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OWNERSHIP OF PATIENT INFORMATION IN THE CONTEXT OF “BIG DATA”

ABSTRACT
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The dissertation contains 257 pages and is structured in 5 main chapters. Includes 4 figures; 11 tables and 2 annexes. The bibliographic list consists of 359 sources, 4 of which are in Cyrillic and 355 in Latin.

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CONTENTS

INTRODUCTION

> "Our data generally belongs to us, but in order to access or manipulate it, we need a guide to guide us from one 'digital' room to another: We do not own our data; we just visit them from time to time (Peck,2018). "

Today, global health systems are undergoing a fundamental change. We have reached the stage of a major transition to ways in which we can improve the generation and, respectively, access to unimaginable amounts of information. Thanks to the emergence and development of Big Data as a result of the Information Revolution, we can now manage and transform the approaches by which we control this information, and in healthcare, as a consequence, the ability to control and cure disease. It is expected that as a result of this, we will see a significant change in the effectiveness of healthcare delivery over the next few years.

As the impact of increasing societal expectations on better health is facing an increasingly sedentary lifestyle and a progressively aging population, it is no coincidence that we are reaching a point where we will not be able to find the means and tools we need for the provision of truly high quality healthcare. In this sense, with the introduction of new technologies, especially geared towards more personalized healthcare and patient care, we are nearing a significant step forward in the efficiency and effectiveness of diagnosis, treatment, management, and ideally, prevention of many diseases. A serious and widespread ambition is that the information-rich digital approach to healthcare will be more successful and patient-centered in the next decade. The emergence of Big Data in healthcare poses additional challenges, especially with regard to the privacy of individuals' personal data, security, ownership, and management. Personal data, which some call the "21st Century New Oil" or "the new currency," is generated at an extremely high rate of speed due to the invention and deployment of many new smart devices, sensors, networks and software applications.

In this sense, it is particularly important to address some of the problematic issues directly affecting medical information. Who owns the patient information, or who would have the fairest claim? Hospitals? The patients themselves? Can the information be publicly owned or belongs to healthcare providers? Where is the interest of data carrier developers (software programs, servers, clouds, social networks)? In general, can the “propertyzation” of patient information in the reality of Big Data help to improve health?

Given the relevance of these, and the ensuing additional issues, the lack of a shared discussion seems like a strange fact. Isolated debates exist in different places around the world, but the interest in improving health care locally as well as globally requires concrete and decisive approaches that address the issues raised and at some point should go beyond a purely theoretical framework. Using and developing the resources available to improve health care and promote traditionally neglected initiatives, such as disease prevention and health promotion, require real discussion and real action. The information resource and the regulation of its use represent a key moment for future care delivery.

AIM AND TASKS

AIM

The purpose of this dissertation is to identify major moral, ethical and regulatory issues related to ownership of patient information in the context of Big Data, to present and analyze trends in the perception of patient information as property, and to propose a just approach to ownership.

TASKS

- To present a brief historical overview of the emergence and development of the Information Revolution and Big Data;
- To analyze the importance of Big Data for the healthcare sector, as well as the major challenges, risks, benefits and opportunities;
- To analyze the role of patient information in the context of Big Data;
- To define the concept of "ownership" in the specific context of patient information and clarify its content;
- To determine the scope of the available scientific literature on the problem and identify the main concepts, theories, sources of evidence, as well as gaps in the field of study (Scoping review);
- To present and analyze trends in the perception of patient information in terms of ownership;
- To identify major moral, ethical and regulatory issues related to ownership of patient information in the context of Big Data;
- To offer a just approach to ownership of patient information.

RESEARCH HYPOTHESES

- The issue of ownership of patient information in the context of Big Data has been poorly studied in academical fields and there is no consensus on the ethical requirement for justice and the necessary legal regulations;
- The problem raised is not considered consistently and in its entirety in terms of ethical, political and regulatory steps;
- The existence of a legally recognized right of ownership of patient information would be justified in the light of individual and public interests aimed at developing and improving medical services and science;
- The issue of ownership of patient information may find a universal solution.

MATERIAL AND METHODS

MATERIAL

Various literary sources have been used to address the research problem - scientific papers, articles, lectures, presentations from scientific, academic, technological forums, philosophical interpretations and books, normative documents, sources from scientific bibliographic databases.

METHODS

The specifics of the problem under consideration in this dissertation suggest a strong theoretical justification. The following methods were used to meet the goals and objectives set:

Determining the scope of available literature (Scoping review)

Choosing the type of study

To determine the scope of the available literature on the ownership of patient information in the context of Big Data, we have carried out the so-called scoping review, which is by definition the most appropriate scientific approach for defining the scope of concepts defining a scientific field and identifying the main sources and types of evidence available, as well as the gaps in the research area.

Arksey and O'Malley provide a framework for the **methodology of preliminary reviews:**

- - Identification of the research question;
- - Identification of the studies to be used;
- - Selection of survey-relevant studies (post hoc criteria for inclusion or non-inclusion);
- - Extract relevant data from the surveys included in the survey;
- - Sorting, summarizing and presenting results;
- - Consultations (optional) - engage consumers and stakeholders with additional recommendations.

While the purpose of a full systematic review is to synthesize evidence from multiple studies and often the knowledge (and wealth) obtained from qualitative evidence is used to enhance the knowledge gained from quantitative evidence, the purpose of the preliminary review is to determine what scope of evidence (quantitative and / or qualitative) is available on the topic and, if necessary, present this evidence visually as mapping or graphs. In a complete systematic review, synthesis is an essential element and a must. In the preliminary review, synthesis is not performed, but rather summarizes the scope of the evidence found, which can be presented graphically. Another difference between preliminary and systematic reviews is that, unlike systematic reviews, preliminary reviews are intended to provide an overview of the existing evidence base, whatever its quality, ie. no formal assessment of the quality of the survey methodology is carried out.

To summarize: the preliminary review presents a preliminary assessment of the potential size and scope of the available scientific literature on the problem under study. It aims to identify the nature and extent of research evidence (usually including ongoing research) and to outline the gaps in the available literature.

According to Pearson (2004) and Munn, Stern et al. (2018), if the question of the study is related to the applicability, appropriateness, relevance or effectiveness of a particular treatment or practice, the best approach is to conduct a systematic review. However, if the question is not so precise, and the authors are more interested in identifying certain features / concepts in articles and studies and summarizing them (mapping), then a preliminary review is better.

This is also one of the reasons for choosing the preliminary review for our study - identifying certain characteristics / concepts and their generalization (in this case the scientific field of publications, aspects of ownership, meaning or perception of ownership, recommendations for solving the problem, implemented solutions).

The choice of this type of review is also dictated by the fact that ownership of patient information in the context of Big Data is a relatively new problem and there are not enough publications on the subject. One reason for the lack of publications is that this issue is not yet fully understood. On the other hand, after a quick look at the freely available Google Scholar and Researchgate, it has emerged that not many of the most recent publications on the issue under consideration (mainly technical ones that could help solve the problem under consideration) come from scientific forums, with authors mainly from China, India and the Middle East, with the corresponding collections of material from these forums not indexed in the bibliographic databases and in most cases not available in full text. Due to uncertainties about the quality of such sources, they are not included in this review.

In addition, the topic is interdisciplinary, incorporating legal, ethical, medical, information, communication, technological aspects, which implies a slightly more sophisticated search and analysis of available sources.

Much of the available publications are in refereed journals indexed in various bibliographic databases, but we have not found any reviews on the topic. As the preliminary review does not necessarily include an assessment of the quality of the sources under consideration, no such assessment was made. We have organized and reported the results in accordance with the Preferred Reporting Elements for Systematic Reviews and Meta-Analyzes (PRISMA) methodology and its Preliminary Review Extensions (PRISMA-ScR).

PRISMA is an evidence-based minimum suite of reporting elements in systematic reviews and meta analyzes. It is designed primarily for reporting in reviews evaluating randomized trials, but can also be used as a basis for reporting in systematic reviews in other research areas, in particular intervention evaluation. The package has been modified for use in conducting and reporting preliminary reviews. To illustrate the source determination process for this preliminary review, we used the PRISMA diagram (Figure 1 below).

Study protocol

As we did not find any reviews on the issue we are looking at (ownership of patient information in the context of Big Data), we chose to use Arksey & O'Malley's methodological framework to conduct scoping reviews in order to investigate the issue more thoroughly and subsequently conduct systematic reviews in this area. In this regard, we have also developed the study protocol. As this is not a systematic review, the Protocol follows both the methodological framework for scoping reviews and the relevant aspects of PRISMA for the sake of transparency and accuracy in the use of the methodology. The protocol includes: 1) Identification of the research question; 2) Identification of the sources to be studied, criteria for inclusion and non-inclusion in the study; 3) Developing a strategy for finding suitable sources; 4) Choice of sources of evidence for the study; 5) Defining the categories for classification of the sources included in the study; 6) Sorting, summarizing and presenting results.

1. Identification of the research question

Considering the fact that the problem of ownership of patient information is very current, and after a quick review of PubMed we found that the publications on the research question we had were very few, we decided to define the question (purpose) of our study a little more generally.

The purpose of this preliminary review is to determine how the medical academic community perceives the issue of ownership of patient information in the context of Big Data, the application of this concept in modern biomedical science, and possible solutions.

To achieve this goal, we identified and summarized three main focus areas of the study: 1) problem: ownership of patient information, 2) area: healthcare (medicine), and 3) context: Big Data.

2. Identification of the sources to be studied, criteria for inclusion and non-inclusion in the study

Following the recommendations of the selected methodology (Scoping review and PRISMA), as well as the pre-developed protocol for the survey methodology, we have included publications that meet the following requirements:

Eligibility criteria for the study:

1. References;

2. Publications discussing the ownership of patient (medical, health, clinical) information (data) in the context of big data;

3. Full-text publications indexed in the recognized bibliographic databases PubMed, Science Direct, Scopus and Springer;
4. Publications in English;
5. Publications from the last 10 years;
6. Publications that are article or review;
7. Publications in proceedings of congresses and conferences, which are indexed in the databases under consideration;
8. International studies or reports, incl. and beyond the databases under discussion that discuss ownership of patient (medical, health, clinical) information (data) in the context of Big Data.

Exclusion criteria for the study:
1. The publication is a study material or book (chapter of a book);
2. The publication does not address the issue of ownership in the field of medicine or healthcare and in the context of Big Data, ie. not in any of the focus areas of the study;
3. The publication does not address any of the key features we have identified in advance;
4. The publication mainly covers Big data analytics, technologies (eg Blockchain) and Big Data applications outside the medical and healthcare fields;
5. The publications focus on the problem of the human genome (this is a large scientific area that should be the goal of a separate study);

3. Strategy for finding the right sources

This process involves defining search keywords and determining the scope of the search.

