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ETHICAL AND LEGAL ISSUES RELATED TO SECONDARY DATA USE IN RESEARCH: PROPOSITION OF A GUIDING MODEL FOR PLANNING, COLLECTING AND ANALYZING INFORMATION IN BRAZIL

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ABSTRACT

Technological advances have resulted in the collection, compilation, and archiving of enormous amounts of information, generating a vast database that can be easily accessible for different purposes around the world. Therefore, despite the potential use of secondary data for research, key issues make it difficult to exploit these resources. Furthermore, it is essential that researchers are aware of these challenges and the legal regulations that may exist on this topic. Thus, within this context, this paper conducts a review of the state of knowledge and documentary research to elucidate some interesting questions about the use of secondary data: What issues are being considered most important in the recent literature on the use of secondary data in research? How is this issue regulated in Brazil, and what are the main legislations and their implications for health research using secondary data?. What precautions should researchers take to ensure the ethical conduct of their work when using health data? Finally, as a result of this essential discussion, a framework is presented containing twenty-three recommendations for clinical investigators and ethics committees in human research, and which may be useful in all phases of research to ensure the ethical conduct of their work when using health data.

KEYWORDS: secondary data; legislation; health research.

QUESTÕES ÉTICAS E JURÍDICAS RELACIONADAS AO USO DE DADOS SECUNDÁRIOS EM PESQUISA: PROPOSTA DE UM MODELO DE ORIENTAÇÃO PARA PLANEJAMENTO, COLETA E ANÁLISE DE DADOS NO BRASIL

RESUMO

Os avanços tecnológicos resultaram na coleta, compilação e arquivamento de enormes quantidades de informação, gerando uma vasta base de dados que pode ser facilmente acessíveis para diferentes fins em todo o mundo. Portanto, apesar da potencial utilização de dados secundários para a investigação, questões essenciais dificultam a exploração destes recursos. Além disso, é essencial que os investigadores estejam cientes destes desafios e das regulamentações legais que possam existir sobre este tópico. Assim, dentro deste contexto, este artigo realiza um levantamento do estado do conhecimento e investigação documental para elucidar algumas questões interessantes sobre a utilização de dados secundários: Que temas estão a ser considerados mais importantes na literatura recente sobre a utilização de dados secundários na investigação? Como essa questão está regulamentada no Brasil, e quais são as principais legislações e suas implicações para a investigação em saúde utilizando dados secundários? Que precauções devem ter os investigadores para assegurar a conduta ética do seu trabalho ao utilizarem dados de saúde? Finalmente, como resultado desta discussão essencial, é apresentado um quadro contendo vinte e três recomendações para investigadores clínicos e comitê de éticas em pesquisa com seres humanos, e que pode ser útil em todas as fases de investigação para assegurar a conduta ética do seu trabalho ao utilizarem dados de saúde.

PALAVRAS-CHAVE: dados secundários; saúde; legislação.

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1. INTRODUCTION

In recent years, technological advances have resulted in vast amounts of information that has been collected, compiled, and archived, generating a vast database that can be easily accessible for different purposes around the world (Madanian et al., 2019; Meystre et al., 2017). In healthcare, these data come from many sources, including primary source documents, electronic health records (EHR), administrative data, hospital records, clinical trials, records of treatment, patient surveys, prognosis, laboratory tests, and more (Burton et al., 2017; Hutchings et al., 2020; O'Keefe & Connolly, 2010).

When used for a different purpose to that for which it was initially collected, this data is referred to as secondary data (Cole & Trinh, 2017; Robertson et al., 2016). For example, the data collected from routine EHR and hospital records for hospital administration and management purposes can also be used in research and analysis to assess and evaluate healthcare services, such as the use of laboratory tests or readmission rates (Meystre et al., 2017).

The rising adoption of secondary data in health research is now widely recognized as an essential alternative to traditional research methods. It allows researchers to develop more robust strategies for conducting intervention studies and even improve the efficiency and effectiveness of healthcare services and pave the way for the development of new healthcare policies (Cowie et al., 2017; Hemingway et al., 2018; Safran et al., 2007).

According to several authors, secondary data have some advantages over primary data – lower costs in the acquisition, storage, and analysis, increased statistical power in research studies due to the larger population size, connection between data collected in different locations, and more (Goodin et al., 2017; Hemingway et al., 2018).

