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Artigo Original

# A Portuguese Consensus for Self-Monitoring of Blood Glucose

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A B S T R A C T

***Introduction:*** Diabetes mellitus is a highly prevalent disease, and its incidence is increasing. A poorer glycemic control has been associated with worse clinical outcomes. Therefore, this study aimed to establish a national consensus on the self-monitorization of blood glucose.
***Methods:*** A systematic literature review was conducted to develop a questionnaire that was made available to a panel of 13 Portuguese physicians. The Delphi methodology was applied, and two voting rounds were performed. The questions for which no consensus (<80%) was obtained in the first round, were subsequently resubmitted for evaluation by the panel.
***Results:*** Participation rate was 100% in both rounds. In total, consensus was reached for 66 out of 85 statements (77.7%). Overall, consensus was obtained for the statements regarding target population, patients' education, patients' quality of life, and self-monitoring techniques, frequency, and impact. Namely, it was considered that blood glucose self-monitoring can be relevant for all types of diabetes and that its frequency should be personalized for each patient. Most statements for which no consensus was reached were related to the type of treatment, due to the influence of the type of treatment in the relevance/usefulness of blood glucose self-monitoring.
***Conclusion:*** The obtained consensus will allow an overview of a myriad of questions concerning the self-monitoring of blood glucose, a method which has the potential to improve glycemic control and to decrease the risk of the emergent complications of diabetes mellitus.

## Consenso Português para a Auto-Monitorização da Glicose

R E S U M O

***Introdução:*** A diabetes *mellitus* é uma doença altamente prevalente e a sua incidência está a aumentar. Um fraco controlo glicémico dos doentes tem sido associado a piores resultados clínicos. Assim, este

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estudo teve como objetivo estabelecer um consenso nacional sobre a auto-monitorização da glicose.
***Métodos:*** Foi realizada uma revisão sistemática da literatura para a elaboração de um questionário, que foi disponibilizado a um painel de 13 médicos portugueses. O questionário foi realizado com recurso à metodologia Delphi, tendo sido realizadas duas rondas de votação. As questões para as quais não se obteve consenso (<80%) na primeira ronda, foram posteriormente submetidas a nova avaliação pelo painel.
***Resultados:*** A taxa de participação foi de 100% em ambas as rondas. No total, foi obtido consenso para 66 das 85 afirmações (77,7%). Em geral, foi obtido consenso para as afirmações relativas à população-alvo, educação dos doentes, qualidade de vida dos doentes e às técnicas, frequência e impacto da auto-monitorização. Particularmente, foi considerado que a auto-monitorização da glicemia pode ser relevante para todos os tipos de diabetes e que a sua frequência deve ser personalizada para cada doente. A maioria das afirmações para as quais não se atingiu consenso são relativas ao tipo de tratamento, devido à sua influência na relevância/utilidade da auto-monitorização da glicose.
***Conclusão:*** Os consensos obtidos permitem uma visão global de uma miríade de questões relativas à auto-monitorização da glicemia, um método que tem o potencial de melhorar o controlo glicémico e de diminuir o risco de complicações emergentes da diabetes *mellitus*.

## Introduction

Diabetes mellitus (DM) affected 529 million adults worldwide in 2021 (global age-standardized prevalence of 6.1%), being up to 96.0% (95% CI: 95.1 – 96.8) of cases attributed to type 2 diabetes.[1] Moreover, its incidence is quickly increasing as it is estimated that more than 1.31 billion (1.22 – 1.39) people will have diabetes by 2050.[1] In Portugal, 72 032 new cases were diagnosed in 2018, with a prevalence of 13.6% in the population aged between 20 to 79 years.[2] DM incidence projections indicate that the number of new cases diagnosed will be 972.77 per each 100 000 Portuguese habitants by 2024.[3]

DM treatment aims to prevent acute hypo and hyperglycemic complications, decrease the risk for conditions associated with diabetes, reduce mortality, and optimize quality of life.[4] Good glycemic control with the decrease of glycemic variability, including hypoglycemia episodes in both type 1 and type 2 diabetes have been associated with a reduction of complications and adverse clinical outcomes.[5-7]

