Monitoring human milk donors: protocol for a scoping review

Acompanhamento de doadoras de leite humano: protocolo de uma revisão de escopo

Seguimiento de las donantes de leche humana: protocolo para una revisión del alcance

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ABSTRACT
The donation of human milk (LH) is a consolidated and essential action for the breastfeeding (AM) of premature infants hospitalized in neonatal units who need human milk (LH) to guarantee food and nutritional security. Human milk banks (BLH) follow up with LH donors from LH collection, pasteurization and distribution of pasteurized human milk (LHP). This paper aims to map and identify in the scientific literature studies that address how the monitoring of women who donate human milk by public reference services takes place. As a method, the scoping review will be conducted in accordance with the recommendations of the Joanna Briggs Institute (JBI). The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist will be used to report the results of the review. After the pilot search, titles and abstracts will be evaluated by two or more reviewers independently and blindly to identify converging evidence for the inclusion criteria defined for the review. This review could provide an overview or map the world evidence on how human milk donors are accompanied by specialized health services. As a conclusion, this scoping review could broadly present the evidence of literature, in order to contribute to new formulations regarding programs, policies and even protocols regarding the process of monitoring human milk donors.

Keywords: human milk donation, milk bank, professional support, nursing.
RESUMO
A doação de leite humano (LH) é uma ação consolidada e essencial para o aleitamento materno (AM) de prematuros hospitalizados em unidades neonatais que precisam do leite humano (LH) para a garantia da segurança alimentar e nutricional. Os bancos de leite humano (BLH) realizam junto as doadoras de LH o acompanhamento desde a coleta do LH, pasteurização e distribuição do leite humano pasteurizado (LHP). O artigo tem como objetivos mapear e identificar na literatura científica estudos que abordem como ocorre o acompanhamento de mulheres doadoras de leite humano pelos serviços públicos de referência. Para tal, será conduzida uma revisão de escopo de acordo com as recomendações do Joanna Briggs Institute (JBI). A checklist do Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) será utilizada para reportar os resultados da revisão. Após a busca piloto, títulos e resúmenes serão avaliados por dois ou mais revisores de modo independente e as cegas para identificar as evidências convergentes para os critérios de inclusão definidos para a revisão. Como resultados, esta revisão poderá fornecer uma visão geral ou mapear as evidências mundiais sobre como as doadoras de leite humano são acompanhadas pelos serviços de saúde especializados. Por fim, conclui-se que esta revisão de escopo pode apresentar de forma ampla as evidências da literatura, de modo a contribuir para novas formulações no que tange programas, políticas e até protocolos quanto ao processo de acompanhamento de doadoras de leite humano.

Palavras-chaves: doação de leite humano, banco de leite, acompanhamento profissional, enfermagem.

RESUMEN
La donación de leche humana (LH) es una acción consolidada e imprescindible para la lactancia materna de los niños prematuros hospitalizados en unidades neonatales que necesitan leche humana (LH) para garantizar la seguridad alimentaria y nutricional. Los bancos de leche humana (BML) realizan el seguimiento de las donantes de LH desde la recogida de la LH hasta la pasteurización y distribución de la leche humana pasteurizada (LPH). Los objetivos de este estudio son mapear e identificar estudios en la literatura científica que aborden cómo se realiza el seguimiento de las donantes de leche humana por parte de los servicios públicos de referencia. Como método será utilizada la revisión del alcance, lo que se llevará a cabo de acuerdo con las recomendaciones del Instituto Joanna Briggs (JBI). Para informar de los resultados de la revisión se utilizará la lista de verificación Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). Después de la búsqueda piloto, los títulos y resúmenes serán evaluados por dos o más revisores de forma independiente y ciega para identificar evidencia convergente para los criterios de inclusión definidos para la revisión. Esta revisión podrá proporcionar una visión general o mapear la evidencia mundial sobre cómo las donantes de leche humana son seguidas por los servicios sanitarios especializados. En conclusión, esta revisión de alcance puede presentar la evidencia de la literatura de una manera amplia, con el fin de contribuir a nuevas formulaciones relativas a los programas, políticas e incluso protocolos para el proceso de seguimiento de las donantes de leche humana.

