REVIEW
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Regulatory assessment of technical complaints about strip-based glucose meters: performance and usability in glycemic monitoring among patients with diabetes

Avaliação regulatória de queixas técnicas sobre glicosímetros com tiras: desempenho e usabilidade no monitoramento da glicemia em pacientes com diabetes

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ABSTRACT

Introduction: This study addresses the evaluation of blood glucose monitoring systems using strip-based glucometers by regulatory agencies, comparing Brazil with Canada, the United States of America (USA), Japan, Australia, and countries in the European continent. It was developed to provide technical support to the Brazilian Health Regulatory Agency (ANVISA). **Objective:** To identify evidence on complaints or adverse events related to the use of glucometers with strips by patients with type 1 or type 2 diabetes mellitus, with regard to the nature and form of monitoring these occurrences. **Method:** An integrative review was conducted to investigate how regulatory agencies evaluate technical complaints associated with blood glucose monitoring systems using glucometers and reagent strips. Searches were performed in MEDLINE (via PubMed), Embase, and SCOPUS databases, as well as in secondary sources, civil society documents, and through manual reference checks. **Results:** A total of 1,220 citations were retrieved. Eight studies were selected, with data on device accuracy, human factors involved in use, and user experiences. The findings indicate frequent failures in the use of devices, low reporting of adverse events by users and a lack of public information on regulatory flows, except in Australia, which adopts a structured risk-based model. The results point to the need for greater regulatory transparency and educational actions for the safe use of these devices. **Conclusions:** Information from regulatory agencies focuses on standards, regulations and guidelines for medical devices, with emphasis on the Australian agency's approach to managing adverse events. There are no details on how other agencies deal with user complaints about the routine use of these devices.

KEYWORDS: Diabetes Mellitus; Blood Glucose Self-Monitoring; Medical Device; Product Surveillance, Postmarketing; Adverse Events

RESUMO

Introdução: Trata-se de um estudo sobre a avaliação de queixas técnicas sobre glicosímetros com tiras nas agências regulatórias comparando Brasil com Canadá, Estados Unidos da América (EUA), Japão, Austrália e continente Europeu, desenvolvido para prover apoio técnico à Agência Nacional de Vigilância Sanitária (Anvisa). **Objetivo:** Identificar as evidências sobre queixas ou os eventos adversos relacionados ao uso de glicosímetros com tiras por pacientes com diabetes mellitus tipo 1 ou tipo 2, no que se refere à natureza e forma de monitoramento dessas ocorrências. **Método:** Foi realizada uma revisão integrativa para responder como ocorre a avaliação das queixas técnicas relacionadas à utilização de sistemas de monitoramento de glicemia com uso de glicosímetro e tiras reagentes nas agências regulatórias por meio das bases de dados MEDLINE via Pubmed, Embase e SCOPUS, fontes de informação secundárias e da sociedade civil organizada e busca manual de referências dos estudos encontrados. **Resultados:** Como resultado das buscas

realizadas nas bases MEDLINE via Pubmed, Embase e SCOPUS, foram encontradas 1.220 citações. Oito estudos foram selecionados, com dados sobre precisão dos dispositivos, fatores humanos envolvidos na utilização e experiências de usuários. Os achados indicam falhas frequentes no uso dos dispositivos, baixa notificação de eventos adversos por usuários e escassez de informações públicas sobre os fluxos regulatórios, exceto na Austrália, que adota um modelo estruturado baseado em risco. Os resultados apontam para a necessidade de maior transparência regulatória e ações de educação para o uso seguro desses dispositivos. **Conclusões:** As informações das agências regulatórias concentram-se em normas, regulamentos e orientações para dispositivos médicos, com destaque para a abordagem da agência australiana na gestão de eventos adversos. Não há detalhes sobre como outras agências lidam com reclamações dos usuários sobre o uso rotineiro desses dispositivos.

PALAVRAS-CHAVE: Diabetes Mellitus; Automonitorização da Glicemia; Dispositivos Médicos; Vigilância de Produtos Comercializados; Eventos Adversos

INTRODUCTION

Diabetes mellitus (DM) is an endocrine-metabolic condition resulting from insufficient insulin production or action, or both. This condition can manifest as acute complications, such as hypoglycemia, and chronic complications, which include microvascular and macrovascular problems[1]. In Brazil, studies suggest a prevalence of diabetes of around 8%, with the condition being more common in adults and the elderly[2,3,4]. The diagnosis of DM is established through the detection of hyperglycemia, which can be assessed using tests such as fasting plasma glucose, oral glucose tolerance test (OGTT), and glycated hemoglobin (HbA1c)[5].

