THE ILLUSION OF ACCURACY: A CRITICAL ANALYSIS OF CONTINUOUS GLUCOSE MONITORING SYSTEMS QUALITY ASSESSMENT METHODS

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Continuous glucose monitoring (CGM) has been established as a method for self-assessment glucose levels in individuals with diabetes mellitus in the Russian Federation for more than 15 years. The main characteristics of CGM sensors are its' accuracy and performance that ensure their effectiveness and safety. Currently, there are no standardized guidelines that outline the minimum accuracy standards for CGM systems.
This review is aimed to codify the current methods for evaluating CGMs accuracy and performance across the different countries, as well as to propose local Russian guidelines on CGM device accuracy evaluation. This involves guidelines for the design of clinical trials to assess sensors accuracy and the minimum acceptable performance requirements for CGM devices to be utilized in clinical settings.

KEYWORDS: continues glucose monitoring; accuracy; guidelines; minimum acceptable accuracy requirements.

ИЛЛЮЗИЯ ТОЧНОСТИ: КРИТИЧЕСКИЙ АНАЛИЗ МЕТОДОВ ОЦЕНКИ КАЧЕСТВА СИСТЕМ НЕПРЕРЫВНОГО МОНИТОРИРОВАНИЯ ГЛЮКОЗЫ

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Непрерывное мониторирование глюкозы (НМГ) применяется более 15 лет в Российской Федерации как метод самоконтроля уровня глюкозы у пациентов с сахарным диабетом. Основной характеристикой устройств НМГ, обеспечивающей их эффективное и безопасное применение, является точность показаний. В настоящий момент отсутствуют единые регламентирующие документы, определяющие минимально приемлемые показатели точности для систем НМГ.
Целью настоящего обзора являлась систематизация существующих подходов к оценке точности систем НМГ в различных странах, а также предложения по разработке российского стандарта оценки точности устройств НМГ, включая требования к методологии дизайна клинических исследований оценки точности, а также к минимально приемлемым показателям точности устройств НМГ, необходимым для возможности их применения в клинической практике.

КЛЮЧЕВЫЕ СЛОВА: непрерывный мониторинг глюкозы; точность; стандарты; минимальные требования к точности.

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INTRODUCTION

Over the past few years, continuous glucose monitoring (CGM) has become a widely used method of glycemic control in patients with diabetes mellitus (DM) in the Russian Federation. Randomized clinical trials and routine clinical practice demonstrated an improvement in glycemic control indicators, such as HbA_{1c}, time in the target range, time below the range, and time above the range when using CGM in people with type 1 DM (T1DM), type 2 DM (T2DM), as well as in DM during pregnancy [1–10].

In accordance with the statements in the Consensus on Use of CGM published in 2017, only those CGM systems that provide a sufficient level of measurement accuracy should be used in clinical practice [11], and over the past 20 years since the development of the first CGM systems and their introduction into clinical practice, an increase in the accuracy of CGM systems has been noted: in early CGM systems, the average absolute relative error (Mean Absolute Relative Difference, MARD) was about 20%, while in the most modern CGM systems it is generally below 10% [12]. Despite the fact that the accuracy of continuous glucose monitoring devices is the main characteristic that can ensure their effective and safe use [13], there are currently no validated international standards, as well as Russian GOSTs, which would regulate approaches to assessment of CGM systems and minimum accuracy criteria for them, which creates problems for regulatory authorities, doctors and end users [14, 15].

APPROACHES TO ASSESSMENT OF CGM ACCURACY, GUIDELINES AND STANDARDS

The guideline Performance Metrics for Continuous Interstitial Glucose Monitoring (POCT05) developed by the Clinical and Laboratory Standards Institute (CLSI), is the only approved guideline that describes the general indicators characterizing the accuracy of CGM systems and approaches to the methodology for assessing these indicators in clinical trials [16, 17]. This document provides general recommendations on how to evaluate the accuracy of CGM systems, discusses the effects of various factors on the results of such assessment. The POCT05 Guideline states that the accuracy of a CGM system should be evaluated by direct comparisons of glucose measurements by the CGM sensor with the readings of a comparator (reference device). A preferred comparator is a laboratory analyzer, as a more accurate device with traceable readings [16].