Palabras clave: donación de leche humana, banco de leche, apoyo profesional, enfermería.
1 INTRODUCTION

The Human Milk Bank (HMB) is a specialised service linked to a maternal and child hospital. Its objective is to promote breastfeeding, collect, process and control the quality of human milk (HM) in all its phases, for subsequent distribution to premature recipients hospitalised in neonatal units. However, it is important to note that the volume of donated HM available in the banks is still insufficient to meet all the existing demand (Soares et al., 2018).

Human milk donation is consolidated through actions involving public institutions, where, in addition to the HMB network, partners such as the fire brigade (FB) are involved in accompanying people to their homes to deliver supplies such as glassware, personal protective equipment (PPE) such as hats and masks, and to collect the donated milk. Against this background, HMBs have in recent years become strategic elements in the promotion and encouragement of breastfeeding and human milk donation and have undergone a series of ideological changes in their institutional practice since the first unit was established in the country in 1943 (Alencar; Seidi, 2010).

HMBs operate within the Unified Health System (Sistema Único de Saúde - SUS) as a measure to improve the quality of neonatal care, with a particular focus on the food and nutritional security of premature infants admitted to neonatal intensive care units. Their operational activities include the collection, processing, quality control and distribution of donated HM to recipients. (Barros; Almeida; Rabuffetti, 2018).

The expansion of the number of human milk banks (HMBs) in Brazil has facilitated the provision of essential nutritional support for the vulnerable population of premature babies, who depend on it for their survival. All milk collected undergoes a process designed to ensure the food and nutritional security of this population (Branco et al., 2015). In this context, human milk banks (HMBs) have become essential specialised services that manage an important action within the food chain of hospitalised premature infants. They are strategic and guarantee food safety for this clientele, contributing to the maternal-neonatal care cycle. They also act as allies of primary health care (PHC) through their collaboration with the promotion of breastfeeding (BF) and the donation of human milk (HM).

In the context of a growing and alarming percentage of premature births and deliveries, especially in the wake of three years of uncertainty following the Covid-19 pandemic, it is crucial...
to understand how human milk banks (HMBs) and human milk collection points (HMCPs) have organised themselves to maintain their activities. These activities involve the collaborative process of guaranteeing the food and nutritional security of premature babies. This process is based on the institutional relationship between the care network (*Rede de Bancos de Leite Humano* – r-HMB) and related services and human milk donors.

In 2015, the United Nations (UN) outlined the objectives of sustainable development (ODS), among which it was stipulated that by 2025 the signatory countries must eradicate all forms of malnutrition. This implies meeting the nutritional goals related to gestation, lactation (including premature births), children, adolescents and the elderly (Conecta Brasil, 2022). In 2023, the World Health Organization (WHO) issued a warning regarding the rising and persistent rates of prematurity. It was noted that one in ten newborns is born prematurely, before 37 weeks of gestation, with estimates indicating that one birth occurs every two seconds. In 2020, it was estimated that approximately one million newborns died due to complications from premature birth, equating to one infant dying every 40 seconds. (WHO, 2023).

Premature birth represents the leading cause of death among children under the age of five, contributing to one in three neonatal deaths, occurring from the first month of life until the infant reaches one year of age. It is recommended that donated human milk be offered in accordance with established safety guidelines, as human milk has been shown to reduce the likelihood of necrotising enterocolitis in premature babies (Kimani-Murage, *et al*., 2023). The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have emphasized that when breastfeeding is not possible for premature infants, donated human milk represents the optimal nutritional therapy in neonatal intensive care units for newborns with low birth weight (Fang *et al*., 2021).