Treatment involves a multifaceted approach, encompassing non-pharmacological measures such as dietary adjustments, smoking cessation, reduced alcohol consumption, weight management, regular physical activity, and stress reduction. Additionally, pharmacological treatment includes the prescription and administration of medications[6].

Among non-pharmacological measures, blood glucose monitoring stands out, with the use of a blood glucose meter with test strips being a widely adopted technology. For home blood glucose monitoring, patients use glucose meters—rapid glucose testing devices that are easily accessible and simple to use, requiring only a small drop of blood[7,8]. The accuracy of blood glucose meter readings is of utmost importance, as it enables proper insulin administration.

A systematic review evaluated the accuracy of blood glucose monitoring using capillary glucometers compared to laboratory tests (including blood gas analysis) in critically ill adults[9]. Twenty-one comparisons from 17 studies were included; in four comparisons, blood glucose meter readings were found to be overestimated, while in two comparisons they were found to be underestimated, both significantly. Overall, glucose levels measured using a meter were overestimated, although the differences in measurements (95% Confidence Interval [CI]) were not statistically significant (0.07 mg/dL [95% CI 0.02 to 0.15])[9].

According to Collegiate Board Resolution (RDC) No. 67, dated December 21, 2009, which establishes technovigilance standards applicable to holders of health product registrations in Brazil, an adverse event is any unintended effect in humans resulting from the use of products under health surveillance. The term "technical complaint," on the other hand, refers to any notification of a suspected change or irregularity in a product or company related to technical or legal aspects, which may or may not cause harm to individual or public health[10].

Since 2009, the Brazilian Health Regulatory Agency (Anvisa) has been mapping complaints and regulatory improvements regarding the usability of glucose meters. The complaints are not brand-specific. Therefore, it is necessary to determine whether such complaints are reported in other countries and, if so, to examine how regulatory agencies address the monitoring of performance deviations in relation to measurements, in order to analyze the strategy adopted in Brazil to improve quality for users.

Thus, this study aimed to identify evidence regarding complaints or adverse events related to the use of blood glucose meters with test strips by patients with type 1 or type 2 diabetes, with regard to the nature and method of monitoring these occurrences.

METHOD

This study consisted of an integrative review designed to answer a research question formulated to guide the search and selection of evidence, the structure of which is presented in Chart 1.

The research question was: How do regulatory agencies assess technical complaints related to the use of blood glucose monitoring systems involving glucose meters and test strips?

Search Strategy

Searches were conducted at the following regulatory agencies:

- Brazil, Anvisa: https://www.gov.br/anvisa/pt-br
- USA, *Food and Drug Administration* (FDA): https://www.fda.gov/
- European Union, *European Medicines Agency* (EMA): https://www.ema.europa.eu/en/homepage
- Canada, *Health Canada*: https://www.canada.ca/

Chart 1. PICOS question (patient, intervention, comparator, *outcomes*, and study type).

Population (P)	**Patients with type 1 diabetes (T1D) or type 2 diabetes (T2D)**
Intervention (I)	Glucose meter with test strips
Comparator (C)	Not applicable
Outcomes (O)	Blood glucose monitoring system; performance; performance complaints; usability; measurement deviation; periodic product evaluation; estimated product lifespan; calibration; user errors (user behavior) and quality deviation.
Study type(s)	Real-world studies, cohort studies, systematic and non-systematic reviews, clinical trials, and qualitative studies.

Source: Prepared by the authors, 2024.
DM: Diabetes mellitus.

- Australia, *Therapeutic Goods Administration* (TGA): https://www.tga.gov.au/
- Japan, *Pharmaceuticals and Medical Devices Agency* (PMDA): https://www.pmda.go.jp/

Initial searches were conducted on November 2 and 3, 2023, and updated on January 8, 2024, to identify documents for the necessary technical and scientific input. Search was also performed in the scientific databases MEDLINE via PubMed, Embase, and the Virtual Health Library (VHL) on November 3, 2023, using keywords restricted to the diabetic population (P) and the intervention (I), resulting in 1,234 studies.

In this initial selection process, no studies were found that addressed the research question of interest, as most aimed to evaluate the accuracy of results provided by strip-based glucose meters, comparing them with different devices or with laboratory data from venous blood draws.

