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A multidisciplinary approach to the Biobank concept: integrative review

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Abstract *Biobanks are multidisciplinary infrastructures and, accordingly, this integrative research seeks to bring out the concept of biobank in the various sciences that construct and interpret it, so as to arrive at a holistic understanding of its essential components. This integrative review – guided by PRISMA and with quality assessment following CASPe – resulted in a selection of 30 articles. Data were analysed by Aristotelian categories and the results were interpreted on the complexity paradigm of Edgar Morin. The biobank concept was clarified by considering it to be the representation of a biological, social and cultural phenomenon in which knowledge and practices from diverse scientific fields enter into complementary, antagonistic and ambiguous types of relationship. This network of signification, analysed here using categories from Aristotelian philosophy, has impacts on the construction of subjectivity and forms of socialisation.*

Key words *Multidisciplinary research, Genbank, Genetic databases, Bank, Biological sample*

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Introduction

Biobanks are infrastructure designed for the collection, recording and storage of human and non-human biological samples together with the related data[1-30]. Both biobanks and biorepositories are institutional installations for the systematic collection of biological material and data, the difference between them being that the former intends these for future research and the latter, for specific current studies[7].

Historically, the development of biobanks can be classified into the following stages: a) they emerged as public projects linking biological samples with related data[15,16,18]; b) sample collection, besides becoming massive and systematic, was conducted with a view to specific current research[22]; c) collection then targeted specific geographical areas, giving rise to population biobanks[15,19]; d) there followed massive, systematic collection with a view to future research[15]; e) then massive, systematic collection coupled with BigData[15]; e) massive samples and data which are stored and delivered for commercial research[20]; and f) lastly, collaboration between biobanks and between the public and private sectors[18,22].

Biobanks are decisively important to the life and health sciences, because they facilitate both basic and clinical research. Such studies include prominently: the Framingham Heart Study (1948)[15,16,18]; the AIDS Specimen Bank (1982)[22]; the Avon Study of Parents and Children (ALSPAC) and European Longitudinal Study of Pregnancy and Childhood (ELSPAC) (1990)[15,19]; the European Prospective Investigation into Cancer and Nutrition (1993)[15]; the Chernobyl Tissue Bank (1998)[22]; the National Cancer Human Biobank (2002)[22]; the UK Biobank (2005)[15]; the Danish National Biobank (2012)[22]; and the BBMRI-ERIC Expert Centre (2013)[18].

Biobanks bring together a multiplicity of agents, including researchers, universities, national and international companies, States and international organisations, while the sample and data collection, filing and storage activities involve practitioners of the life, health, exact and social sciences and the humanities. In view of these characteristics, a number of studies have considered biobanks to involve multi- and interdisciplinary endeavours, regarding either their object, activity or integration. However, there are no reviews that contribute to a multidisciplinary construction of the concept.

That given, an integrative review on the subject is both useful and necessary, because it offers wide-ranging information and permits in-depth understanding of the biobank concept on the basis of a multidisciplinary approach that analyses and synthesises both its most important characteristics and aspects and those that are open to debate, so as to highlight the network or fabric of scientific and human knowledge and practices that converge in the conceptualisation of the biobank and how these influence the construction of its constituent categories.

Methods and materials

Methods

This integrative literature review investigated the biobank concept on a multidisciplinary approach via Aristotelian categories. An integrative review allows the findings of diverse studies and types of source to be analysed and synthesised so as to provide a broad, holistic understanding of a health phenomenon or problem[31]. This is done by a rigorous, systematic, inclusive process of approximation for the purpose of reducing error and bias[32]. The analysis and synthesis identified not only the characteristics of the phenomenon or problem, but revealed the gaps in knowledge, as well as debatable points, thus helping to clarify the issue and support future research. Methodologically, it followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[33].

Search strategy

The data bases were searched using the descriptor *biobanco/biobank*, from 6 March to 5 May 2019, without Boolean Operators, so as to include the largest possible number of studies from diverse sciences and thus perform a multidisciplinary integrative review. The search included publications in English, Portuguese and Spanish in the following data bases: Medical Literature Analysis and Retrieval System Online (PubMed-MedLine), Latin American and Caribbean Literature in Health Sciences (LILACS), Network of Scientific Journals from Latin America and the Caribbean, Spain and Portugal (REDALyC), Education Resources Information Center (ERIC), PAHO-BIREME Virtual Health Library (VHL Regional Portal), WHO Institutional Repository for Information Sharing (IRIS), Science Direct, JSTOR, Scientific Electronic Library Online (SciELO), Digital Repository of the

Economic Commission for Latin America and the Caribbean (ECLAC Digital Repository), Dialnet, World Wide Science and Latindex.

Eligibility criteria

The inclusion criteria were: original articles, systematic, comprehensive literature reviews, editorials and book chapters, published between 2003 and 2019, in Spanish, English or Portuguese, originating in the health, life, exact or social sciences and humanities, using qualitative or mixed methodologies and with open access. It was decided to set the cut-off date at 2003, because that was when UNESCO adopted the International Declaration on Human Genetic Data, which regulated respect for human dignity in the collection, processing, use and storage of human genetic data, human proteomic data and biological samples, resulting in its implementation worldwide[1,2,6,7,14,15,27]. The exclusion criteria were: theses, monographs, dissertations and abstracts published prior to 2003.

Data extraction

The electronic search of the above data bases yielded 1794 publications meeting the inclusion criteria. Each document was then reviewed to ensure that it matched at least two Aristotelian categories, leaving 625. The studies were then reviewed again to assure that their content met the eligibility criteria, which left 62 documents. At this point, a critical reading was made of the documents (by GS, OC, HA and BR) with the aid of the CASPe guides, resulting in a total of 30 publications. That result was discussed and a consensus arrived at, so that the decisions involved no disagreement or stalemate (Figure 1).

Quality assessment

Four authors (GS, OC, HA and BR) performed the assessment by applying the guide to critical reading of qualitative studies of the quality assessment instrument produced by the Critical Appraisal Skills Programme, CASPe[34], then discussed the results and arrived at a consensus.

Sample size calculation

Given the nature of the study, sample size was not calculated, because the selection had to meet the eligibility criteria during the search period.

Data synthesis

For data extraction, two standardised forms were designed in MS Excel. The first contained the criteria year of publication, country of publication, type of publication, plus the questions answered with respect to biobanks. The second contained author, place of publication, type of research, objectives and findings (Chart 1).