Precise information regarding variations in blood glucose levels are relevant for physicians and patients to determine the efficacy of treatment.[4,8] It allows for medication, diet and exercise adjustment, maximization of blood glucose control and assessment of glycemic variability and associated complications.[8] Moreover, regular monitoring of glycemic status also provides important information for patient disease's education, allowing the patients to improve their knowledge and awareness regarding the disease. Although the benefit of self-monitoring has been established for patients with type 1 diabetes (T1D), its relevance for type 2 diabetes (T2D), especially for patients that do not receive insulin or secretagogue drugs, remains a question of debate.[4,9,10] Multiple systems for measuring glucose in people with diabetes have been developed.[11,12] The first consisted of strips that allowed a semi-quantitative indication of the level of glucose in urine.[12] However, the inability of detecting hypoglycemia and the difficulty in drawing conclusions from the level of excreted glucose propelled the search for other systems.[12] Currently, small, automatic, and electronical glucometers are frequently used to measure capillary glucose levels.[11] Additionally, in the last decades, continuous glucose monitoring systems that measure the patients' glucose levels in the interstitial fluid have been developed.[11,12]

International recommendations on the treatment of T2D propose increasingly ambitious glycemic control goals, with less variability and fewer episodes of hypo and hyperglycemia. Simultaneously, there are, currently, more pharmacological options with different efficacy and safety profiles. There is also an increasingly higher volition to actively involve people with diabetes in the management of their disease. To achieve this goal, there is the need to use tools that help the decision-making process of people with diabetes regarding pharmacological and non-pharmacological therapeutical measures. To assess the consensus regarding self-monitoring of blood glucose (SMBG) in Portugal, a panel of 13 physicians with different specialties involved in the treatment of patients with diabetes participated in a Delphi panel, whose results are reported in this work.

## Methods

A Delphi methodology[13] was applied to reach consensus regarding SMBG. A systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) to construct the questionnaire.[14] PubMed® and Web of ScienceTM databases were searched on January 27th of 2022 using the string "diabetes AND (capillary glycemia OR capillary blood glucose) AND (utility OR cost OR monitoring OR pro OR prom OR value OR therapy)" with the filter "human", limited to the last 10 years and to the Portuguese and English languages. After joining the obtained papers and eliminating the duplicates, the remaining papers had their abstract evaluated by two authors to determine their inclusion. For papers where the opinions between the two authors diverged, a third, different author, evaluated the abstract. No reviews or case reports were considered. The PRISMA flow diagram and the references used to design the questionnaire are available in Appendix A.

The statements of the questionnaire were divided into seven different sections: target population, self-monitoring techniques, patients' education, self-monitoring frequency, regimen/type of treatment, self-monitoring impact, and patients' quality of life. The statements were electronically and anonymously made available by the moderator, external to the panel, to the 13 members of the panel who were specialists in Endocrinology, Internal Medicine, and General Practice/Family Medicine, and two voting rounds were performed between September and October 2022. A Likert scale that assessed agreement (totally agree, agree, disagree, totally disagree) was used to evaluate the statements, with 80% being considered the threshold for consensus. At the end of each round the results were analyzed by the moderator and sent to the Delphi panel. To facilitate the interpretation of the results, the evaluations totally disagree/disagree and agree/totally agree were combined under the evaluations disagree and agree.

## Results

Both rounds reached 100% of response rate with all the members of the panel voting in both rounds. In the first round, of the 85 statements, 63 (74.1%) reached consensus, being the remaining 22 statements submitted to the second round. From the 22 statements, 3 (13.6%) reached consensus. Thus, in total, 66 (77.7%) statements reached consensus whereas 19 did not (Fig. 1).

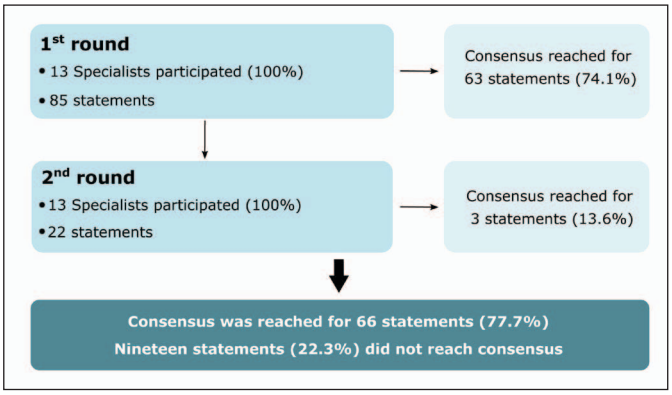


*Figure 1.* Overview of the percentage of consensus obtained for each round in this study.

Table 1 presents the assessed statements and the respective percentages of agreement or disagreement. The results are presented in 7 different sections: target population, self-monitoring techniques, patients' education, self-monitoring frequency, regimen/type of treatment, self-monitoring impact and patients' quality of life.

