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CGM Accuracy in a Fragmented Regulatory Landscape: A Commentary on Harmonisation and Recent Evidence

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1 | Background

Continuous glucose monitoring (CGM), either as a standalone device or as part of an automated insulin delivery (AID) system, represents the standard of care for people with type 1 diabetes (T1D) [1]. The clinical value of CGM and AID in terms of improving glycaemic control and patient-reported outcomes (PROs) is well established [2–5]. CGMs also generate a wealth of data, and CGM metrics such as time-in-range (TIR) are increasingly used as endpoints in clinical trials [6–8]. Moreover, each new generation of CGM systems brings incremental benefits over previous generations in terms of effectiveness, predictive capacity, accuracy, interoperability and/or usability. Improvements in CGM technology over time were reflected in the Food and Drug Administration (FDA) approval of the first factory-calibrated CGM for non-adjunctive use in 2017 [9]. This allowed therapy-related decision-making based on CGM readings alone, reducing the need for confirmatory fingerstick testing and calibration, thereby reducing the burden of disease management for users [9, 10]. However, even with the latest generation of CGM systems, there is still a need to perform fingerstick testing if symptoms do not align with CGM readings or users have reason to doubt the reading [11, 12]. The initial introduction of non-adjunctive CGM systems was accompanied by a degree of scepticism from some clinicians as to whether the accuracy of CGM systems was sufficient to inform decision-making [13, 14].

The regulatory approval processes for CGM systems market access differ across geographic regions. Currently, there is no unified protocol for how CGM performance studies should be conducted and reported. In addition, there are no harmonised performance criteria that CGM systems must meet to be considered sufficiently accurate (when these protocols are followed). This variability allows market access for CGM systems of

uncertain quality and complicates comparisons between devices as well as AID systems. In the first part of this commentary, we aim to explain why harmonisation is needed and give an overview of the ongoing standardisation efforts. Second, recent scientific publications have reported differences in the accuracy of the most widely used CGM systems, including Abbott FreeStyle Libre 3 (FL3), Dexcom G7 (DG7) and MiniMed Simplera (MSP). This has raised questions among healthcare professionals regarding the efficacy of these devices. In the second part of this commentary, we aim to provide a critical appraisal of two manuscripts that have been central to this discussion. We evaluated these manuscripts from both a methodological and clinical perspective and provided further insight into the ongoing discussion.

2 | Part 1: The Need for Harmonisation and Ongoing Efforts

2.1 | Variability in CGM Accuracy Studies and Regulatory Processes

Given the pivotal role of today's CGM systems in the management of people with T1D, the accuracy and reliability of these devices are of critical importance. The authors of several publications have recently highlighted differences in the approval processes for CGM systems across different regions and called for uniform standards for CGM performance evaluation (inclusive of point accuracy, trend accuracy, stability and reliability), as well as the design and reporting of respective clinical studies [15–18]. Indeed, in a scoping review of CGM performance studies published in 2002–2022, the study design was found to be heterogeneous, and many studies had mixed diabetes populations (T1D and T2D) and/or relatively low participant numbers (over half of the included studies had ≤ 50 participants) [16].

There are also considerable differences in the approval processes for medical devices across different countries/regions. In the United States, the FDA stipulates specific requirements around accuracy and interoperability for class II integrated CGM (iCGM) devices (note that CGM or AID systems may alternatively be approved as class III devices, which also requires submission of comprehensive clinical and safety evidence) [19, 20]. Medical devices receiving FDA approval via the premarket approval route, or clearance via the 510(k) route, should be regarded as safe and effective for their intended use [21]. Further, in the United States, labelling is also required to contain clinical study performance data specific to each intended use population and CGM site. Performance data for each population and anatomical insertion site must also meet required benchmarks across different glucose ranges and rates of change [22]. In Europe, Conformité Européenne (CE) marking is required for a CGM system to be marketed, with assessment performed by independent notified bodies (NBs). Of note, one of the changes introduced as part of the European Medical Device Regulation (MDR), which came into effect in 2021, was the positioning of NBs under a greater degree of scrutiny from national authorities. However, to date, there are no ISO standards nor specific minimum performance benchmarks for CE marking of CGM systems specific to the intended use population, despite the importance of accuracy in the era of non-adjunctive CGM use [23]. Similarly, in Latin America, there are also no minimum performance standards [24].