Data analysis

The data were analysed and summarised by applying Aristotelian logical categories so as to ascertain the attributes and conceptual network of the object "biobank"[35]. Five categories were used: definitory, action/teleological, subjective, structural and legal. These categories were analysed and applied to biobanks, then later discussed until a consensus was reached on their properties:

1. Definitory or substance category (generic and specific): this numbers, identifies and describes the set of components that generally make up biobanks, as well as those features that differentiate them, resulting in types of biobank.

2. Action and teleological category: describes and classifies the events, acts and processes performed in a biobank and also determines its purpose.

3. Subjective or relational category: identifies the biological, social, economic, political and legal subjects that perform actions in biobanks. These range from concrete, individual subjects, such as donors, patients or authors through to collective subjects, such as States, pharmaceutical corporations, international organisations and others.

4. Structural or shape category: identifies the set of elements understood as a system that constitute a biobank and characterises their relations, endowing them with place, time and hierarchy.

5. Legal of quality category: identifies the social, ethical and legal norms that determine biobanks as regards their object, purpose, structure, action and so on.

Results

Selection of studies

The result was 30 texts: 18 original articles[1,6,8,12-16,18,20-24,27-30], 4 comprehensive and systematic review articles[4,17,25,26], 2 special articles

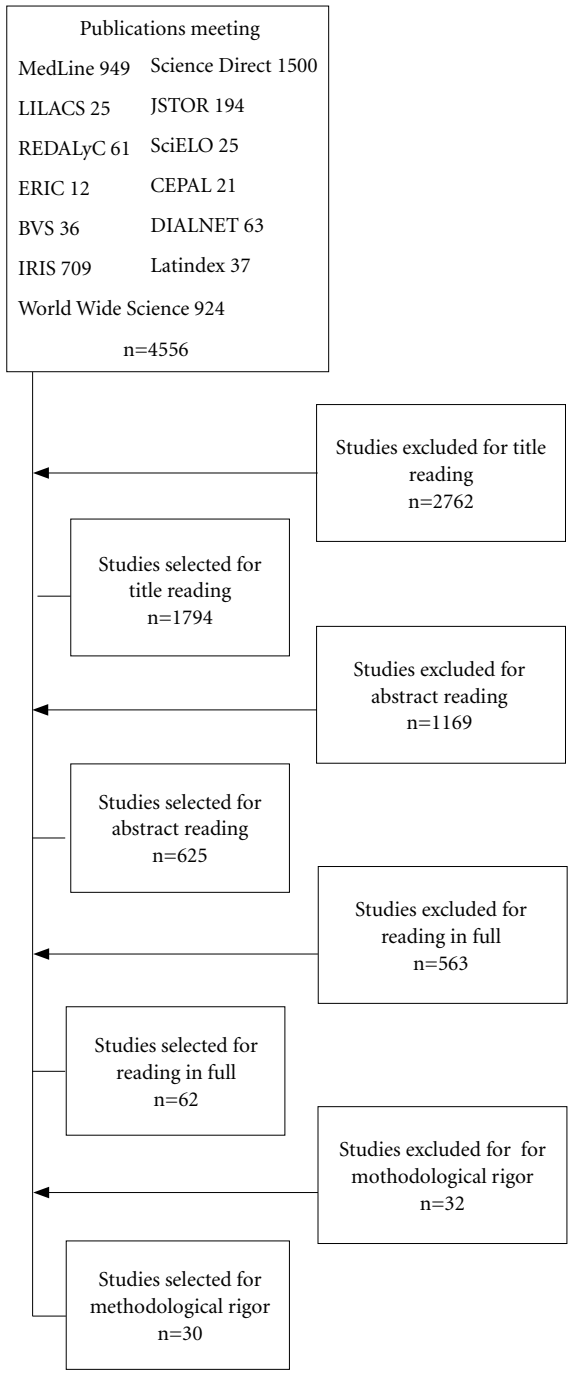

Figure 1. PRISMA selection process for the articles consulted.

Source: Elaborated by the authors.

Chart 1. PRISMA Summary of studies selected and examined.

Author	Country of publication	Year	Qualitative method	Objectives	Findings
Soto-Gómez[1]	Mexico	2014	Legal hermeneutics	To identify, analyse and compare the normative frameworks of biobanks in Mexico and the European Union.	Mexico and the EU share an international regulation, given by rules from the UN, WHO, PAHO, WMA and CIOMS, although individual countries have harmonised their domestic systems in different ways. After analysing the cases of France, England and Mexico, it concluded that there is a lack of legal regulation in Mexico.
Laurence[2]	Mexico	2018	Legal hermeneutics	Gives an overview of the Oviedo Convention and presents current issues.	This international instrument, designed to guarantee protection for human dignity and human rights within the scope of biomedicine, came into being in response to two needs: to protect people from improper use of science and to provide a common framework for protecting human rights.
Garza-Rodríguez et al.[3]	Mexico	2016	Document review	To determine the importance of biobanks in medical sciences.	Identified their importance in various facets of health, such as basic and clinical research, formation of research networks and care and teaching.
Lee[4]	Finland	2018	Document review	To identify the types of link between biobanks and artificial intelligence as regards personalised medicine.	The entry of AI into biobanks centres on methods of automatic learning and natural language processing techniques by extracting information from structured data, such as images, genetic data and unstructured data. In the biobanks' processes, it acts on bioresource collection and management (criteria for specifying and measuring the quality of biospecimens).
Benítez-Arvizu et al.[5]	Mexico	2014	Document review	To examine trunk cell biobanks from a global perspective, emphasising the case of Mexico.	Identified the types of trunk cell worldwide that can be stored, which facilitates their transport in biobank networks. In that connection, it emphasised the existence of international certifying authorities that standardise processes as regards their infrastructure and sample management, information and data management and legal, ethical and social concerns.
Bernal-Gómez and Bernal-Gómez[6]	Colombia	2017	Document review	Considers the consequences of biomedical research and biobanks from a Colombian perspective.	In economic terms, biobanks opened up a new world market determined by the industrialisation of, and trade in, new techniques. Nonetheless, their availability depends on each country's economic development, leading to industrial, IT and biotechnological dependence for the poorer countries.
Instituto de Salud Carlos III[7]	Spain	2007	Document review	To provide recommendations on biobanks to encourage responsible deliberation.	Drawing on the experience of biobanks in Spain and Italy, the working group proposed 19 recommendations addressing organisation, degree of specimen identification, management guarantees, consent, right to know and not to know, consent, specimen harvesting in the deceased, management of pre-existing biospecimen collections, title and commercialisation and payback benefiting the community.

