UNMET NEEDS IN TRADITIONAL GLUCOSE MONITORING
For the more than 30 million Americans living with diabetes, persistent self-management of their disease is important to prevent acute complications and reduce the risk of long-term complications of diabetes. Glucose monitoring is a key strategy to improve glycemic outcomes by allowing patients to evaluate the efficacy of diabetes therapy, adjust the dosage of medications, and understand the impact of lifestyle factors on glucose levels.

Measuring glycated hemoglobin (A1c) levels is the traditional method for achieving recommended glycemic outcomes in patients with diabetes. However, A1c represents the average glucose concentration during a 90-day period and does not account for hypoglycemia or fluctuations in blood glucose levels occurring throughout the day. For patients who require timely adjustments to insulin treatment and immediate knowledge of glycemic results, A1c values alone may not be an appropriate method for disease management.

Blood glucose monitoring (BGM) can be used by patients and clinicians to evaluate the safety and effectiveness of a diabetes management plan, determine response to therapy, modify medications (eg, prandial insulin doses), prevent or treat hypoglycemia, and assess glycemic outcomes. For patients using insulin, BGM may play an important role in monitoring and preventing hypoglycemic and hyperglycemic events. However, patients receiving intensive insulin therapy may be required to test blood glucose levels more than 6 times daily.

BGM is associated with inconvenient testing frequency, time-consuming testing, and painful fingersticks. Due to these patient-reported barriers, some patients may not test as often as required. Patients who perform BGM infrequently or intermittently may not achieve optimal glycemic outcomes and may fail to detect hyperglycemic or hypoglycemic events.

ADVANCEMENTS IN CONTINUOUS GLUCOSE MONITORING
Continuous glucose monitoring (CGM) systems provide measurements of interstitial glucose levels and address many of the limitations of A1c testing and BGM. CGM may offer improved glucose control and reduce exposure to hyperglycemic or hypoglycemic events in patients with diabetes.

Despite the uptake of early CGM systems, the continuation of use was low and these systems have not achieved widespread acceptance. High cost associated with CGM is a potential barrier and may limit its availability to patients. The daily expenses of CGM usage amount to an estimated cost of $5 to $10 per patient; this translates to an annual cost of $3000 per patient with CGM management.

To effectively implement CGM systems as part of disease self-management, patients must engage and invest time in learning how to use the device. Traditional CGM systems may require complex patient education regarding the insertion and removal of the sensor, use of the software, and procedures to follow in the event of a system error. These steps may be burdensome to patients who are unfamiliar with CGM systems.

To ensure the accuracy of CGM results, calibration with BGM is required at least twice daily with fingerstick samples. CGM usage encounters other identified limitations such as the inaccuracy of glucose sensors results and the need of the sensor to be replaced every few days.

FREESTYLE LIBRE SYSTEM
FreeStyle Libre (flash glucose monitoring system) is a unique sensor-based personal CGM device indicated for the management of diabetes in adult patients aged 18 years and older. The FreeStyle Libre system detects trends in blood glucose levels. The FreeStyle Libre sensor has to be scanned every 8 hours to track these glucose patterns throughout the day and it can aid in the detection of hyperglycemic and hypoglycemic events. Patients can interpret glucose readings based on trends and several sequential readings over time, which facilitates acute and long-term therapy adjustments.

The FreeStyle Libre system is a novel system which differs from first-generation CGM devices and self-monitoring of blood glucose (SMBG). Unlike SMBG testing, the FreeStyle Libre system does not require the patient to perform routine fingersticks. As FreeStyle Libre system is factory calibrated, glucose readings are not dependent on any user fingerstick BGM calibrations. The FreeStyle Libre system is available with a prescription at several retail pharmacies. Commercially-insured patients can fill their prescriptions at participating pharmacies without prior authorization. Based on the list price of the FreeStyle Libre system, it is more affordable than other CGM systems.
The FreeStyle Libre sensor is a thin filament (<0.4 mm) which is inserted 5 mm beneath the skin on the back of the upper arm using a single-use applicator. Following a 12 hour warm up, the sensor automatically measures interstitial glucose every minute and can be worn for up to 10 days. The sensor is painlessly scanned by a separate FreeStyle Libre reader that collects immediate glucose measurements and provides trends from glucose readings recorded every 15 minutes. When the reader is brought into close proximity to the sensor (4 cm), a real-time glucose level, a glucose trend arrow, and a graph of up to 8 hours of glucose readings are displayed (FIGURE 1). Patients can scan as often as desired and the FreeStyle Libre device stores up to 90 days of data.