We did the initial search by following the query syntax of the different databases, using terms that identified the three focus areas of the survey: ownership, health, and Big data. After a standard check of the titles, abstracts and keywords in the databases we selected, we found that for 2009 - July 2019 The three focus areas, set at the same time as keywords, define very sparse posting activity (PubMed - 8; ScienceDirect - 1; Scopus - 15; Springer - 67). This does not respond to the utmost importance and timeliness of questions and problems related to the ownership of patient information in the context of Big Data.

In order to obtain more relevant information, we have developed a search strategy. First, we expanded the scope of some of the keywords used. We have added property, and owns to ownership, as this word is included in the title of several well-known publications that are not extracted from databases without using it. We have also expanded the term "health" by adding several related terms: "patient", "medic *", "clinic *". The search strategy is tailored to the requirements and capabilities offered by the various databases. In this case, we developed and used the following search strategy (Table 1):

Table 1. Strategy for finding suitable sources in the bibliographic databases under consideration

Database	Search string	Number of publications
PubMed	(ownership OR owns) AND ("Big data" AND (health* OR patient OR medic* OR clinic*))	42
Science Direct	Find articles with these terms: (ownership OR owns OR property) В заглавието: ("big data" AND (patient OR health OR medical OR clinical)	300
Springer	(ownership OR owns OR property) В заглавието: "big data" AND (patient OR health OR medical OR clinical)	318
Scopus	ALL(ownership OR owns OR property) AND TITLE-ABS-KEY("Big data" AND (patient OR health OR medical OR clinical))	143
	Total:	803

To identify potentially relevant publications for the purposes of our study, on July 1, 2019, we searched the bibliographic databases available to us: PubMed, Springer (SpringerLink), ScienceDirect and Scopus. The search was carried out in accordance with the requirements of the individual scientific databases and on the basis of our developed search strategy. In order to obtain more accurate and relevant information, as well as to save ourselves the viewing of thousands, a priori, unsuitable for the purposes of our study sources, we used a search filter for articles, reviews, and conference proceedings, as well as a publication period (2009-2019) and language - English. In the search for Scopus and Springer, we excluded scientific fields that are not relevant to the problem (physics, mathematics, chemistry, engineering, etc.). 803 publications were identified (PubMed - 42; ScienceDirect - 300; Scopus - 143 and Springer - 318).

We used the Mendeley and Zotero bibliographic software to initially retrieve the extracted records (creating adequate lists of potentially relevant publications for the purpose of the study, eliminating duplicate records). In this way, we received the necessary files to organize all the bibliographic information that was needed.

4. Choice of sources of evidence for the study

To illustrate the source determination process for this preliminary review, we used the PRISMA diagram (Figure 1). Following the PRISMA framework and recommendations, through Mendeley, we removed all duplicate entries and created adequate lists / bibliographies of all publications selected for the study. After removing duplicate records, the total number of all usable publications of 803 went to 717 (from PubMed - 37; from Scopus - 131; from ScienceDirect - 268 and from Springer - 281).

After reviewing the file of all potentially relevant publications (717) containing bibliographic information for each of them, a few more publications were removed manually: with duplicate titles (11), non-abstract publications (19), and non-full publications (85), publications other than articles, reviews or full-text articles published in refereed journals and collections (43), publications not related to Big Data and data ownership in the healthcare field (433). 126 full-text English-language publications remained for detailed study.

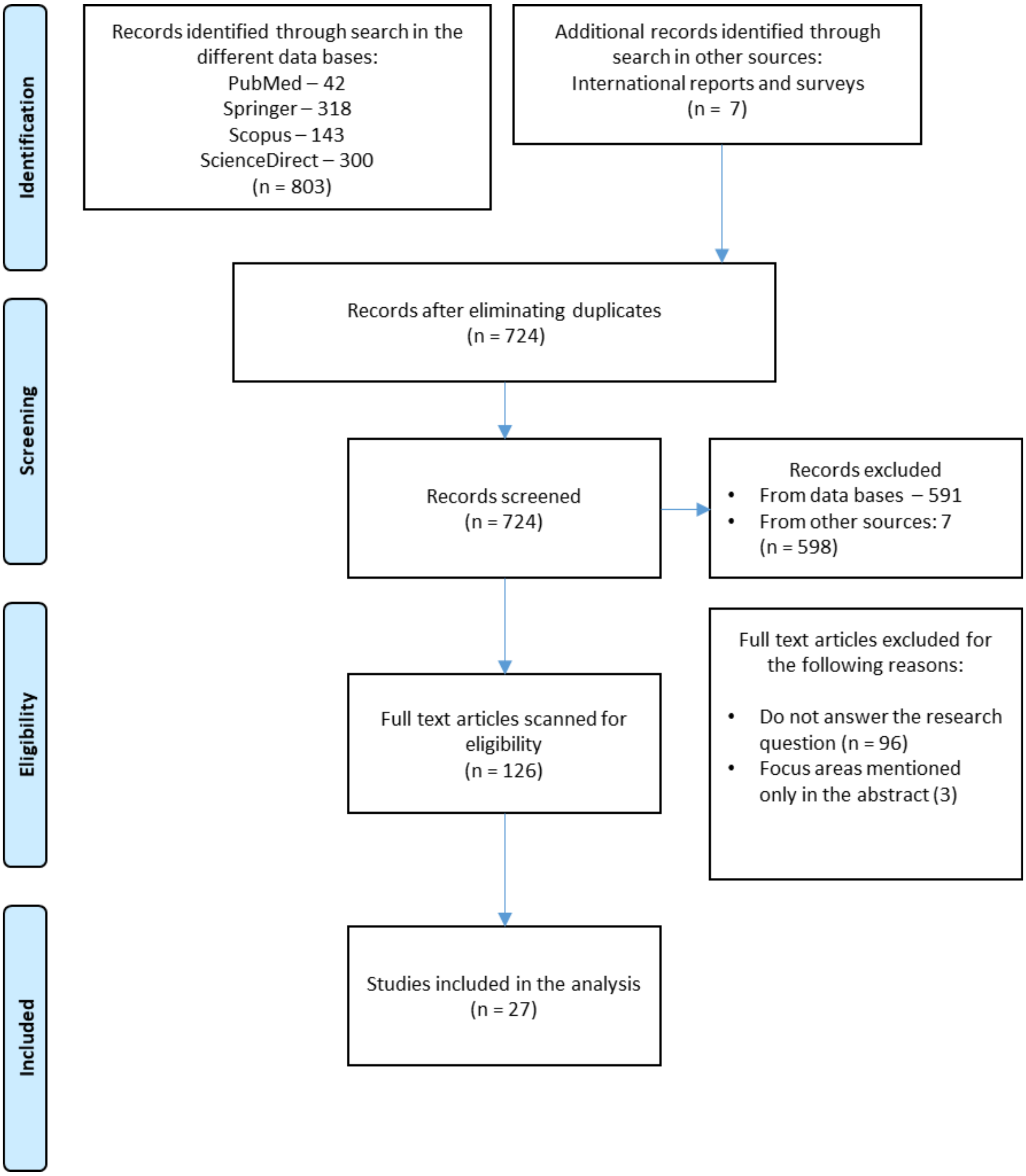

Figure 1. PRISMA diagram - process of selecting sources of evidence for the study.

5. Categories for classifying the sources included in the study

In order to resolve the scientific issue of the study and to carry out the relevant analysis, we have selected the following standard categories of information from the publications in question:

1. Author (s);
2. Year - Year of publication;
3. Title - Title of the publication;
4. Place of work / institution of the authors (Academy, Industry, Trade);
5. Country - Country from which the authors are. If the authors are several and from different countries, the country and institution of the corresponding author shall be taken;
6. Type of publication (journal article / review, congress / conference report, etc.);
7. Edition of the article (the name of the magazine);
8. Scientific bibliographic database in which the publication is indexed;
9. Publishing house;

The next step in the methodology was to define the categories for classifying publications and outlining the scope of available scientific literature on the problem under study in this study. The selected categories are based on existing literature or generated when reviewing the included publications. All 126 publications scheduled for inclusion in the analysis were carefully reviewed summaries, introductions and conclusions and, where appropriate, the entire text, and as a result, we identified the following additional research questions:

- In what scientific area is commenting on the ownership of patient information in the context of big data?
- How is ownership of patient information perceived in the context of Big Data?
- What are the main aspects of ownership of patient information in the context of big data?
- Are there any recommendations, if any, to address the issue of ownership of patient information in the context of big data?
- If so, what are the specific applications for addressing patient ownership in the context of big data?

Based on how you define the questions, we have identified the following categories for classifying publications and outlining the scope of available scientific literature on the problem studied in this study:

10. Scientific **area** of publication in health and medicine;
11. **Aspects** of ownership;
12. **The meaning (perception)** of ownership;
13. **Recommendations** for resolving issues related to ownership of patient information in the context of Big Data;

14. **Applications** developed and proposed to address patient data ownership issues in the context of Big Data.

We organized all 14 categories into a working file in Excel, with categories 1-9 completed for all 126 publications. Each of the 126 publications was reviewed individually and 99 publications were removed under the study protocol, which do not affect all three focus areas of this study: Ownership (and derivatives), Health (and derivatives) and Big data ”. Thus, the total number of publications that remained for inclusion in our study was found to be 27.

In the final stage of reviewing and retrieving the necessary information according to the defined categories for classifying publications and outlining the scope of the study, all 27 publications were very carefully read and classified according to the defined additional categories (10-14).

This review found that all publications were widely cited and published in scientific journals with an impact factor. Given the extreme importance of the issue under consideration and the fact that such bibliometric indicators suggest high quality of the sources themselves, we included two additional categories in our analysis:

15. **Impact factor** of the magazine;
16. **Quotations** of the publication.

All 27 publications were reviewed in the scientific databases and / or the websites of the scientific journals in which they were published to establish citations. For the journals in which the selected articles were published, their respective impact factor was also recorded. The corresponding values were recorded in the working file (categories 15 and 16).

6. Sorting, summarizing and presenting results

We used a descriptive approach to synthesize the results of the study. For the numerical summaries corresponding to the categories studied with respect to the subject of this study, we used an alternative analysis. Given the small number of sources included in the study (n = 27), we presented the main results mainly in tabular form.

Historical method for analyzing the evolution of the Information Revolution and Big Data

The historical method underpins the theoretical rationale in this work, as it addresses key research questions. This historical approach seeks to identify the relationship between past events, practices and ideas, trends, fears about the future and use of information, and their actual manifestations in the present. Documenting patient information is a relatively modern phenomenon in Western medicine. The advent of the Information Revolution, which can be tentatively dated back to ancient times, to the culmination of Big Data at the end of the twentieth century, requires, in essence, historical analysis before turning to contemporary trends.

On the other hand, the specifics of the issue under consideration imply justification through and work with multidisciplinary literature. This peculiarity largely determines why the sources used in the analysis are diverse in terms of historical and scientific literature, which identifies some of the more important moments in history related to the collection and use of information arrays, as well as the technical and technological innovations today.