Thus, it was deemed necessary to repeat this search in the scientific databases, incorporating terms related to post-market surveillance, performance, user experience, usability, and adverse events. The term "adverse events" is commonly used in the scientific literature as a substitute for technical complaints, including when related to medical devices, encompassing both technical failures and human errors in the handling of such equipment.

Consequently, the search strategy was revised on December 26, 2023. We chose not to include comparators, aiming to make the searches more sensitive and less specific. This approach aims to ensure a comprehensive, sensitive, and systematic search, increasing the chance of identifying all available evidence that meets the eligibility criteria and, thus, reducing the possibility of publication bias.

No language or time restrictions were applied, as limiting the search by publication year or language could exclude important studies.

Eligibility criteria

The inclusion criteria adopted in this review were studies that specifically addressed the use of blood glucose meters with test strips, that addressed technical and human factors involved in the handling of these devices, and that reported adverse events associated with the use of blood glucose meters. Studies without a full-text version available and case report-based publications were excluded.

It is worth noting that in recent years, several studies have been published addressing evaluations regarding continuous glucose monitoring in various contexts, including sensors and monitors that provide automatic and continuous measurements of glucose levels. However, as they were not relevant to the scope of this research, these studies were excluded during the selection process.

Study Selection

Initially, duplicate studies were excluded. The selection of studies was conducted by a reviewer in two stages: the first based on reading the titles and abstracts; and the second through analysis of the full texts.

Data from the studies selected based on the inclusion criteria were organized in a spreadsheet (Excel®), in which the following were recorded: authors, year of publication, country of origin, study objective, type of methodological design, main results, and identified shortcomings.

RESULTS AND DISCUSSION

The open-access search conducted in regulatory agencies did not yield results relevant to the study. Among the hypotheses is that information regarding complaints and adverse events related to strip-based glucose meters is not made public. Chart 2 presents the searches conducted in regulatory and health technology assessment agencies.

The search strategies and results in the scientific databases MEDLINE via PubMed, Embase, and SCOPUS are presented in Chart 3.

As a result of the searches conducted in the MEDLINE databases via PubMed, Embase, and SCOPUS, 1,220 citations were found, including duplicates. Initially, eight citations were selected for full-text review, and all were included in this review. The figure presents the detailed flowchart of the study selection process.

Chart 4 describes the main results of the eight selected studies.

Chart 2. History of searches conducted at regulatory and health technology assessment agencies.

