Utilising the Ambulatory Glucose Profile (AGP) combined with the Glucose Pattern Summary to Support Clinical Decision Making in Diabetes Care – A Consensus Position Statement

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Consensus

The Ambulatory Glucose Profile (AGP) enables retrospective analysis of dense data, trends and patterns for people with diabetes and their healthcare team to help achieve appropriate glucose targets and minimise hypoglycaemia and hyperglycaemia.

Background

Continuous Glucose Monitor (CGM)/Flash Glucose Monitor (Flash GM) technology facilitates more frequent and structured glucose profiling to improve clinical care for people with diabetes [1-3]. Indeed, a recent Australian study showed that people with type 1 diabetes who used CGM had lower HbA1c levels, a greater likelihood of achieving a HbA1c of less than 7.0%, less likelihood of achieving a HbA1c of more than 9.0%, and lower rates of severe hypoglycaemia and diabetes-related ketoacidosis [4].

Capillary glucose monitoring is reliant on the person with diabetes conducting a fingerprick test, which can be inconvenient, painful and a barrier to self-care. [5]. CGM and Flash GM enable the ready use of real-time monitoring of interstitial glucose levels. Furthermore, with the increase in data access via CGM/Flash GM, the person with diabetes can make timely interpretations and decisions about their glucose management, which appropriately account for glucose trends across minutes and hours [6]. The advent of 'low' and 'high' Bluetooth-enabled glucose alarms and improved measurement accuracy in devices over recent years provides greater safety and timely self-care for the person with diabetes. In addition to real-time measures, glucose monitoring enables glucose summary patterns and profiles to be automatically generated, so the person with diabetes and their healthcare team can, retrospectively, interpret glucose metrics and patterns to help achieve individualised glucose targets, minimise hyperglycaemia and more importantly minimise hypoglycaemia [7].

An Australian Diabetes Society 'Standardisation of AGP Profile Workshop' was held on April 13th 2018, to identify the clinical effectiveness of glucose profiling in diabetes with a focus on retrospective, summary reporting methods. This document reflects the primary outcomes of that Consensus Workshop, leading to a consensus statement with a practical focus first published in June 2020. This ADS Consensus Statement has been updated in August 2022 to reflect current clinical practice relevant to people with diabetes utilising CGM and Flash GM technology.

Exploring summative Continuous Glucose Monitor (CGM) reporting

The summary glucose metrics that can be derived from interstitial glucose monitoring can be reported as:

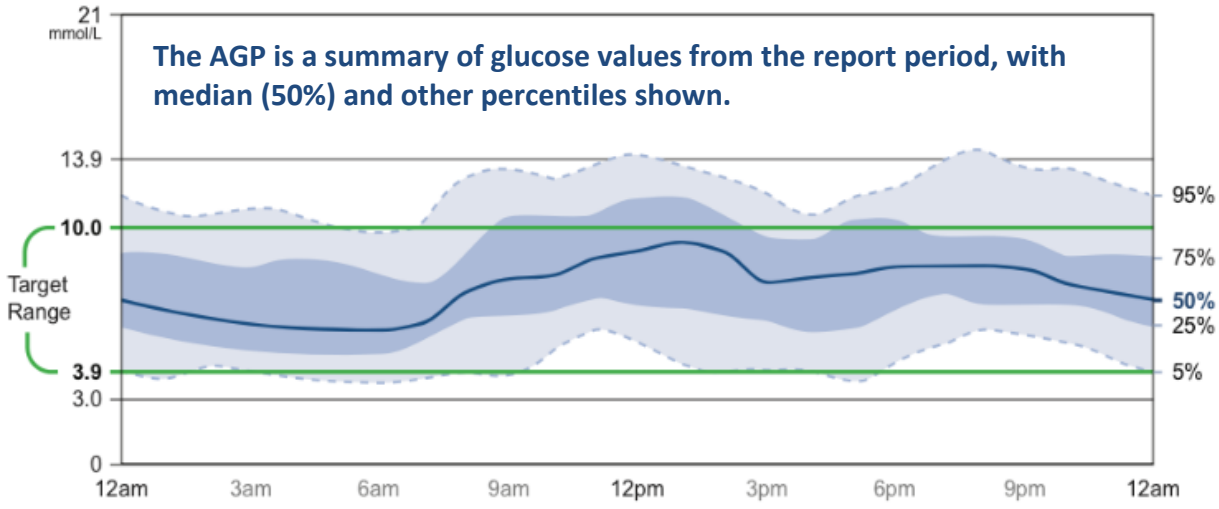
(i) the Ambulatory Glucose Profile (AGP) [8] and
(ii) the glucose pattern summary data [9] (AGP Plus)