However, lots of obstacles limit the use of secondary data for research purposes. These include the lack of uniform standards for data collection, storage, and use; difficulties in standardizing formats for data submission; differences in data content through different sources; lacking of infrastructure to support research on secondary data; and issues related to data quality, including accuracy, completeness, timeliness, and access (Cowie et al., 2017; Shahin et al., 2020).

Moreover, in addition to these operational obstacles, some critical ethical and legal issues also are mentioned in the literature as a challenge in using secondary data in health research, including privacy and confidentiality of information, the confidentiality of participants, and risks to human subjects (Meneses-Oliveira, 2019; Riso et al., 2017; van Veen, 2018).

Therefore, despite the potential use of secondary data for research, essential issues make it difficult to exploit this resourcefully. Researchers must be aware of these challenges and the legal regulations that may exist. Thus, within this context and aiming to contribute to future researches and projects based on secondary data, this article seeks to elucidate some interesting questions about using secondary data for scientific research: What themes

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are being considered most important in the recent literature on using secondary data in research and deserve more attention from researchers? How is this issue regulated in Brazil?, and what is the primary legislation and the implications for health research using secondary data? What precautions should researchers and other parts be involved in developing research projects to ensure the ethical conduct of their work when using health data?

2. KEY ISSUES INVOLVED IN THE USE OF SECONDARY DATA IN HEALTH RESEARCH

In order to present the state of knowledge about the accumulated debate on the most important ethical and legal issues related to the use of secondary data in healthcare scientific research, this section presents a brief literature review of articles that address the topic. Data was collected through a protocol that included planning, searching, screening, and analysis of scientific articles presented in the PUBMED database (https://pubmed.ncbi.nlm.nih.gov/) during December in 2021.

The term we used to search, after tests and methodization was "(ethic* OR bioethic*) AND (issue OR dilemma) AND ("data" OR "electronic health records" OR "Personal Health Record" OR "Personal Electronic Health Records" OR "biobanks") AND ("health research" OR "clinical research")," which resulted a total of 629 documents. After excluding duplicates and applying the defined inclusion criteria (health research with secondary data published in the last five years and discussion of someone's ethical and legal issues in health research) and careful analysis of the papers, a total of 27 scientific articles were considered eligible to support this discussion.

An initial analysis of the selected articles allows us to identify the main research foci addressed using secondary data in health research in the past five years. These appealing areas of interest could guide future researchers, healthcare organizations, and governments to understand the general challenges of sharing individual clinical data and focus their efforts to shape future directions in this field. Therefore, these major issues will be discussed more fully in this article: Sources of secondary data and examples of data using; Personal perspective on the Secondary Use of Health data; Privacy, security, and anonymization of personal health information; Related ethical principles, terms, and values; Ethical and legal issues concerning data protection in Brazil and Policies and strategies.

2.1 Sources of secondary data and examples of data using

Secondary data sources for health research comprise a broad and heterogeneous category. Formal electronic health records (EHR) appears as the most relevant source of secondary data for health research because they are increasingly being used in a large number of health care organizations worldwide, and they could provide an immeasurable amount of information on the entire life of each patient with a higher level of detail (Cowie et al., 2017; Hemingway et al., 2018; Nalbandian et al., 2021).

However, other important data sources for the advancement of health research have been widely reported in the literature, such as human tissue banks (Burton et al., 2017;

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Sanderson et al., 2017), administrative data (e.g., claims-based datasets, statistical and financial reports) (Burton et al., 2017), clinical surveys (e.g., notes, medication, diagnosis) (Meystre et al., 2017), imaging exams (Zhang et al., 2017), genetic research database (e.g., omics databank, microarray data) (Sanderson et al., 2017), wearables (Hicks et al., 2019; Ranjan et al., 2019) and social media such as Facebook and Twitter (Azer, 2017; Hunter et al., 2018).

Due to the advantages of using secondary data, including saving investigation time and costs, researchers seek now and then to optimize the proper use of this information to tackle health problems and enhance patients' quality of life in different medical fields, with an emphasis in recent literature on obstetrics and gynecology (Goodin et al., 2017), Alzheimer's research (Zhang et al., 2017) and cardiovascular clinical research (Cowie et al., 2017; Hemingway et al., 2018). For instance, in a study whose aim was to present the challenges and potential of big data throughout the different stages of translational cardiovascular disease research, it has been shown that despite the many challenges, there are opportunities to disrupt current models of cardiovascular research, especially on early translational investigations such as the discovering and classification of a new heart failure sub-type described by the use of machine learning and data science (Hemingway et al., 2018).

