Diabetes community calls for quality standards for continuous glucose monitoring devices

Francesco Giorgino,[a] Tadej Battelino,[b] Stefano Del Prato,[c] Rahab Hashim,[d] Sabine E. Hofer,[e] Sufyan Hussain,[d] Kasia Karpinska,[f,*] Tom Melvin,[g] Eric Renard,[h] Campbell Hutton,[i] Jannet Svensson,[j,k] Bart Torbeyns,[f] Petra Wilson,[l] and Chantal Mathieu[m]

[a]University of Bari Aldo Moro, Bari, Italy
[b]University Medical Center Ljubljana, University of Ljubljana, Ljubljana, Slovenia
[c]Interdisciplinary Research Centre "Health Science" of the Sant'Anna School of Advanced Studies, Pisa, Italy
[d]King's College London, UK
[e]Department of Pediatrics 1, Medical University of Innsbruck, Austria
[f]European Diabetes Forum, Belgium
[g]Institute for Clinical Trials, University of Galway, Ireland
[h]Montpellier University Hospital, Department of Endocrinology and Diabetes and Institute of Functional Genomics, CNRS, INSERM, University of Montpellier, Montpellier, France
[i]Breakthrough T1D, USA
[j]Steno Diabetes Center Copenhagen, Herlev, Denmark
[k]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[l]HCP Partners, Belgium
[m]Department of Endocrinology, University Hospitals Leuven, Leuven, Belgium

The Lancet Regional Health - Europe 2026;62: 101598

Published Online xxx https://doi.org/10.1016/j.lanepe.2026.101598

Continuous Glucose Monitoring (CGM) devices are increasingly used by people living with diabetes (PwD) and contribute to a more personalised and effective diabetes care, leading to improved glycaemic control impacting diabetes-related complications. Their use is increasing in Europe, and many new manufacturers are coming to the market. CGMs, tracking in real-time glucose levels, are a key tool for PwD and their healthcare teams in the daily diabetes management. Besides tracking glucose changes in response to food, medication and physical activity, alerts are provided when hypoglycemia or hyperglycemia are imminent, allowing immediate intervention. Many CGM devices can be connected to insulin pumps leading to automated insulin delivery. False sensor values can thus harm by missing impending hypo- or hyperglycemia or misleading insulin delivery in automated insulin delivery systems. Having only reliable CGMs in clinical practice is thus of the utmost importance.

The primary legislation applicable to CGM devices in the EU market is the Medical Devices Regulation (MDR)[1] which mandates that devices must meet General Safety and Performance Requirements to demonstrate an acceptable benefit–risk profile with lifecycle risk management. Notified Bodies are appointed to evaluate CGMs. Whereas the Medical Device Coordination Group provides templates and guidance for medical devices generally, and harmonised ISO standards could provide technical detail, no specific guidance nor standards describe specific quality standards for CGM systems for manufacturers, leaving the Notified Bodies only with the evidence and claims submitted by manufacturers. This system thus provides no clear standard setting for the level of safety and performance required and makes evaluation of CGMs entering the EU market untransparent. It is also difficult to compare the devices already on the market based on their supporting studies, as different study designs and procedures are used for different CGM systems. Moreover, no minimum quality requirements in terms of methodology and representativeness of the populations investigated in the studies are prespecified. This lack of regulatory guidance on CGM quality criteria holds a potential risk for PwD and their medical teams as lack of standardisation might affect therapeutic decisions and perceived glycaemic management.[2]

Although most CGMs currently available in Europe are safe and preformant, reports have raised concerns about safety and quality of recently approved devices due to lack of reliable data. In 2022, in an Italian region, a publicly procured CE-marked CGM device was recalled due to its poor accuracy at low and high glucose levels. As a result, 20,000 PwD had to return to using finger pricking.[3,4] In 2024, British diabetologists raised concerns about the lack of published evidence of the CE-marked hybrid closed loop system available in England and other countries, with significant concerns around sensor accuracy leading to glycaemic instability, and in some cases hospitalisation.[5]