Each provides metrics that complements the other, and the two combined form the AGP Report.

(i) The Ambulatory Glucose Profile (AGP)

The AGP is a concept that was formed by Professor Roger Mazze and colleagues in the late 1980s when structured blood glucose monitoring was being developed [10]. Subsequently, software has been developed that helps to assemble glucose levels into a graphical summary. This software has facilitated the presentation of CGM data to enable rational data interpretation in the clinical context [7, 9].

Figure 1



As shown in Figure 1, the glucose data derived are assembled across 24-hour periods, combining consecutive days' results into one summary graph. The median line indicates that 50% of readings fall above the line, and 50% of the glucose readings fall below the line. To reflect variation in data, the 25th and 75th centiles are included as shaded areas, as are the 5th and 95th centiles.

Thus, the AGP provides a graphical representation of data across a series of days, consolidated into one image. Its strengths are:

- ease of interpretation of median glucose levels;
- identifying both hyperglycaemic and hypoglycaemic glucose trends, as shown in a consolidated 24-hour period graph;
- variability in glucose levels between and within days is easily identifiable [7-9].

Challenges are:

- the data generated need to be near-complete to aid interpretation;
- timing of meals, in particular, may vary between days and thus contribute to variability in and across day summary data;
- within day variability may be diluted, and the lowest glucose levels, i.e. below the 5th centile, are not shown on the AGP page [8].

Indeed, as described in the next section, a series of metrics, including time zones across the day and viewing the individual day glucose tracing data, are needed to interpret AGP data appropriately.

(ii) Glucose Summary Data – AGP Plus

A series of additional summary glucose and related metrics have been derived by international diabetes expert panels and health professional organisations, further enhancing the AGP data [1,3,6,10,11]. These include the following components:

(a) **Sensor capture data completeness** - provides information on the completeness of the reading period across a predefined serial time frame. The aim is for this to have at least 70% of the data captured across the entire 14-day time period. Indeed, it is recommended that CGM be worn for 14 days [11].

(b) **Low glucose events graph** – a summary graph indicating the individual hypoglycaemic events, including their timing, duration/time in hypoglycaemia and shape/nadir, which emphasises these clinically important events.

(c) **Glucose management indicator (GMI)** – recent publications have indicated that the use of 14 days of continuous glucose monitoring data generates a glucose management indicator that compares favourably with laboratory based HbA1c values.