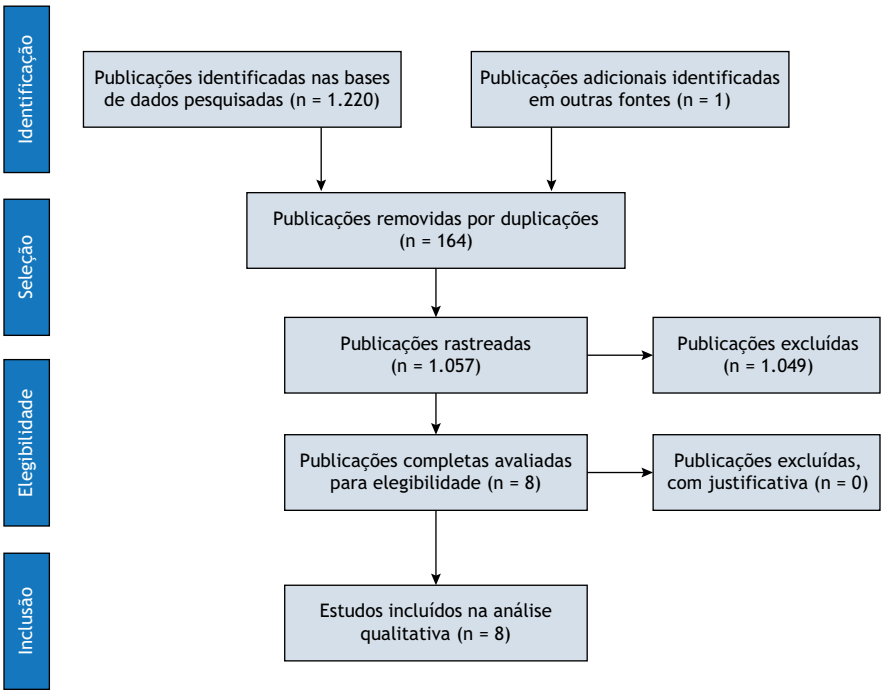
Regulatory agencies	Search term	Results	Number of standards/technical documents and main results
Anvisa[11]	"glucose meter with test strips"	14	**Manual for the registration of medical devices with Anvisa** (https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/produtos-para-a-saude/manuais/manual-para-regularizacao-de-equipamentos-medicos-na-anvisa.pdf/view) - prepared to assist manufacturers and importers of medical devices in preparing applications for registration or filing of medical devices with Anvisa. **Cybersecurity Principles and Practices for Medical Devices** (https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/saiba-mais-sobre- cibersecuranca-in-medical-devices/guide-38.pdf/view) - this guide sets forth Anvisa's understanding of best practices regarding procedures, routines, and methods considered appropriate for compliance with technical or administrative requirements mandated by Anvisa's legislative and regulatory framework.
FDA[12]	("Glucometer with strips" OR "Glucometer strips")	5	**MAUDE - Manufacturer and User Experience Database** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm) **Blood glucose monitoring devices - Guidance documents** (https://www.fda.gov/medical-devices/in-vitro-diagnostics/blood-glucose-monitoring-devices): FDA expands indication for continuous glucose monitoring system, the first to replace fingerstick testing for diabetes treatment decisions How to safely use glucose meters and test strips for diabetes How to report problems with glucose meters and continuous glucose monitoring systems Users of blood glucose meters should only use the test strip recommended for use with their meter NIH *Medline Plus* - Diabetes The FDA warns against the use of older test strips or test strips not authorized for sale in the United States: FDA Safety Communication
	"Self-monitoring of blood glucose"	34	**Over-the-Counter Self-Monitoring Blood Glucose Testing Systems -** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use **Blood glucose monitoring test systems for use in healthcare settings with a prescription - Guidance document (**https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use)
Health Canada[13]	"Glucometer with strips" or "Glucometer strips"	39	No relevant data
	"Self-monitoring of blood glucose"	11	No relevant data
	"Blood glucose meter"	10	Using a blood glucose meter and test strips - **usage guidelines and main causes of inaccuracy** (https://www.canada.ca/en/health- canada/services/drugs-health-products/medical-devices/blood-glucose-meters.html)
	"Blood Glucose Test Strips"	53	A document aimed at the general public was identified, containing information on the cost and use of glucose test strips in 2008. However, it does not provide information on how to proceed in the event of an error or a complaint regarding the product. A document on home diagnostic tests was also identified; however, it presents general legislation for medical devices (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/legislation-guidelines.html)
EMA[14]	"Self-monitoring of blood glucose" Glucometer	0	Legislation/regulations for medical devices were found, establishing responsibilities for the EMA and national authorities in the evaluation of certain categories of medical devices. The Medical Devices Regulation has been in effect since May 26, 2021. Manufacturers must comply with the regulation when placing new medical devices on the market.
TGA[15]	"Self-monitoring of blood glucose"	0	**Document:** https://www.tga.gov.au/resources/resource/guidance/how-tga-manages-medical-device-adverse-event-reports
	Glucometer	6	No relevant data
PMDA[16]	Glucometer	4	No relevant data
	"Glucose self-monitoring"	1	No relevant data
	Self-monitoring of blood glucose	2	No relevant data

Source: Prepared by the authors, 2024.
Anvisa: Brazilian Health Regulatory Agency; FDA: *Food and Drug Administration;* EMA: *European Medicines Agency;* TGA: *Therapeutic Goods Administration*; PMDA: *Pharmaceuticals and Medical Devices Agency*.

Chart 3. Search strategies and number of studies found in the scientific databases MEDLINE via PubMed, Embase, and SCOPUS.