Self-monitoring of glucose levels was unanimously considered relevant for patients with T1D, and insulin treated T2D. For patients with non-insulin treated T2D and gestational DM, 84.6% (11/13) and 92.3% (12/13) of the specialists, respectively, agreed on the relevance of utilizing self-monitoring of blood glucose. Temporary SMBG was considered to be worthwhile in terms of cost-benefit in individuals with non-insulin treated T2D: a) who presented HbA1c values above the target set for themselves; b) who have an education level that allows them to take advantage of SMBG, and c) who are receptive to the need to improve their metabolic control and motivated to make the necessary changes. SMBG was considered especially relevant in cases of recent diagnosis, initiation or change of treatment, presence of comorbidities, poor metabolic control, and inability to recognize hypoglycemic situations.

A high treatment compliance and a good level of disease education by the patients were considered important factors for the success of SMGB. Additionally, it was consensually agreed that the patients' confidence in the ability to recognize the signs of hypo- or hyperglycemia could hinder adherence to SMBG, and that patients who experience more hypoglycemic episodes are more motivated to adhere to SMBG. Consensus was reached regarding the role of SMBG in determining the best course of treatment in patients with high glycemic variability, in preventing overtreatment of elderly patients (less stringent HbA1c levels), and in preventing hypoglycemia and, consequently, reducing fall risk in elderly patients. Nevertheless, the panel unanimously agreed that the correct adherence to SMBG is more difficult in elderly patients due to the possible coexistence of comorbidities and/or physical and cognitive difficulties. Regarding the pediatric population, all experts agreed that glucose monitoring using a continuous system would be a good option, although it was consensually agreed that therapeutic adherence might be a limitation for the use of these continuous systems.

No consensus was reached regarding the usefulness of SMBG for the diagnosis of gestational diabetes. Due to the tighter control of the blood glucose levels obtained when using continuous glucose monitoring systems, it was agreed that its use may contribute to decrease the likelihood of fetal macrosomia in women with DM.

Regarding hemodialysis patients, no consensus was obtained concerning the less accurate reading of glucose levels by flash glucose monitoring systems.

Consensus was reached regarding how the accuracy of capillary glucose quantification depends on analytical and patient-associated factors, how an easy-to-use SMBG system can contribute to a more accurate quantification, how the chosen glucometers must follow international quality standards, and how the use of smartphone apps coupled with glucometers may be useful for SMBG. Moreover, it was agreed that the use of continuous glucose monitoring systems allow for a better understanding of blood glucose patterns, as it is the only way to account for all hypoglycemic events that actually occur and is relevant for the detection of nocturnal hypoglycemia. Accordingly, it was considered that the determination of the association between the average level of blood glucose and glycated hemoglobin will be more precise if the average level of glycemia is determined using a continuous glucose monitorization system. Nevertheless, it was consensually agreed that capillary blood glucose measurements should be taken when the blood glucose levels are below the recommended limit, during periods of rapid variation, and at extreme blood glucose levels, due to the lower sensitivity of continuous monitoring systems in these situations, that measure glucose levels in interstitial fluid and not in the blood. Moreover, it was considered that calibration and reference measurements of continuous monitoring systems, when applicable, should be performed by quantification of blood glucose.

It was considered that the development of novel continuous glucose monitoring systems with, for example, redundant electrochemical sensors or that combine different technologies, could increase the precision of self-monitoring using these systems. Likewise, it was considered that the development of continuous glucose monitoring systems that do not require patient calibration and that can be worn for a longer period of time without the need for replacement could facilitate SMBG in specific populations such as the elderly and children. Similarly, it was considered that patient adhesion to continuous glucose monitoring can increase by combination with insulin pump technology.

Additionally, it was considered that the constant development of tools for transmitting and storing information is needed, so that continuous glucose monitoring can provide increasingly more information that allows for treatment adjustment/choice. It was also considered that the time spent in the target glucose range should consider the modality used to measure glucose as well as the methodology used for its inference.

No consensus was reached on whether there is a concern on recommending continuous glucose monitoring to patients who have frequent hypoglycemic episodes due to the lower accuracy of these devices in hypoglycemic conditions. Similarly, no consensus was reached on the effect of high visibility of flash glucose monitoring sensors on the patients' choice of this glucose monitoring method.

*Table 1.* Statements regarding blood glucose self-monitoring submitted for evaluation and the respective percentage of agreement/disagreement reached.