Overall, opportunities claimed for big health record data highlighted in the literature include: study feasibility, patient recruitment, streamlined data collection, observational research study design, comparative effectiveness studies, safety and efficacy of drug therapies, patient health outcomes, trends in utilization of medications/procedures, prevalence estimates of disease states and patient behaviors, and trends in practice (Burton et al., 2017; Cowie et al., 2017; Goodin et al., 2017; Hemingway et al., 2018; van Veen, 2018). The most common sources and opportunities for using secondary data are summarized below in Figure 1.

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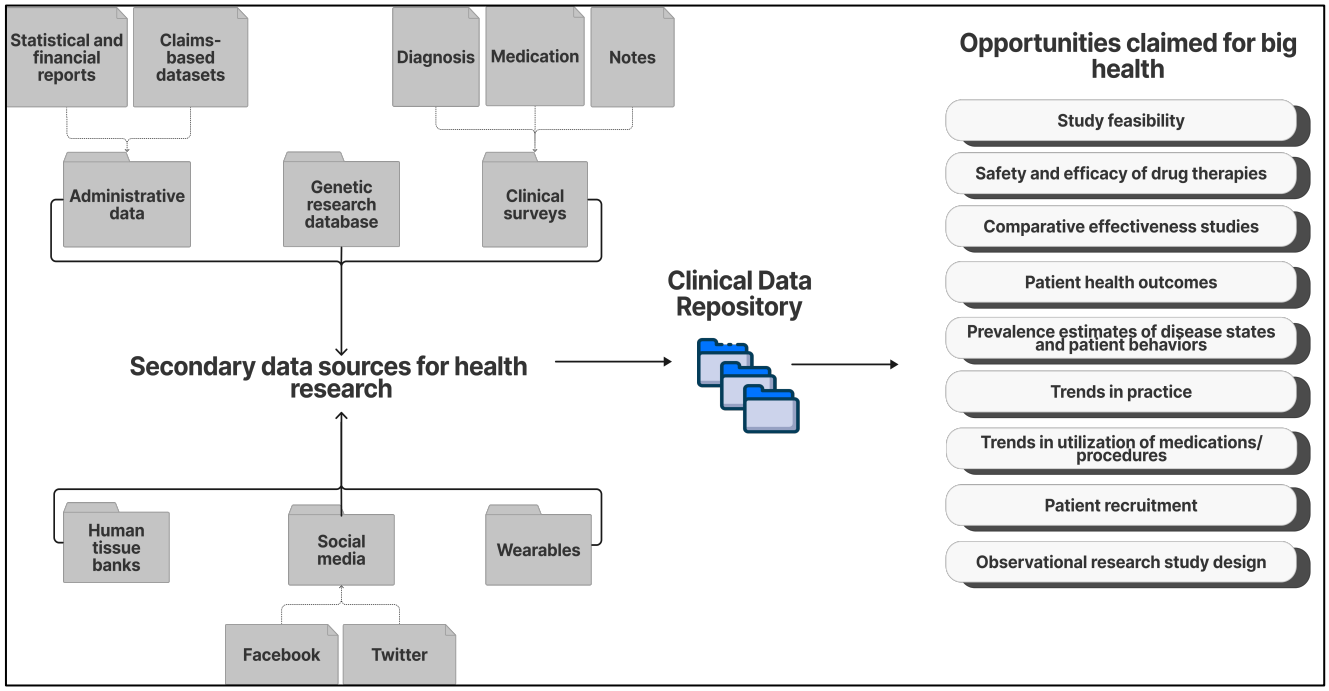

Figure 1: Sources and opportunities for using secondary data in scientific research.

Source: Authors, (2022).

2.2 A personal perspective on the Secondary Use of Health data

In the last few years, the scientific community has been increasing interest in the perspectives of researchers and other relevant professionals (e.g., clinicians), research ethics committees, and patients on the widespread adoption of personal data for purposes other than those for which it was collected.

The willingness of parents of minors and individual users to provide consent for open-ended research use and widespread sharing of their biosamples from tissue banks and data from EHR is by far the most investigated issue in this context (Antommaria et al., 2018; Ballantyne & Schaefer, 2020; Hammack-Aviran et al., 2020; Neves et al., 2019; O'Brien et al., 2019; Sanderson et al., 2017). These studies indicate that most patients feel comfortable sharing data for research purposes. Additionally, a broad permission approach does not negatively affect patient recruitment and might be the most appropriate way to request permission and inform about future data research use.