In recent years, concerns have been raised in several European countries with regard to the performance of some commercially available CGM systems and hybrid closed-loop (HCL) devices [15, 25, 26]. In the United Kingdom specifically, Pemberton et al. [17] noted that, for specific commercially available CGM systems, accuracy in the hypoglycaemic range falls below that of the US standards for integrated CGM devices. They also draw attention to instances wherein some of the indications for specific CE-marked devices are beyond those covered by publicly available clinical data. Moreover, performance data are required for CE marking, so performance may have been evaluated in all indicated groups, although these data are not publicly available. Additionally, in terms of device choice, if performance is assumed to be equal across various available CGM systems, as cost and insurance coverage are factors that may influence choice, CE-marked devices with lower cost represent an attractive option for payers with finite budgets [27, 28].

2.2 | Overview of Standardisation Efforts

In recognition of an absence of consolidated guidance around CGM system performance studies, an International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group on CGM (WG-CGM) has formulated a set of recommendations around study design, reference comparators and reporting [29, 30]. Similarly, Mathieu et al. [23] have proposed minimum standards for a European CGM compliance status, largely based on the FDA's iCGM criteria, covering study design and reporting and performance standards, as well as a reference to meeting all relevant cybersecurity and data privacy legislation. Additionally, the International Diabetes Federation (IDF) Europe has proposed updating the European MDR to include specific requirements for CGM systems and also supports the publication of all clinical data on performance [25]. A consolidated, agreed-upon set of European standards would allow for a stringent quality benchmark and greater transparency around performance metrics for individual devices.

While there is broad agreement on the need for a set of unified performance standards, a few aspects of study design are still subject to debate, for example, whether the most appropriate reference should be venous or capillary glucose levels. Both approaches have proponents and associated arguments. IFCC WG-CGM advocate the use of capillary glucose measurements as the reference standard, among other reasons because of the long-standing use in self-monitoring of blood glucose among people with diabetes, the low risk of adverse events and its ease of use [29, 30]. In contrast, both Kropff et al. and Klonoff et al. advocate the use of venous glucose measurements as the reference standard. Their rationale includes the widespread use of venous glucose measurements in the United States, the fact that venous (or arterialised venous) blood glucose was used in the pivotal trials of currently available CGM systems, the FDA's requirement in iCGM special controls that the comparator for CGM pivotal studies should be an FDA-accepted laboratory-based glucose measurement method, and several practical advantages. These include the availability of larger sample volumes, which facilitate

duplicate measurements, and the avoidance of repeated finger-prick sampling, thereby reducing participant burden [31, 32].

Many of the CGM performance studies published to date focus on MARD as a measure of accuracy; however, as outlined by Heinemann et al. [33], and Vigersky and Shin [20], MARD has both advantages and limitations. Heinemann et al. caution against reliance on MARD alone, noting that it is influenced by the rate of change in glucose levels and does not take into account the directionality of any bias. Alternative approaches, such as error grids, capture both magnitude and directionality of error [34]. Specific criteria for agreement rates are also provided in the FDA class II integrated CGM requirements and in the proposed IFCC WG-CGM guidelines [22, 30]. However, Stephan et al. [35] note that while the FDA specifies limits for lower 95% confidence intervals for agreement rates, no guidance on the preferred method of calculation is provided.

3 | Part 2: A Debate on CGM Accuracy

The discussion around the performance evaluation of current CGM systems has recently been intensified following the publication of two articles on the same study [36, 37]. The authors report the findings from performance evaluations of three widely used CGMs (FL3, DG7 and MSP) with the CGMs compared against each other and against reference comparators (venous blood using the YSI 2300 STAT PLUS [YSI] and Cobas Integra [INT], and capillary blood using Contour Next [CNX]). Both publications included data from 23 or 24 adults with well-controlled T1D, who wore all three CGM systems simultaneously for up to 15 days. The authors reported differences in CGM accuracy and glycaemic metrics (e.g., TIR) between different systems. This is an elegant and well-conducted study, and the importance of such studies cannot be emphasised enough. However, experts in the field of diabetes have interpreted the study findings more broadly than warranted, which inadvertently undermined confidence in the accuracy of well-established CGM systems.