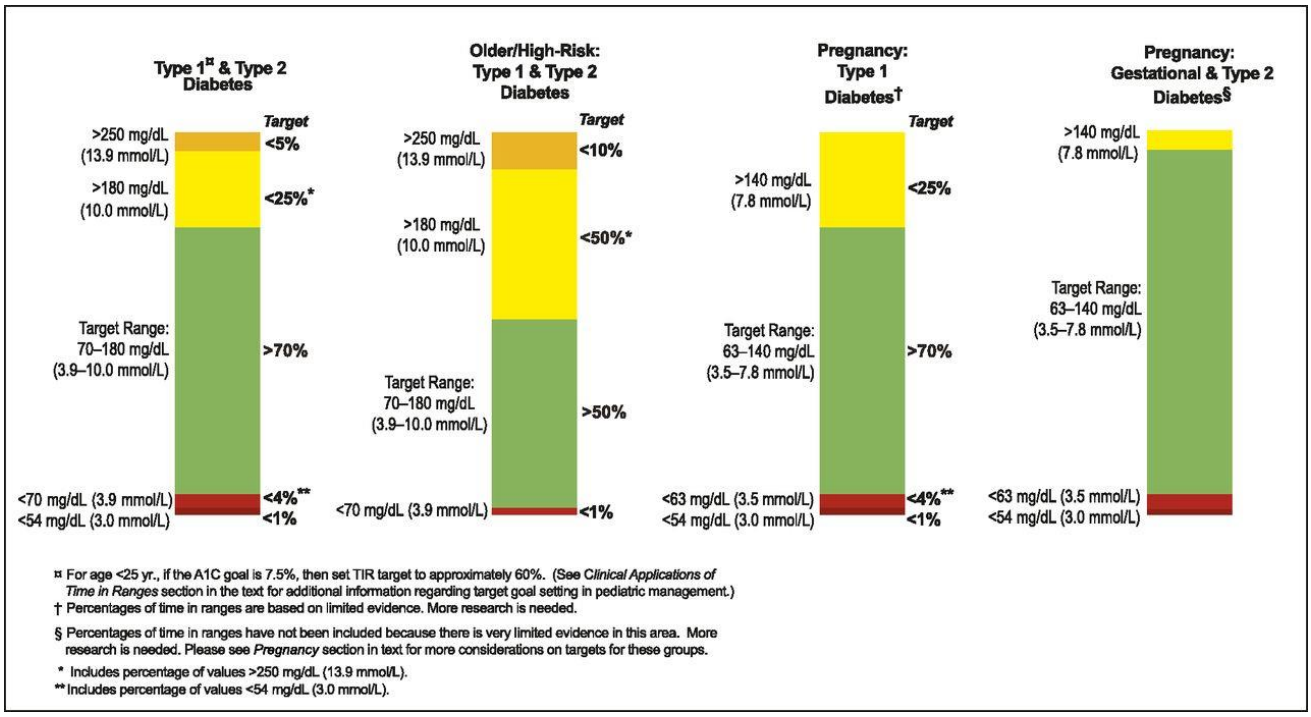
(d) **Time in glucose target range (TIR)** –this metric is increasingly being used to reflect whether an individualised target range is being achieved in the glucose measures monitored. The monitoring period can vary, but a two-week timeframe is most commonly used. Typically, in adults with type 1 diabetes, the range chosen is 3.9-10.0 mmol/L, and the % time in range is aimed at 70% (or higher), with less than 4% below the target range, and less than 25% above the target range. Usually, column or pie graphs are utilised to report the time-in-range data [11].

(e) **% coefficient of variation (CV)** and standard deviation (SD) of glucose – these parameters reflect variability in glucose readings. For people without diabetes, the %CV normal range is at, or less than, 25%, and for people with type 1 diabetes, it should be less than 36%.

(f) **Individual day data graph** – shows daily tracings of the glucose values and may include markers of the timing of main meals and exercise events, thus facilitating interrogation of the patterns within individual days.

Recently, the International Consensus on Time in Range updated a number of clinical parameters, including time in range and above and below range targets. Figure 2 below shows CGM-based targets for different diabetes populations [12].

Figure 2



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)
† Percentages of time in ranges are based on limited evidence. More research is needed.
§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.
* Includes percentage of values >250 mg/dL (13.9 mmol/L).
** Includes percentage of values <54 mg/dL (3.0 mmol/L).