Using the information generated in the FreeStyle Libre summary glucose reports, patients can self-manage their disease to identify glucose levels above or below the desired range. The variety of reader reports may allow patients to proactively make actionable changes such as self-adjustments of therapy for glycemic control.

**CLINICAL EFFICACY OF FREESTYLE LIBRE SYSTEM**

The safety and efficacy of the FreeStyle Libre system were investigated in a total of 328 patients with type 1 diabetes in the IMPACT trial. Patients were randomized (1:1) to diabetes management with the FreeStyle Libre system or SMBG test with strips for 6 months. The primary outcome was the time spent in hypoglycemia (blood glucose level <70 mg/dL) during the 6-month study period. Patients using the FreeStyle Libre system experienced significantly less time in hypoglycemia compared with patients using SMBG (122 minutes vs 196 minutes; *P* < .0001). The FreeStyle Libre group experienced a 38% reduction of time in hypoglycemia compared with the control group. Patients using the FreeStyle Libre system were more active in measuring their glucose; the FreeStyle Libre group achieved a mean of 15.1 sensor scans per day, compared with 5.6 self-monitored blood glucose tests per day.

The safety and efficacy of the FreeStyle Libre system were investigated in 224 patients with type 2 diabetes on intensive insulin therapy in the REPLACE trial. Patients in the FreeStyle Libre group achieved improvements in hypoglycemia outcomes and experienced a 43% reduction of time in hypoglycemia compared with the SMBG group (37 minutes vs 65 minutes; *P* < .001). The mean number of daily tests was higher in the FreeStyle Libre group (8.3 scans per day) compared with the patients using SMBG (3.0 BGM tests per day) for days 15 to 208. FIGURE 2A and FIGURE 2B highlight key efficacy results from the IMPACT and REPLACE trials.

**ROLE OF THE PHARMACIST**

As trusted and accessible health care professionals, pharmacists can help patients with diabetes select the most appropriate glucose monitoring device. Pharmacists at participating pharmacies can conveniently fill prescriptions for commercially-insured patients without obtaining prior authorization. Pharmacists can use National Drug Code (NDC) numbers to order both the FreeStyle Libre reader (NDC: 57599-0000-21) and Freestyle Libre sensors (NDC: 57599-0000-19). Patients will require a FreeStyle Libre reader to use the FreeStyle Libre sensors. When a patient fills their prescription for the first time, they will also need to purchase a reader with their first set of sensors. Each FreeStyle Libre sensor has a wear...
time of up to 10 days. As each package contains 1 sensor, a typical monthly order will consist of 3 sensors for the 30-day supply. Pharmacists can educate patients on potential cost barriers and help patients achieve affordable access.

Additionally, by working collaboratively with patients and an interdisciplinary team to develop a diabetes management plan, pharmacists can help reduce the risk of adverse events. Pharmacists can assess a patient’s readiness to use CGM technology, such as the FreeStyle Libre system, in their management plan and can provide education and training for optimal adherence to the patient’s preferred glucose monitoring method.

REFERENCES


FREESTYLE LIBRE INDICATIONS AND IMPORTANT SAFETY INFORMATION

The FreeStyle Libre Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

CONTRAINDICATIONS: Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The FreeStyle Libre system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The FreeStyle Libre system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. Review all product information before use or contact Abbott Toll Free (855-632-8658) for detailed indications for use and safety information.