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Factors associated with the quality of corneas retrieved for transplantation by Eye Banks: a scoping review protocol

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ABSTRACT

Introduction The cornea is an avascular and transparent layer of connective tissue crucial to retinal image quality. Diseases can impair its quality, affecting vision. Keratoplasty is the only therapy capable of restoring vision quality in severe corneal involvement. Despite the established practice of transplantation, access to corneal tissue is limited in many places, and the quality of retrieved corneas is not always adequate, resulting in disqualification. Not all factors affecting tissue quality are fully understood due to the multifactorial nature of processes and variations in procedures globally.

Objective The objective is to map the global literature to establish the factors associated with the clinical and sociodemographic conditions of donors, and the conditions inherent in the processing of corneas that can influence the quality of this tissue for transplantation purposes.

Methods and analysis A scoping review will be developed based on the methodological framework of the Joanna Briggs Institute. The scientific report will follow the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension checklist for Scoping Reviews. Searches will be conducted in 30 indexed and 12 grey literature databases, without time or location restrictions. The selection of studies will be carried out in three distinct phases: screening, eligibility and inclusion. After defining the sample, data from the selected studies will be systematically extracted into an electronic spreadsheet. The results will be presented descriptively through tables and graphs of absolute and relative frequency. In addition, the PRISMA Scoping Review flow chart will be presented to present the process of searching, including and excluding articles and documents.

Ethics and dissemination This scoping review study does not require prior ethical approval as it uses publicly available and already published studies. The research protocol is registered in the Open Science Framework (osf.io/bw6r7). The findings will be submitted for publication in peer-reviewed scientific journals and presented at ophthalmology and/or transplantation conferences through oral presentations or posters.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The protocol was developed following the Joanna Briggs Institute methodological framework as described in its manual for evidence synthesis, for conducting a scoping review.
⇒ This study adopts a comprehensive research method, which includes consulting various databases of scientific journals and grey literature repositories to ensure a thorough exploration of the literature relevant to the topic.
⇒ The technical documents originating from eye banks are variable, and this may influence the quality of the information that will be extracted from these materials.

INTRODUCTION

The cornea is a layer of avascular and transparent connective tissue located anteriorly to the eyeball that assists in improving the image formed by the retina. When structural dysfunctions lead to the formation of scars, opacifications or irregularities in this tissue, there may be a high degree of vision impairment and even blindness.[1 2]

The WHO estimates that approximately 2.2 billion people have some degree of visual impairment and about one billion of these cases can be corrected through access to appropriate treatment.[1]

Several diseases, such as bullous keratopathy, keratoconus, trachoma, Fuchs' dystrophy and infectious keratitis, compromise the quality of corneal tissue and can result in significant structural damage that affects visual acuity.[2 3]

Corneal opacity is the fifth most prevalent cause of eye disease and affects approximately 4.2 million people worldwide. It is estimated that 1.9 million of these cases can be treated through corneal transplants.[4 5]

Although keratoplasties are essential to restore the quality of life of patients affected by the loss of transparency of corneal tissue, access to this tissue is limited in many countries and is generally concentrated in large cities.[6] Furthermore, not all retrieved corneas are suitable for transplantation, and the

utilisation rate of this tissue can vary from 40% to 90% depending on the institution or country. In many cases, disqualification is not related to sociodemographic and clinical characteristics of donors, but rather to issues inherent in the procurement, storage and processing of the tissue. As a result, not all tissues processed by Eye Banks (EBs) are intended for keratoplasties.[7–9]

Importantly, EBs are responsible for ensuring the quality and biological safety of the collected corneal tissue, as well as establishing appropriate processing and storage standards.[10]

However, the details of the technical, logistical and operational processes related to corneal quality are not yet fully understood.[3 11] Although the scientific literature provides information on the main reasons for the disqualification of corneas,[12] there is still no complete knowledge of all factors that can directly or indirectly influence their quality, given the multifactorial nature of the aspects involved.

The methodological framework developed by the Joanna Briggs Institute (JBI) will be adopted to conduct the present review.[13] In order to avoid duplication of studies with similar proposals under development, a previous search was carried out in databases of protocol records and in databases that publish review studies. The simple search strategy included the terms: Cornea "Tissue and Organ Procurement" and "Eye bank".