Practical Points:

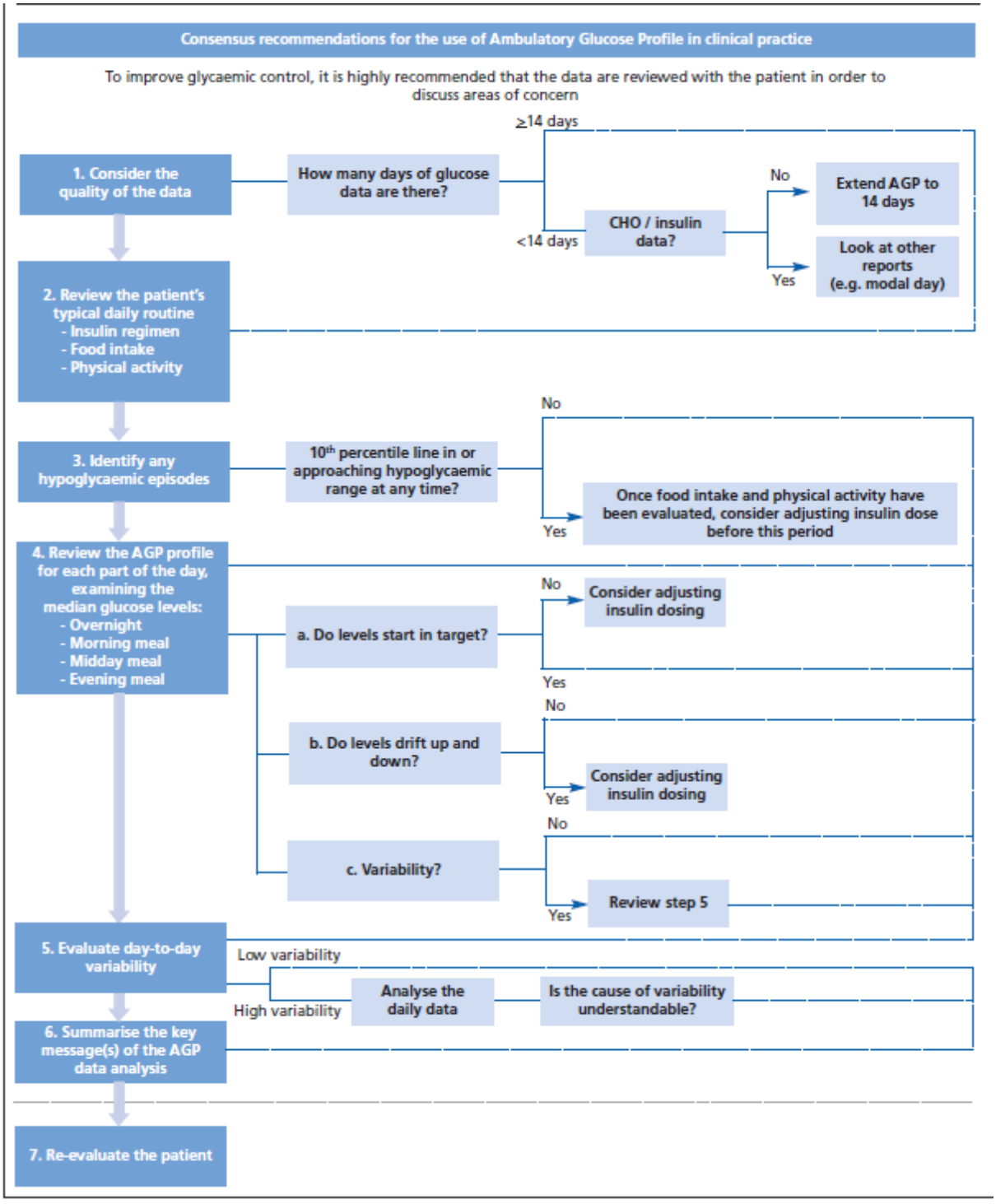
1. In general, for type 1 and type 2 diabetes, a time in range of greater than 70% with a time below range of less than 4% and a time above range of less than 25% is recommended.

2. For older people or those at high risk or with hypoglycaemia unawareness, a time in range of greater than 50% with a time below range of less than 1% and a time above range of less than 50% is recommended.

