



REVIEW

Exchange of secondary data in research with human beings: Ethical aspects

Intercambio de datos secundarios en la investigación con seres humanos: Aspectos éticos

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ABSTRACT

Introduction: currently, there is a call from the scientific community for a responsible exchange of data, being relevant to promote innovation in research through the reuse of secondary data. However, the data exchange is not free of difficulties since it imposes relevant ethical challenges. On the other hand, the data exchange is also limited by legislative aspects of each country in terms of data privacy; for example, the Chilean legal system is presented.

Objective: to identify the ethical aspects of exchanging secondary data in research with human beings.

Methods: integrative review. Data sources: WoS, PUBMED, Scopus, and publications were searched between 2017 and 2022.

Results: the final sample consisted of 12 articles, and they were organized according to ethical aspects, concerns of the research subject, and the researcher's position in the exchange of data in research with human beings.

Discussion: the creation of a Data Access Committee (DAC) and an international ethical framework are initiatives that are promoted to advance the exchange of data in research with humans. However, the legal frameworks become relevant in the context of data protection in each country, as is the Chilean case.

Conclusion: progress must be made in aspects of broad informed consent, which is directly related to the legal framework of each country.

Keywords: Ethics; Research; Data Sharing; Data Management.

RESUMEN

Introducción: en la actualidad existe un llamado de parte de la comunidad científica para un intercambio responsable de datos, siendo relevante para impulsar la innovación en la investigación a través de la reutilización de datos secundarios. Sin embargo, el intercambio de datos no está exento de dificultades, debido a que impone desafíos éticos relevantes. Por otra parte, el intercambio de datos, también se ve limitado por aspectos legislativos de cada país en materia de privacidad de datos, como ejemplo se presenta el ordenamiento jurídico chileno.

Objetivo: identificar los aspectos éticos en el intercambio de datos secundarios en la investigación con seres humanos.

Métodos: revisión integrativa. Fuente de datos: WoS, PUBMED, Scopus, se realizaron búsquedas de publicaciones entre los años 2017 y 2022.

Resultados: la muestra final estuvo compuesta por 12 artículos, y se organizaron de acuerdo a los aspectos éticos, preocupaciones del sujeto de investigación y posición del investigador en el intercambio de datos en la investigación con seres humanos.

Discusión: la creación de un Comité de Acceso a Datos (DAC) y un marco ético internacional son iniciativas

que se impulsan para avanzar en el intercambio de datos en investigaciones con humanos, sin embargo, los marcos jurídicos toman relevancia en el contexto de la protección de datos en cada país, como lo es el caso chileno.

Conclusión: se debe avanzar en aspectos del consentimiento informado amplio, lo cual está directamente relacionado con el marco jurídico de cada país.

Palabras claves: Ética; Investigación; Intercambio De Datos; Administración De Datos.

INTRODUCTION

The extraordinary effort to accelerate the development of treatments and vaccines in response to the COVID-19 pandemic has highlighted the need for the global scientific community to share scientific data openly. ⁽¹⁾ Research data are all records researchers create during their work. ⁽²⁾ It has been impossible to apply a uniform definition across disciplines because research data can be numerical, textual, audiovisual, digital, or physical, depending on the nature of the research. ⁽³⁾ Historically, in the context of human subjects research in health, the data underlying such studies have remained securely in the custody of the data generator, most often a sponsor of academic studies. ⁽⁴⁾

There is a call from the scientific community for responsible data sharing, which is relevant to promote innovation in research through the reuse of secondary data. ⁽⁴⁾ Faced with this, the World Health Organization (WHO) generated an open access policy in January 2022, which ensures that the general public has free access to the published results of their activities and reuse them; ⁽⁵⁾ likewise, the National Institute of Health (INH) in the USA established a policy that from January 2023 all researchers must provide a formal and detailed plan to publicly share the data generated by their research. ⁽⁶⁾

Data sharing is essential to advance collaborative research, create new knowledge and procedures to improve health. ⁽⁷⁾ Data sharing will lead to openness, availability, and reuse of scientific data contributing to an exponential increase in benefits for both science and society. ⁽⁸⁾ However, it has challenges because it imposes relevant ethical challenges, such as patient privacy and informed consent. ^(4,9)

On the other hand, it is also limited by each country's data privacy legislation. ⁽⁷⁾ This integrative review aims to analyze the ethical aspects, the position of the study subject, and the researcher in exchanging secondary data in research involving human subjects.