Database	Search strategy	Results
MEDLINE via PubMed	(Glucometer OR "Blood Glucose Meter" OR "Blood Glucose Self-monitoring") AND ("Population Surveillance"[Mesh] OR "Surveillance, Population" OR "Product Surveillance, Postmarketing"[Mesh] OR "Product Surveillance, Post-Marketing" OR "Post-Marketing Product Surveillance" OR "Post-Marketing Product Surveillances" OR "Product Surveillance, Post-Marketing" OR "Product Surveillances, Post-Marketing" OR "Surveillance, Post-Marketing Product" OR "Surveillances, Post-Marketing Product" OR "Evaluation Studies, Post-Marketing" OR "Post-Marketing Evaluation Study" OR "Post-Marketing Evaluation Studies" OR "Post-Marketing Evaluation Study" OR "Post-Marketing Evaluation Studies" OR "Post-Marketing Evaluation Study" OR "Post-Marketing Product Surveillance" OR "Post-Marketing Product Surveillances" OR "Post-Marketing Product Surveillances" OR "Postmarketing Product Surveillance" OR "Postmarketing Product Surveillances" OR "Adverse Event" OR "adverse event reporting data" OR "Medical Device Report" OR "Adverse Event Report" OR "user performance evaluation" OR "user performance" OR "user experience" OR MAURE OR "Manufacturer and User Facility Device Experience")	112
Embase	('blood glucose meter'/exp OR 'blood glucose meter' OR glucometer OR 'blood glucose self-monitoring') AND ('population surveillance'/exp OR 'population surveillance' OR 'postmarketing surveillance'/exp OR 'post-market evaluation study' OR 'post-market surveillance' OR 'post-marketing product surveillance' OR 'post-marketing surveillance' OR 'postmarket surveillance' OR 'postmarketing evaluation study' OR 'postmarketing product surveillance' OR 'product surveillance, postmarketing' OR 'surveillance, postmarketing' OR 'postmarketing surveillance' OR 'adverse event' OR 'adverse event reporting data' OR 'medical device report' OR 'adverse event report' OR 'user performance evaluation' OR 'user performance' OR 'user experience' OR maure OR 'manufacturer and user facility device experience')	117
Scopus	TITLE-ABS-KEY('blood glucose meter') OR TITLE-ABS-KEY(glucometer) OR TITLE-ABS-KEY('blood glucose self-monitoring') AND TITLE-ABS-KEY('population surveillance') OR TITLE-ABS-KEY('postmarketing surveillance') OR TITLE-ABS-KEY('post-market evaluation study') OR TITLE-ABS-KEY('post-market surveillance') OR TITLE-ABS-KEY('post-marketing product surveillance') OR TITLE-ABS-KEY('post-marketing surveillance') OR TITLE-ABS-KEY('postmarket surveillance') OR TITLE-ABS-KEY('postmarketing evaluation study') OR TITLE-ABS-KEY('postmarketing product surveillance') OR TITLE-ABS-KEY('product surveillance, postmarketing') OR TITLE-ABS-KEY('surveillance, postmarketing') OR TITLE-ABS-KEY('postmarketing surveillance') OR TITLE-ABS-KEY('adverse event') OR TITLE-ABS-KEY('adverse event reporting data') OR TITLE-ABS-KEY('medical device report') OR TITLE-ABS-KEY('adverse event report') OR TITLE-ABS-KEY('user performance evaluation') OR TITLE-ABS-KEY('user performance') OR TITLE-ABS-KEY('user experience') OR TITLE-ABS-KEY(maure) OR TITLE-ABS-KEY('manufacturer user facility device experience')	991
Total		**1,220**

Source: Prepared by the authors, 2024.



Source: Prepared by the authors, 2024.

Figure. Flowchart used in the selection of articles, based on the PRISMA (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*) model.

Chart 4. Main results of the studies selected in the integrative review.

