Strengthening Safety through Regulatory Standardisation for Continuous Glucose Monitoring Systems (anzCGM) in Australia and New Zealand

A statement by the Australian Diabetes Society (ADS), Australian Diabetes Educators Association (ADEA), Australasian Diabetes in Pregnancy Society (ADIPS), Australian and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZSPED) and New Zealand Society for the Study of Diabetes (NZSSD).

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INTRODUCTION

Self-management of glycaemia is a cornerstone of effective diabetes management, targeting blood glucose levels within clinically recommended ranges[1]. People with type 1 diabetes, type 2 diabetes, gestational diabetes and other forms of diabetes, particularly those using insulin, derive significant benefit from frequent glucose monitoring to achieve optimal glucose levels as well as reduce the risk of hypo- and hyperglycaemia. Traditionally, this has been achieved by finger-pricking. However, this can be a painful process and insights into glucose levels are limited by the number of measurements a person with diabetes can reasonably achieve in an average day[2]. Furthermore, there may be significant stigma associated with finger-pricking in a public setting, adding to the distress that a person with diabetes may experience.

In recent times, the introduction and increasing use of continuous glucose monitoring (CGM) devices has revolutionised self-management of diabetes and empowered the person with diabetes and their carer with more data to facilitate decision making[3]. These devices provide continuous interstitial fluid glucose measurements including trend arrows and alarms to alert the person if levels are outside predefined upper and lower limits[4]. CGM related summary statements include the ambulatory glucose profile (AGP) providing aggregated data over 1 week to 3 months highlighting time-in-range, time-above-range and very importantly time-below-range (among other parameters) that can be targeted with appropriate lifestyle and medication adjustments as well as education[5,6]. Numerous studies have shown the benefits of CGM vs finger-pricking in people with diabetes[7].

With these technological advancements, glucose assessment using CGM has become the preferred method of testing for an increasing number of people with diabetes. CGM reflects the current technology standards of care and provides people with diabetes, and health care professionals, with a much better understanding of their glycaemic parameters.

The Need: Why have a performance standard?

CGM devices can be paired with continuous insulin infusion systems (insulin pumps) to form hybrid closed loop automated insulin delivery systems. This integrated technology works together to provide real-time glucose data and dynamically adjusted insulin dosing, which is now considered the standard of care for people with type 1 diabetes[8,9]. Glucose levels measured on CGM devices are also increasingly used by people with all types of diabetes to titrate insulin doses delivered by multiple daily injections. A performance standard for CGM devices is absolutely necessary in this context.

CGM is used across the lifespan of the person living with diabetes and is essential for safeguarding quality of life, promptly detecting hypoglycaemia (particularly if this occurs overnight), as well as hyperglycaemia and glucose variability. Australian data show that after CGM introduction more people achieved the HbA_{1c} target of <7.0% (53 mmol/mol) and CGM use reduced the risk of suboptimal glycaemic management (HbA_{1c} ≥9.0%/75 mmol/mol)[10]. Diabetic ketoacidosis (a life-threatening complication of diabetes requiring hospital admission), was also reduced in the group that used CGM more than 75% of time[10]. Ensuring the accuracy and quality of CGM is essential, as variability in device performance may affect self-management and insulin dosing decisions which can adversely impact glycaemic outcomes[11]. Poorly performing CGM devices may also lead to a loss of confidence in what can be a very useful tool for people living with diabetes, carers and their care providers.

In 2021, the peak national diabetes health professional bodies of Australia (ADS, ADEA, ADIPS and ANZSPED) published a consensus statement on the use of diabetes management technologies in type 1 diabetes[12]. In Australia CGM is fully subsidised for people with type 1 diabetes who are under the age of 21 years or hold a concession card; women with type 1 diabetes who are planning a pregnancy, pregnant or post-pregnancy; or people under the age of 21 years with conditions very similar to type 1 diabetes that require insulin. CGM is partially subsidised for people with type 1 diabetes who are over the age of 21 years and do not hold a concession card. Thus, full or partial subsidisation is available for all people with type 1 diabetes and is provided by the Australian Government through the National Diabetes Services Scheme (NDSS)[13]. In Aotearoa New

Zealand CGM is fully subsidised by Pharmac for people with type 1 diabetes[14]. CGM is not subsidised for people with type 2 diabetes in either country, who are therefore required to self-fund.