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Author	Country of publication	Year	Qualitative method	Objectives	Findings
Chen and Pang[8]	WHO	2015	Document review	To identify the ethical, social and legal problems connected with biobanks' cross-border activities.	Identified practices, differentiated by countries' incomes, as regards the number of biobanks, experience and normative frameworks. Cross-border issues involving Latin America and Asia included inadequate participant protection, unfair distribution of risks and benefits, biopiracy, lack of direct benefits to individuals or communities, reported benefits to only the authors or research centres, i.e., financial benefits, personal recognition, commercialisation of products by patenting. These were found to lead to relations of exploitation and mistrust.
Marodin et al.[9]	PAHO	2012	Document review	To set out and problematise Brazil's legal frameworks for biobanks and biorepositories, and to examine their ethical and operational consequences.	The difference between a biobank and a biorepository is that the former is an institutional installation for the systematic collection of biological material with a view to various future studies, while a biorepository is designed for the collection of biological material for some specific current investigation. That difference entails, in turn, different ethical and operational treatments.
Luna-González et al.[10]	Spain	2016	Document review	To identify the data harmonisation and standardisation challenges facing biobanks.	There were two main challenges: linkage among networks of biobanks, because the harmonisation and standardisation reported was at only the regional or State level (BBMRIERIC in Europe, BBRB and CAP in the USA and Canada and CCB in England), and improving interoperability of biodata in order to develop robust, flexible and secure bioinformatics platforms and to foster socialisation of the related knowledge.
Mendy et al.[11]	WHO-IARC	2017	Document review	To establish a series of guidelines and recommendations for biobanks from a study of validated, evidence-based guidelines.	Guidelines and recommendations for biobanks are designed to increase their interoperability and foster open access to samples and data. The guidelines cover: a) ethical, legal and social issues and governance structures, b) informed consent, c) data privacy and protection, d) feedback of findings, e) sharing of data and samples, f) creation of biobanks, g) informatics system, h) disaster recovery plan and i) record management system.
Martínez et al.[12]	Colombia	2012	Document review	To examine the most important aspects of the development of biobanks in Colombia.	After examining the composition of biobanks, sample storage procedures and regulations on sample conservation, there was found to be a need to introduce an international regulatory framework in order to homogenise practices and boost development.
Capron et al.[13]	USA	2009	Interviewed 42 experts in an international cohort.	To conduct an international study of ethical standards and international governance of genetic data bases.	The findings were: a) views on ownership of genetic samples and data were divergent and confused as to the interests and objectives of "ownership"; b) multilateral trade agreements were generally regarded as an effective vehicle for ensuring responsible management of samples and data; and c) the experts' views differed on how to assure respect for groups' interests.

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Author	Country of publication	Year	Qualitative method	Objectives	Findings
Brena-Sesma[14]	Mexico	2010	Document review	To set out the overall ethical and legal panorama of biobanks of human biological material destined for research.	Legislation is sparse in some Latin American countries, contains legal gaps and needs to be harmonised with international instruments. The study suggested strengthening the functions of research ethics committees, because when they fulfil their duties they prevent data bases' being formed on commercial criteria and establish measures for redistributing individual and collective benefits.
Marodin et al.[15]	Brazil	2013	Document review by interdisciplinary group.	To describe the relationship between democracy and biobanks in Brazil.	Concluded that the dynamics of science modifies social paradigms and, as a consequence, social group morals shape ethical precepts and regulatory frameworks. It highlights Brazil's role in Latin America as regards normative regulation of biobanks.
Gottweis and Lauss[16]	Germany	2012	Document review	To compare biobank governance structures and present a participatory governance structure.	Biobank governance is a mosaic strategy for organising a network of field interactions (scientific-technological, medical-health, industrial-economic, legal-ethical and socio-political). The funding models were: entrepreneurial, biosocial and public. The study suggested a network of participants that is open and not designed top-down, so as to assure participation by all of society, which does not entail democratising the process, but rather developing plural, inclusive political structures.
Paskal et al.[17]	Netherlands	2018	Comprehensive review	To describe and classify biobanks, standard operating systems, informatics systems and ethical and legal dilemmas.	Described and proposed a classification of: biobanks; standard operating systems (SOPs); and informatics systems. Divided the ethical and legal dilemmas into relating to ownership, limitations in informed consent, sample storage, protection of privacy and anonymity, accessibility and the function of the knowledge produced.
Serrano-Díaz et al.[18]	Colombia	2016	Document review	To conduct a critical review of biobanks and of the protocols and rules of the Cardiecol Programme.	Offered two classifications of biobanks, by purpose and scope. The critical analysis of international protocols and standards highlighted how biobanks influence both translational research and the application of scientific and technological advances in innovation.
Milanovic et al.[19]	Great Britain	2018	Document review	To explore how biobanks of human biological material reconfigure human life and socialisation.	Biobanks are spaces where the links between life and technical processes are restructured, because they introduce a new signification of living beings guided by utilitarian and aesthetic criteria, erasing the ontological distinction between living being and artefact. This has led to the emergence of bio-artefacts defined by the triangulation among three types of process: life, technical and social. Social processes have made it possible to set up power institutions and new relations of bio-socialisation and bio-capital.

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Author	Country of publication	Year	Qualitative method	Objectives	Findings
Ommen et al.[20]	Great Britain	2015	Document review	To describe the fundaments of Expert Centres and illustrate the new operating model with examples.	Expert Centres are grounded in public-private (replacing academic-industrial) participation and in the international standardisation of biological sample analysis. The rationale for their creation rests is twofold: access to and availability of data and availability of samples to industry. Both reasons derive from biobanks' economic success in the biotechnology industry, the market for pharmaceuticals and biomarkers, and in the diagnostics industry market.
Godard et al.[21]	Great Britain	2003	Interviews of 50 experts from 12 countries and consensus-building workshop	To examine the social, ethical and legal problems of biobanks of human DNA for biomedical research.	It is a consensus that consent is required for later use of identifiable samples. Nonetheless, there is disagreement as to what consent is required when samples are anonymised for retrospective or prospective studies, because of the ambiguities in: type of sample and control of, and authorisation for, access to and sharing of samples. They stressed that, in biomedical research today, samples and data are not freely transferred. To solve that, they identified a need for an organisation to take the lead internationally.
Bryzgalina et al.[22]	Great Britain	2017	Document review	To examine and think about the consequences and problems posed by biobanks as politico-scientific institutions.	In relation to the biobank industry, it is possible to speak of the development of new kinds of strategy designed to "invade" the individuality of the human body to generate more efficient performance. In that regard, biobanks are biomedical-social-political technologies, political institutions with divergent (scientific, economic, ethical, legal, social, anthropological and other) components. The risks associated with biobanks are: eugenic ("healthy and happy body") projects and a naturalisation of social inequality.
Villarroel[23]	Chile	2013	Document review	To examine the ethical difficulties of biobanks in view of Michel Foucault's "biopolitics".	Studied from the philosophical perspective of Michel Foucault, biobanks reveal the linkages among science, power and capital, where scientific knowledge is also an economic value that deploys a logic of power through an instrumental rationality. From this perspective, biobanks serve as instrumental technical tools that extract information from human beings on their biological, social and symbolic existence. The study proposed drafting broad legislation as a solution.
De Souza and Greenspan[24]	Great Britain	2013	Systematic review	To discuss and characterise the history of biobanks.	Considering the taxonomy of biobanks, the study identified their complexity and the following evolution: a) an early stage dating over 100 years during which samples were conserved for specific studies; b) a second stage moving to larger scale involving technological advances; c) a third stage characterised by biorepositories; and d) a fourth stage involving the emergence of virtual biobanks.

