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

The ADS 'AGP Plus' Working Party
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Consensus

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

Preamble

In recent years, developments in technology and improved access to technology have facilitated more frequent and structured glucose profiling to aid clinical care in people with diabetes mellitus [1]. This enhancement in data is most prominent for frequent interstitial glucose monitoring that characterises both continuous glucose monitoring and on-demand flash glucose monitoring [2].

The interstitial glucose monitoring devices enable ready use of real-time monitoring. Capillary glucose monitoring is reliant on the individual (person) with diabetes conducting a fingerprick test, which can be more inconvenient and for many people a barrier to selfcare. [3]. With the increase in data access via interstitial monitoring, the person with diabetes can make timely interpretations and decisions about their glucose management including trends across minutes and hours [4].

In addition, glucose monitoring across a series of days, enables glucose summary patterns and profiles to be reported, so the person with diabetes and their health care team can, retrospectively, interpret glucose metrics and patterns, in order to help achieve individualised glucose levels targets, and to minimise hypoglycaemia, and hyperglycaemia [5].

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 methods of reporting. This document reflects the main outcomes of that Consensus Workshop, leading to this consensus position statement with a practical focus.

Exploring summative Continuous Glucose Monitor (CGM) reporting

The summary glucose metrics that can be derived from interstitial glucose monitoring can broadly be divided into:

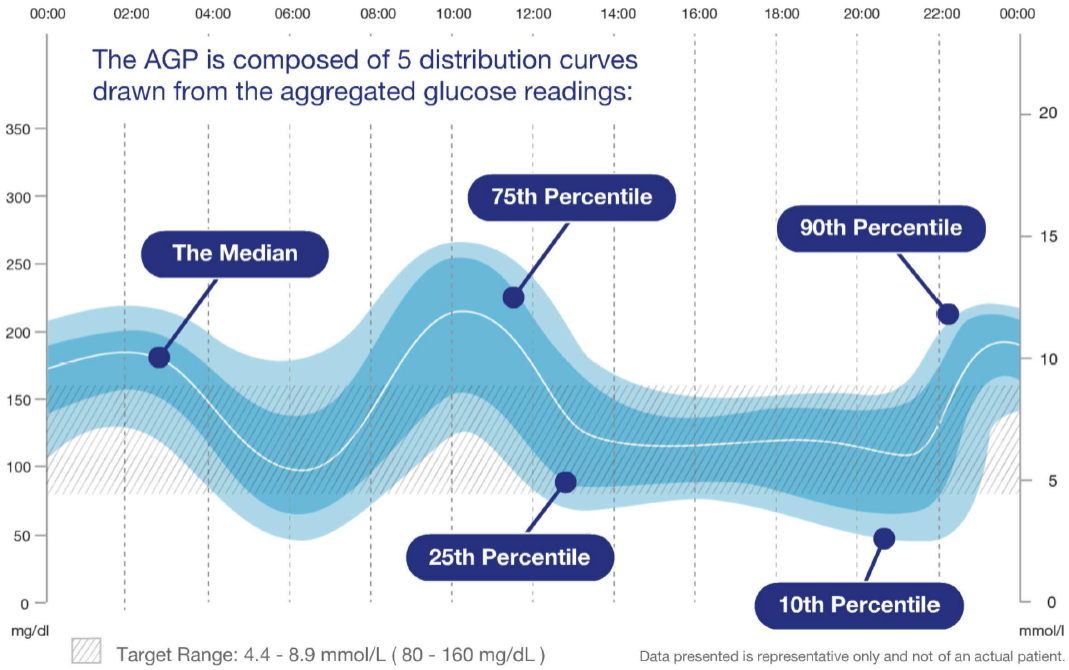
(i) the Ambulatory Glucose Profile (AGP) [6] and
(ii) the glucose pattern summary data [7] (AGP Plus).

Each provides metrics that complements the other.

(i) The Ambulatory Glucose Profile (AGP)

The AGP is a concept that was independently formed by Professor Roger Mazze and colleagues in the late 1980s when structured memory blood glucose monitoring was being developed [8]. Subsequently, software was developed that helped to assemble glucose levels into summary graphical format. This software has facilitated the presentation of CGM data to enable rational data interpretation in the clinical context [5, 7].

Figure 1



As shown in Figure 1, the glucose data derived are assembled across 24 hour periods, combining consecutive days' results into the 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. In order to reflect variation in data, the 25th and 75th centiles are included as shaded areas, as are the 10th and 90th centiles.