People with diabetes in Australia who are eligible for the NDSS subsidy are offered Therapeutic Goods Administration (TGA) listed CGM devices approved for their specific indication. CGM systems were evaluated by the TGA as Class III (high risk) medical devices and were required to meet high standards of accuracy and safety pre-approval. As such, each CGM system was evaluated independently by a panel of experts and had to satisfy the TGA defined 'Essential Principles'; a remnant from pre-July 2024. Presently, CGM devices are considered Class IIb (moderate/high risk). Such rigorous review is no longer applicable today. This reduction in review process and shortened approval period, dependent on overseas regulatory approval such as the European Medical Device Regulation (MDR) and Conformité Européenne (CE) mark, for new CGM devices coming into the Australian and New Zealand markets may require further rigorous clinical and safety review. It is worth noting that acquiring a CE mark does not necessarily imply that a device is accurate.

In Aotearoa New Zealand, the current government is developing a new Medical Products Bill, however at present there is minimal regulation of medical devices, and in particular devices can be imported and supplied even if they have not been approved elsewhere, or if they do not meet appropriate quality standards[15]. Although subsidised CGM devices have undergone review as part of the Pharmac process[14], unsubsidised CGM devices may presently enter the market in Aotearoa New Zealand in the absence of clinical review.

Recognising the problem of regulation, the International Federation of Clinical Chemistry (IFCC) CGM Working Group[16] published minimum expectations for devices in Europe (eCGM) and is in the process of developing performance standards to be used for market authorisation in the region. Furthermore, minimum standards for integrated devices (iCGM) have been developed by the US Food and Drug Administration (FDA)[17]. Both these statements set out the minimum parameters or "standards" that a CGM device needs to meet, demonstrated in clinical and real-world studies, to be relied upon for clinical decision making and best outcomes for people with diabetes.

The Australian Diabetes Clinical Quality Registry 2024 Report shows that approximately 90% of people with type 1 diabetes and 6% of people with type 2 diabetes are using CGM to monitor their glucose levels[18]. It is therefore critically important that manufacturers of CGM devices achieve minimum standards of accuracy, precision and reliability for their device(s) prior to approval by the Australian and New Zealand regulator and prior to being considered for subsidy. Meeting this set of minimum standards ensures the safety and clinical benefit for the person with diabetes who is relying on the CGM device for treatment decisions and appropriate use of tax-payer funds.

Methodology of developing the anzCGM statement

It I important to state that this is a consensus statement that is based on the select literature and clinical expert opinion of the writing group. A formal GRADE process was not employed to assess the literature cited in writing this statement. Members of the Australian Diabetes Society (ADS), Australian Diabetes Educators Association (ADEA), Australasian Diabetes in Pregnancy Society (ADIPS), Australian and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZSPED) and New Zealand Society for the Study of Diabetes (NZSSD) met to develop the consensus statement. The statements by European (eCGM) and American (iCGM) bodies regarding CGM standards were considered[11,16,17] in writing the anzCGM statement, as well as other relevant literature as indicated. All members of the writing committee contributed to the discussion and to editing the statement. Endorsement was then sought and gained from each of the five contributing society boards of directors.

This consensus statement recommends the minimum standards of anzCGM (further detailed below). The methodology, including study design and performance analytical challenges of CGM, are beyond the scope of this article. It is recommended that minimum standards are based on the Clinical and Laboratory Standards Institute guideline POCT05 – Performance Metrics for Continuous Interstitial Glucose Monitoring[19], which

provides consensus information about how CGM data should be assessed for accuracy, what factors can decrease accuracy and how CGMs should be operated for optimal performance. This guideline describes CGM performance features, including point and trend accuracy, evaluation of threshold alerts, system stability and reliability, clinical studies for assessing CGM performance, calibration, measurement traceability, and special considerations such as shelf life, cybersecurity, and product labelling.