In this context, HMBs have become essential specialised services that manage an important action within the food chain of hospitalised premature infants. They are strategic and guarantee nutritional safety for this clientele, contributing to the maternal-neonatal care cycle. The expansion of the number of HMBs in Brazil has facilitated the provision of essential nutritional support for the vulnerable population of premature babies, who depend on it for their survival. All milk collected undergoes a process that ensures the safety of the food and the food and nutritional security of this population (Branco *et al*., 2015).
HMBs operate within the Unified Health System (SUS) as a measure to improve the quality of neonatal care, with a particular focus on the food and nutritional security of premature infants admitted to neonatal intensive care units. Their operational activities include the collection, processing, quality control and distribution of donated HM to recipients (Barros; Almeida; Rabuffetti, 2018).

In a retrospective observational study carried out at the Human Milk Bank of a Hospital located in the South Centre of Paraná State, Schiessel et al. (2020). It is evident that the primary reason for the discarding of donated milk is attributable to the donor's lack of care outside the Human Milk Bank (HMB) environment. This disposal is associated with changes in the milk's microbiological properties, rendering it unfit for use. Furthermore, issues have been identified during the collection process, including the presence of contaminants and dirt due to inadequate sanitisation of utensils and the use of inappropriate containers to store milked human milk (MHM), as well as inadequate personal hygiene practices. Inadequate care during the pre-storage and storage phases, which are essential for maintaining the cold chain in the donor's home, also contributes to the increased disposal of donated human milk. (Schiessel et al., 2020).

In order to function in accordance with the standards set forth by RDC/ANVISA-171/2006, HMBs must maintain their structural integrity. (Brasil, 2006), For this to occur, it is of equal importance that the 47 protocols of the service, including the monitoring of donors proposed by the r-BLH (from registration, collection, transport, pasteurisation and supply to neonatal units), are part of the work of a multi-professional team that is qualified to work collaboratively, in order to guarantee effective results.

One of the most crucial activities at the HMB was the home collection service for HM donations and the recruitment of donors. This was done to ensure that the processes of protection and support for human milk donors were maintained, whether on a routine basis or at odd moments, such as when facing the covid-19 pandemic. The nurse and her team must act autonomously, detecting problems and enabling solutions. Furthermore, they must demonstrate the importance of their nursing practices being systematised (Marchiori et al., 2022).

Given the plethora of information and peculiarities surrounding the context of human milk donation, it is of paramount importance to gain an understanding of the monitoring procedures employed during the human milk donation phase in lactating women. Consequently,
the objective of this scoping review is to map and identify studies in the scientific literature that address the manner in which public reference services monitor women who donate human milk.

2 METHODOLOGY

The scoping review will be conducted in accordance with the recommendations set forth in the Joanna Briggs Institute Manual for Evidence Synthesis. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist will be employed to present the findings of the review.

The principal question addressed in this study is: “What is the current state of the scientific literature with regard to the monitoring of human milk donors?”. Furthermore, this review poses the following sub-questions: “How do nurses monitor human milk donors whose milk is unfit for consumption?” and “What are the critical points identified in the literature that may compromise the quality of the human milk donation process?”.

The protocol for this scope review was registered on the OSF platform, in accordance with the recommendations of the JBI, and can be accessed via the following link: https://doi.org/10.17605/OSF.IO/BWS2N.

2.1 CRITERIA FOR INCLUSION

The scoping review, guided by the mnemonic Population, Concept and Context (PCC), will consider studies in which the population (P) is defined as follows: breastfeeding human milk donors, of any age and ethnicity, and health professionals who monitor human milk donors. With regard to the concept (C), this review will consider studies that present monitoring during the human milk donation process. Furthermore, studies will be considered in which the context is health services, both public and private.

2.2 CRITERIA FOR EXCLUSION

It should be noted that the scoping review will not consider studies that include lactating women who commercialise milked human milk. Studies in which the context is the
commercialisation of human milk acquired from donors via health services will not be considered.

2.3 TYPES OF DATA

The scoping review will consider all types of published and indexed studies that employ a qualitative approach, including case studies, ethnographic studies, phenomenological studies, narrative studies, action research, and mixed methods studies that converge with the objectives of the scoping review. Quantitative studies will also be considered, although not limited to experimental, quasi-experimental, randomised controlled, and non-randomised studies. Furthermore, descriptive observational studies, descriptive case reports, and cross-sectional studies, as well as publicly accessible theses and dissertations, will also be considered. Furthermore, this review will consider studies published at any time, without limitation of studies published in languages in which the review team is proficient.