Other works and publications of different authors and authorities have been reviewed, which have commented, evaluated and contributed directly or indirectly to the debate on the problem. Among these authors are philosophers, doctors, lawyers, economists, specialists in information technology and public health. The historical method considers the origin and development of the Information Revolution and Big Data as products of historical regularity and social relations and covers a period of approximately 400 years, between the seventeenth and twenty-first centuries.

Documentary method for analyzing regulatory documents

The issue of ownership of patient information, though poorly debated, receives a much broader legal (and not just legal) debate in the US than Europe. However, interest in this matter is essentially global, making isolated debates insufficient. Although there are legislative decisions in the US (HIPAA law) and other countries, including within the European political space, regarding the exchange, protection and use of personal data, none of the Directives or Regulations and laws directly addresses the ownership status of patient information. In this regard, a comparative analysis of the scope and some of the specifics related to the protection and use of the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the GDPR European Data Protection Regulation was carried out. The purpose of the documentary analysis is to clarify how the patient information is treated, what rights the information subjects and other interested parties have, and how the patient data is protected.

The problem raised concerns topics which, due to the conditions and trends of our times, have become extremely delicate matter. Although the line of analysis is oriented towards real practice through moral and ethical reflection, it would be pointless if it does not rely on specific results and regulations.

Philosophical analysis of the concept of ownership of patient information

Analyzing the questions raised is based on ethical requirements, suggesting an appropriate interpretation according to the specific field in which - in this case - healthcare is used, and the distinctive problem they are considering - ownership of patient information. Better understood as a broader approach to researching a problem, than strictly methodological, the philosophical, and more specifically, ethical analysis and argumentation aim to challenge - to support or argue against - characteristic or stereotyped, often vague, positions and assumptions that stand in the basis of an area of study. The approach is important to the problem posed in this dissertation, as it uses the tools of argumentation drawn from philosophical traditions, concepts, models and theories, in order to criticise and challenge. Such tools are, for example, the logic and evidence in academic debate, analyzing arguments on fundamental issues, or discussing the root of an existing debate on a particular research issue. This research method involves the application of some basic philosophical teachings, such as ontology, epistemology, axiology, and anthropology.

The ontology describes the nature of reality - what is real and what is not; what is basic and what is derivative. This is important in view of the idea of proposing a specific solution to the problem of ownership of patient information, based on an adequate assessment of reality - in this case, a reasonable balance between the goals, opportunities, risks, rights and interests of public institutions and individuals, which depends to a large extent on the public organization. In this sense, the Social Ontology explores the nature and properties of the social world. It deals with the analysis of the various subjects in the world that arise from social interaction. An important topic in social ontology is the analysis of social groups. Are there any social groups at all? If so, which are the building units, and how are they created? Is the social group different from the sum of the people who are its members, and if so, what is different? What does it take for a group to believe, intend or act, and above all to determine their interests? The consideration of such issues in this dissertation helps to identify how group interest is formed when too personal data is involved, and is there a possible compromise between individual and group interest when it comes to exploiting sensitive information in the specific information environment of the Big data and health needs.

Epistemology is a science that deals with the nature of knowledge: by what means we know and understand, and how we can be sure of it. Epistemological research in this work will focus (where possible) on real evidence, both in terms of the benefits and risks of real or potential decisions regarding the regulation of patient information. Like social ontology, epistemology also has a social application. According to one perspective, social epistemology is a branch of traditional epistemology that studies the epistemic properties of individuals that arise from their relationships with others, as well as the epistemic properties of groups or social systems. One example (of the first kind) is the transfer of knowledge or right from one person to another. Studying such interpersonal epistemic relationships is a legitimate part of epistemology. This is where the idea of social constructionism comes from, and this teaching assumes that meanings and knowledge develop in coordination with others, not individually in each individual. In this way, through interactions with others, we form a real (or not) idea of the information and the possibilities for its use. As far as the use of patient information we perceive as particularly personal is concerned, an epistemological approach would help to outline a realistic framework and highlight the real benefits of utilizing medical data. The problem of ownership of this data is concerned with analyzing whether ownership would help to better understand the possible uses; whether "propertysation" in general would bring more benefits, or could it be problematic in modern societies that are too sensitive to the idea of "owning" things. The analysis here is build on the real-unreal axis, but it also raises the question of whether we can require people to have the same capacity to understand the social and scientific value of medical information, as well as the technological possibilities for utilizing it.

Axiology is a philosophical doctrine of the nature of values, which looks at what values individuals and groups hold and why. In this case, it is interesting to consider how values relate to needs, interests, life experiences and practices related to sensitive elements, such as medical and other related personal information. This has to do with protecting the individual from the misuse of data, property claims, and last but not least, the public interest. An axiological approach can help to find out whether it is possible to think of a universal solution to the problem of ownership and regulation of patient information, or in a world where not everyone moves at the same speed and does not always share same values, it is more reasonable to talk about solutions at a more local level.

Anthropology, as a philosophical study on nature of man, also plays an important role because it examines not only the individual but also his relationships with others in society. Behind the focal issue of ownership of patient information and the dynamic Big Data information environment, there are a number of diverse relationships in which intersubjectivity is a characteristic segment - how two people, entities, or two parties in a relationship whose experiences and interpretations of the world are different, understand and relate to each other. On the other hand, how does the individual relate to contemporary technological realities and opportunities. The issue of ownership of patient information and its peculiarities depend to a large extent on interpersonal interactivity and exchange - the creation and transmission of information for the sake of any benefit. It is through the practice of exchange that the issue of ownership is most visible. What is at stake in the debate over ownership and use of data is not only the legal status of data as property, but also its social role as an artifact of exchange.

Ethical analysis based on the main principles in contemporary biomedical ethics

The distinctive issues involved in this dissertation, as well as the need for ethical guidance according to the information conditions of modern healthcare, affect in various ways the basic principles in biomedical ethics: autonomy, non-maleficence, beneficence and justice.

The principle of respect for the autonomy of the individual is used in connection with the right to make informed choices, the ability of individuals to exercise control over their lives, and privacy. The concept of autonomy and the principle of respect for autonomy relate to individuals and their ability to make decisions in relation to their health, as well as in research that require the use of their health information, taking into consideration the close link between autonomy and decision-making given the right to consent and refuse. For their part, the subjects of information - patients, are viewed primarily as persons, but also as objects or participants in different relationships (with medical professionals, with institutions, with others, with social networks, etc.). The use of patient information is not always solely related to the needs and interests of the patient to whom that information relates. Increasingly, there are hidden uses for which there is a lack of awareness and transparency, which are important and valuable for various research and experiments, but also for commercial purposes and activities, which potentially conflicts with the idea of an autonomous person. This affects both patient data and their residual medical samples stored in biobanks.

Although the traditional arrangement of ethical principles begins with that of autonomy, this does not necessarily mean that it has priority over others, or over other specific moral considerations. The principle of respect for autonomy in the context of ownership of patient information should not be excessively "individualistic" (to the extent that the social nature of individuals and the impact of individual choices and actions on others is neglected) should not be overly "reasonable" (to the point that it completely ignores emotions), nor should be excessively "legitimate" (emphasizing on legal rights), while downplaying social practices and responsibilities that are not necessarily legally regulated.

Non-maleficence (no-harming), which has traditionally been considered a fundamental principle in the Hippocratic tradition, requires a major abstention from harming individuals. In the case of ownership of patient information, harm is considered when making responsible decisions that affect both the interests of individuals and those of the community, especially in initiatives that may prove to be key in the healthcare sector. This principle offers at least two points of view in the context - what can be considered as harm to the individual (non-recognition of property rights) can be beneficial to the collective (the opportunity to benefit from the lack of legal ownership of the information), and vice versa - the individual benefit of hindering one for the community. This deals with the specific notion of harm, which in this case may lead to undesirable consequences for individuals from the unwanted or inconsistent use of their data, or from the lack of consent and transparency for such use. Another potential harm when patient information is used without the patients themselves having any control over it is its commercial use and the generation of profits from third parties. Non-maleficence with regard to the ownership of patient information will need to be directed towards a balanced solution for the individual and the community who are interested in using the medical data. Requiring no-harm in this context leads to the next necessary step - contributing benefits.

Beneficence involves the provision of care, which, in contrast to non-harming, also involves the prevention of such harm, and not just abstaining from harming. Morality requires not only respect for autonomy and non-maleficence, but also actions that contribute to the well-being of people. Closer to the problems raised in this dissertation, beneficence is also relevant to the fact that decisions regarding the constitution and use of patient information should not only be aimed at avoiding harmful consequences for individuals and the community, but should also aim for real benefits at the same time as preventing potential or already occurring harm. The principle of beneficence can be applied in its two main varieties - as positive beneficence and as a utility - a balance between costs, harms and benefits. In this sense, utilization in the use of patient information presupposes, through an analysis based on harm and benefit, harm and alternative harm, as well as the benefit and alternative benefit to individuals and society, to a situation that minimizes risks and harm, and maximizes benefits.

Justice in biomedical sense has traditionally been linked to inequalities in access to health and health status, and also requires a fair distribution of resources and responsibilities, as well as of goods and burdens in society. In the case of ownership of patient data, this principle addresses the points of view of protecting the interests and claims of individuals and the community. The principle of justice plays a key role in determining the priorities that need to be identified with regard to the use of patient information.

Considering the issue of patient information through the lens of fundamental principles of medical ethics reveals another perspective - that the approach to regulating the ownership of that information may be in some ways utilitarian, because the results of certain decisions and actions will be too important, therefore, maximizing benefits and minimizing harms (risks) when discussing patient information regulation is a priority. Philosophical and ethical analysis can provide a basis for the application of ethical decisions in practice, as it allows clarification of guiding principles and practices affecting the individual and the group.

ANALYSIS (RESULTS AND DISCUSSION)

DEFINING THE SCOPE OF AVAILABLE LITERATURE ON OWNERSHIP OF PATIENT INFORMATION IN THE CONTEXT OF BIG DATA (SCOPING REVIEW)

Results

This study included 27 sources. The source determination process is presented in the PRISMA diagram of Figure 1 above. The list of sources used in this study is presented as an Appendix.

Main characteristics

The main characteristics of the publications included in this study are presented in Table 2.

The publications are arranged in alphabetical order of the surname of the first / correspondent author (in the table we use the surname, initials of the first name and country of the first or correspondent author).