Eichenlaub et al. [36] demonstrated that the performance of all CGMs varied according to the reference method used, but that 'across comparators FL3 and DG7 tended to be more accurate compared with MSP'. While the authors stated that all CGM systems performed well and that the study was not intended to rank system performance, in the field of diabetes, MSP was criticised for displaying a high MARD against CNX, suggesting poor accuracy, as well as exhibiting a negative bias that could potentially inflate TIR by classifying out-of-range values as within target range. Although allied to this, Freckmann et al. also note that MSP likely detects hypoglycaemia earlier, but hyperglycaemia later, relative to FL3 and DG7 [37]. As stated, the criticism of MSP accuracy was based on performance relative to CNX, a self-monitoring of blood glucose metre, and to INT, an FDA cleared blood glucose analyser. When all three CGM systems were assessed against YSI, which is widely regarded as the reference standard, the MARD values differed by no more than 0.5%.

Further, in Eichenlaub et al. [36], the overall magnitude of YSI-derived bias was comparable across the three CGM systems, with the key difference being the direction of bias. FL3 and DG7 showed positive bias relative to YSI, whereas MSP showed a negative bias. Notably, the YSI-derived biases reported in Eichenlaub et al. [36] differ from those used for FDA regulatory approval, based on the manufacturer-sponsored pivotal trials (Table 1) [38–40]. Regulatory data show that all three CGM systems exhibit a negative bias, particularly in the hyperglycaemia range. A negative bias in the hyperglycaemia range is generally considered less harmful than a positive one: a positive bias, when glucose is overestimated, may prompt an AID system or users of manual insulin delivery systems (injection pens or non-automated insulin pumps) to administer excess insulin, thereby increasing the risk of hypoglycaemia. Further, the pivotal trial data for all three CGM systems were based on much larger datasets, and even though each pivotal trial used a different study design, all CGM systems received regulatory approval from the FDA (and CE mark), indicating that the designs were considered sufficiently rigorous and reflective of the glycaemic variability

TABLE 1 | YSI-derived biases as reported in Eichenlaub/Freckmann studies and the CGM system pivotal trials [36–40].

	Bias[a]					
	FL3		DG7		MSP	
Comparator range, mg/dL	Eichenlaub/freckmann study[b], *N* = 24	Pivotal trials[c], *N* = 200	Eichenlaub/freckmann study[b], *N* = 24	Pivotal trials[c], *N* = 308	Eichenlaub/freckmann study[b], *N* = 24	Pivotal trials[c], *N* = 116
54–69	8.5 mg/dL (276)	1.4 mg/dL (3111)	7.6 mg/dL (276)	1.1 mg/dL (4530)	3.1 mg/dL (231)	4.9 mg/dL (2030)
70–180	7.2% (1057)	−4.5 mg/dL (10748)	7.1% (1097)	1.1 mg/dL (17910)	−6.5% (1055)	−1.0 mg/dL (8818)
181–250	4.7% (669)	−7.3 mg/dL (4122)	5.6% (674)	−1.9 mg/dL (5905)	−9.7% (646)	−10.0 mg/dL (2625)

Abbreviations: DG7, Dexcom G7 system; FL3, FreeStyle Libre 3 system; MSP, MiniMed Simplera system.
[a]Presented as either mg/dL or % as shown.
[b]Bias values (18+ years) reported as median (number of paired CGM-YSI points) across glucose ranges < 70, 70–180 and > 180 mg/dL.
[c]Bias values (18+ years) reported as mean (number of paired CGM-YSI points).

encountered in everyday life. Findings from another simultaneous wear study by Sanfilippo et al. [41], which compared the same CGMs in an exercise setting, also showed that FL3 and DG7 aligned more closely with CNX, whereas MSP showed somewhat lower glucose readings. It should be noted that YSI was not included in that study.

One interpretation of the differences in CGM system bias relative to CNX and YSI references is that some of the systems examined are designed to track venous glucose, whereas others are designed to track capillary glucose (a distinction often mischaracterised as venous- vs. capillary-calibrated). However, in the pivotal studies, all three CGM systems were evaluated against venous YSI measurements, and these data formed the basis for regulatory approval and the performance information provided in the instructions for use (IFU).