Despite that, some socio-demographic groups require more effort to maximize community trust in the stewardship of their data, especially economically vulnerable groups, lower levels of educational attainment people, and those self-identified as more religious (Antommaria et al., 2018; O'Brien et al., 2019).

Thus, some potential participants' concerns should be addressed to build trust and relationships with communities to increase enrollment and diversity in databanks (Antommaria et al., 2018). Among these, it is imperative to focus on data accuracy, security,

adequacy or understanding of current policies, and developing methods to link databases to minimize the exposure of unique identifiers (Hammack-Aviran et al., 2020; Neves et al., 2019).

Additionally, despite the related high level of Health Care Professionals' understanding about the data used for secondary purposes, policies are needed to stimulate greater involvement of Research Ethics Committees and to provide better training of researchers and health professionals in order to improve the quality and safety of health care delivery (Holm & Ploug, 2017; Neves et al., 2019).

2.3 Privacy, security, and anonymization of personal health information

One of the limiting constraints in data sharing is the legal and ethical difficulties around unconsented patient data and privacy, resulting in a substantial barrier to the public trust in data sharing for health research (O'Keefe & Connolly, 2010). Health data privacy may be understood as the ethical duty to maintain the patient information and data in confidence (Mooney & Pejaver, 2018), and most countries guarantee privacy by specific legislation.

Most researchers recognize the importance of the principles and laws that guarantee privacy and data security. However, they understand that the lack of clarity in the definition of personal data presented by these local regulations could impact some sectors inhibiting the processing of this health information for scientific purposes and consequently limiting the potential of these crucial tools to contribute to human health improvement (Chico, 2018).

Thus, utilizing the potential of information about patients while respecting ethical and legal issues, anonymization, a procedure that removes any trace of the identity of a given data subject, emerges as a viable possibility in health sectors. However, efficient data use and rigorous anonymization are currently incompatible because they vary depending on the amount and quality of valuable data (Mooney & Pejaver, 2018; Ong et al., 2017).

Therefore, some studies have proposed techniques to provide a widely available, legally, and morally relevant alternative to preventing a breach of confidentiality and preserving patient privacy (Rumbold & Pierscionek, 2018; Snäckerström & Johansen, 2019; Yoon et al., 2020).

For example, Rumbold and Pierscionek (2018) proposed an information governance matrix that includes a series of anonymization levels adjusted according to the best evidence on public attitudes toward trustworthiness. According to the authors, the anonymization matrix created provides support for research ethics bodies to recommend appropriate levels of anonymization when obtaining specific consent is not feasible. Additionally, the main potential advantage of this matrix is the possibility to ethically satisfy the requirements of multiple legislations without imposing an excessive regulatory burden (Rumbold & Pierscionek, 2018).

In another study, researchers developed an innovative model of generating anonymization from EHR data, creating robust synthetic datasets using Generative

Adversarial Networks (ADS-GAN) to satisfy the identifiability constraints related to data sharing and privacy assurance. The findings showed that this approach might be used to generate datasets that can be made publicly available while significantly reducing the risk of patient confidentiality being breached (Yoon et al., 2020).

2.4 Related ethical principles, terms, and values

Most of the ethical issues surrounding healthcare have historically been approached by principlism, the dominant bioethical current in discussions on this subject, as well as other bioethical currents such as utilitarianism, deontology, personalism, and other documents such as the Universal Declaration of Bioethics and Human Rights (UDBHR) (Kalkman et al., 2019; Manchola, 2017; Mouton Dorey, 2016).

In the debate about health data sharing, the bioethical discussion becomes increasingly relevant because the guarantee of data privacy seems unfeasible nowadays, indicating a demand for responses beyond these general principles and codes cited above. These demands include a more precise, consistent, and transparent definition of the values and essential factors that should be considered for the moderately and responsibly ethical management and sharing of data.

In this sense and based on the results that have been analyzed, it is possible to state that community or public trust appears to be one of the most critical aspects of establishing respectful scientific procedures to keep people engaged in sharing their health data and contribute with valuable research.

Transparent policies and public awareness emerge in this public trust context, reinforcing the view that researchers, organizations, and governments must demonstrate to society that they can be responsible stewards of health data (Entzeridou et al., 2018; Hunter et al., 2018; Sanderson et al., 2017).