Table 2. Main characteristics of the publications included in the study

Autor (s)	Number of the publication in the analysis	Number in application	Year	Country	Institution	Type of publication
Andreu-Perez, J., et al.	[C1]	[1]	2015	UK	Academy	Article
Asche, C.V., et al.	[C2]	[2]	2017	USA	Academy	Article
Balthazar, P., at al.	[C3]	[3]	2015	USA	Academy	Article
Bietz, M.J., et al.	[C4]	[4]	2018	USA	Academy	Article
Cvrkel, T.	[C5]	[5]	2019	USA	Academy	Article
Esmaeilzadeh, P. & Mirzaei, T.	[C6]	[6]	2018	UK	Academy	Review
Heitmueller, A., et al.	[C7]	[7]	2014	UK	Academy	Report
Hölbl, M., et al.	[C8]	[8]	2018	Slovenia	Academy	Article
Hunter, P.	[C9]	[9]	2016	UK	Other	Article
Ienca, M., et al.	[C10]	[10]	2018	Switzerland	Academy	Article
Kaplan, B.	[C11]	[11]	2016	USA	Academy	Article
Kaplan, B.	[C12]	[12]	2015	USA	Academy	Article
Kish, L.J. & Topol, E.J.	[C13]	[13]	2015	USA	Scripps Research	extended comment
Kostkova, P., et al.	[C14]	[14]	2016	UK	Academy	Article

Kruse, C.S., et al.	[C15]	[15]	2017	USA	Academy	Review
Kulynych, J. & Greely, H.T.	[C16]	[16]	2017	USA	Academy	Article
Maher, N.A., et al.	[C17]	[17]	2019	USA	Academy	Article
Mamoshina, P., et al.	[C18]	[18]	2017	USA	Academy	Article
Mikk, K.A., et al.	[C19]	[19]	2017	USA	MITRE - Research	View
Mittelstadt, B.D. & Floridi, L.	[C20]	[10]	2015	UK	Academy	Review
Roehrs, A., et al.	[C21]	[21]	2017	Brazil	Academy	Article
Timmins, K.A., et al.	[C22]	[22]	2018	UK	Academy	Review
Vayena, E., Blasimme, A.	[C23]	[23]	2017	Switzerland	Academy	Article
Vazirani, A.A., et al.	[C24]	[24]	2019	UK	Academy	Article
Viceconti, M., et al.	[C25]	[25]	2015	UK	Academy	Article
Yaffe, M.J.	[C26]	[26]	2019	Canada	Academy	Article
Yue, X., et al.	[C27]	[27]	2016	China	Academy	Article

Bibliometric characteristics

The bibliometric characteristics of the publications included in the study are presented in Table 3.

Table 3. Basic bibliometric characteristics of the publications included in the study

Number of the publication in the analysis	Number in application	Year	Type of edition	Edition	IF*	Number of citations**	Data Base**
[C1]	[1]	2015	magazine	IEEE Journal of Biomedical and health informatics	4,217	41	Pubmed
[C2]	[2]	2017	magazine	Pharmacoeconomics	3,705	7	Pubmed
[C3]	[3]	2015	magazine	J Am Coll Radiol.	3,785	22	Scopus
[C4]	[4]	2018	magazine	J Am Med Inform Assoc	4,292	0	Scopus
[C5]	[5]	2019	magazine	Journal of Dentistry	3,28	0	Scopus
[C6]	[6]	2018	magazine	J Med Internet Res.	4,945	6	PubMed
[C7]	[7]	2014	magazine	Health Affairs	5,711	26	Scopus
[C8]	[8]	2018	magazine	Symmetry	2,143	14	Scopus
[C9]	[9]	2016	magazine	EMBO Rep.	8,383	4	PubMed
[C10]	[10]	2018	magazine	PLoS ONE	2,776	3	PubMed
[C11]	[11]	2016	magazine	Camb Q Healthc Ethics.	0,941	3	PubMed

[C12]	[12]	2015	magazine	Camb Q Healthc Ethics.	0,941	4	PubMed
[C13]	[13]	2015	magazine	Nat Biotechnol.	31,86	39	Scopus
[C14]	[14]	2016	magazine	Front. Public Health	2,031	18	Pubmed
[C15]	[15]	2017	magazine	JMIR Med Inform	3,188	19	Pubmed
[C16]	[16]	2017	magazine	J Law Biosci.	2,431	9	Scopus
[C17]	[17]	2019	magazine	International Journal of Medical Informatics	2,731	0	SD
[C18]	[18]	2017	magazine	Oncotarget.	3,046	31	Scopus
[C19]	[19]	2017	magazine	JAMA	51,27	5	Scopus
[C20]	[10]	2015	magazine	Sci Eng Ethics	1,859	92	Scopus
[C21]	[21]	2017	magazine	J Med Internet Res.	4,945	0	Pubmed
[C22]	[22]	2018	magazine	International Journal of Obesity	4,514	1	PubMed
[C23]	[23]	2017	magazine	Journal of Bioethical Inquiry	1,592	17	Springer
[C24]	[24]	2019	magazine	J Med Internet Res	4,945	2	PubMed
[C25]	[25]	2015	magazine	IEEE Journal of Biomedical and health informatics	4,217	15	PubMed
[C26]	[26]	2019	magazine	Seminars in Nuclear Medicine	3,798	1	SD
[C27]	[27]	2016	magazine	J Med Syst.	2,415	157	Springer

* IF value presented may differ from that for the relevant issue year
** The number of citations is for BDB only, indicated in the table

Additional categories to outline the scope of available scientific literature on the research issue under study

The categories outlining the scope of the study (***scientific area*** of publication; ***ownership aspects***; ***sense (perception)*** of the subject; ***recommendations*** for resolving patient data ownership issues in the context of Big Data; ***annexes***) are presented in Table 4.

Table 4. Main characteristics of the publications included in the study, according to the categories for determining the scope of available scientific literature on the studied problem in the study

Number of the publication in the analysis	Number in application	Scientific field	Aspect	Sense (perception)	Solution	Application
[C1]	[1]	Scientific research	Legal	Challenge	Yes	No
[C2]	[2]	Scientific research	Ethical	Challenge	Yes	No
[C3]	[3]	Scientific research	Ethical	Challenge	Yes	No

[C4]	[4]	Scientific research	Political and legal	Challenge	Yes	No
[C5]	[5]	Ethical question in the context of Big Data	Ethical	Challenge	Yes	No
[C6]	[6]	Scientific research	Ethical	Challenge	Yes	No
[C7]	[7]	Using Big Data in healthcare	Political (Health policy)	Challenge	Yes	No
[C8]	[8]	Application of blockchains	Political (Health policy)	Control over data	Yes	No
[C9]	[9]	Scientific research	Legal	Challenge	Yes	No
[C10]	[10]	Scientific research	Ethical	Ethical challenge	Yes	No
[C11]	[11]	Scientific research	Ethical	Threat	Yes	No
[C12]	[12]	Scientific research	Legal, ethical	Problem	Yes	No
[C13]	[13]	Ownership and control	Legal, ethical	Opportunity	Yes	No
[C14]	[14]	Scientific research	Political (public policy)	Challenge	Yes	No
[C15]	[15]	Using Big Data in healthcare	Managerial	Challenge	No	No
[C16]	[16]	Scientific research	Legal, ethical	Challenge	Yes	No
[C17]	[17]	Scientific research	Ethical	Challenge	No	No
[C18]	[18]	Scientific research	Legal	Control over data	Yes	No
[C19]	[19]	Ownership and control	Ethical	Control	Yes	No
[C20]	[10]	Ethical question in the context of Big Data	Ethical	Control	No	No
[C21]	[21]	Medical records	Ethical	Challenge	Yes	No
[C22]	[22]	Scientific research	Ethical	Challenge	Yes	No
[C23]	[23]	Scientific research	Ethical	Control	Yes	Yes
[C24]	[24]	Medical records	Legal, ethical	Challenge	Yes	Yes
[C25]	[25]	Scientific research	Legal, ethical	Problem	Yes	No
[C26]	[26]	Scientific research	Ethical	Challenge	Yes	No
[C27]	[27]	Application of blockchains	Legal, ethical	Challenge	Yes	Yes

Analysis and discussion

Main characteristics

The publications are from 2014-2019 - **1** from 2014 [C7]; **6** of 2015 [C1], [C3], [C12], [C13], [C20] and [C25]; **4** of 2016 Fit [C9], [C11], [C14] and [C27]; 7 of 2017 [C2], [C15], [C16], [C18], [C19], [C21] and [C23]; 5 of 2018 [C4], [C6],

[C8], [C10] and [C22]; **4** for the first half of 2019 [C5], [C17], [C24] and [C26]. Considering that for the first half of 2019 the number of publications is close to the average in the previous years, we could expect an increase in the number of publications in the study area. Moreover, applications using Big Data in medicine and healthcare are steadily increasing, which will inevitably lead to an increase in the scientific developments regarding patient data ownership in the context of Big Data, as an important condition for the adequacy of the respective applications.

Almost all publications are from authors employed by academic institutions (25 or 92.59%), with only 2 (7.41%) coming from research centers [C13], [C19]. These are scientific institutes known for their developments in the fields of medicine and health, respectively Scripps Research and MITRE Research, both from the United States.

As might be expected, the publications are mainly from authors from the USA and the UK. About half of the publications (12 or 44.44%) are from the US ([C2], [C3], [C4], [C5], [C11], [C12], [C13], [C15], [C16], [C17], [C18], [C19]); and from the UK they are 9 (33.33%) - [C1], [C6], [C7], [C9], [C14], [C20], [C22], [C24] and [C25]. These are the countries where most work is done on the protection of confidentiality and ownership of medical data. In fact, these are also the countries with the most experience and traditions in the field of medical and health informatics and in which ICTs are most widely implemented in the field of medicine and healthcare, with electronic medical (personal) records being widely used. Two publications are from Switzerland [C10], [C23], one from Brazil [C21], Canada [C26], China [C27] and Slovenia [C8].

The majority of publications, as defined by the scientific publication, are articles (20 or 74.07%), only 4 (14.81%) have been officially published as reviews [C6], [C15], [C20] and [C22] and one report [C7], extended commentary [C13] and point of view [C19]. The latter have been included in the study as they represent extremely important aspects of ownership of patient information and have been repeatedly cited.

Bibliometric characteristics

All the sources included in the study are published in scientific journals that are indexed in one or more scientific bibliographic databases, in this case, the databases in which we have searched for sources suitable for the study: PubMed, Scopus, ScienceDirect and Springer. All of the publications included in the study were from Impact Magazines.

Almost all of the publications were cited, with 12 (44.44%) publications with high citation (more than 10 citations). Only 4 (14.81%) have not been cited, but these are relatively recent publications (1 from 2017, 1 from 2018 and 2 from 2019). The other 11 publications have been cited between 1 and 9 times.

The publications have been published in various scientific journals, with 10 (37.04%) being in journals in the field of health and medical informatics [C1], [C4], [C6], [C7], [C15], [C17], [C21], [C24] and [C25]. This can be explained by the fact that magazines in this field address the medical problems associated with the use of modern information and communication technologies. To these could be added the journals of molecular biology, biomedicine, biotechnology, genetics, mathematics (4 or 14.81%) [C8], [C9], [C10] and [C13]. There are 8 (29.63%) publications in the field of medicine and public health [C3], [C5], [C14], [C18], [C19], [C22] and [C26], and in the field of ethics, law and policy is only 5 (18.52%). It can be said that articles dealing with the problem of ownership of patient information in the context of big data are published by the academic community in the journals of two main areas - modern information and communication technologies in medicine (health and medical informatics) and medical ethics and law. We do not comment here on the many publications in technical scientific journals, since they do not address the issue of ownership of medical data at all, as well as journals that are mainly ethical or legal, as they are highly specialized, which makes them poorly cited and accordingly without the impact factor.