The POCT05 Guideline pays particular attention to recommendations regarding the methodology for conducting clinical trials of the CGM accuracy, since the validity of their results depends on such factors as the correct choice of the patient population to be enrolled in the trial, methods for assessing accuracy measures, and the number of paired measurements. The authors of the document emphasize the assessment of the main clinical and demographic characteristics of subjects for an accuracy trial: the population in clinical trials should be representative for the population of the intended use of the device [16]. The reason for this recommendation is the peculiarities of glycemic variability in patients depending on the DM type, therapy, age and degree of compensation of the main glycemic control indicators. In the case of apparent glycemia variability, more significant differences should be expected between the readings of the sensor measuring the level of glucose in venous blood, due to the physiological lag of glucose in interstitial fluid in relation to blood glucose, especially with rapid changes in blood glucose concentration [18]. On the contrary, with lower glucose level variability, the CGM sensor accuracy will be more favorable, thus, the predominance of T2DM patients in the trial may compromise the reproducibility of its results when used in clinical practice if the device is intended for use in T1DM patients [16]. The effect of one additional episode of hypoglycemia on MARD values is illustrated in the model described in Vigersky RA et al.: when one paired measurement with glucose concentration corresponding to the hypoglycemic range is added to six paired measurements "test sensor-reference analyzer", MARD values increase from 8.79% to 10.26% [19].

Considering the potential impact of pronounced glucose fluctuations on the accuracy assessment results, and taking into account that accuracy need to be determined in clinically significant glycemic ranges (hypoglycemia, hyperglycemia), it is recommended to study accuracy in the entire range of glucose values, as well as to conduct stimulation load tests with glucose and insulin to assess accuracy at very low and very high glucose concentrations, while the number of paired measurements (comparison points) should correspond to a statistically relevant sample size in each of the glycemic states [16]. It should be taken into account that glycemic variability is higher in patients with insufficient glycemic control, as well as in children and adolescents with DM, especially in children of an early age group, which dictates the need to include individuals with different HbA_{1c} values in the trial, and the need to evaluate accuracy parameters in clinical trials separately for the adult and pediatric patient populations if the device is intended to be used in children and adolescents [16, 20]. According to some authors, the CGM sensor insertion site can also affect the accuracy of measurements, therefore, the POCT05 Guideline includes a recommendation on the need to assess the accuracy of the CGM sensor separately for all allowed anatomical areas for sensor insertion or use [16]. Thus, critical evaluation of the trial design and results obtained is of critical importance to the competent regulatory authorities when approving a CGM device, as well as to practitioners when selecting a CGM system. The results of clinical trials designed with methodological errors, which can compromise the efficacy and safety of the device should be considered with extreme caution [14].

The POCT05 Guideline highlights specific approaches to the organization of clinical trials to assess the accuracy of CGM systems in "vulnerable" groups of patients: pregnant women and children. For example, in clinical trials where subjects are pregnant women, which are necessary if the device being studied is supposed to be used in this category of persons, it is recommended to limit the volume of blood samples to the minimum permissible: the total volume of blood taken during the clinical trial should not exceed 50 ml or 3 ml/kg (whichever is lower) during any 8-week period. A similar approach is recommended when conducting a clinical trial of the accuracy of a CGM device in children; it is recommended to use a glucometer for reference (in children under the age of 6 years) and to avoid stimulation tests with glucose and insulin [16].

Table 1. Characteristics of continuous glucose monitoring systems approved for use as a stand-alone glucose self-monitoring method [22, 27]

CGM device intended for use as an independent (non-adjunctive) self-monitoring method	• Intended to replace a glucometer in blood glucose measurements
	• Intended to determine blood glucose levels, as well as assess the direction and rate of change in glucose concentration
	• Used for therapeutic decisions (e.g., calculation of insulin dose)
	• Provides retrospective data on glucose levels and changes, facilitating long-term management of DM

Note: CGM, continuous glucose monitoring; DM, diabetes mellitus.

Taking into account the physiological time delay between glucose in blood and interstitial fluid, it is recommended to assess not only the accuracy of individual measurements, which characterize the agreement between the readings of the CGM device and the reference device at a point in time, but also the accuracy of trending, which reflects the agreement of glucose level trends according to their data [16].