For instance, the secondary use of health data must be openly addressed in ongoing public policy conversations. These operations must be carried out and managed with the involvement of a wide range of stakeholders, with full disclosure of uses and protections provided through transparent and readily available mechanisms (Shahin et al., 2020).

Likewise, a study showing an in-depth overview of the General Data Protection Regulation (GDPR) and its impact on observational health research in Europe introduces the term "governance by," a set of collective governance mechanisms for parties involved in managing research initiatives that are aligned with patient organizations and the public in order to have a more transparent and community-centered research agenda (van Veen, 2018).

Also, to promote respectful scientific practices in order to maintain the trust of individuals in research, another recent study presented six core values considered essential for ethical health data sharing using Information and Communication Technology (ICT) platforms, which are scientific value, user protection, facilitating user agency, trustworthiness, benefit, and sustainability (Riso et al., 2017).

Otherwise, the waivers of informed consent can negatively impact community trust and they are most related to confusion and instability in terminology adopted by some investigators to justify the legitimacy of their research inappropriately. This issue led Ballantyne and Schaefer (2020) to suggest using the term public interest instead of several others referred to in the literature (such as public benefit, public good, and social value). Because public interest is the widest of the competing phrases and lays out the conceptual and normative norms of appropriate data sharing, the authors claim that the term encompasses both the good and negative aspects of a study, as well as welfare, justice, and human rights considerations to justify permission waivers (Ballantyne & Schaefer, 2020).

In addition to public trust, other relevant concepts have been discussed and should be considered in this debate. It is interesting to highlight key terminologies such as societal benefits and value, distribution of risks, benefits and burdens, and respect for individuals and groups. These terms also represent what authors, organizations, and working groups regard as essential parts of managing responsible data-sharing activities (Kalkman et al., 2019).

This relevant discussion and more accurate understanding of essential terms and values for secure data sharing have contributed to ground the concept of public trust and other significant principles. Nevertheless, more in-depth discussions are still needed to establish a coherent framework comprising more straightforward and precise terminology that promotes data sharing while securing transparency and community awareness. It is important to note that each country within its legal system establishes rules through laws, standards, or regulations that provide a framework for guaranteeing the privacy and security of data subjects.

3. ETHICAL AND LEGAL ISSUES CONCERNING DATA PROTECTION IN BRAZIL: THE CEP/CONEP SYSTEM AND THE BRAZILIAN GENERAL DATA PROTECTION LAW (LGPD)

This section briefly introduces the CEP/CONEP Brazilian System, responsible for regulating scientific research involving human subjects on a national level. It presents some considerations about the LGPD and its relationship with major national ethical norms.

Brazil has a robust system for conducting an ethical research evaluation with human subjects linked to the National Health Council (CNS) and covers the entire national territory. This system is called CEP/CONEP and was created by CNS Resolution Nº. 196/1996 and currently regulated by Resolution Nº. 446/2012 and its complementary ones and is constituted by more than 850 Research Ethics Committees (CEP) and the National Commission on Research Ethics (CONEP), (CNS, 2020).

The CONEP implements standards and guidelines to regulate all research involving human beings. It has an advisory, deliberative, normative, and educational function and acts in conjunction with an extensive network of CEPs to protect research participants, guaranteeing their rights, respect, and human dignity (Amorim, 2019). The CEPs are local commissions linked to hospitals and research institutions. They are formed by an

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independent, interdisciplinary, public collegiate that evaluates ethical issues and approves research protocols following the ethical resolutions in force in Brazil (Amorim, 2019).

The CEP/CONEP is a complex system with several operational norms, circular letters, and resolutions that regulate research ethics and the evaluation of research protocols, especially the CNS resolutions 466/2012 and 510/2016. Besides these, other laws are also essential and should be considered by all researchers to maintain ethical guarantees in Brazil: the Federal Constitution of 1988, the Civil Code, the Consumer Code, as well as the Access to Information Law (Law Nº. 12,527/2011), the Credit Law (Nº. 12,414/2011), the Civil Landmark for the Internet (Law Nº. 12,965/2014) and General Data Protection Law (LGPD) (Nº. 13,709/2018).

In the specific context of personal data protection, the LGPD was promulgated on September 18, 2020, and establishes the ethical and legal principles for the protection of the confidentiality of personal and sensitive data, the guarantee of respect for privacy, and the requirement to obtain consent for the use and processing of this data for specific purposes.