The search was carried out on 7 February 2024, in the following repositories: Open Science Framework, International Prospective Register of Ongoing Systematic Reviews (PROSPERO), JBI systematic review register, Database of Abstracts of Reviews of Effects (DARE), Cochrane Library and JBI Evidence Synthesis. No registered record or review under development was found with the proposed theme.

The objective of this study is to survey the literature to identify the factors associated with the clinical and sociodemographic conditions of donors, as well as the conditions inherent in the processing of corneas that can influence the quality of this tissue for transplantation purposes.

Justification

The quality of corneal tissue has a multifactorial nature that involves conditions related to the retrieval, storage and processing, in addition to the individual factors of the donors. Primary studies address these aspects according to their research realities and often do not address all these topics or are not comprehensive concerning each of the factors that can structurally modify the retrieved tissues.

This review is justified, as it will map the existing literature through an exhaustive search of the evidence already produced and, thus, report in a summarised way the conditions and processes that the corneal tissue undergoes which can lead the retrieved tissues to present different qualities.

METHODS AND ANALYSIS

A scoping review will be developed based on the methodological framework of the JBI.[13] For this, the study will follow chapter 11 of the 'JBI Manual for Evidence Synthesis' and will adopt the following topics: title, development of the title articulated with the research question, introduction, inclusion and exclusion criteria, research strategy, selection of the source of evidence, data extraction, and analysis of evidence and presentation of results.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist guidelines will be used to report this scoping review (online supplemental file 1).[14] This protocol has been registered within the Open Science Framework (https://osf.io/bw6r7/).[15]

Research questions

To formulate the research question, the mnemonic 'Population' (corneas collected for transplantation), 'Concept' (factors associated with quality) and 'Context' (Eye Banks) (PCC) were used, which resulted in the following main question: 'What are the factors associated with the quality of corneas retrieved for transplantation in EBs?'

As subquestions of the study, the following will be evaluated:

1. What evidence is there about the logistical process for retrieval of corneas?
2. What are the clinical and sociodemographic factors of the donor reported in the scientific literature that influence the quality of corneal tissue?
3. What are the corneal retrieval and storage techniques used according to the scientific literature?
4. What are the processing conditions to which corneal tissues are subjected in EBs?
5. What are the corneal quality assessment instruments described in the literature, in addition to the slit lamp and specular electron microscope?

Inclusion criteria

Population

Studies presenting corneal tissues from donors of all ages and both sexes registered in EBs.

Concept

In relation to corneas recovered for transplants, it is intended to identify the logistical, technical, procedural and storage conditions from corneal retrieval to the last pretransplant evaluation.

As a criterion to determine the quality of corneal tissue, the study will adopt the classification scores presented after the evaluation of the technical specialists through examination with slit lamp and specular microscopy, as well as other equipment used to evaluate corneas retrieved for transplantation. For this study, the tissue classification scores defined by the Eye Bank American Association[16] and the Pan American Association of Eye Banks[17] will be considered.

A Likert-type scale will be used to classify tissues from 0 to 4, in which corneas classified as 0 will be considered excellent, 1 good, 2 regular, 3 poor and 4 unacceptable for transplants.

Context

We will include studies conducted anywhere in the world with data from EBs, entities responsible for retrieving, processing and storing corneas intended or not for transplantation.

We will include complete studies listed in the databases mentioned in the topic 'Information Source', which retrieve documents in the form of articles, theses and dissertations, after applying the search strategy according to the particularities of each one, without taking into account the study design. In addition, protocols for assessing the quality of corneal tissue that may be provided by transplant regulatory entities and which address the PCC theme will be considered.

Finally, studies will be included without timeframe or language restrictions and the reference lists will be reviewed so that other studies related to the topic of interest can be identified.

Exclusion criteria

News, interviews, images, maps, music, audio and videos, incomplete articles, diaries, letters to the editor, abstracts and expanded abstracts of conferences and congresses, as well as reviews, will be excluded. Duplicate documents will be considered only once.