Taking into account the possible influence of the initial clinical and demographic characteristics of the enrolled patients, as well as the methodological specifics of the trial, the accuracy of various CGM systems should be compared in direct comparative studies in order to avoid the influence of the clinical trial design on the results [21].

CGM FOR SELF-MONITORING AND AUXILIARY USE

Until recently, all CGM systems were intended to be used only as a supplement to a glucometer. To calculate insulin dose, users were recommended to verify CGM readings with a glucometer and test strips. Such use of CGM devices was defined as "adjunctive, that is, in addition to a glucose meter" [22]. As the accuracy of CGM systems improves, the US Food and Drug Administration (FDA) has approved the possibility of non-adjunctive or self-use, which means that verification of CGM readings by a glucometer is not required. Depending on this characteristic, all CGM systems can be divided into 2 groups [12, 22, 23]:

- CGM systems that can only be used as **adjunctive** devices (concomitant use with blood glucose meters). When using such systems, the patient makes clinical decisions (calculation of insulin dose or taking actions in case of onset or suspected hypoglycemia) based on the readings of a glucometer, and CGM is used only as an addition to routine glycemic measurements.
- Systems that can be used as **a non-adjunctive device** for glucose determination and clinical decision making such as insulin dosing and hypoglycemia management. Such systems, which do not require verification by a glucometer, are called CGM for non-adjunctive use. However, even with such CGM systems, capillary blood glucose measurement is still recommended in cases where CGM readings differ from what is expected or the use of CGM is not possible [23].

Complete self-monitoring of glucose levels, which is an integral component of DM therapy [24–26], can only be carried out using CGM systems approved for use as an independent self-monitoring method (non-adjunctive CGMs), which allow both the patient and the doctor to make clinical decisions, for example, calculate the dose of insulin based on the readings of the sensor without the concomitant use of a glucometer. The use of CGM systems approved for independent glucose self-monitoring also provides a number of additional advantages (in comparison with devices that can only be used as adjuncts to a glucometer): convenience and less pain due to a reduction in the frequency of finger punctures for taking a blood sample [22].

Characteristics of CGM systems intended for non-adjunctive use were proposed by FDA and are presented in Table 1.

FDA MINIMUM ACCEPTABLE ACCURACY REQUIREMENTS FOR INTEGRATED CGM SYSTEMS

Satisfactory accuracy is a fundamental property for CGM systems intended for use as an independent means of self-monitoring, since the information provided by the device is used by the patient for disease management. FDA has identified a special category of CGM devices, the so-called *integrated CGM systems* (iCGM), which are approved for use as a stand-alone self-monitoring method and are designed to reliably and securely transmit glucose data to digitally connected devices, including automated insulin delivery systems, and may be used alone or in combination with these digitally connected medical devices to manage diabetes mellitus or a condition associated with glycemic control [27]. The criteria for assessing the accuracy of devices in the iCGM category, developed and implemented by FDA, are the only and at the same time quite strict standards for the accuracy of CGM in the world [22].

The special requirements for accuracy parameters of devices in this category are presented in Table 2 and include not only the criteria for the minimum acceptable accuracy, but also methodological approaches to the organization of clinical trials and presentation of their results, as well as the overall assessment of devices at the pre-approval stage [27]. Compliance of accuracy parameters iCGM with the minimum acceptable values should be assessed in each range of glucose concentration: hypoglycemic (below 3.9 mmol/L), hyperglycemic (above

10.0 mmol/L) and the range corresponding to the target glucose values (3.9-10.0 mmol/L); the accuracy of trends should also be assessed for compliance with the minimum acceptable criteria.

Specific FDA requirements for pre-approval assessment of iCGM include [27]:

1. Design verification and validation must include the following:
   a. Robust clinical data demonstrating the accuracy of the device in the intended use population.
   b. The clinical data must include a comparison between iCGM values and blood glucose values in specimens collected in parallel that are measured on an FDA-accepted laboratory-based glucose measurement method that is precise and accurate.
   c. The clinical data must be obtained from a clinical study designed to fully represent the performance of the device throughout the intended use population and throughout the measuring range of the device.
   d. Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period.
   e. Results of accuracy assessment shall correspond to the minimum acceptable values in Table 2.
   f. Data demonstrating similar accuracy and rate of change performance of the iCGM in the pediatric population as compared to that in the adult population, or alternatively a clinical and/or technical justification for why pediatric data are not needed, must be provided and determined by FDA to be acceptable and appropriate.