The Australian and New Zealand CGM (anzCGM) minimum standard recommendations

The anzCGM minimum standard recommendations presented in Table 1 have been derived from previous publications[11,16,17]. The accuracy of CGM measurements must be tested across different glucose ranges. Power calculations have indicated that at least 100 subjects are required in performance studies. Furthermore, performance requirements are different between adults and paediatric populations (due to blood sampling limitations) with a minimum recommendation of 4,000 paired data points in children compared to 12,000 pairs for adults over a range of blood glucose levels to include values below 3.9 mmol/L and above 10.0 mmol/L.

Table 1: Proposed/Recommended Minimum Standards for anzCGM Devices in Australia and New Zealand

Table 1 below lists the proposed/recommended minimum standards for anzCGM devices in Australia and New Zealand*.

Testing requirements		
At least 100 subjects are required in performance studies.		
A minimum of 4,000 paired data points in children and 12,000 pairs for adults.		
Glucose Range	**Performance against reference reading**	**Lower one-sided 95% confidence bound must exceed requirement**
Hypoglycaemia		
<3.9 mmol/L	Within ± 0.83 mmol/L	>85% of readings
<3.9 mmol/L	Within ± 2.22 mmol/L	>99% of readings
Normoglycaemia		
3.9-10.0 mmol/L	Within ± 15%	>70% of readings
3.9-10.0 mmol/L	Within ± 40%	>99% of readings
Hyperglycaemia		
>10.0 mmol/L	Within ± 15%	>80% of readings
>10.0 mmol/L	Within ± 40%	>99% of readings
Across reportable range	Within ± 20%	>87% of readings
Overall, across all glucose measuring ranges	Within ± 20%	>87% of readings
CGM <3.9 mmol/L when reference >10.0 mmol/L		0 readings
CGM >10.0 mmol/L when reference <3.9 mmol/L		0 readings
CGM ROC ≥ 0.055 mmol/L/min when corresponding true negative ROC ≤ -0.111 mmol/L/min		≤1% of readings
CGM ROC ≤ -0.055 mmol/L/min when corresponding true positive ROC ≥ 0.111 mmol/L/min		≤1% of readings

CGM – continuous glucose monitor; ROC – rate of change
*Adapted from: Pemberton *et al*. *Diabetes Obes Metab* 25:916–939, 2023[11]; Mathieu C. *et al*. *Diabetes Obes Metab* 27:1025-1031, 2025[16]; Klonoff *et al*. *J Diab Sci Tech* 19:1392–1399, 2024[17]

This anzCGM Statement recommends that the manufacturers should publish the performance of their CGM device(s) against the standards in reputable peer-reviewed journals, accessible in public databases (for example FDA Clinical Trials register, or World Health Organisation Clinical Trials platform, or Australian and New Zealand Clinical Trials Registry) and presented in the instructions for use found in the pack inserts.

Studies need to be conducted to meet minimum standards of accuracy and precision throughout the measuring range of the device, including rapid rates of change when approaching hypo- and hyperglycaemia[20]. Furthermore, it is important to evaluate the deviation between CGM values and blood glucose measurements using an appropriate comparator that meets predefined analytical performance specifications for bias and imprecision such as YSI Glucose Analyzer or other comparable laboratory instrument in the first instance. Additionally, the comparator should be used to determine the minimum standards for accuracy (rather than CGM-derived values). Usability studies should also include digitally low literate and vulnerable populations, and non-app access pathways, to ensure equity.