Author/year	Objective	Results	Identified shortcomings
Choi et al.[17]	To discuss the quantity and quality of reports of adverse events related to the use of blood glucose meters in South Korea and the United States.	There were only three reported adverse events related to the use of a blood glucose meter at the selected hospital over nine years, but enhanced surveillance was effective in promoting reporting, increasing the number of notifications to 137 during the 1-year study period following its implementation. Increased reporting of adverse events can contribute to improving the safety of *in vitro* medical device testing and generate real-world evidence.	Many factors, such as that may not meet current device standards, inadequate pre-, and manufacturing issues, may have contributed to the suboptimal performance. In addition to the inaccuracy of the glucose meter itself, analytical factors such as extreme physical environments, polycythemia, anemia, and certain medications can also adversely affect the accuracy of blood glucose monitoring
Pleus et al.[18]	To evaluate system accuracy, measurement repeatability, intermediate measurement accuracy, user performance, and the influence of hematocrit on two blood glucose monitoring systems	*CareSens S Fit* and *CareSens H Beat* met the accuracy criteria of ISO 15197, with 97.5–100% of the results from each batch of test strips falling within ±15 mg/dL or ±15% of the reference method results, and 100% of the results falling within zone A of the consensus error grid (CEG) for all three batches. 's user performance evaluation revealed sufficient accuracy in the hands of lay users, although some handling errors were documented by the study team.	More than half of the participants removed the test strip from the blood drop too early for both systems, meaning they did not wait for an audible signal before doing so, as indicated in the instructions for use. Another common error was pressing the test strip against the finger. One subject held the meter upside down while reading the result and read 58 instead of 85.
Pinelli et al.[10]	To gather evidence on physical and cognitive challenges that patients with type 2 diabetes mellitus encounter when using blood glucose meters for self-monitoring of blood glucose	Most patients felt that the backlit display made it easier to read the results on the screen and that the large application area made it easier to apply blood to the end of the strip. Every patient agreed that the automatic strip ejection enhances hygiene and convenience. Half of the sample used the color scale and agreed that it facilitated understanding or confirming the result and taking corrective actions, while the remaining patients were not even aware of the color scale's presence and therefore did not use it. It was found that only half of the sample found the effort required to learn how to use the new device to be low due to its similarities to previous devices. Some patients noted that the device is easy to use but requires support and training from healthcare professionals.	There was a direct relationship between patients' technological literacy and their appreciation of the glucose meter app's features; those more accustomed to using digital tools, as well as caregivers, feel more at ease knowing that results are automatically stored in the app. To conclude with the final question, most patients stated that they would recommend this glucose meter to elderly patients because the new features improve its usability.
Krouwer[19]	Present the number of adverse events from 2018 to 2020 in the United States for the three diabetes devices: blood glucose meters (BGMs), continuous glucose monitors (CGMs), and insulin pumps.	The number of adverse events related to strip-based blood glucose meters for the years 2018 to 2020 was 19,128, 14,785, and 8,974, respectively, showing a decrease over these years due to the migration of users to continuous glucose monitors, according to the authors.	Several possible factors that may affect the number of adverse events include: changes in the number of people with diabetes; the number of people who switched device (e.g., BG-CGM); accuracy of adverse event reporting, including accuracy of event classification; number of adverse events occurring; changes in the complexity of the devices/user training.
Krouwer[20]	Discuss glucose meter failure events using the MAUDE database and the RGM technique established in the aerospace and automotive industries for reliability management.	The number of glucose meter events reported in MAUDE is likely a subset of all glucose meter failure events. These events differ considerably from the results presented in glucose meter evaluations. RGM is an established method for reducing failure rates and could complement the results of glucose meter evaluations.	The ten most frequent adverse events in MAUDE were: *"Complaint meter read 60, comparison meter 140"; "Complaint: meter read 120, comparison meter* 40"; broken meter; meter in mg/dL used to read in mmol/L; error message; meter failed to store result in memory; meter read 170 mg/dL higher than the hospital meter; meter reading "LO" in the new test on a different meter was 138; fault display; meter won't turn on.

Continue

Continuation

Freckmann et al.[21]	To evaluate user performance on four blood glucose monitoring systems by applying ISO 15197:2013 accuracy criteria.	In the hands of lay users, three systems met the ISO 15197:2013 accuracy criteria, with the batch of test strips investigated showing 96% (A), 100% (B), and 98% (C) of results within the defined limits. All systems met the minimum accuracy criteria when used by study personnel [99% (A), 100% (B), 99.5% (C), 96% (D)]. Regarding calculated insulin dosing errors, all 99% confidence intervals ranged from dosing errors of -2.7 to +1.4 units for measurements performed by lay users and from -2.5 to +1.4 units for study personnel. Frequent errors by lay users included failing to check the expiration date of the test strips and applying blood incorrectly.	The most frequent lay user errors, considering human factors, were: preparation for the measurement (expiration date of a strip was not checked); test strips not inserted correctly (e.g., bent); blood sample (insufficient blood drop or old sample); blood application (insufficient quantity, the fingertip was pressed against the test strip; blood was not applied to the test area correctly); device handling (blood applied before the meter was ready for use, the test strip was removed before the measurement was complete, the fingertip was not removed from the test area after the beep); and a significant number of measurements performed incorrec ly.
Mandl et al.[22]	Evaluate social media as a complementary source of information on device failures and adverse events.	Of the 549 participants, 75 reported device-related adverse events, with nearly half (48.0%) requiring intervention by another person to manage the event. Only three (4.0%) of these were reported by participants to the FDA. All reports contained information on outcomes, compared with 22% of reports to the FDA. Hypoglycemia and hyperglycemia were experienced by 48.0% and 49.3% of participants, respectively. In all 75 reported device-related adverse events reported (associated with insulin pumps, continuous glucose monitors, blood glucose monitors, and insulin pens), nearly half of the users (48.0%) required help or intervention from another person to manage the event. Just over half of the AEs (53.3%) were reported to some other individual or entity. The events were most commonly reported to a healthcare professional (32.0% of events) or to the device manufacturer (28.0%). Of the total 75 ADEs reported in the survey, only three (4.0%) were reported to the FDA. From October 2011 to September 2012, 20,423 reports of ADEs involving diabetes devices were submitted to MedWatch. Almost all (99.9%) reports were from manufacturers; only 23 reports (0.1%) were voluntarily submitted by users. The event date was available for 8,100 notifications (39.7% of the total), and information on patient outcomes was available for 4,579 (22.4%). Of these events, 49% required intervention and 24% required hospitalization.	The digital blood glucose monitor was the most commonly used device, reported by 95.3% of those who reported using a blood glucose monitor. The frequency of ADEs was lowest among blood glucose monitors, with only 10 of the 463 users (2.2%) reporting any ADE related to their blood glucose monitor.
Raine[23]	To assess the frequency of user error in selecting the appropriate code for glucose test strips during self-monitoring of blood glucose.	A considerable number of patients with diabetes do not use glucose meters properly. Clinical decisions based on this data may result in adverse events. Glucose meters and test strips should be examined during clinical visits, and patients should be periodically re-educated on self-monitoring of blood glucose techniques.	SMBG data can become inaccurate due to various, including the following: (1) Failure to store glucose test strips properly; (2) Failure to set the glucose meter code to match the strip code accurately; (3) Failure to apply sufficient blood to the test strip; (4) Failure to use control solutions; (5) Use of expired control solutions; (6) Use of expired test strips; (7) Failure to clean the optical surface of certain meters