| Statements | Agreement (%) | Disagreement (%) |
|---|---|---|
| **Section 1: Target population** | | |
| 1. Self-monitoring of the glucose levels is relevant in: | | |
| a) Type 1 diabetes mellitus; | **100** | 0 |
| b) Insulin-treated type 2 diabetes mellitus; | **100** | 0 |
| c) Non-insulin-treated type 2 diabetes mellitus; | **84.6** | 15.4 |
| d) Gestational diabetes mellitus; | **92.3** | 7.7 |
| 2. For individuals with non-insulin treated type 2 diabetes mellitus, temporary blood glucose self-monitoring may be indicated (in terms of cost-benefit): | | |
| a) In a patient with HbA1c values above the target set for themselves and who receives adequate education on how to perform blood glucose self--monitoring and the appropriate actions depending on the results; | **100** | 0 |
| b) In patients who have an education level that allows them to take advantage of blood glucose self-monitoring; | **100** | 0 |
| c) In patients who are receptive to the need to improve their metabolic control and motivated to make the necessary changes; | **92.3** | 7.7 |
| d) In patients with poor metabolic control. | **100** | 0 |
| 3. Blood glucose self-monitoring is especially relevant in cases of: | | |
| a) Recent diagnosis; | **92.3** | 7.7 |
| b) Start or change of treatment; | **92.3** | 7.7 |
| c) Presence of comorbidities; | **84.6** | 15.4 |
| d) Poor metabolic control; | **100** | 0 |
| e) Inability to recognize hypoglycemic situations. | **100** | 0 |
| 4. Blood glucose self-monitoring is useful for the diagnosis of gestational diabetes mellitus since it allows detailed analysis of blood glucose levels. | 53.8 | 46.2 |
| 5. Blood glucose self-monitoring plays a relevant role in determining the best course of treatment in patients who have high glycemic variability. | **92.3** | 7.7 |
| 6. Blood glucose self-monitoring may play a role in preventing overtreatment of elderly individuals, for whom international guidelines suggest less stringent HbA1c levels. | **92.3** | 7.7 |
| 7. Blood glucose self-monitoring in the elderly population may contribute to the prevention of hypoglycemia, reducing fall risk. | **92.3** | 7.7 |
| 8. Although there is a higher prevalence of type 2 diabetes mellitus in elderly individuals, correct adherence to self-monitoring is more difficult in this population due to comorbidities and/or physical and cognitive difficulties. | **100** | 0 |
| 9. Blood glucose self-monitoring through a continuous monitoring system is a good option for glycemic control in the pediatric population (children and adolescents). | **100** | 0 |
| 10. Therapeutic adherence may be a limitation to the use of continuous monitoring systems in children and adolescents (unless they are connected to a continuous insulin infusion pump). | **84.6** | 15.4 |
| 11. Blood glucose self-monitoring through flash monitoring systems is less accurate in hemodialysis patients. | **61.5** | 38.5 |
| 12. High treatment compliance is an important factor for the success of blood glucose self-monitoring. | **92.3** | 7.7 |
| 13. Diabetes mellitus education is an important factor for successful blood glucose self-monitoring. | **92.3** | 7.7 |
| 14. Patients' confidence in their ability to recognize the signs of hyper- or hypoglycemia can hinder adherence to self-monitoring. | **84.6** | 15.4 |
| 15. Patients who experience more hypoglycemic episodes are more motivated to self-monitor their blood glucose. | **92.3** | 7.7 |
| **Section 2: Self-monitoring techniques** | | |
| 16. The accuracy of capillary glucose quantification depends on analytical and patient-associated factors (e.g., hand washing, finger squeezing, alcohol drying before finger pricking). | **100** | 0 |
| 17. A blood glucose self-monitoring system that is easy to use can contribute to a more accurate quantification by minimizing patient-related factors. | **100** | 0 |
| 18. The chosen glucometers must follow international quality parameters. | **100** | 0 |
| 19. The use of cell phone apps coupled with glucometers may be useful for self-monitoring of blood glucose. | **92.3** | 7.7 |
| 20. The use of continuous self-monitoring systems allows for a better understanding of the blood glucose patterns of individuals with diabetes mellitus, providing data necessary for treatment optimization. | **100** | 0 |
| 21. Self-monitoring using continuous monitoring systems (including flash systems) is the only way to account for all hypoglycemic events that actually occur. | **100** | 0 |
| 22. By allowing a tighter control of blood glucose, continuous self-monitoring of glucose may contribute to a decrease in glucose fluctuations and, consequently, decrease the likelihood of fetal macrosomia in women with diabetes mellitus. | **100** | 0 |
| 23. Constant development of tools for transmitting and storing information is needed so that self-monitoring of blood glucose can provide more and more information that allows for treatment adjustment/choice. | **92.3** | 7.7 |
| 24. Due to the lower sensitivity of continuous monitoring systems (including flash systems) in hypoglycemic situations, capillary blood glucose measurements should be taken when blood glucose values are below the recommended limit. | **92.3** | 7.7 |
| 25. When using continuous monitoring systems (including flash systems), capillary blood glucose measurements should be taken during periods of rapid variation and at extreme blood glucose values (e.g., exercise), due to the lower sensitivity of these systems under these circumstances. | **92.3** | 7.7 |
| 26. The fact that continuous monitoring systems are more accurate in hyperglycemic situations than in hypoglycemic situations is a concern when recommending this type of monitoring for patients who have frequent hypoglycemic episodes. | **76.9** | 23.1 |
| 27. Calibration and reference measurements of continuous monitoring systems should be performed by quantifying capillary blood glucose. | **92.3** | 7.7 |
| 28. The development of new continuous glucose monitoring systems that have, for example, redundant electrochemical sensors, or that combine different technologies, could increase the precision of self-monitoring through the use of these systems. | **100** | 0 |
| 29. The development of continuous glucose monitoring sensors that, for example, do not require patient calibration and that can be worn for a longer period without the need to be replaced, could facilitate self-monitoring of blood glucose in more difficult populations such as the elderly and children. | **100** | 0 |
| 30. Patient adhesion to continuous self-monitoring can increase by using a system which combines continuous monitorization and insulin infusion. | **100** | 0 |
| 31. Self-monitoring blood glucose using continuous monitoring systems is relevant for the detection of nocturnal hypoglycemia, especially in patients receiving medication that might induce hypoglycemia (e.g., insulin, sulfonylureas). | **100** | 0 |
| 32. The determination of the association between the average level of blood glycemia and glycated hemoglobin will be more precise if the average level of glycemia is determined using a continuous monitorization system. | **84.6** | 15.4 |
| 33. The high visibility of the sensors in flash monitoring systems may discourage patients from choosing this method. | **69.2** | 30.8 |
| 34. The interpretation of the time spent in the target range should consider the modality used to measure glucose and the methodology used for its calculation. | **92.3** | 7.7 |