The Brazilian LGPD is organized into ten chapters and 65 articles that, in general, address the treatment of sensitive personal data, such as that of children and adolescents. In addition, it determines the guidelines for the treatment of personal data by public authorities and the international data transfer and presents questions about responsibilities and compensation for damages. In this respect, the plurality of information in the LGPD strengthens the data protection needed, significantly when the relationship between privacy, science, and ethics is weakened due to capital and economic interests or political and ideological reasons (Ramos et al., 2021).

To assign responsibilities and legal obligations, thus increasing transparency in the data processing both for those who receive the data and those who store and process it, article 5 creates the controller's figures, the operator, and the processor of data. The controller is defined as: "a natural or legal person governed by public or private law responsible for taking decisions regarding the processing of personal data"; the processor is: "a natural or legal person governed by public or private law who processes personal data on behalf of the controller"; and the administrator: "the person appointed by the controller and the processor to act as a channel of communication between the controller, the data subjects and the National Data Protection Authority (ANPD)"; (Brasil, 2018)

By analyzing the chapters present in the LGPD, it is possible to verify the consonance in several aspects with the research ethics required by the CEP/CONEP system, such as respect for privacy, informational self-determination, and inviolability of intimacy, honor, and image, and are related to bioethical principles of autonomy, non-maleficence, beneficence, and equity/justice, as presented in the preliminary provisions of Resolution 466/2012 of the National Health Council (CNS).

Even though there are similarities concerning the object of protection, the research participant in the CEP/CONEP system, and the data subject in the LGPD, it is possible to observe some weaknesses as can be seen in Article 7 of LGPD establishes the requirements

for processing personal data. In its IV paragraph, it states that "for the conduct of studies by research organizations, guaranteed, whenever possible, the anonymization of personal data; also in article 11, II, 'c' that refers to the treatment of sensitive personal data, as well as in article 16, II presents in the section that refers to the end of the data treatment. (Brasil, 2018, art.11, § II).

Although the LGPD regulates data confidentiality, it also opens a somewhat subjective gap by allowing "whenever possible," which slows down the ethical guarantees of data subjects and generates uncertainty about the limits of access and protection of information (Martins et al., 2021).

Further dissonance can also be encountered, such as the definition of proposing institution in resolution 466/12, II.8, as "organization, public or private, legitimately constituted and empowered, to which the responsible investigator is attached." At the same time, the LGPD treats the research organization as being:

> "organ or entity of direct or indirect public administration or private non-profit legal entity legally constituted under Brazilian laws with headquarters and jurisdiction in the country, which includes in its institutional mission or social or statutory objective basic or applied research of historical, scientific, technological or statistical nature" (Brasil, 2018, art.3, § XVIII).

These concepts conflict since the LGPD restricts private research organizations, only non-profit institutions with headquarters and jurisdiction in the country (Nunes, 2019). Therefore, some questioning arises: Are for-profit institutions excluded from the possibilities of data processing by the LGPD and consequently from the obligation to meet the legal, ethical safeguards? Would the institutions that do not have headquarters and jurisdiction in the country also not be under the supervision of this law since the control of the data occur in foreign domains? These questions must be urgently and adequately addressed to prevent severe ethical and legal implications for individual research participants, investigators, and the organizations involved in the studies.

Another inconsistency observed is that resolution 466/2012 guarantees the "full freedom of research participants to refuse to participate or to withdraw their consent at any stage of the research, without any penalty." (Brasil, 2018, art.3, §IV, b). In this sense, the data should also be removed when the participant decides to leave the research, but the LGPD, in its article 16, states that "personal data will be deleted after the end of their processing... " (Nunes, 2019. p. 104). In this case, analyzing from an ethical point of view, the focus should not be on the completeness of data processing but rather on respect for the decision of the data owner and the immediate removal of information at any stage of the research.

To these inconsistencies of the LPGD is added that in Brazil, there is no specific legislation for clinical research and that the legal framework for conducting it is based on weak rules, often of an administrative nature (Pereira, 2019). Another weakness that can lead us to reflect on this law regarding the complete protection of personal data in clinical

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research can be observed in article 12, whose ".... anonymized data will not be considered personal data for this Law, except when the anonymization process to which they were submitted is reversed, using exclusively own means, or when, with reasonable efforts, it can be reversed". In other words, data anonymization would be enough to allow the use of personal data indiscriminately. (Brasil, 2018)

This last question brings some reflections that become imperative in this extensive debate on the use of personal data, especially on the anonymization process. We would ask: what is the understanding of anonymization nowadays? What would be the regulation, for example, of the large information technology companies that collect and use our data obtained in real-time from tools such as smartphones, smart TVs, GPSs, watches, notebooks, among others, and often have access to health data such as heart rate, blood pressure, body temperature, oximetry, blood glucose, calorie expenditure, and body movement patterns? Since in many cases, the condition of anonymization could not be maintained just by hiding a name, and personal identification could be made by the pattern of behavior as the data, in a subtle and seemingly naive way, is provided to these companies. With this extensive monitoring of our lives, is anonymization regulated through the LGPD sufficient to protect our data and our security?

