



# Glucose Management Indicator (GMI): Insights and Validation Using Guardian 3 and Navigator 2 Sensor Data

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The glucose management indicator (GMI) is an updated approach for estimating HbA<sub>1c</sub> from continuous glucose monitoring (CGM) data (1). GMI is calculated using the formula  $GMI (\%) = 3.31 + 0.02392 \times \text{mean glucose in mg/dL}$ , which has been derived by regressing contemporaneously measured HbA<sub>1c</sub> values (*y*-axis) against mean sensor glucose levels (*x*-axis). GMI was conceived using data collected solely with Dexcom glucose sensors; thus, generalization and validation of the formula for other sensor makes is currently unknown (1). Here, we assessed GMI using Guardian Sensor 3 (Guardian 3) (Medtronic Inc., Northridge, CA) and Freestyle Navigator II (Navigator 2) (Abbott Diabetes Care, Alameda, CA) glucose sensors and evaluated the difference between GMI and laboratory-measured HbA<sub>1c</sub> values.

We used data from three recently published 12-week randomized controlled trials evaluating the safety and effectiveness of closed-loop in comparison with sensor-augmented pump therapy in adults and children with type 1 diabetes and HbA<sub>1c</sub> between 7.5% and 10% (58 and 86 mmol/mol): APCam11 (Home Testing of Day and Night Closed Loop With Pump Suspend Feature) (*n* = 86,

Guardian 3) (2), AP@home04 (Closing the Loop in Adults With Sub-optimally Controlled Type 1 Diabetes Under Free Living Conditions) (*n* = 33, Navigator 2), and APCam08 (Closing the Loop in Children and Adolescents With Type 1 Diabetes in the Home Setting) (*n* = 25, Navigator 2) (3). APCam11 was a parallel design study, while AP@home04 and APCam08 were crossover design studies. Participants in the latter two studies contributed two sets of 3 months' CGM and HbA<sub>1c</sub> data. HbA<sub>1c</sub> was measured at a central laboratory using the International Federation of Clinical Chemistry–aligned method during the APCam11 study and at local laboratories during AP@home04 and APCam08 studies.

Table 1 shows the degree of concordance between the GMI calculated from mean sensor glucose and laboratory-measured HbA<sub>1c</sub> for the Guardian 3 and Navigator 2 sensors, compared with the Dexcom sensor. The percentage of individuals with similar GMI and laboratory HbA<sub>1c</sub> (absolute difference 0 to <0.1%) was comparable between the three sensors (19–20%), but the confidence intervals were wider for Guardian 3 and Navigator 2 sensors related to smaller sample sizes. The

percentage of those with >0.5% deviation between GMI and laboratory HbA<sub>1c</sub> were 32% and 36% for Guardian 3 and Navigator 2 sensors, respectively, compared with 28% for Dexcom sensors, with substantially overlapping CIs.

Our data provide validation of the formula used for calculating the GMI using Guardian 3 and Navigator 2 sensors. We found that across these three CGM sensors, there were overall substantial numbers of individuals with type 1 diabetes who had what appears to be a clinically meaningful difference between laboratory HbA<sub>1c</sub> and sensor glucose-derived HbA<sub>1c</sub> (GMI). This difference, irrespective of the sensor used, should be considered important information by clinicians and individuals with diabetes to help personalize glucose management decisions. For example, as mentioned in the original GMI publication (1), if a person has a GMI always considerably lower than expected from measured HbA<sub>1c</sub>, one has to be careful not to set the therapeutic goal based on the laboratory HbA<sub>1c</sub> target too low and to ensure that time spent in hypoglycemia is not excessive.

Further studies with larger databases using these and other sensors will be

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**Table 1—Difference between GMI (calculated from CGM-derived mean glucose) and laboratory-measured HbA<sub>1c</sub>**

Absolute value of difference between GMI and laboratory HbA <sub>1c</sub> (%)	Percentage of values (95% CI)		
	Guardian 3 sensor (n = 85)	Navigator 2 (n = 114)	Dexcom sensors**
0 to <0.1	19 (11–29)	20 (13–29)	19 (16–22)
≥0.1	81 (71–89)	80 (72–87)	81 (78–84)
≥0.2	66 (55–76)	68 (58–76)	67 (63–71)
≥0.3	54 (43–66)	56 (46–65)	51 (47–55)
≥0.4	42 (32–54)	46 (36–56)	39 (34–43)
≥0.5	32 (22–43)	36 (27–46)	28 (24–32)
≥0.6	24 (15–34)	28 (20–37)	19 (15–22)
≥0.7	13 (7–22)	21 (14–30)	12 (9–15)
≥0.8	11 (5–19)	12 (6–19)	8 (5–10)
≥0.9	5 (1–12)	8 (4–15)	4 (3–6)
≥1	3 (1–10)	5 (2–10)	3 (2–4)

\*\*Dexcom data from Bergenstal et al. (1).

helpful to inform clinicians how meaningful the difference in laboratory HbA<sub>1c</sub> versus GMI is when aiming to personalize HbA<sub>1c</sub> for diabetes management. In addition, further work is required to understand the impact of glucose variability on the difference in laboratory HbA<sub>1c</sub> and sensor glucose-derived HbA<sub>1c</sub> (GMI).

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Care; and consulting fees from Insulet, Bigfoot Biomedical, and Eli Lilly. R.M.B. has received research support from, consulted for, or been on a scientific advisory board for Abbott Diabetes Care, Dexcom, Eli Lilly, Johnson & Johnson, Medtronic, Novo Nordisk, Onduo, Roche, Sanofi, and UnitedHealthcare. R.M.B.'s employer, the nonprofit HealthPartners Institute, contracts for his services and no personal income goes to R.M.B. R.H. reports having received speaker honoraria from MiniMed Medtronic, LifeScan, Eli Lilly, B. Braun, and Novo Nordisk; having served on advisory panels for Animas, MiniMed Medtronic, and Eli Lilly; having received license fees from B. Braun and Becton Dickinson; and having served as a consultant to Becton Dickinson, B. Braun, Sanofi, and Profil. No other potential conflicts of interest relevant to this article were reported.

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