| Statements | Agreement (%) | Disagreement (%) |
|---|---|---|
| **Section 3: Patients' education** | | |
| 35. It is necessary to implement education programs so that patients who will use self-monitoring can make the necessary therapeutic adjustments according to their blood glucose values. | **92.3** | 7.7 |
| 36. In order to prevent anxiety symptoms, it should be instilled in patients who self-monitor their blood glucose, that adequate control does not imply that all readings are in the target range. | **92.3** | 7.7 |
| 37. During the education of patients who are going to use self-monitoring of blood glucose, blood glucose monitoring at regular intervals (of approximately 15 minutes) should be recommended after a hypoglycemic event and until they regularize. | **92.3** | 7.7 |
| 38. Patients who receive training in the use of continuous monitoring systems should be informed of the error associated with predicting changes in capillary blood glucose, to ensure their safety and prevent loss of motivation. | **100** | 0 |
| **Section 4: Self-monitoring frequency** | | |
| 39. The frequency of self-monitoring of blood glucose should be personalized to each patient considering: | | |
| a) Age; | 76.9 | 23.1 |
| b) Disease duration; | **84.6** | 15.4 |
| c) Presence of micro and macrovascular manifestations; | **92.3** | 7.7 |
| d) Learning ability; | **100** | 0 |
| e) Interest and motivation; | **84.6** | 15.4 |
| f) Limitations of the environment in which the patient operates (social and family) | **100** | 0 |
| **Section 5: Regimen/type of treatment** | | |
| 40. Considering the treatment regimen, self-monitoring of blood glucose is **most useful** in the: | | |
| a) Multiple daily insulin injections; | **100** | 0 |
| b) Continuous subcutaneous insulin infusion; | **100** | 0 |
| c) Usefulness is independent of the regimen. | **23.1** | 76.9 |
| 41. Considering the mechanism of action of the drugs used in the treatment of different types of diabetes mellitus, self-monitoring will be **relevant** under treatment with: | | |
| a) Fast-acting insulin; | **100** | 0 |
| b) Intermediate-acting insulin; | **100** | 0 |
| c) Long-acting insulin; | **92.3** | 7.7 |
| d) Secretagogue drugs; | **92.3** | 7.7 |
| e) Sensitizing drugs to insulin action; | 30.8 | 69.2 |
| f) Drugs that slow glucose absorption; | 30.8 | 69.2 |
| g) Drugs that increase glycosuria; | 23.1 | 76.9 |
| h) Dipeptidyl peptidase 4 inhibitors; | 23.1 | 76.9 |
| i) Amylin analogs; | 38.5 | 61.5 |
| j) GLP-1 receptor agonists; | 30.8 | 69.2 |
| k) Self-monitoring relevance is independent of the type of treatment. | 15.4 | **84.6** |
| 42. Considering the mechanism of action of the drugs used in the treatment of different types of diabetes mellitus, self-monitoring will be **useful** under treatment with: | | |
| a) Fast-acting insulin; | **100** | 0 |
| b) Intermediate-acting insulin; | **100** | 0 |
| c) Long-acting insulin; | **92.3** | 7.7 |
| d) Secretagogue drugs; | **92.3** | 7.7 |
| e) Sensitizing drugs to insulin action; | 23.1 | 76.9 |
| f) Drugs that slow glucose absorption; | 30.8 | 69.2 |
| g) Drugs that increase glycosuria; | 23.1 | 76.9 |
| h) Dipeptidyl peptidase 4 inhibitors; | 23.1 | 76.9 |
| i) Amylin analogs; | 38.5 | 61.5 |
| j) GLP-1 receptor agonists; | 30.8 | 69.2 |
| k) Self-monitoring **usefulness** is independent of the type of treatment. | 15.4 | **84.6** |
| **Section 6: Self-monitoring impact** | | |
| 43. The self-monitoring of blood glucose may decrease the number of times the patients resort to health care and ease the burden of healthcare professionals. | 84.6 | **15.4** |
| 44. The investment necessary to obtain continuous glucose monitoring devices can be compensated by the decrease of the impact of diabetes mellitus in the healthcare system/health resources. | 84.6 | **15.4** |
| 45. It will be necessary an actualization of the clinical practice so that the glycemic levels detected by continuous glucose monitoring can be included in therapeutical decisions. | 92.3 | **7.7** |
| **Section 7: Patients' quality of life** | | |
| 46. The questionnaires "Diabetes Treatment Satisfaction Questionnaire – Status" and "Diabetes Treatment Satisfaction Questionnaire – CHANGE" are relevant to evaluate the satisfaction of patients using self-monitoring of blood glucose. | 100 | **0** |
| 47. The continuous monitorization system alarm, associated with the presence of glycemic levels outside the recommended intervals, causes anxiety in patients. | 61.5 | **38.5** |
| 48. The continuous monitorization system alarm, associated with the presence of glycemic levels outside the recommended intervals, is a decisive factor in the improvement of the patients' metabolic control. | 84.6 | **15.4** |