It is noteworthy that despite some conflicts and inconsistencies of the LGPD, the general rules that regulate data using in health research and what is advocated by the CEP/CONEP system, the first one has been consolidated as a solid and necessary legal instrument that has established in a single document the rights and duties for data processing, as well as administrative sanctions for those who do not comply (Lousana, 2019).

Finally, for the moment, even in the certainty that there are other congruent as well as conflicting imbrications, the LGPD emerges as an essential tool in setting limits on the use of data and, by force of law, contributes to some extent to an ethical beaconing, which makes it essential for health researchers who use secondary data from the most diverse sources.

4. POLICIES AND STRATEGIES

Policy and strategy are the themes of most significant interest to those involved with the safe and ethical sharing of health data. Because of the issues outlined in the preceding sections, there is an urgent need for rules, standards, and best governance practices that guide and support the collection, storage, aggregation, linkage, and large-scale transmission of health data.

The literature reviewed and the ever-increasing volume of health data allow us to state some critical considerations that can potentially be useful for healthcare researchers in the years ahead. First, it is essential to achieve deeper integration among all the stakeholders involved: researchers, industry, regulatory bodies, policymakers, and patients (Burton et al., 2017; Cowie et al., 2017).

After that, some actors must become more vocal and influential in this process to ensure more transparency and security in the use of clinical data, particularly individual

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patients or participants advocacy groups (Shahin et al., 2020) and Human Research Ethics Committees (Holm & Ploug, 2017). Even more, the inclusion of a certified, senior Health Information Manager in research teams and on institutional HRECs has been suggested to avoid possible ethical and legal issues (Robinson, 2021).

Subsequently, should be promoted public educational initiatives related to the benefits and the potential value of secondary use of health data and improve researcher training on best practices in data sharing to encourage better access to data and adequately information governance (Burton et al., 2017; Canaway et al., 2019; Cowie et al., 2017; Holm & Ploug, 2017; Shahin et al., 2020).

Furthermore, the scientific community and regulatory bodies must provide more accurate frameworks with a firm policy, standard, and best practice infrastructure to guide the secondary use of health data on research in different contexts such as social networks (Azer, 2017), data anonymization (Rumbold & Pierscionek, 2018), genomic and health-related data (Fiume et al., 2019) and EHR data sharing (Cowie et al., 2017; Jacquemard et al., 2021). A particular framework feature that appears to be relevant is the potential to satisfy the needs of different jurisdictions without adding unnecessary regulatory burdens (Rumbold & Pierscionek, 2018).

Finally, specifically regarding the use of data in clinical research in Brazil, investigators should be aware of the legislation that deals with this topic, such as the LGPD as mentioned above and resolution CNS 466/2012. Since there are still inconsistencies in these legislations that need to be improved, it is also important that researchers have access to some important documents: the international legal frameworks to which Brazil is a signatory (such as the International Human Rights Law); the essential documents elaborated by the United Nations Educational, Scientific and Cultural Organization (UNESCO), especially the Universal Declaration on Bioethics and Human Rights *(Universal declaration on bioethics and human rights: UNESCO, 2005) a*nd the Recommendation on Science and Scientific Researchers documents available in the records of the 39th session of the General Conference in Paris, 2018 (United Nations Educational, Scientific and Cultural Organization: UNESCO, 2018); the specific statutes, especially those that seek to ensure the protection of vulnerable people.

Therefore, with all this background and knowledge in mind, we propose a model containing some suggestions for care on primary data sharing for research, presented in Table 1. In the effort to support researchers and members of human ethics committees in handling the different stages of a research study, the model contemplates the stages of research project planning, data collection; data analysis and treatment; and general care.

Table 1: A model containing suggestions for primary care data sharing for research.

Source: Authors, (2022).