METHODS

An integrative review was performed according to the methodology proposed by Crossetti ⁽¹⁰⁾, where the question that guided the search was: What are the ethical aspects in the exchange of secondary data in human research? The different searches were organized in Spanish, English, and Portuguese, using the descriptors validated in the Health Sciences Descriptors (DeCS) thesaurus and Boolean descriptors described below: ("Ethics research") AND ("Data sharing"). Web of Science (WoS), PUBMED (United States National Library of Medicine), and Scopus are the databases used. The search strategies and filters used in each database are shown in table 1.

	Database	Search strategy	Filters applied
1	WoS	All fields	-Years of publication: 2017-2022 -Type of documents: Articles -Language: English, Spanish and Portuguese.
2	PUBMED	All fields (all fields)	-Publication date: 2017-2022 -Language: English, Spanish and Portuguese.
3	SCOPUS	All fields (all fields)	-Year: 2017-2022 -Type of document: Article -Language: English, Spanish and Portuguese.

The inclusion criteria used were articles in the previously mentioned languages, published during the period 2017-2022 (until June), and related to ethical aspects in the exchange of data in human subjects; the exclusion criteria correspond to letters to the editor and reviews. The results obtained will be organized according to ethical aspects, concerns of the research subject, and position of the investigator in the exchange of data in human subjects research.