The US has adopted specific accuracy and performance standards for CGM devices–such as but not limited to - the FDA-approved integrated CGM (iCGM) requirement 21CFR862.1355. Nevertheless, issues reported in the MAUDE database and recent FDA

*Corresponding author. European Diabetes Forum, Schuman Roundabout 6/5, 1040, Brussels, Belgium.
E-mail address: kasia.karpinska@eudf.org (K. Karpinska).

warning letters to an iCGM system manufacturer suggest even more robust accuracy and performance standards are required for patient safety. Such standards are being discussed by several European bodies represented in the International Federation of Clinical Chemistry (IFCC) working group on CGM.[6] Pending consensus among stakeholders, interim solutions[7,8] that have been defined in the EU, UK[9] and peer approved, alongside the iCGM recommendations, can serve as a guidance.

Harmonised CGM-specific EU standards would improve patient safety and outcomes, streamline Notified Body assessments, and reduce regulatory burden for manufacturers. Centralising and standardising the approval process would further accelerate access to innovation and ensure consistent evaluation across EU Member States, thus also ensuring that only devices meeting safety and performance standards are marketed in Europe.

CGM devices contribute to more personalised and effective diabetes care. However, it is crucial to ensure that PwD have access to safe and high-quality CGMs. We call upon the European Commission to consider our concerns and take appropriate measures to uphold the rights and ensure continued safety of PwD.

Contributors

All authors contributed equally to the writing process, including the review and final editing.

Declaration of interests

FG has received research support paid to University of Bari from Eli Lilly and Roche Diabetes Care; has received consulting fees from Eli Lilly and Novo Nordisk; has received honoraria from Boehringer-Ingelheim, Eli Lilly, Lifescan, Merck Sharp & Dome, Medtronic, Novo Nordisk, Roche Diabetes Care and Sanofi; has received travel support from Eli Lilly and Sanofi; serves on advisory boards for AstraZeneca, Boehringer-Ingelheim, Eli Lilly, Lifescan, Merck Sharp & Dome, Medimmune, Medtronic, Novo Nordisk, Roche Diabetes Care and Sanofi; has received medical writing support from Eli Lilly, Novo Nordisk, Roche Diabetes Care and Sanofi; is President of the European Association for the Study of Diabetes (EASD) and the of European Foundation for Study of Diabetes (EFSD), Vice-Chair of European Diabetes Forum (EUDF), is President of Fo.Ri.SIE (Research Foundation of the Italian Society of Endocrinology). TB has received research support paid to University of Ljubljana from Abbott, Medtronic, Novo Nordisk, Sanofi, Novartis, Sandoz, Tandem, Slovenian Research and Innovation Agency, the National Institutes of Health, BreakthroughT1D, Helmsley Foundation, and the European Union; has received consulting fees from Novo Nordisk, Sanofi, Eli Lilly, AstraZeneca, Medtronic, Abbott, Pfizer, Tandem, and Roche; has received honoraria from Eli Lilly, Novo Nordisk, Medtronic, Abbott, Sanofi, Dexcom, Aventis, AstraZeneca, and Roche; serves on advisory boards for Eli Lilly and SAB Pharma. SDP has received consulting fees from Abbott, Altimmune, Applied Therapeutics, Biomea Fusion, Eli Lilly, Menarini International, Hoffman-La Roche, Novo Nordisk, and Sun Pharma; and speaker's fees from Abbott, Astra Zeneca, Boerhinger Ingelheim, Eli Lilly, Menarini International, Novo Nordisk, and Sanofi. SH has received research support from Medical Research Council, JDRFI, NIHR, Abbott and Insulet; has received consulting fees from Roche; has received honoraria from Abbott UK, Insulet, Dexcom, Medtronic and Eli Lilly; serves on advisory boards for Tandem, Dexcom, Medtronic and Vertex; is a board member of the International Diabetes Federation Europe and European Diabetes Forum, is a Vice-Chair of the Association of British Clinical Diabetologist's Diabetes Technology Network, a member of the Diabetes UK's Steering Group and a Medical Advisor for Diabetes to Secretary of State for Transport. TM has received research support paid to the University of Galway from the European Union; is serving on a Scientific Advisory Board of Edvance; is a member of the European Society of Cardiology's Regulatory Affairs Committee, member of the European Medicines Agency's Medical Device Expert Panel and a Chair of the Regulatory Affairs Committee of the Biomedical Alliance in Europe. ER has received consulting fees from Abbott and Dexcom; has received speakers' fees from Abbott and Dexcom. CM has received financial compensation paid to KU Leuven for serving on advisory panels for Novo Nordisk, Sanofi, Eli Lilly and Company, Dexcom, Bayer, Roche, Abbott, Medtronic, Insulet, Biomea Fusion, SAB Bio, vTv Therapeutics, and Vertex; has received research support paid to KU Leuven from Dexcom, Novo Nordisk, and Sanofi; serves on the speakers bureau for Novo Nordisk, Sanofi, Eli Lilly and Company, Medtronic, Dexcom, Insulet, Abbott, and Vertex; is former President of EASD and the current Chair of EUDF. RH, SH, CH, JS, PW, BT, and KK declare no competing interests.