Table 2. FDA requirements for minimum acceptable accuracy of devices in the category of integrated continuous glucose monitoring systems [27]

Specific accuracy requirements for iCGM [95% lower one-sided CI]	
Accuracy over the entire range of iCGM	
The percentage of all measurements within ±20% of the reference analyzer readings should be determined, and the lower bound of the one-sided 95% CI should be more than 87%	
Glucose concentration by iCGM sensor <3.9 mmol/L	
The percentage of all measurements within ±**0.83 mmol/L** (15 mg/dL) of the reference analyzer readings should be determined and the values of the lower bound of the one-sided 95% CI should be **more than 85%**	The percentage of all measurements within **±2.22 mmol/L** (±40 mg/dL) of the reference analyzer should be determined and the values of the lower bound of the one-sided 95% CI should be **more than 98%**
For iCGM system glucose readings <3.9 mmol/L, there should be no paired reference analyzer reading >10.0 mmol/L	
Glucose concentration by iCGM sensor 3.9–10.0 mmol/L	
The percentage of all measurements within ±**15%** of the reference analyzer readings should be determined, and the values of the lower boundary of the one-sided 95% CI should be **more than 70%**	The percentage of all measurements within ±**40%** of the reference analyzer readings should be determined, and the values of the lower boundary of the one-sided 95% CI should be **more than 99%**
Glucose concentration by iCGM sensor >10 mmol/L	
The percentage of all measurements within ±**15%** of the reference analyzer readings should be determined, and the values of the lower boundary of the one-sided 95% CI should be **more than 80%**	The percentage of all measurements within ±**40%** of the reference analyzer readings should be determined, and the values of the lower boundary of the one-sided 95% CI should be **more than 99%**
For iCGM system glucose readings >10 mmol/L, there should be no paired reference analyzer reading <3.9 mmol/L	
Specific requirements to trend accuracy	
There should be no more than 1% of iCGM measurements that indicate a positive glucose rate of change greater than 0.056 mmol/L/min [+1 mg/dL/min] when the corresponding negative glucose rate of change as determined by the reference analyzer is less than -0.11 mmol/dL/min [-2 mg/dL/min].	There should be no more than 1% of iCGM measurements that indicate a negative glucose rate of change less than -0.056 mmol/L/min [-1 mg/dL/min] when the corresponding positive glucose rate of change as determined by the reference analyzer is greater than 0.11 mmol/dL/min [2 mg/dL/min].
Thus, the percentage of measurements when iCGM readings show an increase in glucose concentration, while the reference device readings show a decrease in glucose concentration, should not exceed 1%.	Thus, the percentage of measurements when iCGM readings show a decrease in glucose concentration, while the reference device readings show an increase in glucose concentration, should not exceed 1%.

Note: CI, confidence interval; iCGM, integrated continuous glucose monitoring.

   g. Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically significant gaps in sensor data availability that would prevent any digitally connected devices from achieving their intended use.
2. Design verification and validation must include a detailed strategy to ensure secure and reliable means of iCGM data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the iCGM glucose data.
3. Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications.
4. The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications.
5. The manufacturer must confirm that the device includes appropriate measures to ensure that disposable sensors cannot be reused or used beyond its claimed sensor wear period.
6. Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
7. The labeling must include a separate description of the following sensor performance data observed in a clinical study for each intended use population, in addition to separate sensor performance data for each different iCGM insertion or use sites (e.g., abdomen, arm, buttock): a description of the accuracy in different blood glucose concentration ranges, a description of the accuracy of positive and negative rate of change data (downward and upward trends), a description of the frequency and duration of gaps in sensor data, a description of the true, false, missed, and correct alert rates and a description of the available glucose concentration alert settings, if applicable.

However, it should be noted that many of FDA recommendations regarding the requirements to evaluation and validation of clinical trial design are quite general and lack adequate details, as compared, for example, with POCT5. This creates the preconditions not only for a divergence of approaches in conducting clinical trials, which will make it difficult to compare and evaluate their results, but also determines the possibility of choosing more favorable conditions in terms of achieving higher accuracy.