3. It is recommended that the AGP Plus report be complemented by clinical assessment including individualising glucose targets and assessing for the occurrence of any severe hypoglycaemic events.

An expert panel of diabetes specialists in Europe [13] developed a step-by-step approach to assist clinicians in undertaking the analysis of AGP reports in clinical practice (Figure 3). The group supported the view that the AGP can be an effective standard for the analysis of glucose data. The step-by-step approach is expected to improve glycaemic control and may help patients better understand and become more involved in the management of their diabetes. The focus and priority should be on preventing and managing hypoglycaemia, including nocturnal episodes.

Figure 3



RECOMMENDATION:

Minimum CGM data sets for clinical interpretation

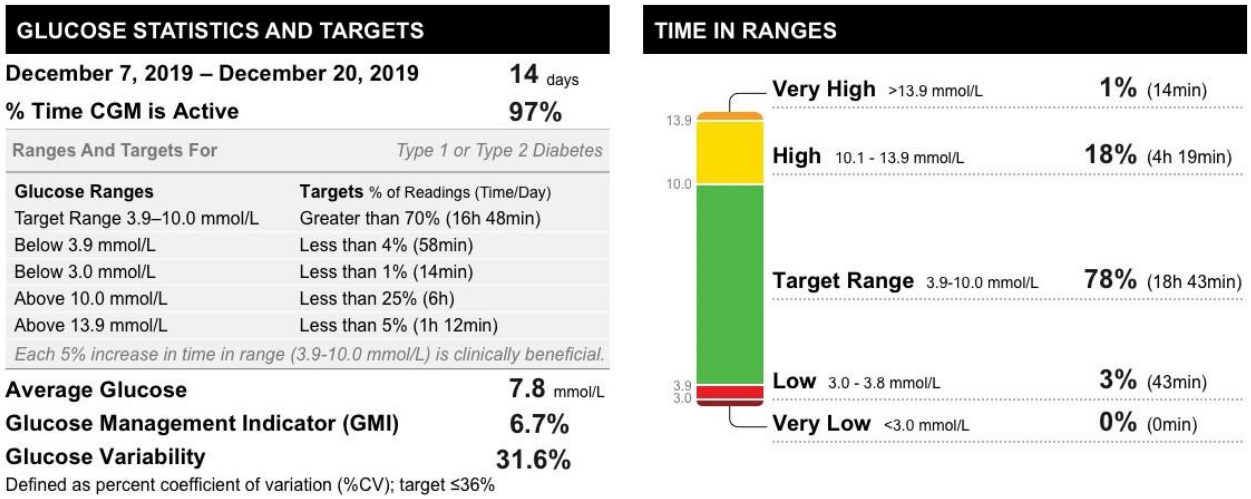
The Australian Diabetes Society recommends that the minimum CGM summary data set for patient summative CGM reporting is the AGP combined with the Glucose Summary Data (a) to (f) inclusive, given above. This combined series of parameters of Summative CGM Reporting is termed here AGP Plus. The AGP Plus data should be interpreted in the clinical context for the particular person with diabetes undertaking CGM, and the individualised HbA1c and target glucose range setting.