Sources of information

To define the sources of information of indexed literature, the Journal Portal of the Coordination for the Improvement of Higher Education Personnel[18] was accessed, which is an agency of the Brazilian Ministry of Education for regulating postgraduate studies. The Federated Academic Community was then logged into to access the proxy of the Federal University of Mato Grosso do Sul.

Access to the Coordination for the Improvement of Higher Education Personnel's Periodicals Portal and researchers' institutional login into the Federated Academic Community are initial steps necessary for researchers to access the content of the databases used in the study free of charge. This access is facilitated through contracts maintained by the Brazilian government, enabling researchers to fully use the content provided by these databases.

This action allows you to expand searches by incorporating materials that are not open access and thus reduce limitations or possible biases in the study and make it more robust.

Two approaches will be used to search for information sources. One will be a systematised strategy, while the other will be for convenience, based on the researchers' knowledge of sources that can retrieve documents related to the investigated theme.

To define the databases most appropriate to apply the search strategy, a systematic search was conducted by the Journal Portal collection of the Coordination for the Improvement of Higher Education Personnel on 2 July 2024, specifically within the 'Lists of Databases and Collections' section. On accessing the webpage, a search was made by the area of knowledge, namely, 'Health Sciences', and then, in the subcategory, the filter 'Ophthalmology' was applied to refine the results. In this first stage, 25 databases were identified in electronic portals (online supplemental file 2, box 1).

For the second stage of the search for sources of information included for convenience, we identified databases that were not present in the subcategory of the previous stage, but which are large repositories of data in health sciences, potentially containing documents that meet the inclusion criteria of the study. The sources of information that will be selected for convenience and the search strategies that will be applied are found in online supplemental file 2, box 2.

Another determining aspect for the choice of the sources of information is that the databases included in this way were worked during the course of literature review studies in a graduate programme. This meets the criteria of a comprehensive search in the literature, by going beyond the systematic search, and also includes a technical criterion since researchers have greater knowledge about the best search strategies in these databases.

The search for the sources of indexed information included for convenience was performed by searching for 'titles' in the 'List of databases and collections' section of the Journal Portal collection of the Coordination for the Improvement of Higher Education Personnel.

The complete search strategy to select the databases that will be used in the scoping review will be defined after validation by two PhD researchers using the checklist for Peer Review of Electronic Search Strategies (PRESS).[19]

The selection of grey literature information sources will also occur for convenience and the databases that will be consulted are found in 'online supplemental file 2, box 3'.

Search strategy

Controlled descriptors from Medical Subject Headings (MeSH), Descriptors in Health Sciences (DeCS) or EMTREE thesaurus[20–22] will be used in the database searches, according to the specificity of each database.

The search strategy will be determined for the search in electronic web portals and built individually for indexed literature databases and grey literature databases.

The search will take place in three stages, to increase comprehensiveness in the literature search. Initially, based on the experience of researchers with the subject studied, the MEDLINE/PubMed databases (via the National Library of Medicine)[23] and Scopus[24] were selected because they are two relevant sources of information on the theme under study.

This stage was performed on 2 July 2024. A simple search was made with the MeSH descriptors[20] "Cornea", "Tissue and Organ Procurement" and "Eye Banks", using the Boolean operator "AND": "Cornea" AND "Tissue and Organ Procurement" AND "Eye Banks".

For the search in MEDLINE/PubMed (via National Library of Medicine),[23] the strategy used was the following: ((Cornea) AND ("Tissue and organ procurement")) AND (Eye Banks), resulting in a total of 141 documents.

In the Scopus database,[24] the simple search strategy (TITLE-ABS-KEY ("cornea") AND TITLE-ABS-KEY ("Tissue and Organ Procurement") AND TITLE-ABS-KEY ("Eye Banks")) was used, resulting in 135 documents.

After reading the titles, abstracts and keywords of documents from the two initial databases on 16 February 2024, the controlled MeSH descriptor[20] "Corneal Transplantation" was identified in texts that met the research inclusion criteria, thus being incorporated into the search strategy.

The other keywords and controlled descriptors identified in this first stage do not add to the strategy without deviating from the proposed theme. Therefore, the second stage was initiated with the use of the initially proposed controlled descriptors and the descriptor retrieved through the first stage, together with its respective alternative or synonymous terms.

