a. All patients underwent nutrition and physical activity education
    b. Individual goals were made by each patient surrounding one area of nutrition and physical activity
3. Analyzing if patient treatment regimens are more appropriate when using CGM data versus random daily finger sticks
    a. Due to small sample size, it is still too early to determine. Preliminary data from the patients that have completed the study shows that we have more information in which to make more informed decisions for therapy options.
4. Citing translational data to potential cost savings that CGM provides for routine management and cost avoidance of diabetes-related hospitalizations.
    a. A manuscript is planned for this project upon completion.

- Which, if any, of your goals and objectives were not achieved as intended? Please explain these and what impact you believe it has on the overall project success.

    We were able to meet our goals and objectives for a small subset of patients. We continue to enroll patients. Public health emergency rules have allowed more patients to obtain continuous glucose monitors via Medicare, Medicaid and commercial insurances. We have been targeting our uninsured and underinsured populations to increase our population size. We will continue to utilize the resources that were obtained with this grant to see the project to the end.

Overall, we have seen an improvement in glucose variability. This means that the individual's blood sugars are not fluctuating as greatly as they were before. What this means for the patient is that they are not feeling the "roller coaster" effect that high variability can have on the body. Although in one patient the variability remains high it is much improved. This makes a difference on symptoms like fatigue and lethargy. Patients state they feel like they have more "energy". This feeling of being energized or having more energy allows patients to become more active which helps bring their blood sugar down.

- Do you expect this project and its results to be sustainable at your practice and reproducible in other pharmacy settings? Do you anticipate any barriers to sustainability and/or reproducibility? Please explain.

  Yes, I see the use of CGM continuing and increasing. The current move within the diabetes specialty is to highlight the use of CGM during COVID-19 and how its use allowed remote monitoring and therapy adjustment to keep individuals with diabetes better managed. With wider acceptance of these devices, potentially more brands coming to market, I see the price of these devices being driven down. At this point, someone must be committed to managing their diabetes and willing to pay out of pocket (if they are uninsured) for the sensors. The manufacturer has patient assistance programs, although they cut the cost by 50%, in some instances this remains out of reach for most individuals.

  Professional CGM may be used by the pharmacist to gain more information regarding the management of an individual's diabetes. A program such as this would be relatively easy to implement. Areas for consideration when piloting or starting up a service like this would be from a financial standpoint: billing for CGM placement and interpretation, paying for the reader and sensors, and having a dedicated staff member who can provide high touch follow up with the patients.

- What impact will the outcomes of this project have on pharmacy practice in Iowa?

  I feel that pharmacists will be able to assist in management of persons with diabetes more readily. They will be able to review the CGM data, make recommendations for therapy adjustments or utilize collaborative practice agreements whereby the pharmacist can independently make the change and monitor the patient. Pharmacists can do these things now, but often we are unable to obtain appropriate clinical information due to lack of interoperability of electronic health records or time intensive processes to obtain the clinical information necessary in making treatment care plan decisions.

Final Budget Report

Based on the funded amount from the IPA Foundation, please complete the grant budget in the table format below. Grant budgets must include all costs as well as any matching funds or in-kind support. Please include items from the entire project interval (pre- and post- interim report)

Budget Line Items	**Total Costs**	**Source if outside grant (eg in kind or other funding)**
Skin tac wipes 300 ct	71.56	
Tegaderm 4x4 25 ct	24.95	
Freestyle Libre Covers 30 ct	14.49	
Freestyle Libre Clear Covers 165 ct	44.70	
Freestyle Libre Professional Reader x1	75.00	
Freestyle Libre Professional Sensors x102	5904.80	230.00 (credit on account)
Faculty salary		1250.00
TOTAL	$6135.50	$1480.00

Please provide a summary of your project to be published in the Journal of IPA. (300 word maximum) I know you won't be able to use all of the copy here. Please use the paragraph starting at…"Individuals (n=5)…" for the summary of the project.

Diabetes is a chronic disease that requires consistent attention to food intake, physical activity and management of blood sugar levels. The use of continuous glucose monitors (CGM), newer devices that are worn on the body and measure interstitial glucose levels are revolutionizing diabetes management. Where a person with diabetes had to test their blood sugar by sticking their finger with a small lancet device upwards of four or more times a day, the CGM allows a person with diabetes to use their smartphone or a device known as a reader (that is connected to the CGM sensor by Bluetooth/infrared technology) to view their blood sugars with the swipe on their phone screen or a wave over the sensor with the reader device. As you can imagine, these devices are expensive but a true game changer when it comes to monitoring and adjusting diabetes treatment.

This study aimed to highlight improved blood glucose control with the use of a professional CGM device to add value to the primary literature and gain payer attention and better access for persons with diabetes to these devices. In addition, the secondary objectives included: increased blood glucose monitoring and better diabetes management, increased lifestyle modifications including nutrition and physical activity, analysis of treatment regimens when using self-monitored blood glucose tests (finger sticks) versus data from a continuous glucose monitor and lastly, citing translational studies to suggest cost avoidance from ED visits, hospitalization or death.

Individuals (n=5) were identified in the clinic by the diabetes care and education specialist or a medical provider as having unmanaged diabetes. The person received informed consent regarding the study. If they agreed, a professional Freestyle Libre CGM device was applied, and the person wore it for 14 days. At the end of the 14 days, the person returned to the clinic for removal of the device and interpretation of the data collected from the device. Therapy changes were made to the person's diabetes treatment plan. The person adhered to the new plan for 4 weeks and then returned to the clinic to wear a second CGM for 14 days. Data from this CGM wear was recorded.

The average glucose was decreased by approximately 20mg/dL. The glucose variability was decreased by more than 8% and the average GMI was decreased by 1%. Looking at the time-in-range data, recall that the changes in these numbers are occurring over a 6-week time period. In most clinical practices, an A1C would be drawn every 12 weeks. These averages are heavily skewed by individual patients who had very high glucose at the beginning of the study period and although improvement in the blood glucose ranges occurred, they remained above the target range. The more impressive improvement was the average low or very low was decreased by 2.7%. This is an area of importance because this decrease in hypoglycemia and severe hypoglycemia has a cost savings of emergency department visit, hospitalization or death attributed to it. Lastly, you can see that the high touch follow up that was being performed has been beneficial to these patients, resulting in more interactions and subsequently more frequent adjustments of their insulin dosages.

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