GLP-1: glucagon-like peptide 1; HbA1c: glycated hemoglobin.

It was considered that the implementation of structured, continuous educational programs was necessary. Moreover, it was consensually agreed that during the education process, it should be mentioned that adequate control did not necessarily mean that all readings need to be within the target range, and that SMBG should be conducted at regular intervals after a hypoglycemic event and

until regularization of the levels. For patients who use continuous glucose monitoring systems, it was unanimously agreed that they should be informed of the error associated with the changes in capillary blood glucose predicted by these systems.

No consensus was reached on whether age had an influence in the determination of the frequency of self-monitoring, whereas the patients' learning ability and the limitations of the patients' environment were considered to have influence by 100% of specialists. Additionally, it was consensually agreed that disease duration, presence of micro- and macrovascular manifestations, and the patients' interest and motivation, are factors that influence the determination of self-monitoring frequency.

It was unanimously agreed that SMBG would be useful for patients receiving multiple daily insulin injections and continuous subcutaneous insulin infusion. Regarding the type of treatment and considering the mechanism of action of the different drugs, it was consensually agreed that SMBG would be relevant and useful when taking fast, intermediate, or long-acting insulin and secretagogue drugs. No consensus was reached regarding the relevance and usefulness of SMBG in patients under treatment with sensitizing drugs to insulin action, drugs that slow glucose absorption or that increase glycosuria, dipeptyl peptidase 4 inhibitors, or GLP-1 receptor agonists. Accordingly, the panel consensually disagreed with the statements that considered SMBG relevant or useful, regardless of the type of treatment. Therefore, SMBG might be more relevant/useful for certain types of treatment.

Consensus was reached on the impact of SMBG in the healthcare system. It was considered that SMBG might decrease the number of times that patients resort to healthcare and ease the burden of the healthcare professionals. Moreover, the panel agreed that the investment on continuous glucose monitoring devices can be compensated by the decrease of healthcare resource utilization, and that an update of the clinical practice to include the glucose levels detected by continuous glucose monitoring in therapeutic decisions will be necessary.

It was unanimously agreed that it would be relevant to apply the "Diabetes Treatment Satisfaction Questionnaires – Status and Change" to evaluate the satisfaction of patients performing SMBG. Accordingly, it was consensually considered that the continuous monitoring system alarm, combined with the presence of glycemic levels outside the recommended intervals, is a decisive factor for the improvement of the metabolic control of patients. Nevertheless, a consensus was not reached on whether these factors caused anxiety.