Scientific field

Although the issue of ownership of patient information in the context of big data is extremely important, it appears that the academic community's interest in it is not very high. Thousands of publications on Big Data, including Big Data in Health and Medicine, included in our bibliographic databases, found that only 27 concern the issue of ownership of medical data. From the analysis made, we have identified the following scientific areas in which the publications reviewed can be classified (Table 5):

Table 5. Distribution of the publications in question according to the scientific field in which they are classified

Field	Number (relative share)	Publications
Scientific research	17 (62,96%)	[C1], [C2], [C3], [C4], [C6], [C9], [C10], [C11], [C12], [C14], [C16], [C17], [C18], [C22], [C23], [C25], [C26]
Medial records	2 (7,41%)	[C21], [C24]
Using Big Data in healthcare	2 (7,41%)	[C7], [C15]
Application of blockchains (ICT)	2 (7,41%)	[C8], [C27]
Ownership and control	2 (7,41%)	[C13], [C19]
Ownership as ethical issue in Big Data	2 (7,41%)	[C5], [C20]

Only two publications examine the ownership of medical data on their own, without this being part of another study. Both publications concern the area of *ownership and control* of medical data. One examines why patients should own medical data [C13] and the other explains why patients deserve to own and control their medical data [C19].

As expected, publications (17 or 62.96%) in the field of research have the highest share, with publications commenting on the ownership of medical data, both in the context of Big Data and other aspects. The main issues addressed are related to:

- *medical studies*, including clinical trials [C1]; biomedical research [C18], [C23]; biomedical calculations [C25]; Obesity research [C22] and medical imaging [C26];
- *access to and use* of medical / health data for research, including the use of personal health data (from wearable devices) [C4], validation and linking of data [C2], [C3], data sharing [C6] and sharing and linking, opening medical research data [C14];
- *secondary use* of medical data for research, including the sale of health data [C11], [C9]; marketing [C12]; genetic data [C16]; use of passive data (data generated from different devices) [C17];
- *ethical challenges* to Big Data in medical and biomedical research [C10];

Two of the publications are in the field of medical records, including the interaction of patients with their personal health records [C21] and the use of blockchains to solve medical record problems [C24].

The other two publications are on the use of Big Data in healthcare, one discussing the development of public policies for the use of big data in healthcare [C7] and the other the challenges and opportunities of big data in healthcare [C15].

Another area is the application of blockchains and other healthcare information and communication technologies, namely: research into the use of blockchains in healthcare [C8] and an application using a blockchain architecture that allows patients to own, control and securely exchange their own its data [C27].

Two publications consider ownership as an ethical issue in the context of Big Data, one paying particular attention to ownership of medical data as one of the important ethical issues related to big data [C20] and the other addressing data access and data ownership issues in mHealth applications [C5].

Aspect

The aspects where publications view ownership of medical data are not clearly distinguished but can be summarized as: ethical, legal, political and managerial, and in combinations such as legal and ethical and political and legal (Table 6):

Table 6. Distribution of the publications under consideration according to the aspect in which they consider ownership of patient information

Aspect	Number (relative share)	Publications
Ethical	13 (48,15%)	[C2], [C3], [C5], [C6], [C8], [C10], [C11], [C17], [C19], [C20], [C21], [C22], [C23], [C26]
Legal	5 (18,52%)	[C1], [C9], [C13], [C18], [C27]

Legal and ethical	4 (14,81%)	[C12], [C16], [C24], [C25]
Political	3 (11,11%)	[C7], [C14]
Political and legal	1 (3,70%)	[C4]
Managerial	1 (3,70%)	[C15]

This is understandable given the nature of the issue under consideration. Set as ethical in order to be resolved, the (co-)operation of legal and political institutions, as well as the capabilities of modern technologies, is needed. *This illustrates a consistent structure from problem to solution - the first step is ethical analysis and the determination of right / wrong, useful / harmful, fair / unjust; the second step is a subsequent public and political debate; the third step is a rulemaking act.*

In most publications (19 or 70.37%), ownership of patient data, whether primary or secondary, is considered ethically, legally or legally and ethically. The legal and the ethical are not necessarily the same, as Kaplan [C12] points out, but their common ground must be found with regard to property.

Expectedly, the largest share is of publications that consider the ownership of patient information in the context of Big Data in an ethical aspect. Data has been created and used since the beginning of civilization, but what is changing is the speed at which we create and store data, and the fact that we already have not only methods but also the processing capacities that allow us to extract useful information from this vast amount of data. Hence one of the main ethical questions regarding data - who owns it and how can it be used? It is the ownership of patient / medical data in the context of Big Data as an ethical aspect that underlies about half of the publications (13 or 48.15%): [C2], [C3], [C5], [C6], [C8], [C10], [C11], [C17], [C19], [C20], [C21], [C22], [C23], [C26].

About one fifth of publications (5 or 18.52%) consider ownership of medical data in legal terms [C1], [C9], [C13], [C18], [C27]. According to Hunter [C9], as the volume and scope of personal health data that is collected increases, the greatest requirement is greater transparency regarding the use of that data, which should be harmonized. According to Kish and Topol [C13], in order to realize the benefits of digital medicine, it is necessary not only to find a common home for personal health data, but also to give individuals the right to own it, but also the issue of personal identity. data is a historical challenge for lawyers. Added to this is the question of whether personal data, in particular biological data, is a form of property that is bought and sold. Mamoshina [C18] states that patients have no control over access to their medical records and do not know the true value of the data they have, which is a real challenge for regulators and the idea that they should own it. It cannot be determined whether a proprietary regime that allows total control of the data would actually be the best solution for patients, provided that medical information may be an enigma for them.

Four publications (14.81%) view property as a legal and ethical issue [C12], [C16], [C24], [C25]. According to Kaplan [C12], individuals should at least know how their own data is collected and used. Moreover, it is not legally settled whether the data are merely "spoken words" or "property". Consideration should be given to how this data is used and the ethical development of social norms and laws, as new technologies affect the integrity and protection of health data.

Two articles look at property in political terms [C7], [C14]. Heitmueller [C7] views ownership as a political lever - relinquishing ownership of patient data will improve health and also control health data sharing. Allowing the patient to control his or her health data can also be a valuable alternative to the difficult task of making the existing healthcare system work. With respect to opening up data to medical research, Kostkova [C14] points out that there are no transparent legal rules regarding ownership of user-generated data, which are at the same time becoming a thriving business for the social media industry and outline two radically different approaches data ownership, use and sharing: first, government-regulated clinical and research medical data (including individual and government data collected by government organizations) and, second, private health data generated by users collected from social media, applications, online searches and wearable devices.

A publication looks at data ownership in a slightly different aspect - managerial. According to Kruse [C15], data management and data ownership will need to move to the organization's priority list and should be treated as a core asset of the business instead of a by-product. In fact, this idea is not new and more and more researchers are supporting it. Several publications discuss the sale of medical data - for research, both medical and pharmacy [C9], [C11], [C12], [C14], [C18].

Only one publication discusses a study among patients and researchers on the barriers to the use of personal health data for research purposes, with data ownership being considered ethically as well as legally [C4].

Meaning

In two-thirds of publications (18 or 62.96%) ownership of patient data is considered challenging; as a problem - in 2 publications; as a control tool - in 5 publications; threat and opportunity - one publication (Table 7).

Table 7. Distribution of the publications under consideration in terms of ownership of patient information

Sense (perception)	Number (relative share)	Publications
Challenge	18 (66,67%)	[C1], [C2], [C3], [C4], [C5], [C6], [C7], [C9], [C10], [C14], [C15], [C16], [C17], [C21], [C22], [C24], [C25], [C26],
Means of control	5 (18,52%)	[C8], [C18], [C19], [C20], [C23]
Problem	2 (7.42%)	[C12], [C27]
Threat	1 (3,70%)	[C11]
Opportunity	1 (3,70%)	[C13]

Obviously, ownership of health data is taken first and foremost as a *challenge*. This was reported in 18 (66.67%) of the surveyed sources.

Ownership of medical data is generally considered a challenge to perform *medical research* [C3], [C4], [C9], [C16], including in the field of obesity [C22], medical imaging [C26], and the *use of passive medical research data* [C17] and the *secondary use of medical data for research*, especially in the field of the human genome and electronic medical records [C15].

Data access challenges, such as data ownership, data security and data value, are often also a barrier to access [C2], [C5], data exchange [C6], access to electronic medical records [C24], and the use of personal health data [C21].

Data ownership, along with data privacy, privacy and security, as well as data management are a serious social and legal challenge to big data [C1].

In several articles, ownership of medical data is taken as a *challenge to policy* [C7], an *ethical challenge* [C10] and a *challenge to modern technologies* [C25], a *challenge to medical research and business* (sales and data sharing) [C14]. In fact, the link between medicine and business, most often expressed in the sale of medical data - both for medical research and research in pharmacoepidemiology and for commercial purposes - is a growing trend [C9], [C11], [C12], [C14], [C18].

Apart from being a challenge, ownership of health data is also seen as *control* [C19], [C20], [C23], controlling access to data [C8], and controlling data for biomedical research [C18].

Two publications view the ownership of medical data as a *global problem* (along with the use of health data, patient and clinical data protection) for biomedical informatics, patient and physician integrity, and regulatory authorities [C12] and as a problem (deficiency) of the use of modern blockchains technologies [C27].

Ownership of medical data is also seen as a threat to the secondary use of data, especially when selling health data [C11].

Ownership of medical data as a civil right is also seen as an opportunity or strategy for the further digitalisation of medicine [C13].

The solution

A solution to the issue of ownership of patient data is available in 24 (88.89%) publications. Only three publications do not offer such a solution [C10], [C21] and [C22]. In fact, apart from the application of different, mainly new technologies, the solutions are rather proposals to the government and the governing bodies of the healthcare institutions and are primarily concerned with finding consensus between ethical and legal aspects, in most cases mainly related to the right to ownership and control of patients on their own data and protection of data integrity. According to Vayena, [C23] control of information has one typical individual right, and that is property. It is widely acknowledged that a person has control over what is his or her or, in other words, ownership gives rise to the privilege of exercising some exclusive form of direct control over what he owns. This intuition also establishes the conceptual link between control and ownership.

The proposed solutions can be summarized in the following categories: *technology*, *law*, *policy*, and combinations between them - *technology and law*, *ethics and law*, *policy and law*, *policy and technology* (Table 8):

Table 8. Distribution of the publications under consideration by proposed solutions to the issue of ownership of patient information

Solutions (categories)	Number (relative share)	Publications
Technologies	7 (25,92%)	[C1], [C2], [C6], [C8], [C18], [C25], [C27]
Technologies and lagislation	1 (3,70%)	[C24]
Ethics and legislation	5 (18,52%)	[C3], [C5], [C11], [C12], [C20]
Law	4 (14,81%)	[C7], [C9], [C13], [C19],
Policy	4 (14,81%)	[C14], [C15], [C17], [C23]
Policy and law	2 (7,41%)	[C4], [C16]
Policy and technologies	1 (3,70%)	[C26]

Most solutions are related to the use of different technologies, highlighting solutions related to the application of blockchains: using blockchains to preserve and protect data ownership [C6], [C25], to own, share data and health records and access control [C8], [C27]. Use of blockchains and artificial intelligence that will enable users to gain ownership of their data and access privileges, as well as allow them to sell their data directly to consumers at a fair price [C18].

