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

Kristen M. Pluchino, Yiduo Wu, Alain D. Silk, Jisun Yi, and Courtney H. Lias

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Hemoglobin A_{1c} (HbA_{1c}) is well established in the clinical community as an indicator of diabetes management, where prolonged elevated HbA_{1c} indicates suboptimal control of blood glucose levels and predicts long-term diabetes complications (1). Laboratory-based and point-of-care assays for determining HbA_{1c} from blood samples are routinely used in clinical practice for assessing the effectiveness of blood glucose control and for the diagnosis of diabetes per guidelines from the American Diabetes Association (2). Devices that are used to measure HbA_{1c} are regulated by the U.S. Food and Drug Administration (FDA) to ensure that these devices are safe and effective for their intended use.

With advances in diabetes technology, especially with regard to the wider adoption of modern continuous glucose monitoring (CGM) devices and a corresponding flood of available glucose data, a new term, "estimated HbA_{1c}" or eA1C, started to emerge to describe a new index based on mean glucose values (typically calculated based on CGM data) that had been converted into percent units to provide an estimate of an individual's percent HbA_{1c}. As this "estimated HbA_{1c}" or eA1C became more widely used, FDA began to receive reports of significant confusion from patients and health care professionals (HCPs) about the meaning of an eA1C value. Patients misunderstood this term and believed that an eA1C result reflected their true measured blood HbA_{1c} values. HCPs were encountering patients who cancelled critical HbA_{1c} blood tests because they thought eA1C values could replace a blood test. Furthermore, for a significant number of people with diabetes, eA1C and true HbA_{1c} (i.e., HbA_{1c} measured in blood using a laboratory method) often do not align, which leads to significant confusion in the interpretation of these measurements. For example, FDA became aware of reports where treatment decisions were made based on eA1C results in cases where that index value was discrepant from laboratory HbA_{1c} results. Given these significant questions, FDA opened a dialogue with stakeholders to share knowledge on this issue and to discuss a potential path forward on how best to ensure that the valuable glucose data and trend information from CGMs can be leveraged for diabetes management while simultaneously ensuring that it is clearly differentiated from laboratory-based HbA_{1c} methodologies.

As discussed in their recent article (3), after extensive research and discussion with the diabetes community, Bergenstal et al. have proposed that this index based on mean CGM-derived glucose be identified as a "glucose management indicator" (GMI). FDA recognizes the efforts made by Bergenstal et al. (3) to establish useful terminology in this area and thanks the authors and the community for their efforts to address this emerging issue. FDA acknowledges that the term GMI is both descriptive of the use of the index and clearly unrelated to other established clinical results such as HbA_{1c}. FDA believes the authors' proposal to reshape the narrative around this metric through the proposed new terminology is an important step for the proper use of the metric and that the inclusion of GMI in certain diabetes management devices (e.g., software) could potentially offer additional insight into glycemic control. FDA anticipates that this new terminology, along with continuing open dialogue regarding its clinical utility within the context of diabetes management devices, will allow HCPs and patients to use GMI as an additional tool for the effective management of diabetes.

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Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Silver Spring, MD

Corresponding authors: Kristen M. Pluchino, kristen.pluchino@fda.hhs.gov, and Courtney H. Lias, courtney.lias@fda.hhs.gov

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