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Broadening Access to Continuous Glucose Monitoring for Patients With Type 2 Diabetes

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Persons from racial and ethnic minority populations, those in low-income groups, and other socially marginalized groups are disproportionately affected by type 2 diabetes and experience higher disease prevalence, poorer glycemic control, higher rates of diabetes complications, and higher prevalence of comorbid conditions.[1,2] Achieving glucose targets that will reduce the risk of diabetes complications, particularly among high-risk groups, is critical to improve the health and well-being of those with diabetes and to reduce health care utilization and expenditures. Yet, diabetes control remains elusive. Self-monitoring of blood glucose, while still a standard part of diabetes self-management, has not been shown to result in self-adjustments to insulin in primary care settings. This represents a significant opportunity gap because 30% of patients with type 2 diabetes are treated with some form of insulin.[3]

Real-time continuous glucose monitoring (CGM), which measures glucose levels in subcutaneous interstitial fluid as frequently as every 5 minutes, has been shown to improve diabetes control, reduce hypoglycemia, and be cost-effective for patients with type 1 diabetes.[4,5] Less research has been conducted among patients with type 2 diabetes, but clinical trials involving patients using intensive insulin regimens (eg, basal/bolus insulin) have shown reductions in hemoglobin A_{1c} (HbA_{1c}) levels and shorter intervals of hypoglycemia.[6,7] Several questions remain: Can the results of clinical trials of patients with type 2 diabetes be translated into usual care settings? Can patients with type 2 diabetes who use less intensive insulin regimens benefit from CGM? Can CGM be feasibly implemented in primary care settings, where most of type 2 diabetes management occurs? In this issue of *JAMA*, the randomized clinical trial (RCT) reported by Martens et al[8] and the observational study reported by Karter et al[9] provide new data that help provide answers to these questions.

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Martens et al[8] conducted an RCT of CGM (n = 116) vs blood glucose meter (BGM) monitoring (n = 59) among adults with type 2 diabetes who were taking basal insulin without prandial insulin and were recruited from primary care practices. At 8 months, the mean HbA_{1c} level improved from 9.1% to 8.0% in the CGM group and from 9.0% to 8.4% in the control group (adjusted difference, −0.4% [95% CI, −0.8% to −0.1%]). This effect size may have been greater if the control group had received usual care rather than instructions on how to self-titrate insulin based on BGM data. Compared with the BGM group, the time in range, or the amount of time spent in the target blood glucose range (70-180 mg/dL), was 3.6 hours per day higher, the mean glucose level was 26 mg/dL lower (95% CI, −41 to −12), and the time with glucose levels greater than 250 mg/dL was 3.8 hours per day less in the CGM group (all $P < .001$). There were also high rates of satisfaction among CGM users.

Karter et al[9] conducted a retrospective cohort study of 41753 adult patients (36 080 with type 2 diabetes, 5673 with type 1 diabetes) who were treated with insulin and were receiving care at Kaiser Permanente.[9] The authors followed the outcomes of those who initiated CGM (3806 patients) compared with those who did not; the CGM group primarily used basal/bolus insulin regimens, whereas the control group was treated with various types of insulin. Over the 4-year study period (which ended in December 2018), the authors reported a difference-in-difference reduction in HbA_{1c} level of −0.40% (95% CI, −0.48% to −0.32%) and in rates of emergency department visits and hospitalization for hypoglycemia of 2.7% (95% CI, −4.4% to −1.1%). The net change in HbA_{1c} level was greater among patients with type 2 diabetes (−0.56% [95% CI, −0.72% to −0.41%]) than among patients with type 1 diabetes (−0.34% [95% CI, −0.43% to −0.25%]) (P value for interaction = .003). In addition, a sensitivity analysis revealed a dose-response association between CGM adherence (0, 1, or ≥2 claims for CGM transmitters) and changes in HbA_{1c} level and hypoglycemia health care utilization.