Other technological solutions are also available: the use of an identifier for the data collected for the individual, and their security must be assured at all levels of the health system, including at every point where the data is collected [C1]. Use of distributed networks to provide adequate access to the data, both in efficacy and pharmacoepidemiological studies [C2]. Use of Secure Multi-Party Computing (MPC) - Secure multilateral computing that allows third parties to perform calculations with patient data without compromising their integrity [C27].

With modern technology, these solutions are fully adequate and feasible. Unfortunately, problems with ownership of medical information in the context of Big Data cannot be a technical solution alone. In order to reach such a decision, it is necessary to develop an appropriate legal framework in compliance with ethical standards.

One publication combines technological means with legal norms. According to Vazirani, the storage and sharing of medical data (interoperability) are vital to improving health outcomes, but they become a challenge as they need to be sensitive to sensitive medical information. In this regard, with appropriate regulatory documents and standards, Blockchains can serve as a means of managing informed access to health data, as some of their most important features are security, confidentiality and legal restrictions. This will increase interoperability without compromising security while respecting patients' integrity [C24]

There are, of course, no proposals for ethical solutions. Six publications propose ethical solutions. According to Balthazar, the community of radiologists, ethics professionals and computer scientists must understand the appropriate way to deal with privacy, confidentiality, data ownership, informed consent, epistemology and inequalities in the most equitable, ethical way [C3] . Cvrkel proposes to move to a consent-focused framework: incorporating data ownership, access and profit agreements into well-developed informed consent [C5]. The combined efforts and expertise of lawyers, ethics and computer scientists on the legal and ethical collection and use of data, together with the technical knowledge to pool and identify them, can contribute to the development of more informative policies [C11], [C12]. Taking into account both forms of ownership: the right to "control" and the right to "profit from" data, in order to exercise adequate data access rights in the Big Data era, it is necessary to define the terms "commercial" and "scientific" value. From an ethical point of view, consideration should be given to group-level ethics, the ethical implications of growing epistemological challenges, the impact of Big Data on trust-based relationships, academic ethics in commercial practices, ownership and intellectual property generated by Big Data, and the content and barriers to significant data access rights. It is necessary to develop specifications for adequate rights and, where necessary, restrictions on access, as well as to modify data protection practices or legislation to oblige "data keepers" to provide data owners with reasonable access to them, in so far as this is possible [C20].

Legal solutions are available in four publications: Delegating Patient Data Responsibility and Creating Sharing Networks [C7]; Improving legal frameworks to protect patient anonymity, informed consent and data quality assurance [C9]; Promoting the ownership of medical data as a civil right and as a major strategy for the further digitalisation of medicine, providing new resources to potentially assist any individual who wishes to participate in it [C13]; A contract between patients and third parties (data managers, ie healthcare and trade organizations) that will allow individuals to control their digital records over time [C19].

Policy solutions are offered in four other publications: Public and political discussion on ownership and responsibility for patient-generated data. A public policy for the preservation of personal information, which at the same time allows the use of such data to improve public health [C14]; Data management will need to move up the list of organizations' priorities and should be seen as a core asset, not a business by-product. Data ownership and data management need to create new business roles that involve analyzing big data, and new partnerships will have to mediate data sharing. The vast amount of information generated in the healthcare field must be organized for universal accessibility and transparency between healthcare organizations [C15]; active involvement of individuals in informed consent procedures [C17]. Researchers should protect the data at the point of collection, as well as use standardized and validated ways to securely share data, and survey participants should be aware of their data ownership. Shared ownership of data across countries [C17]. Extended control through participation management schemes. To develop networks of regional cooperatives, potentially worldwide, and to offer open source software for the development of data analysis tools. In this way, the idea that individuals have direct control over their data can be applied to different national characteristics as well as to international research projects aimed at analyzing data from different countries [C23].

Two publications combine policies and rules: Developing policies and rules, as well as joint ownership between different countries [C4], and offering patients some degree of control over their own data, especially when used for scientific purposes studies [C16].

One publication proposes a political and technical solution: Sound policies regarding the security and privacy of medical data are needed to allow more flexible access to that data, especially when it comes to medical research. Facilitate access to various registries (cancer, mortality, rare diseases, etc.) at moderate risk: instead of severely restrictive policies that do not benefit anyone, benefits should be assessed, especially when an adequate number of cases (images) required to conduct a study can only be found through multi-institutional studies. The development of effective and practical mechanisms to allow the safe exchange of health data between institutional (and in some cases international) borders will help to flourish medical research [C26].

To sum up, the solutions proposed are split between technology (8), ethics and law (9), and politics (7).

Applications

Despite the many solutions proposed, real applications related to ownership of patient information in the context of Big Data are only commented in three publications.

One application is presented by Vayena [C23]. This is a MIDATA data cooperative model developed by MIDATA.coop (Switzerland) that provides an example of how individuals can gain control over their own data through new-type management mechanisms. The purpose of MIDATA is to store health-related data from a variety of sources and to provide it to scientific projects, whilst allowing data owners to make their own decisions about their data use. It is a non-profit organization, but the potential profits generated by consumers will be reinvested in the maintenance of the cooperative or the funding of research [C23]. Owners who are registered with MIDATA can actively contribute to medical research and clinical trials by allowing selective access to their own data. They may become members of the cooperative and participate in its management. The MIDATA model is designed for international application: MIDATA Switzerland supports the creation of regional and national MIDATA cooperatives that share the data platform and infrastructure.

The second application is cited by Vazirani [C24], who in his review describes several applications of blockchain technologies for electronic health records, one of which is MedRec, which uses blockchain technology and smart contracts to access data and manage access permissions. Other applications are mentioned in the review, but they do not affect the ownership of medical data.

The third application is presented by Yue [C27], which presents an application architecture called the Healthcare Data Gateway (HGD) based on blockchain and which, in addition to patients' access to their own clinical data and medical records, allows patients to own, control, share and manage their own data easily and securely without compromising their privacy, and which provides a potentially new way to improve the health system's intelligence while maintaining patient data ownership. The data is stored in a private blockchain (centralized database with restricted access control, accessible only to authorized or specific users).

Conclusions

- Publications are mainly articles with authors primarily from academic institutions, predominantly from the USA and the UK, from 2014-2019, with the tendency for the number of articles in the research area to increase.
- Our study supports the hypothesis that the issue of ownership of patient information in the context of Big Data is poorly researched, and there is no consensus on the ethical requirement for justice and the necessary legal regulations.
- Our study confirms the hypothesis that the problem posed is not addressed consistently and in its entirety - in terms of ethical, political and regulatory steps.
- The articles have been published in Impact Factor scientific journals indexed in one or more scientific bibliographic databases with high citations. The publications are mainly in journals in the field of health and medical informatics and medical ethics and law.
- There are six scientific fields in which the publications under review can be classified: "research", "medical records", "use of big data in healthcare", "blockchains application", "ownership and control" and "ethics", while predominant is the area of “research”. The other areas are represented by two publications. Only two publications examine the ownership of medical data on their own, without this being part of another study. Both publications concern the area of ownership and control of medical data.
- The aspects in which publications consider ownership of medical data are not clearly distinguished, but can be summarized as: ethical, legal, political and managerial (rulemaking), and in combinations such as legal and ethical and political and legal. Expectedly, the largest share is of publications that consider the ownership of patient information in the context of Big Data in an ethical aspect.
- Ownership of patient data is perceived primarily as a challenge, with this challenge being fundamental to conducting medical research, including access to and use of medical data, which is generally considered a matter of

ethics. In several articles, ownership of medical data is taken as a challenge to policy, ethics, modern technology, medical research and business (data sales and sharing). Apart from being a challenge, ownership of patient data is also seen as a means of control, a problem, a threat, and an opportunity, which is also primarily about medical research.

- The solutions proposed fall into the following categories: technology, law, policy, and combinations of them - technology and law, ethics and law, policy and law, policy and technology, which can be summarized in three broad areas: technology, ethics and law and politics. All three strands are extremely important, but they are clearly not sufficiently represented in the publication activity, and in order to adequately address the ownership of patient information in the Big Data information context, these three strands need to be combined. In order to develop and implement an adequate technological solution, it must, in addition to complying with generally accepted ethical standards, comply with certain regulatory documents and policy decisions.
- Despite the many solutions proposed, real applications related to the ownership of patient information in the context of Big Data are commented on in only three publications. It is well known, and it is obvious, that technologies do not prevent the creation of suitable applications. What is missing is, in fact, adequate policy decisions expressed through the relevant legal framework. And in order to develop appropriate policies and regulations, ethical principles must be known, understood and upheld.

Limitations of the study

The study conducted has several major limitations. *First*, only four scientific bibliographic databases were used - PubMed, ScienceDirect, Scopus and Springer. These were the databases we had access to. We have not checked the bibliographic databases ProQuest, EMBASE, Web of Knowledge, as well as the databases that mainly index technical publications. *Second*. Mostly used are sources published in magazines. No reports of congresses and conferences published in the respective collections have been used. The reason for this is that for most of the potentially relevant publications, the full text was not found. *Third*. Due to the first two constraints, the number of publications included in the study remained only 27. With a larger number of publications, we could present some correlation between the different categories, but with this limited number of publications and the relatively large number of categories considered, a statistically significant relationship between them was not established.

Conclusion

Obviously, the scientific area in question must find its place in the scientific publishing field. The issue under consideration may receive more adequate answers if special editions of renowned scientific journals are organized to address the issue of ownership of patient information in the context of Big Data; organizing seminars and roundtables during biomedical forums, regularly conducting such scoping reviews.

In conclusion, this study may serve as a starting point for future research in this area. Once it is clear that technologies are not an obstacle to the creation of suitable applications, what remains is to implement adequate policy solutions expressed through the relevant regulatory framework. Given the technological and scientific developments, as well as the rapid commercialization of Big Data, the ethical, political and policy-making debate is sure to become more important, more important, and more widespread. In view of this, the following analysis will look at how patient information fits into the information features of Big Data - taking into account both the challenges and opportunities as well as the potential risks.

BIG DATA IN HEALTHCARE AND PATIENT`S INFORMATION PLACE - CHALLENGES, RISKS AND BENEFITS, POTENTIAL OPPORTUNITIES

The term "Big Data" has become especially up-to-date, with the frequency of its use doubling every year over the past few years according to common search engines and databases. Big data in healthcare refers to meaningful data sets that are too big, too fast, and too complex for healthcare providers to process and interpret with existing tools. This is due to the continued efforts to improve the efficiency and sustainability of health services, taking into account the demands of a constantly growing population, as well as the change in the paradigm of healthcare delivery aimed at prevention, early intervention and optimal management of processes in the sector.