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Chart 1. PRISMA Summary of studies selected and examined.

Author	Country of publication	Year	Qualitative method	Objectives	Findings
Domaradzki and Pawlikowski[25]	Switzerland	2019	Systematic review	To provide an overview of existing research into social attitudes to biobanks.	Identified a generalised lack of information about biobanks, although there was also a willingness to donate, determined especially by knowledge about biobanks, the type of tissue donated, the purpose of the research, data security concerns, the preferred type of consent and trust in biobanks.
Kinkorová and Topolčan[26]	Switzerland	2018	Systematic review	To identify the social challenges and projects connected with biobanks in Horizon 2020.	Identified the main challenges in 2020: health, demographic change, wellbeing, food security, sustainable agriculture, marine and maritime research, bioeconomy, climate action and efficiency in resources and raw materials. To tackle these challenges as regards biobanks, they recommended: a multidisciplinary approach, international collaboration and education and research programmes.
Nemogá-Soto[27]	Colombia	2012	Document review	To examine protection for individual and collective rights in Colombia with the establishment of human genetic biobanks.	No appropriate framework has been put in place to regulate constitutional guarantees for individual and collective human rights. This makes authors more likely to participate irregularly in international projects as simple providers of biological samples and related data. For research in indigenous communities or groups, in addition to free and informed consent, there should be prior consultations based on the culture and cultural context.
Domaradzki[28]	Poland	2019	Document review	To set out and examine the concept of geneticisation and related social problems.	Geneticisation is an excessive generalisation of genetics-related ways of thinking, which can be subdivided into: genetic reductionism, genetic determinism, genetic essentialism and genetic fatalism. The related social problems are: creation of a single genotype, geneticisation of diagnosis, risk of genetic discrimination, commercialisation of genetics and genetic patenting.
Hamilton[29]	Great Britain	2008	Document review	To examine biopiracy and its relation to intellectual property rights and the bioeconomy.	The components of biopiracy are: cultural knowledge, intellectual property rights and genetic resources. Biopiracy entails a semantic and conceptual combination that resignifies the relation between Nature (genetic resource) and Culture (traditional knowledge). Two trends are identified: when the interpretation leans towards Nature, the debate is between discovery and invention, while when it inclines towards Culture, the debate is about ownership.
Brochhausen et al.[30]	Great Britain	2019	Founding open biological and biomedical ontologies.	To develop an ontology of biobanks that extends data integration so as to permit data analysis and sample sharing.	Fostering semantic data integration for the greatest possible number of users and consumers is connected with the possible merging of two or more ontologies. The study showed that it is possible to merge two ontologies - OMIABIS and BO – because both are based on the principles of the Open Biological and Biomedical Ontologies (OBO) Foundry, they share a common design methodology and they extend the same Upper Ontology and Reference Ontology.

Source: Elaborated by the authors.

or collaborations[3,7], 2 editorials[5,19], 1 technical note[10], 1 standards protocol[11], 1 current issues article[9] and 1 book chapter[2].

General characteristics of the studies

The study summarised information published in 12 countries and by 3 international organisations, as follows: 7 studies from Great Britain[19-22,24,29,30], 5 from Mexico[1-3,5,14], 4 from Colombia[6,12,18,27], 2 from Switzerland[25,26], 2 from Spain[7,10], 1 from Brazil[15], 1 from Germany[16], 1 from Chile[23], 1 from Finland[4], 1 from Netherlands[17], 1 from Polonia[28], 1 from USA[13], 1 from WHO[8], 1 from PAHO[9] and 1 from WHO-IARC[11]. By year of publication, there were: 3 from 2019[25,28,30], 5 from 2018[2,4,17,19,26], 3 from 2017[6,11,22], 3 from 2016[3,10,18], 2 from 2015[8,20], 2 from 2014[1,5], 3 from 2013[15,23,24], 4 from 2012[9,12,16,27], 1 from 2010[14], 1 from 2009[13], 1 from 2008[29], 1 from 2007[7] and 1 from 2003[21].

Study quality was evaluated using the quality assessment instruments of the Critical Appraisal Skills Programme (CASPe)[34], which assesses three aspects – rigour, credibility and relevance – by way of "Yes", "No" or "Can't tell" responses to 10 questions. The first three questions evaluate the objectives, methodology and the relation between the two and, in the 30 studies selected, the answers were "Yes". Accordingly, the studies were evaluated by the other 7 questions, which address: participant selection strategies, data collection techniques, reflexiveness, ethical concerns, rigorous data analysis, whether the findings are set out clearly and how applicable they are.

As the objective of this review was a multidisciplinary approach to the biobank concept based on a synthesis of a general approximation from various sciences and sources, studies that elicited a "No" to some of the questions were not excluded[36], in the following cases: a) those that did not address the participant selection question, because most were document-based or theoretical qualitative studies, except for two that used interviews[13,21]; b) those that did not explicitly state their method, although it was implicit in the study process, especially in studies originating in the social sciences and humaniti es[1,2,6,10,14,16,19,20,22,23,27,28]; c) those that were proposals to regulate standards, guidelines or protocols which also did not state their method explicitly, but used the legislative technique[7,11]; and d) those that were expert opinions or contributions, such as special articles, editorials or current affairs studies[3,5,7,9,19].

Qualitative summary of the findings

The data summary using Aristotelian categories and their properties yielded the following information (Figure 2):

1. Definitory category: 96.57% of the articles defined the biobank concept[1-26,28-30] and 76.59% stated that it was global in nature, by virtue of both the activities pursued there and the participants involved[1-9,11-14,16-18,20-22,24,26,28,30]. As regards types of biobanks, 23.31% considered that they were expert centres that store biological samples[7,11,17,20,21,24,26], but only 13.32% mentioned that they were bioinformatics or biostatistics centres that store data[11,20,21,24].