The controlled descriptors MeSH, DeCS and EMTREE thesaurus[20–22] that will be used to construct the search strategies are found in online supplemental file 3.

To validate the search strategy in the databases, an adapted form of the PRESS[19] checklist will be applied. This adaptation is necessary because, although the PRESS recommendations suggest that the validation should be carried out by librarians or information scientists, the researchers involved in this study do not have access to these professionals. Therefore, the checklist will be applied by two PhD researchers with experience in developing search strategies for review studies, who will perform the validation in a non-anonymous manner and through a double-checking process.

The third and last stage of the search strategy will consist of analysing the references of all full texts of the final sample selected for the scoping review, to identify documents not initially retrieved. If necessary, the researchers undertake to contact the authors of the primary studies or reviews to request additional data that may contribute to a more complete analysis.

The search strategies will not have language or date restrictions. Table 1 presents the complete pilot search strategy recommended by the JBI Manual for Evidence Synthesis used in the MEDLINE/PubMed database (via the National Library of Medicine) with MeSH descriptors.[20 23] The remaining strategies for the information sources reported in online supplemental file 2 will be constructed after peer validation of the protocol.

Finally, the Global Alliance of Eye Bank Associations will be contacted through email to gather information on the institutional protocols for procurement, storage, processing and evaluation of tissues by the key EBs affiliated with each local association within the alliance. This contact is important because the information may not be readily available in published literature. It is worth noting that some organisations may be constrained by local ethical standards, potentially affecting the availability of this data.

Screening process

The selection of studies will take place in three stages: screening, eligibility and inclusion. In the screening stage, two methods will be used. In the indexed literature and grey literature portals that allow the export of studies

Table 1 Search strategy for MEDLINE/PubMed (via National Library of Medicine), Brazil, 2024

Search number	Query	Results
1	(Cornea) OR (Corneas)	96 408
2	((((((((((((((Corneal Transplantation) OR (Transplantation, Cornea)) OR (Keratoplasty)) OR (Keratoplasties)) OR (Cornea Transplantation)) OR (Cornea Transplantations)) OR (Transplantations, Cornea)) OR (Transplantation, Corneal)) OR (Corneal Transplantations)) OR (Transplantations, Corneal)) OR (Grafting, Corneal)) OR (Corneal Grafting)) OR (Graftings, Corneal)) OR (Keratoplasty, Lamellar)) OR (Keratoplasties, Lamellar)) OR (Lamellar Keratoplasties)) OR (Lamellar Keratoplasties))) OR (Penetrating Keratoplasty)	26 542
3	((((((((((((((((((((Tissue and Organ Procurement) OR (Organ Procurement))) OR (Organ Procurements)) OR (Organ Procurement Systems)) OR (Organ Procurement System)) OR (Tissue Shortage)) OR (Shortage, Tissue)) OR (Tissue Shortages)) OR (Organ Shortage)) OR (Required Organ Donation Request)) OR (Required Request)) OR (Required Requests)) OR (Tissue Donation)) OR (Tissue Donations)) OR (Tissue Procurement)) OR (Tissue Procurements)) OR (Organ Donation)) OR (Organ Donations)) OR (Donor Cards)) OR (Donor Card)) OR (Cornea Donation))) OR (Cornea Shortage))	312 858
4	(((Eye Banks) OR (Bank, Eye)) OR (Banks, Eye)) OR (Eye Bank)	4029
5	S1 AND S2 AND S3 AND S4	493

Research carried out on 27 May 2024 with the 'all fields' option.

in 'Research Information System', '.BibTex' or '.NBIB' formats, this option will be used directly by the platform.

For portals that do not allow direct export of documents, the search will be conducted in the databases described in the 'Source of information' section. The retrieved studies will be manually searched on Google Scholar. On identifying these documents, folders will be created in the 'My Library' section of Google Scholar, referencing the names of the databases, and the studies will be saved manually. After completing the searches, the studies included through this strategy will be exported in '.BibTex' format to a designated folder for use in subsequent phases.

For documents not found in Google Scholar, a reference will be manually generated in Mendeley[25] to continue the screening process.