2.4 RESEARCH STRATEGY

The research strategy will focus on locating both published and unpublished studies. An initial, limited search was conducted in PubMed, the Cochrane Library, and JBI Evidence Synthesis to identify studies on the subject. Terms were identified in the titles and abstracts of relevant articles and the indexing terms used in the articles to develop the MEDLINE (Medical Literature Analysis and Retrieval System Online) search strategy (see Table I). The research strategy, which incorporates all indexed terms and keywords, will be adapted for all databases and/or information sources. In addition, the reference lists of all the sources of evidence will be examined for the inclusion of any further relevant studies on the subject.

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<td>Search #3</td>
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Table 1 - Embase database search strategy, carried on 31 May 2024
Pilot research yielded one scoping review on the subject, which aimed to present the barriers and facilitators to human milk donation and its acceptability. This scoping review is therefore justified in order to map out the evidence centred on the process of human milk donation, with regard to monitoring donors.

2.5 SOURCES OF INFORMATION

The databases that will be employed for the purpose of conducting the searches are as follows: The following databases will be consulted: Scopus, MEDLINE (Medical Literature Analysis and Retrieval System Online), SciELO (Scientific Electronic Library Online), Excerpta Medica Database (EMBASE), WOS (Web of Science), Nursing Databases (BDENF) and LiLACS (Latin American and Caribbean Literature on Health Sciences). In order to identify any unpublished studies or grey literature, a search will be conducted on Google Scholar.

2.6 SELECTION OF STUDIES

Following the completion of the database searches, all evidence will be collated and downloaded in full, and all duplicates will be removed. Following the pilot search, the titles and abstracts will be assessed by two or more reviewers independently and blindly to identify evidence that meets the inclusion criteria defined for the review. Evidence sources identified in the study reference lists will be retrieved in full, read in full, and assessed for inclusion criteria by two or more independent reviewers. The reasons for the exclusion of sources of evidence that fail to meet the inclusion criteria will be clearly stated in the scoping review.
Should any discrepancies arise between the reviewers at any stage of the selection process, these will be resolved through discussion between the reviewers, or by consulting a third reviewer, or by contacting the authors of the study to clarify the points of disagreement.

The results of the searches and the process of including studies will be reported at the end of the scoping review and will also be presented in the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Review (PRISMA-ScR) diagram.

2.7 DATA MINING

The data from the sources of evidence will be extracted by two or more reviewers independently, using the data extraction tool adapted from the model presented by the JBI (Table 2). The data extracted will include specific details of the participants, the concept of human milk donor follow-up, the context, the method used in the studies, and relevant information that answers the review question.

The framework for information extraction is presented in Table 2 below. This methodology has been adapted from the JBI Manual for scoping reviews and tested. Should any revisions be necessary during the data extraction process for each source of evidence, these will be detailed in the scoping review. Any discrepancies between reviewers will be resolved through discussion or by consulting a third reviewer. Should the need arise, contact will be made with the authors of the evidence sources to clarify any missing information or to request additional information when necessary.

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<td>Actions for monitoring breastfeeding women who donate human milk:</td>
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2.8 DATA ANALYSIS AND PRESENTATION

The data analysis will entail descriptive analysis, which will enable the objectives of the review and the review questions to be answered. The data will be presented in graphical, diagrammatic or tabular form. A narrative summary will be presented in conjunction with the results in tables and/or graphs, with specific reference to the objective and review questions.

3 EXPECTED OUTCOMES

This scoping review could provide an overview or map the worldwide evidence on how human milk donors are monitored by specialised health services. This would help to clarify the actions, technologies used in monitoring, protocols, and care professionals involved in the process.

4 CONCLUSIONS

It can be concluded that this scoping review can present the evidence from the literature in a broad way, in order to contribute to new formulations regarding programs, policies and even protocols for the process of monitoring human milk donors.

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REFERENCES