Seven criteria were found for classifying biobanks: by sample or data destination; by sample type; by funding model; by level of organisation; by administration type; by governance type; and by support type. The aspects, characteristics and purposes considered varied by the science or author examining the concept.

2. Action category: the activity of biobanks was divided into a biological procedure connected mainly with the biological samples (96.57%)[1-22,24-30] and a data-related bioinformatics procedure (96.57%)[1-22,24-30].

3. Subjective category: the main subjects engaged in biobanks were found to be States (100%)[1-30]; universities (96.57%)[1-22,24-30]; businesses or the private sector (83.25%)[2,4,6,8,10-30]; and lastly the civil population (49.95%)[6,8,11,14,16,17,19-22,25,27-30]. In 96.57% of the data reviewed, biobanks displayed mixed integration characterised by cooperation among these subjects[1-22,24-30]. Also, the expert centre model involving the public and private sectors presupposes collaborative operation[7,11,17,20,21,24,26].

Three problematical practices were found to cause debate: difficulty in applying the payback principle[20,21]; biopiracy in emerging or developing countries[8,10,12-14,16,19,21,22,25-28,29]; and the clash between the individualist view of western knowledge and the communal or community view held by the peoples of emerging States where human and non-human biological samples tend to be collected[6,12,13,16,19,28,29].

4. Structural category: 6 elements were found to be necessary to the structure of a biobank: a governance committee (26.64%)[6,7,11,13,15,17,21,27]; an ethical-legal committee (86.58%)[1-3,5-7,10-24,26-30]; a biosafety committee (66.6%)[3,6,7,9,11,13-22,26-30]; a sample access committee (69.93%)[3,6,7,9-11,13-22,26-30]; a scientific committee (29.97%)[6,7,9,11,15,16,20,21,26]; and a public participation committee

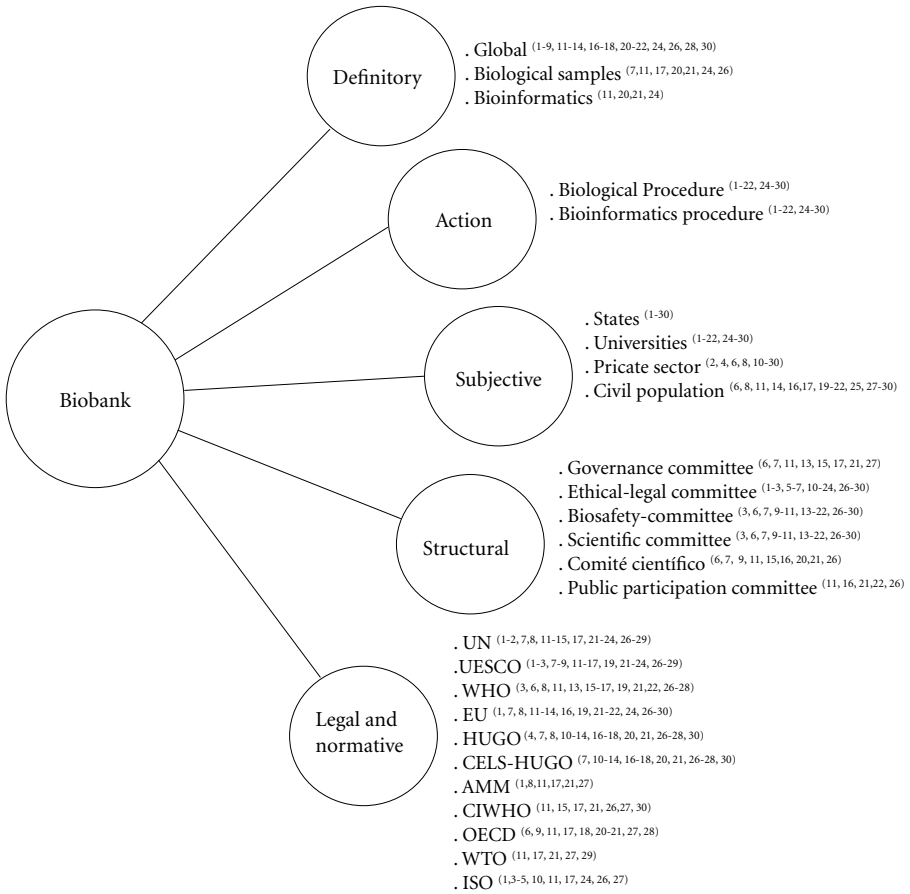

Figure 2. Categories and properties of the biobank concept.

Source: Elaborated by the authors.

(16.65%)[11,16,21,22,26]. The latter committee is recent and is set up for the purpose of responding to the need both for bioethics and for more democratic biomedical research.

5. Legal and normative category: the main instruments applied are those originating in the UN (59.94%)[1,2,7,8,11-15,17,21-24,26-29]; UNESCO (73.26%)[1-3,7-9,11-17,19,21-24,26-29]; the WHO (46.62%)[3,6,8,11,13,15-17,19,21,22,26-28]; the EU (63.27%)[1,7,8,11-14,16,19,21,22,24,26-30]; HUGO (56.61%)[4,7,8,10-14,16-18,20,21,26-28,30]; CELS-HUGO (49.95%)[7,10-14,16-18,20,21,26-28,30]; the AMM (19.98%)[1,8,11,17,21,27];CIWHO(23.31%)[11,15,17,21,26,27,30]; the OECD (29.97%)[6,9,11,17,18,20,21,27,28]; the WTO (16.65%)[11,17,21,27,29]; and the ISO (33.3%)[1,3-5,10,11,17,24,26-27].

None of the normative instructions were applied 100%, mainly because of States' normative sovereignty in entering into international treaties, i.e., they are free to accede to rights and obligations with other States or regional and international organisations. This in turn leads to normative conflicts which authors propose to solve by setting up an international authority and introducing global governance[1-5,8,10-30].

From the analysis and summary of the categories and properties that constitute a biobank, it can be deduced that it is a complex weave of heterogeneous but inseparably associated elements, i.e., it is a concept that represents a complex phenomenon[37]. In this respect, from the standpoint of the complexity paradigm (distinction-conjunction), it is a bio-socio-cultural phenomenon, characterised by simultaneous relationships of three types: complementary, antagonistic and

ambiguous[38]. These relations stem from the practices and knowledge of the scientific fields that shape biobanks, in the following manner:

- Complementary relations: the fields mentioned in the studies that add or contribute knowledge or practices to biobanks were Medicine, Biology, Chemistry, Informatics, Law, Political Sciences, Economics, Sociology, History and Philosophy[1-30].