When presenting the performance of a CGM device, it is important to:

- recruit a study demographic that is powered to allow full analysis of study outcomes for each intended sub-population with diabetes
  (including paediatric, adolescents and older populations would be preferable
- outline the testing protocol and selection of comparator samples
- describe the methodology and statistical analysis used
- use at least 3 unique sensor lots
- have sufficient readings taken at each anatomical insertion site
- have sufficient readings reflecting start, mid and end of sensor wear duration with minimal signal loss to maintain connectivity and visibility
- have sufficient readings taken as per standard testing procedures in extreme glucose ranges (e.g. during exercise or during rapid changes in glucose levels) across several days of sensor use

The data are presented according to:

- diabetes type
- age
- adiposity
- pregnancy status (using the current consensus overall glycaemia target range and the consensus fasting glucose range for pregnancy)
- mean absolute relative difference (MARD)
- agreement rates across full glucose range or outside range
- time in range (TIR)
- time below range (TBR)
- time above range (TAR)
- coefficient of variation (CV)
- days of sensor use
- time between sensor insertion and first glucose reading
- CGM companion software and applications should comply with Software as a Medical Device (SaMD) regulatory standards demonstrating security, accuracy, consistent data transfer, usability, and robust protection of health information

Other parameters that are important to consider include:

- sensor stability
- calibration stability
- threshold alert reliability and predictive alert reliability for hypo- and hyperglycaemia
- sensor survival
- data availability
- interfering substances (e.g. paracetamol, high dose Vitamin C)
- %20/20 accuracy
- %15/15, %20/20, %30/30, %40/40, and >%40/40 accuracies
- concurrence of CGM and comparator values
- mean relative difference (MRD)
- mean absolute difference (MAD)
- mean difference (MD)
- % CGM values in Zone A and Zone B of Consensus Error Grid
- precision absolute relative difference (PARD)
- alert performance
- hypoglycaemia alert rate
- hypoglycaemia detection rate
- hyperglycaemia alert rate
- hyperglycaemia detection rate
- CGM sensor life
- lag time
- post-surveillance data to be provided to the regulatory authority to ensure ongoing safety of the device – e.g. annual high-risk device reports to capture adverse events, device failures, and usability issues, especially in high-risk populations and pregnancy

The Value of mean absolute relative difference

Mean absolute relative difference (MARD) is the average of the absolute difference of measured sensor glucose reading and capillary glucose reading and is often used as a key report of CGM accuracy. However, it should only be one element in the assessment of accuracy and has a number of limitations[21]. The MARD is impacted by a number of factors including the number of comparison measurements and the time periods within which the comparisons are made. Important factors not accounted for in MARD is the rate of change of glycaemia and the clinically important impact at different glucose extremes, especially hypoglycaemia.

Pregnancy

Tight glycaemic management during pregnancy is critically important to confer improved outcomes for the mother and baby. As a result of blood volume expansion in pregnancy, fasting glucose levels are 10-20% lower, hence the target fasting glucose range is low and tight (~3.5-5.5 mmol/L). However, the accuracy of CGM devices within this low and narrow glycaemic range recommended for pregnancy remains insufficiently validated, as

most major device accuracy analyses do not specifically target pregnant populations or the hypoglycaemic spectrum relevant in this context[22]. While no international standard currently mandates pregnancy-specific accuracy requirements for CGM devices, evaluating performance in this specific range is particularly important when considering their use during pregnancy. Validation should incorporate metrics between 3.5-5.5 mmol/L – particularly focusing on performance in the hypoglycaemic range (<3.9 mmol/L) which is critical for maternal and foetal care.

It is important to note that several factors including sensor site, movement and hydration can influence MARD. Although body composition has not been shown to affect MARD, studies have not been conducted in underweight and class 3 obese populations. There is uncertainty on the accuracy of CGM at these extremes of body mass and adiposity. CGM devices should be tested in underweight populations and populations with class III obesity and above[23].

Summary

In light of this growth, it is essential that CGM technologies can demonstrate meeting clearly defined minimum standards recommended in this consensus statement to ensure they deliver meaningful clinical benefit and maintain user safety. Establishing and upholding these standards is imperative to ensuring responsible investment and long-term confidence in the technology, working towards healthier glucose parameters and management for people living with diabetes.

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