Influence of health Literacy on the self-monitoring of capillary glycemia: a systematic review protocol
Influência do letramento em saúde no automonitoramento da glicemia capilar: protocolo de revisão sistemática

ABSTRACT
Objective: To synthesize the main scientific evidence on the influence of functional literacy on health and numeracy in people with diabetes who perform self-monitoring of capillary glycemia. Method: Systematic review of convergent and segregated mixed methods conducted and developed according to the premises of the Joanna Briggs Institute. A search for published and unpublished studies will be carried out in MEDLINE (PubMed), LILACS, CINAHL, Web of Science, EMBASE, SCOPUS, Cochrane Library (central), Google Scholar, OPENGRAY, and the Networked Digital Library of Theses and Dissertations (NDLTD). There will be no language restrictions or time interval for publication. The identified scientific documents will be organized with the help of EndNote and repeated documents will be deleted, keeping only one version. Selection will take place through the analysis of independent reviewers, who will critically analyze and evaluate the selected studies and extract data using standardized instruments with the help of Rayyan software. The results of the review will be reported according to the PRISMA guidelines. Registration number on PROSPERO platform: CRD42023408045. Descriptors: Blood Glucose Self-Monitoring; Diabetes Mellitus; Health Literacy.

INTRODUCTION
Currently, Diabetes Mellitus (DM) is one of the health challenges due to its rapid growth in the 21st century. According to the International Diabetes Federation, 537 million people (1 in 10 adults) worldwide live with this disease, and it is expected that this number will reach 784 million by 2045(1). DM is among the top 10 causes of death worldwide(2), accounting for 6.7 million deaths in 2021; that is, one death every five seconds(1).
In this context, capillary glucose self-monitoring (GMA) is a strategy that allows the knowledge of glucose values for decision-making in the treatment. Currently, with the advent of new technologies, we highlight the Continuous Monitoring of Glucose (MCG), which happens through sensors applied subcutaneously, allowing the continuous measurement of current and real glucose levels, emerging new metrics for the evaluation of glycemic control, as Time in Range (TIR)\(^3\). These strategies allow the prevention of complications of DM and improve the quality of life of people living with DM\(^4\).

However, despite the potential health benefits associated with AMCG and MCG in the treatment of DM, several barriers still need to be studied. The authors pointed out that there is high variability in the performance and irregular daily frequency of GMA among people, which interferes with low adherence to GMA, either by glycosmeter or glucose sensor\(^4-6\).

The success of these new technologies can critically depend on the level at which people are educated, empowered, and motivated to use them. Thus, one of the main barriers is the ability to interpret each of these glycemic values, patterns and trends. Therefore, Functional Health Literacy (LFS) and numeracy are essential to achieve favorable results with these technologies and metrics\(^7\).

LFS is defined as "the degree to which people can access, search, obtain, understand, evaluate, and apply health information to make informed decisions about their condition to maintain quality of life over time"\(^8\). Health numeracy is considered part of the LFS and was defined as "the ability to perform basic reading and numerical tasks necessary to function in the health environment\(^9\)."

LFS in DM focuses on the skills needed to apply health information\(^10\); on the other hand, numeracy in DM refers to mathematical skills for effective self-management of DM, such as counting carbohydrates, reading food labels, administering and applying insulin doses and prescribed medications, and using TIR\(^11\). Thus, inadequate LFS and numeracy can influence the success of self-care, especially in the accomplishment of GMA, achieve TIR and other management actions for DM. Therefore, it is essential to evaluate LFS before planning interventions that include educational information\(^12\).

It should be noted that some systematic reviews (RS) previously carried out have investigated the relationship between LFS and health outcomes in people with DM, the association between LFS and knowledge about DM, the impact of LFS on self-management of DM, the association between LFS and the knowledge about DM, the impact of LFS on self-management of DM, and strategies used with LFS in people with DM, instruments used to measure LFS and numeracy in people with DM\(^10,13-17\). These studies have shown that LFS affects medical care and results in health, knowledge of the disease, reduction of glycated hemoglobin levels, influence on glycemic control, development of self-efficacy in DM and the importance of evaluating the LFS of people with DM to direct better health education interventions.