Source: Prepared by the authors, 2024.
BG: *Blood glucose meters*; CGM: *Continuous glucose monitors*; FDA: *U.S. Food and Drug Administration*; MAUDE: *Manufacturer and User Facility Device Experience*; SMBG: *Self-monitored blood glucose*; RGM: *Reliability Growth Management*; EA: Adverse events; FDA: *Food and Drug Administration*.

The pharmacological or non-pharmacological treatment of patients with DM must be monitored to prevent further damage. The recommended assessment parameters are HbA1c, and capillary (or plasma) blood glucose levels measured while fasting, before meals, 2 hours after meals, and at bedtime[5].

Daily capillary blood glucose measurement is performed through the practice of self-monitoring of capillary blood glucose (SMCG). Self-monitoring is widely recognized as an essential component of treatment for patients with DM, enabling them to monitor their blood glucose levels. SMCG involves applying a small drop of capillary blood to a disposable biosensor strip containing glucose dehydrogenase or glucose oxidase, both of which are connected to a medical device called a glucometer. Accuracy in glucose measurements and appropriate insulin dosing plays a crucial role in the immediate prevention of hypoglycemia or hyperglycemia, as well as in mitigating long-term complications[5,24].

Assessing the accuracy of glucose meters is crucial to ensuring proper performance, since monitors that display incorrect readings—whether excessively low or high—can result in risks associated with elevated HbA1c levels or hypoglycemic episodes. In 2003, the International Organization for Standardization (ISO), in collaboration with international regulatory authorities, established quality standards for *in vitro* glucose monitoring systems. This covers the measurement of glucose concentrations in capillary blood samples, as defined by ISO 15197:2003[25]. This standard was updated in 2013 (ISO 15197:2013), stipulating that 95% of measured glucose values must fall within ±0.83 mmol/L (±15 mg/dL) of the mean values measured by the reference measurement procedure at glucose concentrations < 5.55 mmol/L (< 100 mg/dL) or within ±15% at glucose concentrations ≥ 5.55 mmol/L (≥ 100 mg/dL). These results must be evaluated in accordance with an established protocol, under controlled conditions described in the standard, and by trained operators, as part of the performance validation process[26].

On May 17, 2018, Anvisa, through Normative Instruction No. 24, required all companies holding marketing authorizations for blood glucose self-monitoring products to submit the necessary performance reports. The deadline for submitting these studies was 180 days from the publication of the aforementioned regulation. This monitoring process resulted in the cancellation of the registration of products that did not submit the required information to Anvisa or did not demonstrate compliance with the established requirements[27].