- Antagonistic relations: prominent issues raised involving contradictions or oppositions between the knowledge and practices of specific fields included informed consent for indigenous communities or peoples, commercialisation of samples and data, private sector participation, the principle of benefit payback, unfair distribution of risks and benefits, public participation and democratisation, and stigmatisation and discrimination. Regarding Latin America, Asia and Africa, the issues were traditional cultural knowledge and expertise, exploitation and technological dependence[1-6,10,11-30].

- Ambiguous relations: uncertainty and confusion are caused by the plurality of meanings attributed to the knowledge or practices of scientific fields. In the case of biobanks, this involved three main issues: global governance, applicable legal instruments and international certifying authority[1-5,8,10-30].

This tangle of significations has had an impact on how Humanity and the human world are conceived. New problems were pointed up by Philosophy, including the Ontology of Being through subjectivity (genetic reductionism, determinism, essentialism and fatalism) and Ontology of the World (bioartefacts); by Ethics, questioning the criteria (utility, justice, law and so on) for setting guidelines and determining what is good; and lastly, by Political Philosophy, debating State sovereignty and cosmopolitanism and pointing to global governance, as well as the problems arising from multi- and pluri-culturality.

Discussion

Summary of the evidence

Definitory category

From the analysis and systematisation of the preceding information, it was possible to identify recurrent elements, from which the following definition was proposed[1-26,28-30]: a biobank is the physical space that houses human samples (DNA, RNA, cells, fluids, tissues and organs) and non-human (plant and animal) samples, necessarily linked to a virtual space where its data base is hosted associating the biological information sample (biological data) with donor information (patient data), such as clinical history, geographical location, ethnicity, lifestyle, labour history, personality and environment.

The various sciences characterised biobanks as, among other things, rational, systematic, not-for-profit and guided by solidarity (regarding the community payback principle). As regards their objects and purposes:

- Health sciences emphasised research and experimentation, personalised medicine, pharmacogenetics and others[3,5-7,12,13,15,17-21,25,26,30].

- The exact sciences stressed their virtual space, data bases and technology[4,7,10,12,14,15,26,30].

- The social sciences highlighted the applicable legal norms; human rights and intellectual property rights; regional and global political agendas; control, authority and global governance; social problems, such as stigmatisation or discrimination by ethnic origin; economic problems, such as conflicts of interest; sociological and anthropological problems, such as the new forms of socialisation processes with regard to bio-objects; and others[1,2,6,7,10,13-15,19,21,23,27-29].

- The humanities pointed to concerns with bioethics, philosophy of science and technology, ontology, political philosophy, artificial intelligence, biological and technological determinism and others[1-30].

Also striking was that the meaning of the scientific definitions (discourses and practices) and the uses of technology varied by socioeconomic group. For example, the private sector directed definitions towards pathology, pharmacogenomics, genomic aesthetics, transgenic research in plants and animals[20,26,28,29], while the public sector was oriented towards achieving the public good and public health[7,9,25] and the social sector moved by collective interests[22,28] looked to pathologies associated with specific social groups or connected with social struggles[16].

From the analysis and systematisation of the documents, the following typology of biobanks was established[1-30]:

• By end purpose of the data and information: Teaching, experimentation and research; Personalised or genomic medicine (prevention, diagnosis and treatment of diseases); Epidemiological purposes; Criminal and forensic research; Population biobanks.

• By sample type: Human, animal and/or plant samples; Trunk, tumour, dental and other

Ciência & Saúde Coletiva, 26(9):4321-4339, 2021

cells; Cells, fluids, tissues and organs; DNA, RNA, proteins; Seeds (Svalbard Global Seed Vault) for conservation and biodiversity.

• By model of funding: Mixed model with public, social and/or private participation; Social model; Public model.

• By level of organisation: National biobanks or networks; Regional networks of biobanks; World networks of biobanks; Networks of networks of biobanks; Expert centres (Large-scale; Large biobanks or consortia of small biobanks; Public and private biobanks; Bioinformatics and/or statistics centres).

• By power arrangement type: Centralised; Decentralised.

• By type of governance: Global; Corporate; Project; Market; Network; Multilevel; Transversal; Intercultural.

• By type of support: Physical; Virtual.

Action category

The analysis and systematisation identified two major types of process[1-22,24-30], the first relating to the biological samples, here termed the *Biological Process*, and second, relating to the data extracted from the samples and the systematisation of information, termed the *Bioinformatics Process*.

The purposes of the *Biological Process* were to preserve, identify, classify and safeguard the sample and, when appropriate, transfer it in part or whole. In this connection, an international endeavour is underway to homogenise both techniques and procedures. The stages into which the process was divided depend on the type and characteristics of the biological material, but generally speaking they can be considered to be the following[1-22,24-30]:

1) Acceptance of the proposal of informed consent by the ethics, expert and biosafety committees;

2) Explanation of the intervention, its purpose, duration, risks, cost (where appropriate) and other characteristics depending on the object of the research or treatment;

3) Signing of the informed consent;

4) Application of selection and biosafety protocols;

5) Procurement and reception of the biological sample;

6) Identification and characterisation of the biological sample;

7) Chemical, physical or biological processing to conserve the biological sample;

8) Storage of the biological sample;

9) Management;

10) Analysis or investigation of the biological sample;

11) Report resulting from the analysis or experiment;

12) Assignment or transfer of the biological sample in part or whole; and

13) Conservation or destruction of the biological sample.

The purposes of the *Bioinformatics Process* were to acquire, record, organise, analyse, interpret, store and distribute the biological data or information extracted directly from the samples, patients or donors and/or authors, which entailed producing data bases, algorithms, statistical tools and software to permit experimentation *in silico* (simulators, such as digital sequencing). For these purposes, biobanks had four 4 protocols, covering data base, data base security, catalogue formation and data access and sharing. The stages common to all biobanks were[1-22,24-30]:

1) Recording informed consent;

2) Ethics committee and expert committee approval of informed consent;

3) Uncoupling of data from the biological sample, as required by the analysis or research;

4) Data classification: By data type (text, images, videos); By data origin (from the sample, patient or donor, from experimentation with samples, from data analysis etc.); By descriptors (of the biobank, sample, analysis or experimentation, standardised operating procedures);

5) Data coding;

6) Data protection (accessibility);

7) Determination of: Conflicts of interest (Conflicts of Interest, COI); Transferrable material (Material Transfer Agreement, MTA); Transferrable data (Data Transfer Agreement, ADT);

8) Sending of the data or data base

9) Reception of other data from authors' analyses and findings or reports produced by the donors or patients themselves.