Despite the available evidence suggesting that LFS is related to GMA and to the interpretation of glycemic values, the results are inconclusive, and no RS has focused deeply on this self-care activity, which represents a little explored topic. In contrast to these reviews, the present study will synthesize the influence of LFS and numeracy in the accomplishment of the GMA and MCG, in order to perform it in a more detailed and critical way, in order to visualize the impact of these concepts along the qualitative aspects that can be presented from their influence.

Therefore, it is important to conduct an RS of the influence of LFS in people with DM who perform GMA to improve their experience when performing it, as well as the health results obtained and later, based on the results, to create strategies to improve LFS and patient numeracy to achieve better glycemic control through AMGC.

Therefore, the objective of this RS is to synthesize the main scientific evidence on the influence of LFS and numeracy in people with DM who perform AMGC.

**METHOD**

The RS protocol will be conducted and developed according to the premises of the Joanna Briggs Institute (JBI) for systematic reviews of mixed methods\(^18\), as well as the steps proposed by Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)\(^19\). This protocol was registered in PROSPERO (CRD42023408045).

**Review question**

The review question was developed using the PICO strategy\(^20\), which represents an acronym for population (People with DM), Phenomenon of interest (AMGC OR MCG) and Context (LFS and Numeracy). Thus, the RS question was: “What is the influence of LFS and numeracy on people with DM who perform AMGC or MCG?”.
Inclusion Criteria

Participants
Studies will be considered that include individuals with type 1, 2, or gestational DM, regardless of gender, age, socioeconomic status, and race or type of drug treatment.

Intervention
This review will consider studies that discuss any effects related to LFS and numeracy in people with DM who perform AMGC, which may be continuous self-monitoring, intermittent self-monitoring and glycosometers.

Comparator
This review will not consider any comparator.

Results
The results considered by this review will be: LFS and numeracy levels, capillary glycemia, glycated hemoglobin, TIR, health education, treatment and self-management, as presented in individual studies.

Interest Phenomena
It will be the experiences of people with DM who perform AMGC, aiming at the interaction between LFS and numeracy in the performing of the AMGC, seeking to determine which “barriers” or “facilitators” people have when performing a certain action.

Context
Studies that focus on and describe the influence of LFS and numeracy on people with DM who perform any type of self-monitoring, in any clinical or geographic environment, and without limitations on cultural, gender or socioeconomic characteristics.

Types of studies
Quantitative, qualitative and mixed methods studies will be considered for review. Therefore, experimental and quasi-experimental clinical research studies, randomized clinical trials, controlled trials, pragmatic trials, and before and after observational studies (longitudinal, cohort) will be included. Qualitative studies with phenomenological, ethnographic, and action research, among others. Studies of mixed methods, provided that quantitative and qualitative data can be extracted separately. Gray literature will also be considered. There will be no language restrictions for the included studies, and the publication period will cover since the beginning of the databases.

Sources of information
The search for published studies will be carried out in the following databases: Medical Literature Analysis and Retrieval System Online (MEDLINE), PubMed, Latin American and Caribbean Health Sciences Literature (LILACS), Cumulative Index to Nursing & Allied Health Literature (CINAHL), Web of Science Core Collection, Embase, Scopus and Cochrane Central Register of Controlled Trials (CENTRAL). Searches for unpublished studies will be performed through Google Scholar, OPENGRAY and Networked Digital Library of Theses and Dissertations (NDLTD).

Search strategy
The search strategy aims to locate published and unpublished studies. An initial search was limited to MEDLINE (PubMed), CINAHL and Scopus, in order to identify relevant publications for review. For each database, the key terms were initially determined, and their synonyms were specified using MESH. Additional words, phrases and index terms pertinent to the review question have been identified and used to build search strategies. The definitive search strategy for MEDLINE, EBSCO and Scopus (Figure 1) will be applied to all other databases and electronic portals included, with adaptations made when necessary through advanced search.
### Data management and selection of studies

After the search, all identified citations will be collected and imported into EndNote VX.X (Clarivate Analytics, PA, USA), and duplicates will be removed. Two researchers will independently review the titles and abstracts according to the inclusion criteria, with the help of Rayyan software. Potentially relevant studies and their details will be recovered in full. The selected full texts will be evaluated by two independent reviewers based on the inclusion criteria. Studies that meet the exclusion criteria will be eliminated, and their reasons will be reported in the RS. In case of differences between the reviewers during the screening and selection of the studies, a third reviewer will be contacted for discussion and resolution of the divergences.