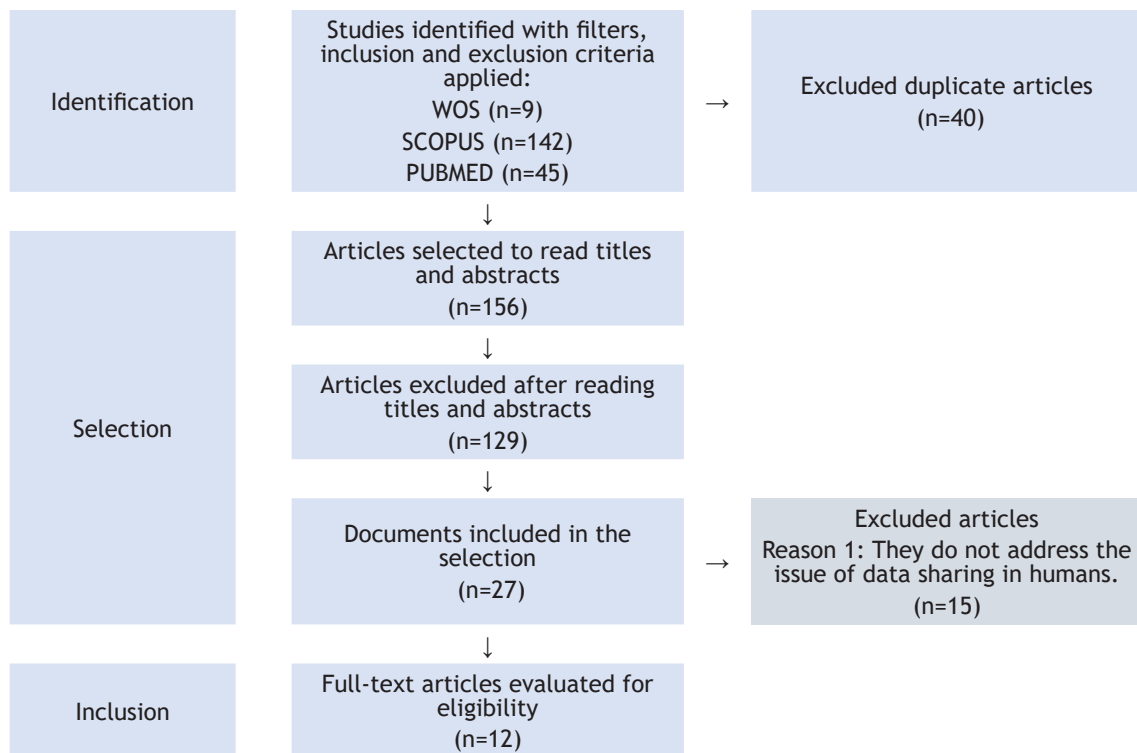


Figure 1. State of the art review flowchart

RESULTS

The final sample was composed of 12 articles; 8,3 % corresponds to the year 2017, 16,6 % to the year 2018, 16,8 % to the year 2019, 33,6 % to the year 2020, and 25 % to the year 2021. The articles come from the USA, Switzerland, Thailand, Greece, Costa Rica, the United Kingdom, and Australia.

Ethical Aspects of data exchange

There is currently no single international ethical framework for data sharing. Therefore, the investigator must be guided about different guidelines for considering the use of secondary data produced by other scientists, leaving ethical considerations in a risky position; the WHO and Council for International Organizations of Medical Sciences (CIOMS) guidelines are broad. In this context, the evidence suggests developing an ethical framework for data exchange, helping those countries with weak ethical safeguards.⁽¹¹⁾

A definite structural aspect is that Scientific Ethics Committees (SECs) protect research subjects by applying ethical principles and legal norms. At the same time, Data Access Committees (DACs) promote secondary data sharing while mitigating any potential risks and, in turn, should be a mechanism for implementing institutional policies for secondary data sharing.⁽¹²⁾

It is noted that CECs cannot monitor the use of secondary data due to their financial and infrastructural limitations. However, they remain the most appropriate ethical authority to help control the risks of data sharing.^(11,12)

DACs allow access to data as long as secondary data reuse has a potential social value. In this context, secondary data sharing should be guided by the principles of public health ethics.⁽¹³⁾

Given that, in most cases, universities, laboratories, and principal investigators do not own the research data, and given that each country's legislation is concerned about data confidentiality, investigators should plan for data sharing from the beginning of the project, including guidelines for broad informed consent to allow them to use the data in secondary research.⁽¹⁴⁾

Addressing issues related to secondary data use and the need for new respective consent is the most challenging problem. Therefore, amendments at the legislative level in each country should focus on increasing harmonization, confirming the concept of broad informed consent, and defining a pathway for the use of secondary data.⁽¹⁵⁾

Concerns of the research subject

Regarding the concerns of the research subject, there is the re-identification of the data, which may generate discrimination by health insurance companies and employers.⁽¹⁶⁾ Research subjects are willing to share data but in an anonymized form.⁽¹⁷⁾

Willingness to participate in research studies differs significantly depending on the potential user of the data. Research subjects have higher levels of trust in their physician and researchers at public universities than in private organizations. This presents challenges and suggests the need to support dialogue about the role of public-private research partnerships.^(16,17,18,19,20)

Trust and transparency about who will benefit from access to data is critical for research subjects, so there must be clarity about the potential benefits of the research, who will receive those benefits, how it will be conducted, and for what purposes.⁽¹⁸⁾

A survey reveals that another factor of concern for research subjects is the governance of their data when it is shared with other research teams, noting as a key process that data should be securely safeguarded. They would also require that requests for access to these data by other groups of scientists be reviewed and authorized by a panel of designated experts. In addition, they would require the initial data manager to monitor data use when transferred to the other team.⁽¹⁷⁾

Position of the Researcher in data exchange

In the face of the new open science paradigm, where data sharing is a condition for publication and funding, researchers have presented arguments against data sharing. Some of these arguments point to the hard work of data collection, which they believe will not be rewarded if another researcher can use these data to test a new idea. They also claim that making the data available for subsequent analysis could be unethical.⁽²¹⁾