Evaluation of technical performance and analytical accuracy

The included studies primarily addressed the accuracy of strip-based glucose meters, comparing results with laboratory standards or with the criteria of ISO 15197:2013. Devices such as CareSens and other systems demonstrated satisfactory performance, with high compliance with accuracy criteria[18,21]. However, it was observed that performance in controlled environments does not always reflect actual patient use, which requires periodic evaluation and post-marketing monitoring.

Literature reinforces the importance of proper calibration and verification of the test strip expiration date, aspects frequently neglected by users. Although these aspects were included in the PICOS outcomes, they were scarcely explored in the identified publications.

Patient experience and usability

The usability of blood glucose meters plays a vital role in the user experience. Intuitive interfaces, clear instructions, and ergonomic *design* are crucial elements to ensure that patients can perform tests with ease, promoting adherence to regular monitoring. Good usability can also contribute to reducing human errors and adverse events.

The study by Pinelli et al.[10] investigated the physical and cognitive issues related to the use of blood glucose meters by patients with T2D aged 65 years or older. Most patients felt that the backlit *display* made it easier to read results on the screen and that the large testing area made it easier to apply blood to the end of the strip. Some patients noted that the device is easy to use but requires support and training from healthcare professionals and stated that they would recommend the blood glucose meter to older patients because the new features improve its usability.

Thus, the effectiveness of blood glucose meters is closely linked to their usability. The ease of use of these devices is essential for encouraging patient adherence to regular monitoring, ensuring more efficient disease management. Despite the benefits, it is crucial to address adverse events associated with the use of blood glucose meters. Reading errors, improperly stored test strips, and potential mechanical failures can lead to inaccurate results, negatively impacting patients' treatment decisions. The identification and mitigation of these adverse events are fundamental to the safety and reliability of these devices.

Adverse event reporting systems and registries

A low rate of voluntary reporting by users was observed, with a predominance of reports submitted by manufacturers, as reported by Krouwer[19] and Mandl et al.[22]. The Manufacturer and User Facility Device Experience (MAUDE) is a database maintained by the FDA that serves as a reporting system for adverse events related to medical devices. Its primary objective is to collect, track, and make available information on problems and adverse events associated with the use of medical devices, including blood glucose meters and other tools used in glucose monitoring. The FDA uses MAUDE data to conduct analyses and continuously monitors the safety and performance of medical devices. These data can be valuable for identifying patterns, trends, or recurring problems.

Australia was the only country whose regulatory agency (TGA)-[14]publicly makes available the complete workflow for analyzing adverse events, with clear steps for triage, risk-based prioritization, and feedback to the reporter. This model stands out for its transparency and effectiveness, representing an international best practice that could be considered as *a* benchmark by Anvisa.

International Comparison and Regulatory Gaps

The comparative analysis among agencies revealed significant disparities in the transparency and systematization of the regulatory response to technical complaints. While the TGA adopts a robust model, the other agencies provide fragmented or poorly accessible information on adverse event review mechanisms.

Adequate training and education in SMCG should be an integral part of diabetes therapy. User performance evaluation must demonstrate that intended users can obtain accurate measurement results when operating blood glucose meters, taking into account the instructions for use and training materials routinely provided with the systems. Incorrect blood application, such as applying an insufficient amount of blood, pressing the fingertip onto the test strip, applying blood outside the test field, and failing to check the expiration date of the strips are common errors[28].

CONCLUSIONS

This study aimed to identify the main technical complaints related to the use of strip-based blood glucose meters and to analyze the response of regulatory agencies. Due to the lack of publicly available detailed information from the agencies, it was necessary to rely on the best available evidence from scientific literature.

The information available from regulatory agencies focuses primarily on registration standards and user guidelines. The Australian agency details its approach to adverse events, but there is little public information from other agencies on how they handle user complaints.

The integrative review identified studies focused primarily on the analytical accuracy of blood glucose meters, with an emphasis on advances in continuous monitoring systems. Only eight studies met the eligibility criteria, addressing adverse events reported to the FDA and the usability of strip-based blood glucose meters, highlighting human factors such as failures in proper storage and handling.

Studies on the accuracy of continuous monitoring systems were identified above all, suggesting that the scientific literature reflects a clinical trend toward replacing strip-based glucose meters with more advanced technologies.

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Ungari AQ - Data analysis, interpretation, and drafting of the manuscript. Ramos MC - Drafting of the manuscript. Elias FTS - Conception, planning (study design), and drafting of the manuscript. All authors approved the final version of the manuscript.

Conflict of Interest

The authors declare that there is no potential conflict of interest with peers, institutions, politicians, or financial entities related to this study.

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Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.

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