## Discussion

Multiples advantages of SMBG have been identified, with SMBG being associated with the decrease of HbA1c.[15] SMBG has been considered beneficial as it enables therapeutic adjustments due to the detection of altered blood glucose levels, allows the confirmation of episodes of acute hyper- or hypoglycemia, and gives more self-care responsibilities to patients, which might motivate patients to be more conscious regarding the management of their disease and to engage in healthier behaviors.[15]

In this work, SMBG was considered relevant for all types of DM. This might be associated with conflicting reports. A consensus report by the American Diabetes Association and the European Association for the Study of Diabetes, considered that routine SMBG for individuals with non-insulin treated T2D was of limited additional clinical benefit while being associated with added burden and costs,4 whereas other reports describe the benefits of SMBG in this population.[6,15] Nevertheless, consensus was reached because, as evaluated in question 2 (Table 1), which reached consensus for all options, there are situations where SMBG might be relevant for non-insulin treated T2D patients (increased HbA1c levels, poor metabolic control, motivated to make changes, and appropriate education regarding the disease and SMBG). Accordingly, it was considered that the relevance and usefulness of SMBG is dependent on the type of treatment. The only treatments for which the need for SMBG reached consensus where treatments with insulin and secretagogue drugs, which have the potential to induce episodes of hypoglycemia.[16] No consensus was reached regarding the use of this technique to perform diagnosis of gestational DM. This might be related with the fact that whereas some specialists recognize that this could be useful in the future, it is not how diagnosis is currently performed.[17] Additionally, the use of glucometers for diagnosis of gestational DM is associated with poor analytic and clinical accuracy and can lead to an underdiagnosis of women with gestational DM.[18] There is no international consensus regarding gestational DM screening and diagnosis, and the blood glucose levels that justify the introduction of diet or insulin therapy are still under debate.[17] Nevertheless, the panel consensually agreed on the relevance of SMBG in gestational DM to promote adequate screening and prevent complications.

The education of patients on the disease and its management was considered relevant with all questions achieving close to 100% of consensus (3 questions reached 92.3% and one reached 100%). Hence, SMBG frequency also takes into account the learning ability of the patients. Furthermore, the frequency will have to be determined for each patient considering also the patients' interest and motivation, disease duration, presence of micro- and macrovascular complications, and the patients' environment. Age was not considered a relevant factor for the determination of SMBG frequency.

Continuous glucose monitoring systems were considered the only measurement tool that could detect all hypoglycemic episodes. No consensus was reached for the diminished accuracy of glucose measurements using continuous glucose monitoring systems in hemodialysis patients. Accordingly, contrasting reports exist in the literature. Whereas some studies report a lower

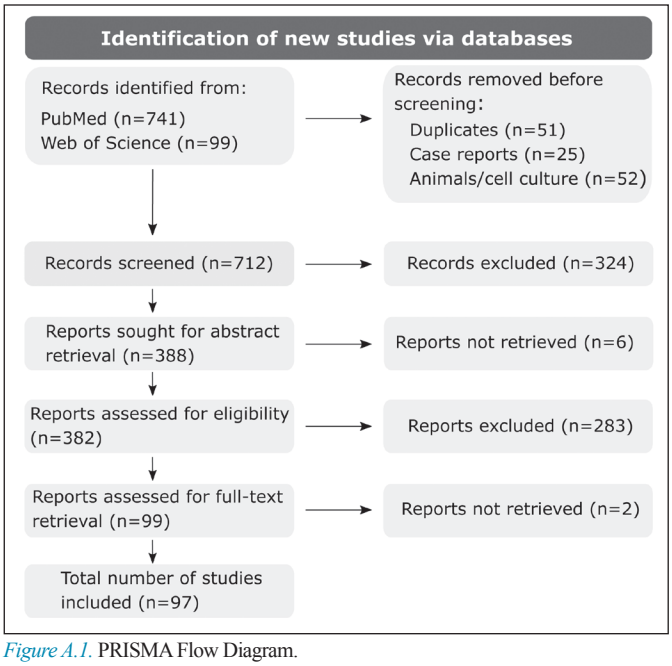


*Figure A.1.* PRISMA Flow Diagram.

sensitivity in the measurement of glucose levels in hemodialysis patients using these systems,[19,20] a systematic review considered continuous glucose monitoring an useful tool for this population.[21] This review considered 12 studies and concluded that, while the mean amplitude of glucose levels variation was higher on hemodialysis days, the use of continuous glucose monitoring systems could reduce hypoglycemic episodes. This is particularly important since patients undergoing hemodialysis are more susceptible to hypoglycemia.[21]

No consensus was reached for the existence of a concern when recommending continuous glucose monitoring to patients who experience frequent hypoglycemic episodes, even though there are some reports of lower accuracy in readings during these episodes.[16,22] This might be explained by the observation that more reliable sensors are constantly being developed.[23] Moreover, since measurements during these episodes are not accurate, constant monitoring can predict a significant drop in glucose levels before extremely low values are reached. Accordingly, the alarm of continuous glucose monitoring systems that indicate the presence of glycemic levels out of the recommended intervals was considered to be decisive for the improvement of metabolic control of patients, but was not consensually regarded as it could induce anxiety in patients.