APPROACHES TO ASSESSING THE ACCURACY OF CGM: PROPOSALS FROM THE UK AND EUROPEAN UNION EXPERT WORKING GROUPS

In 2023 in the UK, Pemberton et al. analyzed data from clinical trials that studied the accuracy of approved CGMs in the UK from the standpoint of compliance of the methodology and results of studies with FDA requirements developed for iCGMs [14]. The analysis has shown that many manufacturers of CGM systems do not publish clinical trial data on the accuracy of manufactured devices, and available publications indicate the presence of methodological errors in the organization of clinical trial design:

- inconsistency of patient populations in trials and registered indications for use by demographic and clinical parameters, lack of data on device accuracy in children and adolescents;
- predominance of patients with T2DM in some trials;
- lack of results on the device accuracy in various ranges of blood glucose concentration, including at very low or very high concentrations;
- lack of data on accuracy measures at different periods of sensor operation.

The use in clinical practice of CGM devices, whose properties declared by the manufacturers do not correspond to the presented data of clinical trials, or CGM devices for which the data on clinically significant results of accuracy assessment are absent, can increase safety risks of DM therapy associated with the use of CGM, even despite the availability of approval from authorized regulatory authorities [14]. For example, in 2022, in the Campania region in Italy, as part of the compensated provision of DM patients receiving glucose-lowering therapy with insulin, a batch of CGM devices was purchased, the device was approved for use in the European Union. Despite the fact that the system has received regulatory approval for use in DM, patients and clinicians have reported poor system accuracy at low and high glucose concentrations, leading to the refusal of prescribing the device by clinicians and the recommendation that patients return to using glucometers for self-monitoring. This situation affected 20,000 patients receiving insulin therapy in the Campania region [13].

Based on the analysis results, the working group proposed the introduction of a stepwise approach to the critical assessment of the design, results obtained and accuracy of CGM systems in the UK, based on the principles presented in the POCT05 Guideline (Performance Metrics for Continuous Interstitial Glucose Monitoring) and the criteria for the minimum acceptable accuracy of iCGMs recommended by FDA [14, 16, 27].

- At the first step of the algorithm proposed by the working group, the study design and methodological approaches to its implementation declared by the manufacturer should be evaluated:
  - ✓ Have the study results been published in a peer-reviewed scientific journal?
  - ✓ Is the patient set representative? (For CGM systems approved for use in T1DM, the proportion of T2DM patients enrolled in the accuracy trial should not exceed 2% for the pediatric population (<18 years) and 30% for the adult population of patients 18 years and older);
  - ✓ Is the number of paired measurements sufficient for each anatomical area of the intended sensor insertion (more than 10,000 for the adult patient population and more than 2,500 for children and adolescents under 18 years of age);
  - ✓ The availability of accuracy evaluation at different times during sensor operation (initial, intermediate, and final)?