Healthcare is becoming one of the key users of Big Data, and is even involved in defining and trying to better understand this information phenomenon by setting some unique characteristics of Big Data in its specific environment. For example, programs such as Fitbit and Apple ResearchKit can provide researchers with access to a vast pool of biometric data for consumers to test hypotheses about nutrition, fitness, disease progression, treatment success, and the like. Similarly, hospitals also seek to reduce the incidence of re-hospitalizations by focusing on patients for whom predictive algorithms show that they appear to be at highest risk based on an analysis of available data collected from existing medical records. However, these and many other potential applications underpin a number of legal and ethical challenges related to, among other things, privacy, discrimination, property, tort and informed consent, which affect research, clinical ethics and, in fact, the relationship between individuals and medical professionals.

Health and biomedicine have been particularly affected by the rise of Big Data, with appropriate examples in clinical and laboratory practice, and especially in genomic sequencing and the increasing scope of genomic research. Advances in bioinformatics and analysis are related to the use of personal data for the development of health and biomedical knowledge and applications. New machine learning techniques are now being used to analyze Big Data and help doctors diagnose and treat it.

One of the key questions is related to the many regulatory implications of new opportunities and technologies - how to assess the various changes brought about by technological advances and create a new public consensus around them? While the serious potential strength of Big Data analysis reveals sought-after models in healthcare and biomedicine, it also calls into question traditional approaches, prevailing social norms, and existing regulatory schemes regarding autonomy, integrity, identity and other values.

Information asymmetry between researchers or institutions and entities is compounded by the ambiguity of the legal obligations and ethical practices of researchers using commercial or other sources with Big Data for health or commercial purposes. In addition, regulation and ethical guidance may impose requirements that cannot be met in the new Big Data paradigm. These and related examples demonstrate the complex issues involved, including the value conflicts that arise at the intersection of technology, law and ethics, social norms and market forces. They need to be taken into consideration when looking at Big Data in the context of healthcare.

It is argued that societal requirements and expectations for healthcare conflict with technological capabilities to achieve them. People want better care, faster delivery, and more affordable health, but it depends heavily on their willingness to share information and make compromises.

To imagine the bigger picture in terms of human health, we need to make sure that all sources of data are properly identified. While some medical data are accurate and potentially more reliable, many other sources of information can only be useful if they are accessed, evaluated and used in the right context. If a holistic approach is agreed, this would allow for an upgrade from the current scientific and medical focus on the disease already developed, to an approach oriented more towards maintaining health and preventing the onset of diseases. This approach may include patient-generated content related to his or her lifestyle, which will allow greater involvement of patients in informed decision-making regarding the management of their personal health care. These are obviously not only patient-generated health data, but also a growing range of information about social determinants. Wealth of data does not necessarily mean wealth of information. The data we currently have is not optimized enough. Clearly, better analytical tools will be needed to help make sense of the arrays of additional data. Big data needs to be “unlocked” - the more organized they are, the more effectively they will be used for fundamentally important initiatives such as health promotion and disease prevention.

Markets also play a crucial role today. As health data is increasingly commercialized and marketed through new markets, these markets need to be assured of the origin and quality of information as well as of marketing authorizations - even if the data is anonymous. Other stakeholders have emerged in recent years - technology innovation corporations, start-ups and established IT companies looking to improve well-being and overall patient survival. These also require high quality, possibly anonymous, and aggregated patient datasets to build, test, and develop new services.

Obviously, information reality today is literally vast, and the mere fact that people are so actively involved in shaping it by creating and sharing their own data logically suggests the problem of the lack of ownership of this information. However, this is related to different interests. A fundamental question is emerging: is there a possible compromise in which the recognition of ownership of patient information by patients themselves overlaps with the guarantee of public interest? Is it possible for patients to own all their information and to be adequately informed of the enormous personal and public interest in providing this information for public health purposes?

Shared challenges

There are a number of issues that arise in the context of patient information and Big Data, and which appear to be shared challenges and concerns that need to be addressed properly. Such challenges relate to security and confidentiality, trust, integration, access rights and the underlying issue - ownership of patient information.

Security and privacy point to ownership, but also to familiar techniques, such as de-identification and anonymization of data. As anonymous data is easier to transfer and sensitive health data is an increasingly important target for cyber-attacks, questions are raised about the benefits of centralized and decentralized data and the overall impact of localization.

Trust is a key segment in the whole picture. In many places, trust between the different actors in the health sector relationship must either be restored or built up. New technology platforms and improved communication with the public play an important role. One of the most effective ways to build trust is through more accessible information. There should be clear mutual proposals for sharing and improving transparency. Patients should be given greater advice and support so that they can more easily decide what is advisable to share and give them clear reasons for doing so - especially on sensitive issues. Creating common standards for datasets can be a major driver of change.

The advent of Big Data in healthcare, including big related data from patients' electronic records, as well as streams of geographically located real-time health data collected from wearables and "open data" (a movement that allows sharing of data sets) create new challenges in terms of ownership of personal data while opening up new research opportunities and commercial exploitation mechanisms. Against this dynamic digital-informative environment, the privacy of consumer information and ownership of user-generated data represent an under-explored territory in terms of policy and regulation, while becoming a thriving business for the social media and networking industry and medical technology manufacturers. In the absence of transparent regulation of data ownership, different approaches emerge, targeting ownership, use and responsibility in sharing and accountability.

Ideally, the data generated from multiple sources should be made available for research, regardless of where the data came from and from whom it was collected, or their potential will never be realized either for the individual user or for society as a whole. However, the rights to valuable personal information must be respected.

A significant challenge to progress lies in the barriers and constraints that result from treating medical care data as private goods from participating countries, although there is no regulatory framework governing this. Increasing access to and use of health data for new promising endeavors requires not only promoting the reliability and interoperability of data systems, but also addressing their ownership and the extent to which data is essential for improving data systems. health and healthcare should be a public good.

Ownership versus Access

If access to patient data is expected to have real impact, it must be aggregated and shared, which provokes concerns about ownership and, accordingly, who should make decisions about the use of patient information. Patients may have greater control over their data, but whether they are their true caregivers and whether they are able to control access to them depends on factors such as competence, cultural characteristics, regulation and need. The question is how realistic and how adequately citizens want to be and can be realistically engaged.

As expectations grow, it becomes increasingly important to understand who, and whether, someone should necessarily have health data, who should control it, and therefore who should best make decisions about access and use. Some believe that absolute ownership of patient information must belong to the individual - "supremacy" over the data. This is especially relevant since health data is already being generated on personal devices. So why not extend this decision-making ability to other aspects of health data? However, we can also point out some real concerns. For example, although organizations and healthcare professionals understand how, where, and why to use new data sources, it does not necessarily mean that patients themselves will understand what the applications and the implications of what they choose to share . This may limit their ability to make authentic choices for the use of their own records. Dynamic technological developments and the ability to capture patient information may not be applicable to everyone, as factors such as age and lack of competent management of new technologies pose natural barriers that will gradually be overcome in the next few generations. However, it is doubtful whether this will be achieved at a global level, with a more realistic answer being no.

However, the idea of creating conditions for individual supervision is promising: the possibility for citizens to download a copy of all their health data, with the primary objective of pushing for the possibility of individual supervision of all health data regardless of the source, so that the patient can control how his information is used.

Whatever the approach, patients will have more control over their data in the future and will have access to more information. However, the interpretation of 'control' is different. Key questions that have not yet been addressed concern the benefits of full or partial control, access, the link between control and responsibility, and improved use of data to help patients better understand the choices they make for their health.

Potential problems

Although they are not yet equally visible, nor do they have the same meaning everywhere, some problems represent an interesting debate. These are areas of challenge for which a clear consensus has not yet been reached, and some may have many different political and commercial implications in the future. However, they are also topics that could have a clear impact on how the future of patient data is actually unfolded, how and where the greatest benefit can be gained, and who can benefit the most. Such area is the sovereignty of the data.

More and more countries are seeking to limit the exchange of health data beyond their borders. This is due to concerns about national security, the desire to protect commercial interests and different cultural attitudes towards privacy. Data sovereignty refers to the fact that data stored in a 'cloud' by a particular care provider can potentially fall under the jurisdiction of more than one country. This has specific implications for the healthcare sector. As more organizations seek to integrate multiple patient data sources around the world, the adoption of local and regional rules and regulations is a growing concern. In parallel, as more data move to the cloud, traditional geopolitical boundaries are being challenged and questions are being raised about where exactly they are stored and under what jurisdictions. From the point of view of health research, access to global databases could have the potential to transform real evidence into medicine and healthcare.

Geographic location and national identity are becoming increasingly important when exchanging data. In addition, there is a potential risk that a future war on the use of bio-weapons may use health data and no one has yet determined the extent to which patient data can compromise state security.

Trends in patient information regulation (comparative analysis between GDPR and HIPAA)

Currently, the law does not clearly define interests in the ownership of patient information, and respectively, does not explicitly regulate it. Although there are various regulatory measures (Laws, Directives, Regulations) regarding the protection of personal data, they do not affect the issue of ownership. In most countries, the law treats patient medical records a priori as material property owned by doctors and hospitals, usually allowing patients and insurers to access the information contained therein.

Indeed, there is no political debate and subsequent regulatory action on the ownership of patient information, but there are other major laws and regulations that deal with the protection and protection of personal data in general and with different scope. of which are health data. In the EU, this is GDPR and in the US it is HIPAA law. It is noteworthy that both regulatory sources provide a detailed framework of protection but do not in any way affect the status of ownership of the information.

In the USA since 1996 the federal Health Insurance Portability and Accountability Act (HIPAA) regulates the disclosure of patient information by certain entities. However, HIPAA does allow significant disclosure and sale of patient data. Adopted by HIPAA in 2003. the amendments allow the entities involved to share medical information about patients with the healthcare business (including employers, pharmaceutical and insurance companies, marketing firms, accounting firms, banks and financial services companies, data warehouses) and also allow sharing information that does not identify the individual patient's identity, and HIPAA does not include in its scope personal health records that Google, Microsoft, and other companies have developed.

In Europe, on 08.04.2016 a new data protection framework was adopted in the form of a Regulation (Regulation EU 2016/679) (General Data Protection Regulation - GDPR, effective 25.05.2018). whose task is to regulate the protection of individuals with regard to the processing of personal data and the free movement of such data. The Regulation is applicable in all Member States, without the need for national legislation to be applied.