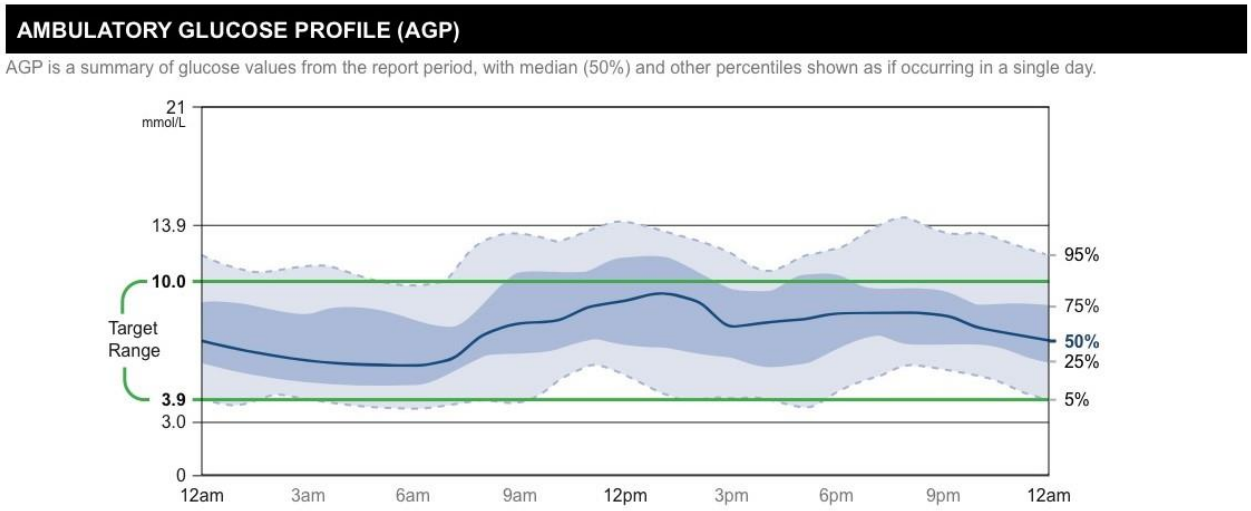
Structured consensus-based approaches have recently been developed to enhance the education of health care professionals as well as people with diabetes [3,7,11]. This includes education about real time CGM related self-care, and management decisions and should take into account the available retrospective data provided in the form of AGP Plus.

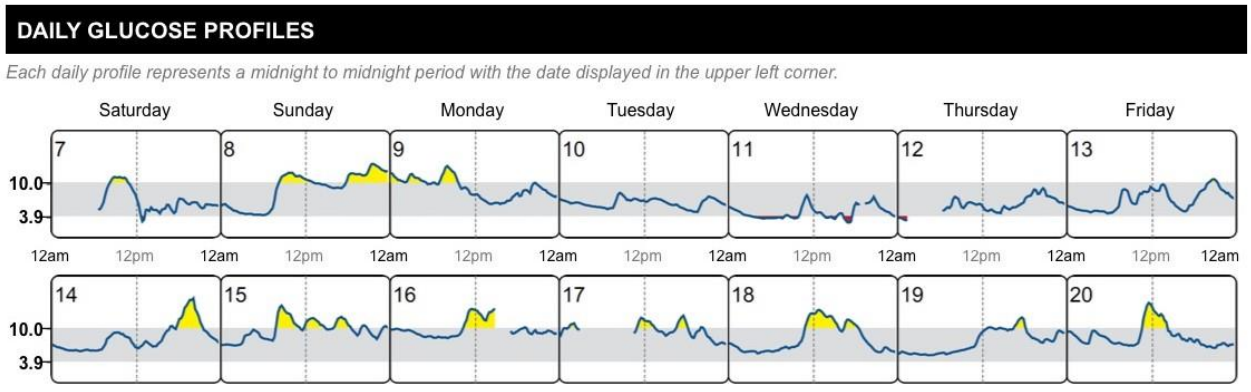
While it is beyond the scope of this Consensus Position Statement to provide detailed clinician and patient education for AGP Plus, Figure 4 below aids in the identification of the key components of the Summative CGM Reporting outlined in this Consensus Statement. It is expected that utilisation of AGP Plus will enhance clinical decision making for both clinicians and people with diabetes.

Figure 4

An example of the AGP combined with available Glucose Summary Data of the AGP Plus (collectively forming an AGP Report)). For an explanation of the parameters described, refer to the text.







Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." *Diabetes Care*, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

Declarations of conflict/potential conflict of interest:

Stephen Twigg is the Academic Chair and Neale Cohen is a member of the Australian National Advisory Board for Abbott Diabetes Care (Freestyle Libre Flash Glucose Monitoring System).

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