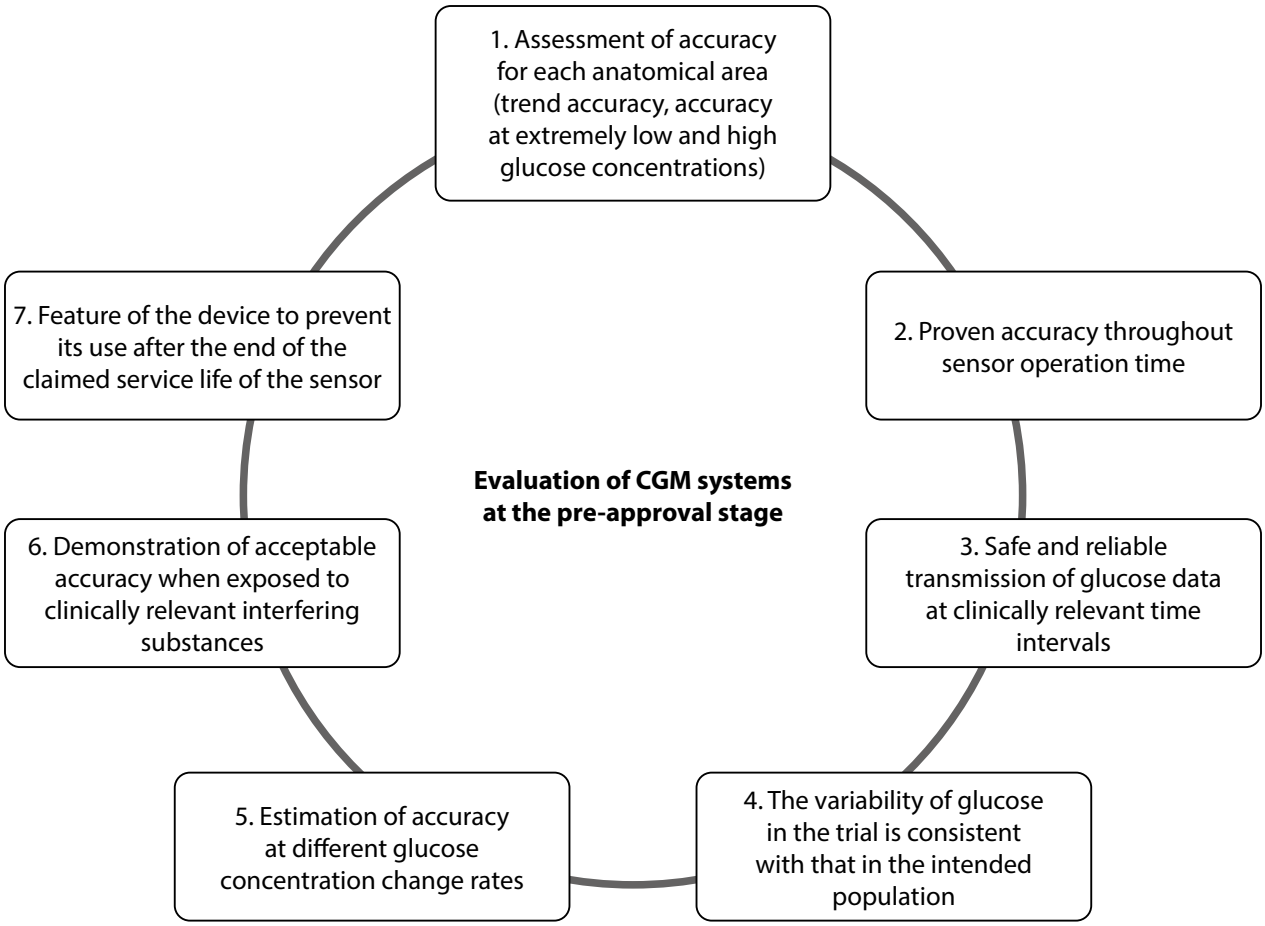

Figure 1. Minimum requirements for the accuracy of continuous glucose monitoring systems proposed by the European Expert Working Group [13].

Note: CGM, continuous glucose monitoring.

- ✓ The availability of data of loading tests with glucose or carbohydrates (food intake) and insulin to stimulate a high rate of change in glucose concentration and to study accuracy at very low and very high values;
- ✓ Whether the proportion of paired measurements obtained in the hypoglycemic and hyperglycemic ranges corresponds to those recommended by the POCT05 Guideline? (More than 8% of measurements in the range with glucose concentration below 4.4 mmol/L; more than 5% of measurements in the range with glucose concentration above 16.7 mmol/L).

• At the second step, the working group recommends assessing how correctly the study results are presented: accuracy results for different types of patients (T1DM and T2DM) and different age groups (children and adults), whether accuracy data are presented at different periods of sensor operation and in different acceptable deviation ranges at glucose concentrations corresponding to the hypoglycemic, hyperglycemic and euglycemic range; whether sensor precision results are presented; whether the time between sensor activation and the first glucose value was estimated.

• If the requirements described in steps 1 and 2 are met, the authors consider it possible to proceed to step 3, during which the results of the clinical trial are evaluated. At this stage, the results obtained are evaluated for compliance with FDA criteria developed for the iCGM and presented in Table 2.

The introduction of this stepwise approach will contribute to a more balanced choice of CGM devices in patients with DM, based on the principles of evidence-based medicine and the position of existing guidelines [14].