Acknowledgements

The authors would like to acknowledge the contribution of all members of the European Diabetes Forum (EUDF).

References

1 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. *European Union*. 2017;117:1–175.
2 Kim SJ, Hirsch IB. Intersystem accuracy in continuous glucose monitoring: when does this matter? *Diabetes Care*. 2025;48(7):1161–1163. https://doi.org/10.2337/dci25-0035.
3 Amendolaria F. *Don Vincenzo's Delusion about Diabetes*. Milan, Italy: Panorama; 2023. Available from: L'abbaglio di Don Vincenzo sul diabete. Accessed 26 November 2025.
4 Caruso A. Diabetes patients. In: *Campania and Molise alarm for FGM: Zinzi questions the minister*. Rome, Italy: The Watcher Post; 2023. Available from: Diabete, allarme in Campania per il FGM: interrogazione di Zinzi. Accessed November 26, 2025.
5 Association of British Clinical Diabetologists. DTN Statement Regarding the use of Medtrum HCL Systems DTN statement regarding the use of Medtrum HCL systems | The Association of British Clinical Diabetologists: London, UK. 2024. Available from: https://abcd.care/announcement/dtn-statement-regarding-use-medtrum-hcl-systemsLocation. Accessed 26 November 2025.
6 Pleus S, Eichenlaub M, Dabla PK, et al. Clinical assessment and acceptance criteria for continuous glucose monitoring (CGM) system performance: a proposed guideline by the IFCC Working Group on CGM. *Clin Chim Acta*. 2025;580:120728. ISSN 0009-8981 https://doi.org/10.1016/j.cca.2025.120728.
7 Mathieu C, Irace C, Wilmot EG, et al. Minimum expectations for market authorization of continuous glucose monitoring devices in Europe-'eCGM' compliance status. *Diabetes Obes Metab*. 2025;27(3):1025–1031. https://doi.org/10.1111/dom.16153.
8 Cohen O, van den Heuvel T, Mallas G, Shin J, de Portu S. Comment to 'minimum expectations for market authorization of continuous glucose monitoring devices in Europe-"eCGM"'. *Diabetes Obes Metab*. 2025;27(11):6820–6822. https://doi.org/10.1111/dom.70072.
9 BSI. Fast-track Standard PAS 2600:2025. Continuous glucose monitoring systems. Design verification and validation of performance. Specification. Available from: https://knowledge.bsigroup.com/products/continuous-glucose-monitoring-systems-design-verification-and-validation-of-performance-specification. Accessed November 26, 2025.