A key strategy to address these issues raised and promote data sharing is through a framework of ethical principles, which are universal and feasible to implement.⁽²²⁾

DISCUSSION

The international trend in data exchange in research involving human subjects has already been established, evidenced by internal policies in some international organizations, such as the WHO⁽⁵⁾ and INH⁽⁶⁾. However, the ethical aspects are among the limiting and worrying aspects of the exchange of data in research with human beings. Some initiatives have been postulated to address this concern, including creating a DAC⁽¹²⁾ and an international ethical framework for data exchange.⁽¹⁰⁾ To carry out the above, there must be legislative support in each country that is a regulatory framework for data exchange, which integrates the concept of broad informed consent and defines a route for the use of secondary data.⁽¹⁴⁾

In the Chilean case concerning privacy and personal data, the constitution guarantees the right to privacy and other norms signed and ratified by the country, forming the constitutional system of privacy protection.⁽²³⁾ In this way, all persons are assured the respect and protection of their private life and, likewise, the protection of their data.⁽²⁴⁾ Specifically, Law 19.628 on "Protection of privacy" was enacted in Chile, which in particular legalizes the "Protection of personal data," generating the general obligation to maintain the security of personal data to the person responsible for the data bank, as well as to take care of them with due diligence and be responsible for damages.⁽²⁵⁾ Likewise, Law 20.120 on "scientific research on the human being, its genome, and prohibits human cloning" states that the collection, storage, treatment, and dissemination of the genome of persons shall be by the provisions of Law 19.628. It emphasizes the regulation of the treatment of personal data in registries or data banks by public or private organizations so that the human genome data that allows the identification of a person must be encrypted for its storage and transmission. However, its implementation is not explicit.⁽²⁶⁾

Even with this set of rules, the provisions on security obligations for systems that process personal data are limited in Chile, making it difficult to protect them against the risks of technological development, specifically the exchange of large databases in human research. Currently, there is a bill that modifies most of the existing rules in Law 19.628, together with the incorporation of many new provisions in order to adapt the regulations to international standards on protection in the treatment of personal data, which includes the exchange of research data and data storage in large repositories.⁽²⁷⁾

Moreover, informed consent should be broad, allowing research subjects to be asked to consent to unspecified future research, either through primary enrollment in a research repository or through secondary research.⁽²⁸⁾ Ethical approval of studies using broad consent includes mechanisms to ensure that such consents are respected, and their inherent expectations are upheld.⁽²⁹⁾

Undoubtedly, research teams and institutions face a great challenge with the new paradigm of open science, conceptualized variably, from the publication of research results to access to data and the research process, research evaluation, and peer review,⁽³⁰⁾ despite this context, evidence points out that researchers have made arguments against data sharing.⁽²¹⁾

CONCLUSIONS

The present integrative review responds to the objective of identifying the ethical aspects in the exchange of data in research with human beings; in the findings identified, ethical aspects, concerns of the research

subject, and position of the researcher in the exchange of data stand out, highlighting the creation of an International Ethical Committee for the exchange of data and a DAC. It is also evident that progress should be made in the concept of broad informed consent protected by each country's legal and regulatory frameworks.

The challenge of establishing a dialogue between public-private partnerships to increase the confidence of the research subject in the exchange of data to advance in aspects of broad informed consent, which is directly related to the data protection legislation of each country, is evident. Therefore, it is a priority to harmonize the key aspects that make the exchange of secure data possible and thus define a route for the use of secondary data, which becomes preponderant in the current scenario of open science, where researchers should join these new requirements. It is pertinent to continue generating spaces for discussion about the ethical aspects of data exchange in human research. This will contribute to further clarifying and enriching the state of knowledge on a subject that is becoming increasingly relevant and a current requirement for researchers.

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DECLARATION OF CONFLICT OF INTEREST

The authors declare that they are independent with respect to the supporting institutions, and that during the execution of the work or the writing of the manuscript no interests or values other than those usually involved in the research have been involved.

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