Expanding Flash Continuous Glucose Monitoring Technology to a Broader Population

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According to the Centers for Disease Control and Prevention, 88 million people have prediabetes, and another 34.2 million have diabetes (1). Projections indicate that, by 2060, the number of adults with diabetes in the United States will triple (2). The literature is rife with data indicating that a large majority of people with diabetes fail to reach optimal glucose control despite advances in diabetes care and technology (3). Similarly, a large majority of individuals with prediabetes develop diabetes, despite widespread public health interventions (4,5). Technological advances in diabetes care to address these shortcomings are needed.

Since the introduction of continuous glucose monitoring (CGM) more than 20 years ago, rapid advancements in its accuracy, reliability, and ease of use have occurred (6). As CGM technology continues to evolve, it has become clear that appropriate use of CGM can lead to improvements in glycemic control, although assessment of patient preference, willingness to wear a CGM device, potential for adherence, cost, need for alarm features, and ability to integrate with an insulin pump need to be considered for each patient (7).

Although use of real-time CGM has improved, rates of adoption remain less than anticipated and lower than what is likely to be beneficial to patients in clinical practice (8). On the other hand, use of flash CGM (sometimes called intermittently scanned CGM) continues to increase rapidly in the United States since its approval 3 years ago (9). Flash CGM allows a person with diabetes to wear a CGM device more discreetly and for a longer period of time (up to 14 days) and is more affordable than traditional real-time CGM systems. Flash CGM has also been shown to be less costly than self-monitoring of blood glucose (SMBG) (10). In a cost-comparison study of patients using an intensive insulin regimen, SMBG was modeled at 3, 6, and 10 tests daily and compared with flash CGM (10). The annual cost of flash CGM was shown to be 60% lower than SMBG at 6 and 10 tests per day and was comparable to SMBG at 3 tests per day (10). These benefits of flash CGM over real-time CGM and SMBG have likely driven the improvements in patient satisfaction seen across several studies (11–13). However, notable shortcomings of the first-generation flash CGM device (FreeStyle Libre, Abbott Pharmaceuticals) included the inability to use the device in children and adolescents, lack of an alarm feature, and lack of ability to integrate with insulin pumps.

In June 2020, the U.S. Food and Drug Administration (FDA) cleared a second-generation flash CGM device (FreeStyle Libre 2, Abbott Pharmaceuticals) (14). This version improved on the first-generation system, with inclusion of a customizable alarm feature and an expanded age of approved use of ≥4 years and without any decrease in accuracy (14). The median absolute relative difference (MARD; a measure of system accuracy) also improved to 9.3% (9.2% in adults and 9.7% for pediatrics), compared with the first-generation system, which has a MARD of 9.4% for the personal version and 12.3% for the professional version (14,15). The FreeStyle Libre 2 also uses Bluetooth technology, which allows for enhanced data communication (14). Additionally, it was approved with the "integrated CGM" designation, which allows a CGM system to be used as part of an integrated system (14). Accordingly, this designation would allow it to be used in conjunction with automated insulin delivery devices such as insulin pumps in the future (14). Differences between available flash CGM devices are shown in Table 1.

Limitations to currently approved flash CGM devices must also be considered. Although the sensor is about the size of two U.S. quarters stacked, patients frequently inquire about alternate site placement other than the back of the upper arm. At the time of writing, alternate sites were not approved.

A second limitation is that sensors may not adhere well to the application site, resulting in the sensor falling off. To

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TABLE 1 Selected Differences in Available Flash CGM Devices

	FreeStyle Libre	FreeStyle Libre Pro	FreeStyle Libre 2
FDA age approval, years	≥18	≥18	≥4
Approved for nonadjunctive use (i.e., for medication dosing)	Yes	Yes	Yes
Approved application site	Back of upper arm	Back of upper arm	Back of upper arm
Blinded data	No	Yes	No
Possible integration with insulin pump	No	No	Yes, via integrated CGM designation
Wear time, days	14	14	14
Water resistance	3 feet for 30 minutes	3 feet for 30 minutes	3 feet for 30 minutes
Warm-up time, hours	1	1	1
Calibrations/day	None	None	None
Frequency of glucose readings	Every 1 minute (historical data storage every 15 minutes)	Every 1 minute (historical data storage every 15 minutes)	Every 1 minute (historical data storage every 15 minutes)
MARD, %	9.4	12.3	Adults: 9.2; pediatrics: 9.7
Alarms for hypoglycemia/ hyperglycemia	No	No	Yes, customizable

address this problem, proper sensor application site preparation must occur. This preparation should include ensuring that lotions or soaps are not present on the site, that the site is clean-shaven, and that an alcohol pad is used on the site before sensor application (16). A hypoallergenic and latex-free skin barrier (e.g., Skin Tac) can be applied between the sensor and the skin surface (16). Alternatively, bandages (e.g., Tegaderm) can be applied over the sensor without causing interference between the sensor and scanning device (16).

Finally, as intermittently scanned devices, all available flash CGM systems require users to scan the reader (or a compatible smartphone) over the sensor. The sensor must also be scanned at least once every 8 hours to support a continuous stream of glucose data (15).

Whether these shortcomings will limit continued expansion of flash CGM use by people with diabetes is not yet known, as there is still a role for real-time CGM in certain patients. However, the following three barriers still exist and require additional investigation:

1. Inexperience with flash CGM among clinicians in primary care settings. Ultimately, this problem hinders providers' ability to interpret patients' CGM-generated ambulatory glucose profile reports effectively and maximize the benefits of flash CGM to adjust drug therapy and make clinical decisions. Because most patients with type 2 diabetes do not receive specialized care from an endocrinologist, primary care providers must form a true team and leverage diabetes educators, dietitians, pharmacists, social workers, and population health nurses to improve diabetes care overall.
2. Lack of high-quality evidence to recommend patient self-management actions based on trend arrows. Although several expert recommendations exist for using flash CGM trend arrows, their usability at this time is limited to those using insulin (17–20). A growing body of evidence supports the use of flash CGM in people with type 2 diabetes who are not using insulin therapy (21–23); yet, how to support and empower these patients who are not using insulin to act on their trend arrows remains unclear.
3. Payers have yet to fully understand the benefits of flash CGM. Eligibility criteria for CGM are outdated (24) and do not incorporate findings from recent flash CGM trials (13,25). Additional advocacy efforts are necessary to better inform health policy stakeholders about the clinical and economic benefits of flash CGM.

Significant advancements in flash CGM use have been greatly anticipated within the diabetes community, including expansion to use in children and adolescents, as well as the addition of alarm features. As a community, it is time to address the aforementioned shortcomings to fully harness the benefits of flash CGM in an expanded population of people with diabetes.

DUALITY OF INTEREST

No potential conflicts of interest were reported.

AUTHOR CONTRIBUTIONS

K.C. is the sole author and guarantor of this work.

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