After completion of the primary retrieval of studies, the duplicates will be removed using the Mendeley software, and then the files will be imported into the results management software Rayyan for the screening of titles and abstracts.[25 26]

The second stage of eligibility will take place by calibrating the evaluators using the Kappa index. To calculate the index, a random sample of 25 articles will be selected for reading of titles and abstracts by two researchers. After the reading, each researcher will individually record their decision in a Microsoft Excel file and the kappa index will be calculated using the R Software (V.4.0.5). A kappa coefficient between 0.81 and 1 will indicate near perfect agreement. If the index does not reach this level, a discussion between the evaluators will be held to reach a consensus and ensure that the researchers are calibrated to continue the analysis of the whole sample.

After removing the duplicates and calibrating the evaluators, all documents included in the sample will be analysed to start the inclusion phase. Researchers will blindly read titles and abstracts to avoid any anchoring bias, and each will decide whether the study will be included or not.

The concealment of the selected documents will be controlled by the Rayyan software,[26] and after the completion of the reading by both researchers, a third team member with greater experience will open the blinding. If there is disagreement about which texts should be included for the full reading, the third researcher with a PhD and specialised in the theme who is the supervisor of this study will decide after a group discussion.

To resolve the disagreements, a meeting will be held with the two researchers who read the titles and abstracts and the supervisor. For each text that presents divergence, discussion rounds will be held to explain the points of view of each evaluator in order to decide whether the text will be included in the sample for full reading or excluded for not meeting the inclusion criteria of the study. On completion of the meeting, the sample for full reading will be set to confirm its pertinence for review.

A new round of analysis with the reading of the selected texts in full length will be carried out to define which documents will be included for the data extraction stage, that is, to define which documents meet the inclusion criteria. In case of divergence, a new debate will be held with the third most experienced researcher to resolve the points of controversy and define the final sample to be used in the scoping review.

Data extraction

Data extraction will take place after the selection of the final sample. For this phase, the extraction of information will be conducted through a data collection instrument adapted from the JBI manual,[13] with the inclusion of some variables of interest for this review.

To perform data extraction, a pilot form will be created that will be randomly applied to 10% of the sample selected for data extraction by two researchers in order to identify possible adjustments and the inclusion of new items that may complement the result. If new divergences arise at this stage, they will be mediated by the supervisor to adapt the best instrument for extracting information.

After adjustments to the extraction form, data collection will be performed on a specific spreadsheet using Microsoft Excel software and will occur independently by a researcher. After data extraction is complete, another researcher of the team will double-check the information to ensure that important data is not lost due to human errors during this phase of the study.

Initially, for this study, the following data will be collected:

1. Title of the paper.
2. Year of publication.
3. Type of study.
4. Place (country or region).
5. Language.
6. Area of knowledge (nursing, medicine).
7. Population.
8. Indexes found.
9. Evaluative scores of corneal tissue.
10. Morphological evaluation of tissue.
11. Clinical features and physical screening.
12. Processing conditions of tissue.
13. Evaluation techniques used to classify corneal quality.

Data management

The Mendeley software will be used for the removal of duplicates.[25] The analysis of titles and abstracts will be conducted blindly by two researchers, and a third reviewer responsible for the blinding. The Rayyan software will be used in this stage.[26] The collected data will be recorded in a Microsoft Excel spreadsheet.

The kappa index will be used to assess the degree of agreement between evaluators during the screening process of the documents that may comprise the study sample. This calculation will be performed using R software (V.4.3.3) through the RStudio interface (2023.12.1).

Data synthesis

The results will initially be presented descriptively through tables and graphs of absolute and relative frequency. In

addition, the PRISMA-ScR flow chart[14] will be displayed to represent the entire process of search, inclusion, and exclusion of articles and documents.

ETHICS AND DISSEMINATION

As this is a scoping review protocol, the studies to be used are publicly available and have already been published. Therefore, it is not necessary to obtain preliminary ethical approval for the research. The research protocol was registered in the Open Science Framework with the registration osf.io/bw6r7/. The findings obtained in this scoping review will be submitted to peer-reviewed scientific journals. Additionally, the discoveries will be disseminated at ophthalmology and/or transplantation congresses, either through oral presentations or posters.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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