### Data extraction

Two reviewers will independently extract the following data: year of publication, objective, language of publication, country, publication magazine, Qualis CAPES, impact factor, Oxford evidence level, data collection method, sample, data collection instruments, theoretical structure (for qualitative articles), data analysis method, main quantitative results, or qualitative results (participants’ speech), conclusions and limitations (Supplementary material I and II). Disagreements between reviewers will be resolved by discussion or by a third reviewer. If necessary, the authors of the studies will be contacted to request missing or additional information about the selected articles.

### Evaluation of methodological quality

Articles with quantitative methodology and quantitative parts of articles of selected mixed methods, before being included in the review, will be evaluated by two independent reviewers for methodological validity, using standardized instruments for critical evaluation of JBI. The same process will be repeated for articles with qualitative methodology and for the qualitative part of articles with mixed methods. In the event of disagreements between reviewers, they will be resolved with the intervention of a third reviewer.

### Data Summary

The results of the research will be fully reported in the final RS and presented in a PRISMA flowchart to ensure transparency and reproducibility of the study. This RS will follow a segregated convergent approach for synthesis and integration, according to the JBI methodology for systematic reviews of mixed methods, and will use JBI SUMAR! This will involve a separate quantitative and qualitative synthesis, followed by the integration of the resulting quantitative and qualitative evidence. The findings of each single method synthesis included in this RS will be configured according to the JBI methodology for mixed methods. The juxtaposition and organization/linkage of quantitative and qualitative evidence in a line

## Table

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<tr>
<th>Database</th>
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<tr>
<td>PubMed</td>
<td>(“Diabetes Mellitus”[MeSH Terms]) OR (“Diabetes Mellitus”) OR (“Diabetes Mellitus, Type 1”[MeSH Terms]) OR (“Diabetes Mellitus, Type 1”) OR (“Insulin-Dependent Diabetes Mellitus”) OR (“Juvenile Onset Diabetes Mellitus”) OR (“Type 1 Diabetes Mellitus”) OR (“Insulin Dependent Diabetes Mellitus 1”) OR (“Autoimmune Diabetes”) OR (“Diabetes Mellitus, Type 2”[MeSH Terms]) OR (“Diabetes Mellitus, Type 2”) OR (“Type 2 Diabetes Mellitus”) OR (“Noninsulin Dependent Diabetes Mellitus”) OR (“Adult Onset Diabetes Mellitus”)) OR (“Diabetes, Gestational”[MeSH Terms]) OR (“Diabetes, Gestational”) OR (“Gestational Diabetes”) OR (“Home Blood Glucose Monitoring”) OR (“Continuous Glucose Monitoring”)</td>
<td>34</td>
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of argumentation will be carried out to produce a configured global analysis. In cases where configuration is not possible, the results will be presented in narrative format[26].

**Ethical considerations**

When it is a mixed method RS protocol (secondary studies), it is not necessary to submit it to the Research Ethics Committee.

**CONFLICT OF INTERESTS**

The authors have declared that there is no conflict of interests.

**REFERENCES**


**AUTHORSHIP CONTRIBUTIONS**

Project design: Medina LAC, Brandão MGSA, Teixeira CR de S

Data collection: Medina LAC, Brandão MGSA, Lima GA

Data analysis and interpretation:

Writing and/or critical review of the intellectual content: Medina LAC, Brandão MGSA, Lima GA, Zanetti ML, Pace AE, Teixeira CR de S

Final approval of the version to be published: Medina LAC, Brandão MGSA, Lima GA, Zanetti ML, Pace AE, Teixeira CR de S

Responsibility for the text in ensuring the accuracy and completeness of any part of the paper: Medina LAC, Brandão MGSA, Lima GA, Zanetti ML, Pace AE, Teixeira CR de S

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