Some potential sources of bias should be discussed. First, regarding study sample size, a study population should ideally be of such size that individual variability does not influence the overall outcome. Freckmann et al. showed substantial variability in CGM metrics between trial participants as well as between CGMs [37]. Together with the absence of normally distributed TIR values (note that Freckmann et al. reported medians rather than means), this indicates that the study may carry a risk of selection bias due to small sample size. Indeed, the small sample size was acknowledged as a limitation of the analyses by the authors [37].

Another potential limitation is that a portion of the analyses (approximately 21 h) was conducted during in-clinic sessions using a study protocol that included conditions that are relatively uncommon in routine clinical practice. These in-clinic sessions were designed, in part, to assess CGM performance under 'extreme' glycaemic conditions, such as rapid glucose fluctuations (exceeding 3 mg/dL/min). However, such conditions may accentuate the physiological lag between venous blood glucose (measured by YSI), capillary blood glucose (measured by CNX) and peripheral interstitial glucose (measured by CGM). This type of stress testing is essential from a safety perspective, as CGM systems must perform safely under challenging conditions. However, the frequency and duration with which such extreme conditions occur in real-world use are not clearly documented [42–44]. Interestingly, these extreme conditions may have had an impact on the accuracy metrics reported by Eichenlaub et al., while they are less likely to have substantially influenced the 14-day analyses reported by Freckmann et al.

Notably, the IFCC WG-CGM recently proposed guidelines outlining requirements for CGM accuracy study design, including specifications for comparator characteristics, as well as minimum performance criteria that CGM systems should meet in such evaluations [30]. To establish these minimum performance criteria, data from two studies involving FL3 were used to define a benchmark. Consequently, FL3 would, by default, meet the proposed criteria. However, based on the study data from Eichenlaub et al. and Freckmann et al., it remains unclear whether the other two CGM systems, DG7 and MSP, would also meet these thresholds (especially when YSI would be used as a comparator). Second, in a recent Letter to the Editor [45], the data from Eichenlaub et al. and Freckmann et al. were used to evaluate whether FL3 and DG7, both of which received FDA clearance as iCGM systems, would again meet the same iCGM criteria when the IFCC WG-CGM procedures were actually used. Interestingly, neither system met all iCGM criteria under these conditions (especially when YSI was used as a comparator). Together, these publications may have inadvertently created the perception in the diabetes field that FL3, DG7 and MSP fall short in terms of accuracy. This perception is however not aligned with clinical reality. For more than 20 years, these CGM systems, and earlier generations thereof, have contributed to more effective diabetes management, substantially improving the lives of people with diabetes. Furthermore, the clinical outcomes associated with all three systems, including earlier iterations, have been evaluated across multiple studies [46–51].

Lastly, although some reports have suggested that CGMs, particularly MSP, may overestimate TIR [52–54], there are also studies not supporting this observation. Recently, data were published from a small but adequately powered randomised crossover study involving 24 individuals with T1D who used the MiniMed 780G AID system for two 6-week periods, paired alternately with MSP and the Instinct CGM (which is the same CGM as the Free Style Libre 3+, developed by Abbott exclusively for MiniMed) [55]. CGM outcomes were statistically non-inferior to each other, suggesting that any differences in CGM accuracy were not reflected in clinically meaningful glycaemic outcomes. HbA1c seemed similar as well, and although the cross-over period was 6 weeks, HbA1c is known to represent a weighted mean of glycaemic exposure over the previous 3 months with glucose levels during the most recent 6 weeks contributing most strongly to the measured value. Consistent with these findings, a large U.S. real-world evidence study presented demonstrated that among > 4000 users who transitioned from MiniMed 780G with Guardian 4 Sensor to MiniMed 780G with Instinct, no meaningful differences in TIR were observed (data on file at the University of Indiana, Prof. Viral Shah).

4 | Conclusion

While the need for a comprehensive and transparent benchmarking framework is widely recognised, and several groups have proposed draft guidance, there remains a need to align efforts across the different groups and stakeholders and to develop international consensus standards for evaluating CGM systems. In this commentary, we have shown that careful critical appraisal of the literature is essential in moving toward such standards. Until harmonised standards are in place, direct comparisons of CGM system accuracy remain complex. Data from the FDA likely provide the most robust available assessment of device accuracy.

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Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

Peer Review

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