Subjective category

Diverse agents intervene in the creation, administration and regulation of biobanks, but it was a consensus that States[1-30] and universities[1-22,24-30] intervene.

• Mexico: at Universidad de Nuevo León, Universidad Autónoma de Guerrero, Universidad de Guadalajara, Instituto Nacional de Salud, Instituto Nacional de Cancerología de México, Instituto Nacional de Medicina Genómica, and recently the Red Ciencia Forense Ciudadana.

• Brazil: at the Instituto Nacional de Infectologia Evandro Chagas (INI), Fundação Oswaldo

Cruz (FIOCRUZ), Sociedade Beneficente Israelita Brasileira, biological materials bank of the Hospital Camargo, Serviço de Biobanco de Patologia at the Universidad Federal de Uberlândia, Banco Nacional de Tumores e DNA (BNT-INCA), tumor bank of the Hospital de Câncer de Barretos, tumor bank of the Instituto do Ceará and others.

• Argentina: PoblAr, Laboratorio Eco-epidemiología (FCEyN, UBA), Instituto de Oncología "Angel H. Roffo", Hospital Italiano de Buenos Aires, Museo de Arqueología de Alta Montaña de Salta, Hospital de Pediatría "J.P. Garrahan", Hospital de Oncología "María Curie", Instituto de Investigaciones en Ingeniería Genética y Biología Molecular (INGEBI), Centro de Educación Médica e Investigaciones Clínicas "Norberto Quirno", FLENI and the Hospital Interzonal General Agudos Eva Perón en Argentina.

There are national biobank networks, as in Spain, and regional networks involving groups of States, as in the LatinBanks (Germany, Argentina, Brazil, Chile, Colombia, Costa Rica, Spain, France, Mexico and Portugal)[6], the Red de Biobancos de América Latina y el Caribe (REBLAC)[10] and the BBMRI-ERIC in the EU, which brings together 19 countries and an international agency, WHO-IARC, and has established sharing of knowledge and experience[11,17] on ethical, legal and social issues (ELSI), information technologies (IT) and quality management (QM).

In the private sector, there are national, international and even transnational agents that intervene in biobanks. Prominent among these are pharmaceutical corporations, such as Hoffman, Roche Laboratories, Pfizer, Johnson & Johnson, GlaxoSmithKline, Siemens Healthcare and others; genomic medical care firms such as Decode, Navigenics, 23andMe, Illumina and others; banks and insurers in the United Kingdom, Taiwan, Korea and China; software firms, such as BC Platforms, NorayBio, Alatel, Dataworks, Thermo Fisher, LabWare, Krishagni Product, oBiBa and CBSR; and practitioners' associations, such as the World Medical Association (WMA), Council for International Organisations of Medical Sciences (CIOMS) and the Human Genome Organisation (HUGO) International[10,11,17,19,20,21].

Recently, the EU has promoted the BBMRI-ERIC Expert Centre and Trusted Partner as a new public-private model for analysing samples and generating data in countries of origin under internationally standardised conditions. In 2019 there were two recognised centres: a) in Austria, the CBmed gained recognition as an expert centre linking the public sector with private pharmaceutical corporations and diagnostic and IT centres; and b) the ATMA-EC Platform in Italy, which links the public and private sectors, has centred on developing a platform to verify and validate biomarkers and is improving and expediting communication between academic and pharmaceuticals sectors[20]. Lastly, in Spain, the Centro Nacional de Análisis Genómico - Instituto de Análisis Genómico (CNAG-CRG) is in the process of being recognised as an expert centre for its outstanding quality management (ISO 9001: 2015 certification, ISO 17025: 2017 accreditation, Illumina and Agilent Exome Sequencing service provider certificates and membership of the Roche Sequencing Solutions Technical Certification Programme)[20].

Lastly, the subject essential to the biobank process is the human participant from whose body a biological sample is taken and who is legally entitled to a series of rights guaranteed by the declaration of informed consent[1-30]. For proper protection, the competent authority of the biobank has to evaluate whether the type of informed consent is appropriate to the research. The main types of informed consent include consent waiver, consent opt out, consent opt in (subtypes: specific consent and specific and broad consent), broad consent, re-consent and dynamic consent[7].

Standing in opposition to this individualistic view of Humanity is the historical and community perspective, from which there emerges a collective subject formed from an accumulation of individuals who share culture and are thus bound together by identity, values, traditions and history. In this case, the human rights of peoples and communities have been protected by the declaration of collective or community informed consent[6,12,13,16,19,28,29]. Note that, in spite of various cases (India, Brazil, Kenya, Bolivia, Japan, Malaysia, China and others), the form and content of collective consent has not been standardised, except that it should feature three components: a) the collectivity should understand the research; b) the authority representing the group should give authorisation; and c) the process should comprise three stages: prior consent, assent and permission[11,13,21].

The issues raised in the subjective category were, firstly, emerging or developing countries' technological dependence on developed countries: the countries with most biobanks and samples are located geographically in the EU[6,8]. Secondly, the benefit payback principle is not ap-

plied in emerging or developing countries where human and non-human biological samples are collected: most of the resources produced return to Europe[8,20,21]. Some of the causes identified in countries of Asia, Africa and Latin America[8] were: economic poverty, digital poverty and lack of legal regulation of medical research and/or patents. Thirdly, biopiracy has been reported in these countries[8,10,12-14,16,19,21,22,25-28,29]. There are two senses of biopiracy: the first connected with obtaining a biological sample without permission, as with genetic samples in China given to foreign academics and pharmaceutical corporations, and the second relating to illegal access, appropriation, use or exploitation of biological resources and/or their derivatives, such as indigenous peoples' or communities' knowledge by way of forms of intellectual property, such as patents, a situation that has often occurred in Latin America, as well as in Egypt and India[8,13,11,19].

Structural category

A biobank's structure refers to its constituent elements or components and their relations and disposition, i.e., its organic structure, which should not be confused with the form of organisation, which tends towards global governance (be it processual-normative, corporative-managerial, market-competition or network) nor with the form of funding, which tends to mixed participation.

Biobanks can comprise a diversity of elements or components, but the data analysis warranted proposing the following committees as essential[1-30]:

• Governance or executive committee – responsible for setting up the biobank and directing it and for establishing the philosophy, objectives and action and verification plans[6,7,11,13,15,17,21,27].

