



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

*Diabetes Care* 2019;42:e60–e61 | <https://doi.org/10.2337/dc18-2479>

Lalantha Leelarathna,<sup>1,2</sup> Roy W. Beck,<sup>3</sup>  
Richard M. Bergenstal,<sup>4</sup>  
Hood Thabit,<sup>1,2</sup> and  
Roman Hovorka,<sup>5,6</sup> on behalf of  
APCam11, AP@home04, and  
APCam08 Investigators

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

<sup>1</sup>Manchester Diabetes Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, U.K.

<sup>2</sup>Division of Diabetes, Endocrinology and Gastroenterology, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, U.K.

<sup>3</sup>Jaeb Center for Health Research, Tampa, FL

<sup>4</sup>International Diabetes Center Park Nicollet, Minneapolis, MN

<sup>5</sup>Wellcome Trust-MRC Institute of Metabolic Science, University of Cambridge, Cambridge, U.K.

<sup>6</sup>Department of Paediatrics, Cambridge University Hospitals NHS Foundation Trust, Cambridge, U.K.

Corresponding author: Lalantha Leelarathna, [lalantha.leelarathna@mft.nhs.uk](mailto:lalantha.leelarathna@mft.nhs.uk)

Received 3 December 2018 and accepted 19 January 2019

© 2019 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at <http://www.diabetesjournals.org/content/license>.

**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).

**Funding.** AP@home04, APCam08, and APCam11 studies were supported by grants from JDRF and the Seventh Framework Programme of the European Union, with additional support from a National Institute for Health Research Cambridge

Biomedical Research Centre and Wellcome Strategic Award. Medtronic and Abbott Diabetes Care provided discounted sensors for the above studies. R.M.B.'s research is partly funded by the National Institute of Diabetes and Digestive and Kidney Diseases (grant DK108611).

**Duality of Interest.** L.L. reports having received speaker honoraria from Animas, Abbott, Insulet, Medtronic, Novo Nordisk, Roche, and Sanofi; having served on advisory panels for Animas, Abbott, Novo Nordisk, Dexcom, Medtronic, Sanofi, and Roche; and having received research support from Novo Nordisk and Dexcom. R.W.B.'s nonprofit employer has received research funding from Dexcom, Bigfoot Biomedical, and Tandem Diabetes Care; study supplies from Roche, Ascencia, Dexcom, and Abbott Diabetes

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.

**Author Contributions.** L.L. analyzed data and wrote the manuscript. R.W.B., R.M.B., H.T., and R.H. contributed to discussion and reviewed and edited the manuscript. L.L. and R.H. are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

## References

- Bergenstal RM, Beck RW, Close KL, et al. Glucose management indicator (GMI): a new term for estimating A1C from continuous glucose monitoring. *Diabetes Care* 2018;41:2275–2280
- Tauschmann M, Thabit H, Bally L, et al.; APCam11 Consortium. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. *Lancet* 2018;392:1321–1329
- Thabit H, Tauschmann M, Allen JM, et al. Home use of an artificial beta cell in type 1 diabetes. *N Engl J Med* 2015;373:2129–2140