These studies are important for several reasons. First, they confirm that CGM is a technology that can be effectively used by patients with type 2 diabetes to improve glycemic control. The trial by Martens et al[8] recruited a diverse sample of patients who have disproportionately had barriers to fully accessing health care and health care-related technology and also have had disproportionately lower rates of adherence to diabetes treatment plans. Most patients in this RCT were non-White persons (53%), had less than a college degree education (55%), and did not have private insurance (58%). Exploratory analyses suggested that the reduction in HbA_{1c} level did not differ across age groups, baseline diabetes control, education level, and diabetes numeracy, thus indicating a broad population benefit for CGM among patients with type 2 diabetes. The observational study from Karter et al[9] demonstrated the benefits associated with CGM in usual care settings and found a greater improvement in diabetes control among patients with type 2 diabetes than those with type 1 diabetes.

Second, the clinical trial by Martens et al[8] demonstrated the promise of using CGM in primary care settings, where most patients with type 2 diabetes receive their care. This trial, in which study clinicians met with trial participants during in-person clinic visits followed by virtual visits, provides a model that could be replicated or modified in many

primary care practices throughout the US. For example, having an initial consultation with an endocrinologist followed by telehealth visits with advanced practice nurses in an endocrinology practice could allow for download and interpretation of the CGM data in the specialty practice without requiring primary care practices to develop this expertise. A recent telehealth program that included remote monitoring of CGM demonstrated statistically significant reductions in HbA_{1c} levels among 594 patients with type 2 diabetes.[10] Project Extension for Community Health Outcomes (ECHO) successfully used remote learning as a venue for subspecialists to train primary care physicians to treat a range of conditions, including complex diabetes care,[11] and could be an alternative strategy for integrating CGM usage into primary care practice.

Third, these studies suggest that patients with type 2 diabetes who use less intensive insulin regimens may have similarly robust glycemic benefit as those who require more intensive regimens. In both the clinical trial, in which the intervention group received basal insulin only, and the observational study, in which 97% of the type 2 diabetes CGM group was taking basal/bolus insulin, the difference in HbA_{1c} reduction compared with the group that did not initiate CGM was −0.4%. This has significant implications for health policy. While patients in the RCT were taking basal insulin only and monitoring their blood glucose 3 or more times per week, the current American Diabetes Association grade A guidelines for CGM use include multiple daily injections of insulin (or an insulin pump) and Medicare guidelines require 3 or more daily injections of insulin (or an insulin pump) and self-monitoring of glucose 4 or more times daily.[12,13] The RCT by Martens et al[8] demonstrates that CGM is effective in patients with type 2 diabetes who are treated with less intensive insulin regimens and adds to the body of evidence that CGM is effective among patients with less intensive blood glucose monitoring.[14] The Medicare criteria have created significant administrative barriers to CGM use even for patients who are currently eligible because of the substantial documentation requirements that are unfamiliar, time-consuming, or both to clinicians and their staff. These criteria also create access barriers for patients who could clinically benefit from CGM but are not currently eligible. It is time to revise the Medicare criteria for CGM to reflect the current scientific evidence and simultaneously mitigate disparities in CGM access and diabetes control.[13,15]

Fourth, the RCT results suggest that patient engagement (ie, improved insulin adherence, changes in diet, or increased physical activity in response to CGM readings) was the most likely source of improved glycemic control because there were no differences in the total amount of insulin between study groups or in the amount of medication adjustments by clinicians. Activated patients are a powerful part of achieving diabetes control.[16] Patients in the clinical trial by Martens et al[8] reported high rates of satisfaction with the CGM, including high mean “benefits” scores and low mean “hassle” scores, suggesting a willingness of this diverse patient population to engage with the technology. Access to diabetes-related technology, including CGM, has been restricted among marginalized populations. These studies add to the literature by demonstrating that persons from racial and ethnic minority populations, low-income persons, and those with low numeracy want to be engaged, and can successfully be engaged, in diabetes-related technology that enhances self-management and improves diabetes control.

In summary, the studies by Karter et al[9] and Martens et al[8] provide additional evidence that patients with type 2 diabetes benefit from the use of CGM in terms of improved HbA_{1c} level, time spent in the target blood glucose range, and reduced hypoglycemic episodes. The glycemic benefits may be primarily due to patient factors, such as insulin adherence and lifestyle modifications, and provide a powerful narrative that CGM may be a useful technology that helps control diabetes among multiple patient groups. Important policy changes in Medicare eligibility to CGM for type 2 diabetes and institutional changes that promote its use in primary care will go a long way to improving diabetes control and reducing complications, particularly among the populations most in need. The time has come to broaden access to CGM for patients with type 2 diabetes.

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