Thus, the AGP provides a graphical representation of data across a series of days, consolidated into one image. Its strengths are in the ease of interpretation of median glucose levels, identifying both hyperglycaemic and hypoglycaemic glucose trends more comprehensively in a 24-hour period, and variability in glucose levels both between and within days [5-7]. Challenges are that: 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 that the lowest glucose levels, ie below 10th centile, are not shown on the AGP page [6]. 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 appropriately clinically interpret AGP data.

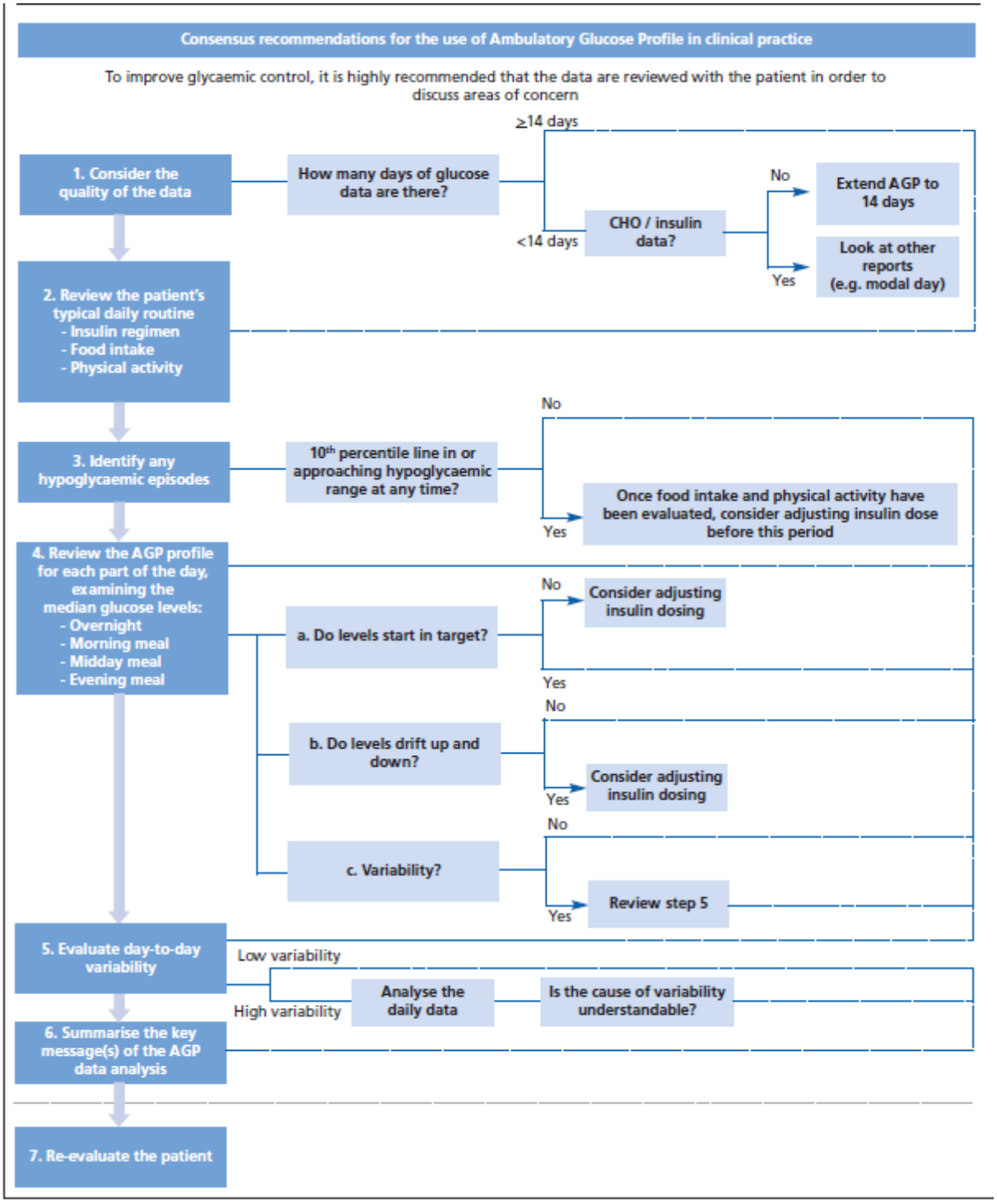
(ii) Glucose Summary Data – 'AGP Plus'