Research Stage	Recommendations
Research project planning	1. Read and understand the laws regulating ethics and the use of secondary data (LGPD and resolution 466/2012, in Brazil) 2. Consult legal documents of the banks and repositories responsible for storing the data. 3. Request the proper organization for authorization for data collection. 4. Ensure that the secondary data, when related to traditional/vulnerable peoples and specific groups protected by statutes, has legal support 5. Identify the potential risks and consequences of personal data leakage, and propose safeguards to minimize the potential damage or avoid the most predictable damage. 6. Identify the public interest of the research and justify the need for data collection. 7. Establish policies for data curation and stewardship, ensuring privacy and data protection. 8. Provide a stable and safe data storage environment. 9. Define authorized researchers for data management. 10. Obtain ethical approval for data collection by control bodies.
Data collection	1. Give high priority to obtaining the owner's consent, and when this is impossible; 2. Anonymize or de-identify data ensuring anonymity and privacy 3. Inform that personal data will be made available to a data processing agent (controller and operator), according to LGPD; 4. Inform, if any, of the necessity of international data transfer and ensure that the information is shared only with countries or international bodies that ensure an adequate level of protection in the LGPD. 5. In case of divergence in understanding between ethical resolutions and LGPD, it is suggested to adopt the most protective, prudent, preventive, and precautionary measure in relation to the data subject.
Data analysis	1. Ensure technical, legal, and ethical training of the team responsible for data management.

	2. Inform a controller or operator will treat that personal data under the terms of LGPD if the treatment occurs only in Brazil and in another country or international body, by similar legislation that provides the same degree of protection by LGDP. 3. If a research participant withdraws, the data must be immediately removed from the data analysis.
General care and norms	1. Maintain continuous and proactive data security, ensuring a secure data storage and sharing environment. 2. Ensure the guarantee of respect and human dignity to all research participants, considering the interests involved and protecting human rights. 3. Encourage transparency and socialization of the resulting knowledge in an accessible language to the researched group. 4. Maintain ongoing communication with the researched and patients and their advocacy groups to increase public trust. 5. Emphasize the figure of "data controller" on LGPD terms, as well as his/her identity and contact information clearly and objectively, for probable complaints, communication, clarifications, and measures related to personal data.

Clinical investigators must use this model as a framework to ensure an ethical and legal approach during all stages of the research in Brazil, and even, with some changes, especially regarding specific regulatory legislation on data use and research involving human subjects, this model satisfies the requirements of multiple legislations worldwide. Additionally, we encourage research ethics committees to use this material as an essential support tool during ethical reviews of research protocols.

5. FINAL CONSIDERATIONS

This essay has discussed such vital questions regarding using secondary data in clinical research. Investigators and organizations must use it and the public as an essential tool during all clinical research stages and encourage policies and improvement discussions on clinical data security in the future.

In anticipation of contributing to this ethical and legal debate, the state of knowledge showed that the main topics of interest that should be further explored are the sources of secondary data and examples of data using, personal perspective on the secondary use of health data, privacy, security, and anonymization of personal health information, and finally the related ethical principles, terms, and values.

Specifically in Brazil, it is essential to encourage discussion and awareness among the scientific society and population regarding the specific legislation on the use of personal and sensitive data and ethical issues in research involving humans, especially the LGPD and resolution 466/2012 of the CNS.

Finally, as a result of this essential discussion, a framework containing twenty-three recommendations for clinical researchers is presented and can be helpful in all research stages, from research project planning to data analysis, to ensure the ethical conduct of their work when using health data.

As can be seen throughout what has been discussed in this article, data protection transcends the boundaries of research-related laws, resolutions, and regulations and invites us to incorporate ethics and bioethics-based thinking and practices into our research, from project planning, through data collection, as well as its analysis and subsequent data destination.

In this regard, we reinforce our recommendation that researchers and institutions should appropriate and disseminate the information contained in important UNESCO documents, such as the Universal Declaration on Bioethics and Human Rights (DUBDH) and the Recommendation on Science and Scientific Researchers, adopted by the General Conference at its 39th session in November 2017, and which provides researchers, scientists, and policymakers with a set of international guidelines and values.

In conclusion, further studies and reviews are needed to delve deeper into health research's ethical and legal issues using secondary data. In addition, the framework presented here must undergo further improvement and validation to be used on a large scale and help researchers and organizations to improve public trust. However, it is crucial to bring this issue to the center of the debate when the volume of data collected is increasing exponentially and can bring severe risks to the population.

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