• Ethics and legal committee – responsible for issuing opinions and advice to all the internal committees so as to guide their activities. Its composition is multidisciplinary and its concerns are ethical, legal and political[1-3,5-7,10-24,26-30].

• Laboratory safety and/or biosafety committee – responsible for regulating, overseeing and guaranteeing safety in the biobank space by controlling risks[3,6,7,9,11,13-22,26-30].

• Sample and data access committee – responsible for classifying, storing, protecting and safeguarding data, information and data bases. It also must receive, and decide on the admissibility or otherwise of, requests for biological material, data or information[3,6,7,9-11,13-22,26-30].

• Scientific and/or expert committee – responsible for advising the biobank's internal constituents in the scientific field, with a view to developing biological sample collection strategies or research plans[6,7,9,11,15,16,20.21,26].

Note that, in the EU[11,16,21,22,26], it is recommended that a public participation committee be constituted to learn public opinion with regard to the biobank's activities, specifically its objectives or research projects. That committee also engages in scientific publication and national and/or international public policy activities, as well as advisory activities. Examples are the participation committee of adolescents (UK Biobank Ethics and Governance Council, 2009) of the Avon Longitudinal Study of Parents and Children (ALSPAC) and also the subcommittee of the NIH Precision Medicine Initiative Cohort Program (2015)[11].

Legal category

From the analysis and systematisation of the information, three types of legal norms applicable to biobanks emerged. By their content, they regulate: a) human rights; b) practices and processes by standardisation; and c) private property and trade.

Human rights: the main normative instructions and guidelines that protect life, human dignity and health, internationally and regionally, were described in Chart 2.

Standardisation of biological and bioinformatics processes: the main norms for standardising and/or certifying biobank processes originate from the Human Genome Organisation (HUGO)[4,7,8,10-14,16-18,20,21,26-28,30], the *HUGO Committee on Ethics, Law and Society (CELS)*[7,10-14,16-18,20,21,26-28,30], the World Medical Association (WMA)[1,8,11,17,21,27] and the Council for International Organisations of Medical Sciences (CIOMS)[11,15,17,21,26,27,30].

Private property and trade: in biobanks, assignment of property rights is rendered complex not just by the existence of two levels of legal regulation (State and international), but by the plurality of elements that converge in biological and bioinformatics processes, because on the one hand are the donors' property rights to their biological material and the related data and, on the other hand, are the intellectual and industrial property rights in favour of authors and, where appropriate, the public or private institutions that finance the research, such as universities and pharmaceutical corporations.

The organisations that play a role in regulating authors' biobanks are: a) the World Intellectual Property Organisation (WIPO)[29]; b)

Chart 2. International legislation applicable to biobanks.

UN [1,2,7,8,11-15,17,21-24, 26-29]	**UNESCO** [1-3,7-9,11,15,17, 21-24,26-29]	**WHO** [3, 6, 8, 11, 13, 15-17, 19, 21, 22, 26-28]	**EU** [1, 7, 8, 11-14, 16-19, 21, 22, 24, 26-30]
Universal Declaration of Human Rights (1948)	Universal Declaration on the Human Genome and Human Rights (1997)	Standards and operational guidance for ethics review of health-related research with human participants (2011)	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine – the Oviedo Convention (1997); and its 4 protocols: 1 Human cloning 2 Transplantation of organs and tissues 3 Biomedical research 4 Genetic testing for health purposes
Convention on Biological Diversity (1992)	Declaration on the Responsibilities of the Present Generations Towards Future Generations (1997)	Operational guidelines for ethics committees that review biomedical research (2000)	On setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (2004/23/EC)
Declaration on Human Cloning (2005)	Declaration on Science and the Use of Scientific Knowledge (1999)	Biorisk management: laboratory biosecurity guidance (WHO/CDS/EPR/2006.6)	Principles and Detailed Guidelines for Good Clinical Practice as regards Investigational Medicinal Products for Human Use (2005/28/EC)
Principles of Medical Ethics (1982) General Assembly Resolution 37/194	Universal Declaration on Cultural Diversity (2001)		Resolution R (78) 29 on Harmonisation of Legislations of Member States Relating to Removal, Grafting and Transplantation of Human Substances
	International Declaration on Human Genetic Data (2003)		Recommendation Rec (94) on human tissue banks
	Universal Declaration on Bioethics and Human Rights (2005)		Recommendation Rec (98) on provision of haematopoietic progenitor cells
	International Health Regulations (2005)		Recommendation Rec (2004) 8 on autologous cord blood banks
			Recommendation Rec (2006) 4 on research on biological materials of human origin

Source: Elaborated by the authors.

the Organisation for Economic Cooperation and Development (OECD)[6,9,11,17,18,20,21,27,28]; c) the World Trade Organisation (WTO)[11,17,21,27,29]; and d) the International Standards Organisation (ISO)[1,3-5,10,11,17,24,26,27], to avert technical obstacles to trade and facilitate legal harmonisation.

In addition to the foregoing are studies and guidelines signed by the WTO, WHO and WIPO to regulate intellectual property rights in health, to promote access to technologies and innovation and to regulate health from three perspectives – as part of public law (public health), private law

(intellectual property) and mercantile law (trade) – resulting in the signing of the Doha Declaration on the TRIPS and public health agreement (2001) and the Hong Kong Ministerial Declaration on TRIPS and public health (2005).

Limitations and strong points

This review has limitations, of course: temporal, language-related, limited open access, geographical and cultural. It endeavoured to identify studies originating in a variety of fields of knowledge so as to produce a multidisciplinary panorama. Despite the best efforts, however, not all could be included. The PRISMA criteria guarantee a certain quality to the research, while the CASPe quality assessment criteria were applied to all the selected studies. Nonetheless, in studies from the social sciences and humanities and in the normative projects, methodologies and data collection techniques tend to be implicit in the article and not to involve participant selection. Note that, from the search for instruments for measuring research quality, the CASPe guide proved the best suited to the diversity of sources and methodologies that the study worked with. Risks and possible biases were minimised by eliminating the grey literature and by the four authors' (GS, OC, HA and BR) working independently. The study's strengths include its originality: as far as is known to the authors and in view of the bibliographical search, no studies were found to take a multidisciplinary approach to biobanks. The findings summarise the general and most relevant information from a diversity of sciences and, as such, may serve other studies.

Collaborations

RN Guerrero Sotelo: study idea and design; data search, analysis and interpretation; article drafting, final review and approval. JE Orellana Centeno: study idea and design; data analysis and interpretation. LI Hernández Arzola: participated in data analysis and interpretation. Critical review and approval of draft article. E Balderas Ruíz: participated in data analysis and interpretation. Critical review and approval of draft article.

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