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]. 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 90% of the data captured across the entire time period.
(b) Low glucose events graph – a summary graph indicating the individual hypoglycaemic events, including their timing, duration/time in hypoglycaemia and shape/nadir, adds emphasis to these clinically important events.
(c) The estimated HbA1c – recent publications have indicated that use of 14 days of continuous glucose monitoring data can provide an estimated HbA1c level that compares favourably with laboratory based HbA1c values.
(d) Time in glucose target range (TIR) – increasingly this metric is being utilised to reflect whether an individualised target range is being achieved in the glucose measures monitored. The period of monitoring can vary but most commonly a two week timeframe is used. Typically in adults with type 1 diabetes, the range chosen is 4.0-10.0 mmol/L and the % time in range is aimed at 60%, with less than 5% below the target range, and at most the remaining 35-40% above the target range. Usually, column graphs or pie graphs are utilised to report the time-range data.
(e) % coefficient of variation (CV) and standard deviation (SD) glucose variability data – this parameter reflects 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 day by day tracings of the glucose values, and may include markers of the timing of main meals and exercise events, thus facilitating interrogation of the readings' trace within individual days.

An expert panel of diabetes specialists in Europe (11) developed a step by step approach to assist clinicians in undertaking the analysis of AGP reports in clinical practice (Figure 2). 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 prevention and management of hypoglycaemia, including nocturnal.

Figure 2



RECOMMENDATION:

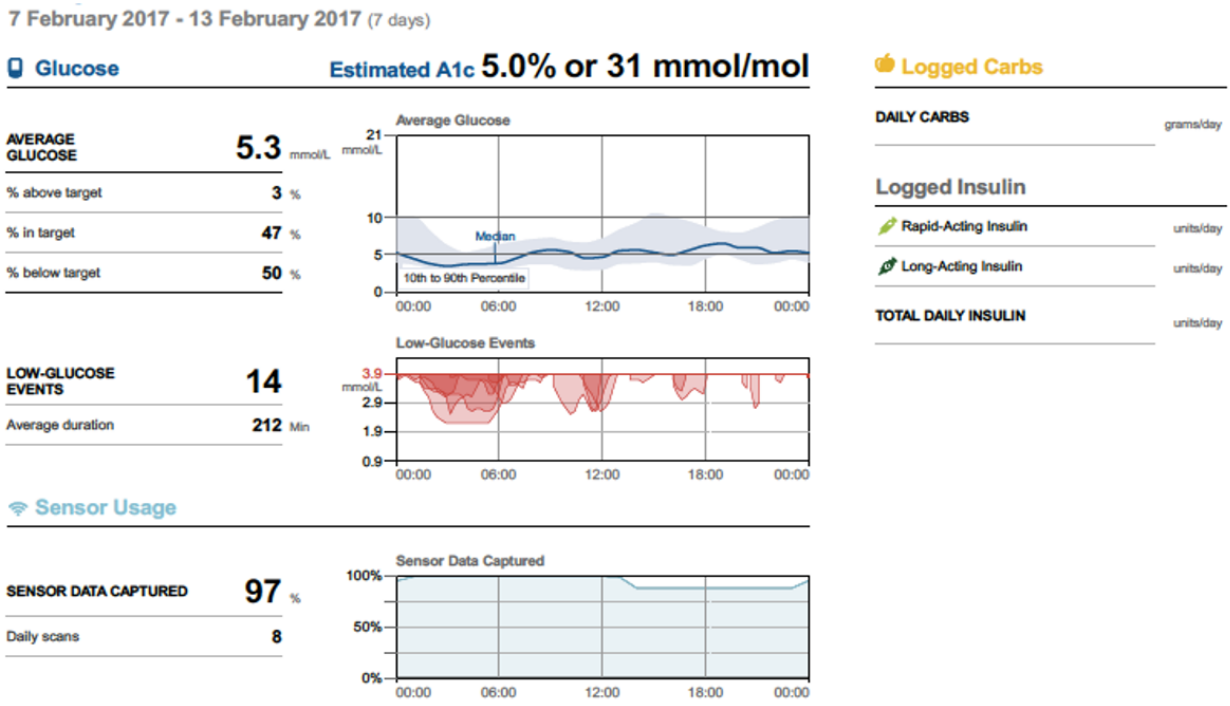
Minimum CGM data sets for clinical interpretation

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 of the rationale for the particular person with diabetes to be 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 [2, 5,10]. This includes education about real time CGM related self-care, and management decisions should take into account the available retrospective data provided in a 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', Figures 3 and 4 below aid identification of the key components of this Summative CGM Reporting outlined in this Consensus Statement. It is expected that utilisation of AGP Plus will enhance ease of patient care for both clinicians and people with diabetes.

Figures 3

An example of available Glucose Summary Data and the AGP combined (AGP Plus or Summative CGM Reporting). For an explanation of the parameters described, refer to the text. To convert glucose levels to mmol/L, divide the glucose level in mg/dL by 18.



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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