RESPONSE TO COMMENT ON BERGENSTAL ET AL.

Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring. Diabetes Care 2018;41:2275–2280

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We thank Pluchino et al. (1) from the U.S. Food and Drug Administration (FDA) Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, for their thoughtful and detailed commentary. They conclude that our proposed continuous glucose monitoring (CGM)–derived measure called glucose management indicator (GMI) (2) is appropriate for inclusion in CGM software to generate a metric conveying extended glucose exposure that may also prove to be a helpful additional tool to personalize diabetes management.

In our estimation, this example of Dr. Lias and her colleagues from the FDA being willing to engage in a dialogue with the authors and the diabetes community focused on finding a solution to a clinical and regulatory quandary (in this case, the use of the potentially confusing term estimated A1C) is worthy of highlighting as a model for future productive clinical problem solving. While clear regulatory expectations and rigorous clinical trials to generate required outcome data are the essential elements needed to secure approval of new devices, drugs, or clinical indications, open dialogue focused on arriving at a solution is highly desirable.

Pluchino et al. (1) point out that HbA_{1c} continues to be an important population health metric closely associated with diabetes vascular complications. We concur with this point and also look forward to the new metric called GMI being included in all CGM data reports so patients and clinicians can better understand the laboratory-measured HbA_{1c} for each person with diabetes and agree upon appropriate individualized or personalized glycemic targets. CGM is increasingly being used as a tool to facilitate safe and effective glucose management, and thus clinicians and patients are no longer just relying on HbA_{1c}, or even GMI, to guide clinical decision making. They are closely evaluating the key CGM metrics like time in target range and time in hypoglycemia, as well as discussing the standardized CGM glucose profile, to create a therapeutic action plan (3).

There is every indication that with continued innovation in CGM development, additional CGM clinical trials and real-world implementation data, and new models of remote care and efforts to reduce the burden of living with diabetes, CGM use will greatly expand. It is helpful to know a dialogue between regulators, clinicians, researchers, and diabetes associations can overcome hurdles that may slow implementing innovations to advance safe and effective diabetes care.

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