No consensus was obtained on whether the high visibility of sensors would prevent patients from choosing continuous glucose monitoring. This lack of consensus probably stems from the difference of opinion on the stigma associated with DM. Although the stigma exists and has been reported,[24] efforts for educating the population might have shifted the negative perception of both patients and general population.

Even though the majority of recent papers focus on continuous glucose monitoring, the consensus obtained for the statements regarding capillary glucose measurements highlight the importance of this tool and reinforce that this method still has a place in clinical practice. Namely, capillary glucose values are still recommended for acute treatment decisions due to the delay in the measurement of interstitial glucose.[25] Moreover, the cost associated with continuous glucose monitoring systems might not be cost-effective for patients with more easily manageable conditions.

Overall, and although there is insufficient data, it was the consensual opinion of the panel that SMBG might decrease healthcare resource utilization and, consequently, decrease the burden associated with DM on the healthcare system.

## Strengths and Limitations

The panel included physicians specialized in Endocrinology, Internal Medicine and General Practice/Family Medicine, and thus includes opinions from the different specialties that usually treat patients with DM. Moreover, the panel included specialists with different levels of experience and from different hospitals throughout mainland Portugal, which allows a consensus representative of the Portuguese reality.

Nevertheless, this study also presents some limitations. First, the terms used for systematic literature review may not capture all articles about continuous glucose monitoring. Since continuous glucose monitoring systems measure glucose levels in the interstitial fluid, some of those articles do not include the term "capillary". However, the terms used allowed a broad review of the SMBG theme, and several articles about continuous glucose monitoring were included, allowing the formulation of various statements on this subject.

The latest self-monitoring devices that measure both blood glucose and ketone levels can be particularly relevant for some DM patients for the management of hyperglycemia and to prevent ketoacidosis.[26] However, self-monitoring of blood ketones is not a topic of debate in this study since further studies are necessary to determine optimal home testing and cutoff values.[26] Additionally, this consensus was focused on the SMBG by DM patients in their daily lives activities and in-hospital use was not approached.

Since a 10-year limit was applied to the systematic literature review, more information was included regarding the latest monitoring systems than regarding other monitoring systems. Furthermore, periodic updates will need to be performed to account for technical and pharmacological developments.

## Conclusion

In conclusion, this work reinforces the importance of SMBG and shows that, although the future of SMBG includes the new continuous systems of monitoring, capillary glucose measurements are still essential. In summary:

- SMBG was considered relevant for situations of recent diagnosis, initiation/change of treatment, presence of comorbidities, poor metabolic control, and inability to recognize hypoglycemic situations.
- Education programs are very important for patients to correctly monitor their glycemia and consequently adequately adjust their treatment/behaviors.
- SMBG frequency should be defined for each patient considering disease duration, presence of micro- and macrovascular manifestations, learning ability, interest and motivation, and the patients' environment.
- SMBG usefulness and relevance is dependent on the treatment regimen and type of diabetes, being especially important when the patients are treated with insulin or secretagogue drugs.
- Continuous glucose monitoring is the only method that enables the detection of all hypoglycemic events that occur in the 24 hours period, allowing for a better understanding of the blood glucose patterns of patients and, thus, providing relevant information for treatment optimization.
- Capillary blood glucose measurements should be performed when the blood glucose values are below the recommended limit, at extreme values, and in periods of rapid variation.
- SMBG can decrease the burden of DM on healthcare systems.

## Contributorship Statement / Declaração de Contribuição:

JJC, EP and JFP: Conception of the work, review of the statements, members of Delphi panel and critical review.
CI, MM, MM, EN, ASN, AN, JSN, MR, JAS and PAS: Review of the statements, members of the Delphi panel, critical review.
All authors reviewed and approved the final version of the manuscript.

JJC, EP e JFP: Conceção do trabalho, revisão das afirmações, membros do painel Delphi e revisão crítica.
CI, MM, MM, EN, ASN, AN, JSN, MR, JAS e PAS: Revisão das afirmações, membros do painel Delphi, revisão crítica.
Todos os autores analisaram e aprovaram a versão final do manuscrito.

## Responsabilidades Éticas

**Conflitos de Interesse:** Os autores declaram não possuir conflitos de interesse.
**Suporte Financeiro:** O presente trabalho não foi suportado por nenhum subsidio o bolsa ou bolsa.
**Proveniência e Revisão por Pares:** Não comissionado; revisão externa por pares.

## Ethical Disclosures

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