

The Need for Performance Standards for Continuous Glucose Monitors

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Abstract

Self-monitoring blood glucose (SMBG) devices or glucose meters currently provide a means for patients to manage insulin dosing through intermittent monitoring of blood glucose levels several times a day, but newer continuous glucose monitor devices (CGM) offer the potential of real-time glucose monitoring with less pain and lower cost. Unlike SMBG devices that sample glucose levels in circulating blood, CGM samples from the interstitial fluid. CGM devices generate not only a single level, but through averaging with past glucose results, can predict future trends. While consensus guidelines exist for evaluating the agreement of SMBG devices to other glucose and laboratory methods, no guidelines currently exist for CGM devices. Standards are needed to define the performance of CGM devices, both in terms of spot accuracy and trend information, as well as the level of performance required for clinical management. The Diabetes Technology Society (DTS) has been in close communication on the development of CGM guidelines with the Food and Drug Administration (FDA) and the Clinical and Laboratory Standards Institute (CLSI). Development of standards for CGM devices if adopted by the FDA would set minimum requirements of performance for manufacturers to meet in producing CGM devices and define common terminology for the display and clinical utilization of CGM data. It is expected that CGM performance standards will advance over time as technology improves and consumer demands change. The development of CGM standards will also play an important role in accelerating the development of an artificial pancreas, which relies on CGM technology.

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Abbreviations: (CGM) continuous glucose monitor, (CLSI) Clinical and Laboratory Standards Institute, (DTS) Diabetes Technology Society, (FDA) Food and Drug Administration, (SMBG) self-monitoring blood glucose

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