A similar approach to the formation of minimum requirements to the accuracy measures of CGM systems at the pre-approval stage to improve the safety of DM management was proposed by the European Expert Working Group, published in 2025 and presented in Figure 1; the minimum acceptable accuracy criteria for CGM systems approved for use as a stand-alone self-monitoring method and/or designed to transmit glucose data to digitally connected devices, including automated insulin delivery systems, fully comply with FDA criteria developed for the iCGM category [13, 27].

APPROACHES TO EVALUATION OF METHODOLOGY AND RESULTS OF CLINICAL TRIALS OF CGM ACCURACY PROPOSED BY THE RUSSIAN EXPERT GROUP

The unified approach to assessing the accuracy of CGM systems for their approval for clinical use is currently absent in the Russian Federation [17]. International experience suggests that an increase in the number of approved CGM devices in the absence of clear standards for their assessment at the pre-approval and post-approval stages may lead to an increase in the safety risks associated with the use of CGM in DM management [13, 14].

On February 1, 2025, a discussion was held in Moscow on issues related to the accuracy of CGM devices used in clinical practice, as well as opportunities related to the standardization of approaches to assessing the accuracy of CGM systems at the pre-approval stage in the Russian Federation. The discussion ended up with recommendations for the evaluation of the design and results of clinical trials of accuracy of CGM devices, as well as a proposal for the minimum acceptable accuracy measures necessary for the approval of such devices for use in clinical practice.

RECOMMENDATIONS FOR EVALUATION OF DESIGN AND RESULTS OF CLINICAL TRIALS OF ACCURACY OF CGM SYSTEMS FOR REGULATORY AUTHORITIES (PRE-APPROVAL ASSESSMENT) AND PRACTITIONERS (POST-APPROVAL ASSESSMENT)

When evaluating the results of accuracy trials of CGM systems, it is advisable to take into account the following.

1. Has the design and results of a clinical trial evaluating the accuracy of the CGM device been published in a peer-reviewed scientific journal?
2. Have CGM readings been compared using a glucose measurement method that is more accurate and reliable (e.g. a laboratory analyzer)?
3. Has the manufacturer provided robust clinical data demonstrating the accuracy of the device in each of the intended use populations (adult patients, children, pregnant women)? Are the accuracy results comparable across all patient populations presented?
4. Has the accuracy of the device been evaluated in each of the intended anatomical areas of the sensor insertion, and has information been provided on the results of such evaluation?
5. For systems intended for use in T1DM patients: Is the proportion of patients with T2DM below 2% in the pediatric population and 30% in the adult population?
6. Is the method for forming paired measurements appropriate for the clinical use of the CGM device presented and used? Is the number of paired measurements included in the analysis enough? (More than 10,000 for the adult patient population and more than 2,500 for children and adolescents younger than 18 years)
7. Has accuracy been assessed at various times during sensor operation (start, mid and end)? Are the results of the accuracy assessment consistent during these periods of sensor operation?
8. Has the accuracy of the device been evaluated in the full range of glucose concentrations?
9. Were glucose and insulin loading tests performed to stimulate a high rate of change in glucose concentration and to study the accuracy of the device at very low and very high values?
10. Is the number of paired measurements in the hypoglycemic and hyperglycemic ranges sufficient? (More than 8% of measurements in the range with glucose concentration below 4.4 mmol/L; more than 5% of measurements in the range with glucose concentration above 16.7 mmol/L)
11. Does the device meet the minimum acceptable accuracy criteria presented in Table 2, including trend accuracy results?
12. Are data presented to support the reliability and safety of real-time glucose readings transmission at clinically meaningful time intervals from the CGM sensor to devices intended to receive data from the sensor?
13. Has the manufacturer confirmed that appropriate measures have been taken to ensure that disposable sensors cannot be reused or used beyond its claimed sensor wear period?
14. Has the accuracy of alerts generated by CGM device been evaluated? Are the results of this assessment provided?

CONCLUSION

Thus, the only acceptable approach to improving the safety of using CGM devices is to develop and implement standards and guidelines, on which the regulatory authorities could base their decisions on the approval of CGM devices for use in Russia, and which practitioners could use to select a CGM system for their patients. In the development and implementation of these guidelines and standards international expertise should be taken into account.

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All authors approved the final version of the text prior to publication and agreed to accept responsibility for all aspects of this study, which implies due investigation and resolution of any issue related to the accuracy or integrity of any part thereof.

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