The General Data Protection Regulation is a set of compliance requirements and is implemented by any organization that deals with data provided by EU citizens. In other words, the Regulation can apply to any organization, even if it is based outside the EU, if it processes data relating to patients who are nationals of a Member State of the Union. The new Regulation takes into account that the protection of individuals with regard to the processing of personal data is a fundamental right, as is explicitly mentioned in the Charter of Fundamental Rights of the European Union and the Treaty on the Functioning of the EU. Everyone has the right to the protection of their personal data. According to Art. 4 of the Regulation, "The processing of personal data should be intended to serve humanity. The right to the protection of personal data is not an absolute right but must be considered in connection with its function in society and must be balanced with other fundamental rights in accordance with the principle of proportionality. "

GDPR covers all personal data defined as any data through which a living individual, directly or indirectly, can be identified or potentially identified. This broad definition includes data that is outside the scope of HIPAA, but also leaves some discretion for Member States to specify some of the rules contained therein, including with regard to the processing of specific categories of personal data - "sensitive data" (Art. .51). These are data whose disclosure could lead to vulnerability, inconvenience or harm to the data subject (race, ethnicity, views, genetic or biometric data, etc.).

However, the GDPR specifically defines health data as personal data relating to a person's physical or mental health, including the provision of health services that disclose information about his or her health status (Article 35).

Some of the key elements of the European Regulation that directly affect the data subjects are:

- Strict adherence to the informed consent of the patient to receive his or her personal data. Organizations can no longer use dubious opt-out strategies that accept patient consent (opt-out strategies) by default; (Art. 32)
- Right to be forgotten - healthcare providers can no longer store patient data for an indefinite period of time and must permanently delete this information at the request of the data subject (Art. 65).
- High security storage - It is imperative that healthcare providers put in place adequate mechanisms for protecting, encrypting, pseudonymizing, reducing, and detecting unwanted intrusions into systems to ensure that patient data is not compromised in any way. (Section 2, Article 32)

On the other hand, the HIPAA - Health Insurance Portability and Accountability Act is an ordinance designed to protect personal information and data collected and stored in medical records. HIPAA establishes a national standard that is used in all physicians' offices, hospitals and other places or for endeavors where personal medical information is stored. In addition to protecting personal medical information, HIPAA also entitles patients to review their medical records and request changes if the information is incorrect. HIPAA commits to full protection of patient data stored and exchanged between hospital servers and, like GDPR, makes it mandatory for healthcare providers to strive to strengthen their patient information protection methods and relevant security protocols when manage patient data.

Protected Health Information (PHI) is defined under the HIPAA regime, any individually identifiable information related to past, present or future physical or mental health status, health care provision, or payment for health care. The US Department of Health and Human Services states that PHI includes names, addresses, and demographic information if those individuals whose comments are commented are patients of a healthcare provider, even if not included. specific diagnostic or billing information.

Thus, both regulations relate to more specific health information and suggest protection, without addressing ambiguity about ownership at all, but differing in some specifics. The scope of the two regulations is one of the most fundamental differences between GDPR and HIPAA. GDPR covers EU citizens, regardless of where their information is processed (Chapter 1, Article 2), while HIPAA is restricted to US citizens and healthcare organizations (OCR Privacy Rule, 2003). GDPR is a consumer-oriented regulation - every organization in the world has a duty to adhere to these strict regulations when dealing with data relating to EU citizens. HIPAA, on the other hand, is an organization-oriented law and all data processed by organizations outside the US is outside its scope.

Other important differences between the two regulations that must be taken into account concern informed consent, the right to be "forgotten" and violations related to unauthorized access (breakthrough) in the protected information.

With regard to informed consent, HIPAA provides for some permitted disclosures of PHI without the patient's consent. According to HIPAA, healthcare providers can disclose another provider's PHI for the treatment activities that they need to perform without the patient's consent. HIPAA defines "treatment" broadly, such as the provision, coordination or management of health and related services by one or more providers. Another permitted disclosure of proprietary information is for some healthcare initiatives. If certain criteria are met, the healthcare provider may disclose PHIs to other providers or business associates without the patient's consent.

This is not the case with GDPR; instead, explicit consent from EU data subjects should be obtained for any use of protected information that does not affect direct patient care. In other words, unlike GDPR, where organizations must obtain active consent from the patient before storing some of his or her personal data in their database, there is no such requirement from HIPAA. Healthcare organizations are free to process these details as long as they are stored and transmitted with appropriate security.

The right to be forgotten is an interesting topic, especially when it comes to healthcare. While this is an important point in the GDPR (Art. 66), there is no such right in HIPAA. This means that any record of a patient on the hospital database cannot be deleted simply because the patient desires to. In contrast, GDPR implies that an organization must comply with these consumer demands.

With regard to consent, GDPR permits the use of health-related personal data with the “explicit consent” of the subject, unless consent can be relied upon because it is prohibited by EU or Member State law (Art. 111). The "explicit consent" must meet a higher standard than the consent for the processing of other forms of personal data - the individual must be clearly informed about the use of his data and take positive action to demonstrate his consent. HIPAA permits the use or disclosure of PHI in accordance with an individual's permission, which must include a number of required elements. In the protection of vital interests where the subject is unable to consent, the GDPR permits the processing of sensitive personal information, such as health-related personal data, when necessary to protect the vital interests of the data subject, whether physically or legally cannot consent. HIPAA permits the disclosure of information to a person's personal representative who is presumed to be able to protect the vital interests of the individual when he or she is unable to make certain decisions. (Art. 111).

With respect to the public interest and required by law, the GDPR permits the processing of sensitive personal information necessary for reasons of serious public interest based on EU or Member State legislation, which is proportionate to the objective pursued and contains appropriate safeguards (Art. 50) HIPAA provides for the use or disclosure of PHI as required by law. This means that there is a requirement in the law that compels the subject to use or disclose PHI, and that such use or disclosure is applicable in court (HIPAA, 2014).

In relation to medical treatment, GDPR involves the processing of sensitive personal information, where necessary for the purposes of preventive or occupational medicine, to evaluate an employee's work capacity, medical diagnosis, health or social care, treatment or management of systems and services. health, social care services based on EU or Member State legislation, or a contract with a healthcare professional (Chapter 2, Article 9). HIPAA authorizes the use or disclosure of PHI for therapeutic purposes, which includes the provision, coordination or management of healthcare and related services between healthcare providers or by a healthcare provider with a third party, consultation between healthcare providers on a patient, referral per patient from one healthcare provider to another (HIPAA, 2014).

For public health considerations, the GDPR permits the processing of sensitive personal information that is necessary for reasons of public interest in the field of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety for healthcare and medicinal products. or medical devices (Chapter 2, Article 9) HIPAA authorizes the use or disclosure of PHIs by public health authorities legally authorized to receive such information ration for the prevention or control of disease, harm or injury. This includes, for example, reporting a disease or injury; vital events such as births or deaths; conducting investigations or interventions (HIPAA, 2014). In terms of research, GDPR allows (Chapter 2, Art. 9) the processing of personal information for scientific, historical or archival purposes, while HIPAA allows the use of proprietary information for research purposes (HIPAA, 2014).

Patient information as property. Trends.

Although the limited debate on the subject is a strange fact, popular theories are split between the idea of ownership of information - public or private, and others believe that personalization would not solve the problems posed and only complicate them.

Patient information as public property

Public ownership of patient data is necessary to ensure the provision of data necessary for key government activities that promote public health, individual patient safety and the development of medical science.

Public ownership of this data is also required for effective public and private oversight of medical technology, insurers, healthcare providers and companies that provide drugs, medical devices and medical supplies. Using data directly from patients' medical records would allow such assessments to be made at a much lower cost, faster and with constantly updated information. This would provide information on populations and variables not otherwise included in clinical trials.

Commenting on the possibility of patient data being publicly owned and legally derived, some authors believe that this creates risks to patients' privacy. However, the risks to privacy and privacy may not be greater than if the data were privately owned by the patients, institutions or organizations themselves. Hiding credentials in medical information is an important element of its subsequent use. However, even with anonymized information, the patient's medical record may indicate his doctor, preferred pharmacy, hospital where the hospitalization, postal code or insurer occurred. It turns out that when combined with other information that is public or purchased by private individuals, it is often possible to identify who the patient is. In short, what was previously considered anonymized is actually not usually. Therefore, they need to develop a means of encrypting data and controlling its use, regardless of their status and what they are used for.

Whether the property is public or private, we need safeguards in place to protect confidentiality.

Patient information as privately owned

Patient information as private property also has some advantages, as long as we do not take it as an extreme. We have already indicated that it sounds intuitive for patients to own information about themselves. However, if they are the absolute owners, if they have total authority and control, it means that they can restrict whenever they consider it appropriate for its subsequent use. This could potentially be in conflict with the public interest. If we take the option of private property, it must be so regulated that, like the idea of public property, the rights of citizens are guaranteed without harming the interests of the public. From an ethical perspective, it would be most acceptable for individuals if the law recognizes them as the owners of their information, provided that their right is inalienable but not unlimited. The public interest sometimes requires that the individual not be prerogative.

Regulation of patient information without property right implied

Regulation of patient information through regulations that exclude property rights as a foundation is a model that is actually applied today. Various pieces of legislation regulate above all the right to the protection of the personal data of individuals without indicating whether they own the data or only their physical media. Given the huge market for patient information as well as the prevailing public interest, this disregard for ownership may not be so surprising. If a regulation specifies specifically who owns it, it would have an economic claim to the use of the information, which could be contrary to the various interests of others, including the public. Balancing the different options is a complex initiative, but resolutely not possible. Maneuvering between private and public interest requires attention to the needs and rights of individuals and the maximum public benefit.

PHILOSOPHICAL ANALYSIS

Today's information environment and Big Data challenge our understanding of how to utilize and tailor elements, concepts and problems that are fundamental to modern healthcare and medical practice, such as: informed consent, privacy, access to health care and its improvement, communal and social responsibilities, research, and experiments involving human beings. In this sense, the philosophical reflection on the "moral" makes it possible to explore, and where appropriate - to divide, between traditional understandings of the biomedical sciences and public health, and to offer new perspectives on mastering problematic aspects in these fields. One of these problematic aspects, which has received little attention, at least so far, is the ownership of patient information. Using a philosophical and ethical approach to the problem of ownership of patient information, it can be assumed that ethical considerations have been taken into account and thus more likely to find a place in a real application.

However, the answer to the question of what is the "right" balance is not just technical or scientific, but rather ethical and social in its nature. In a sense, this answer depends on the values of the participants in the relationships affecting the patient's information, and these values can vary significantly in a multicultural world in which people and the accompanying stereotypes travel quickly and freely.

Ontological approach to the problem of ownership of patient information

The issue of ownership of patient information comes from two important interest-related positions - those of the individual and the group. In this sense, ontological research looks at how individuals form their interests and whether this changes when they are in a group. When is individual interest different from group interest, and how is balance possible?

It is logical for everyone to aim to defend their own aspirations and claims, and doing so can hurt others. In this sense, if we assume that it is natural for every person to possess information that relates to him, especially medical, which is literally obtained from his body, then one will use it as one finds fit, limiting others from access and benefits, thus potentially harming them. This indicates that it is intuitive for the individual interest to diverge with that of the group if one does not associate with and through the group. Hence the important concern: the danger of recognizing ownership of patient information is related to the manifestation of a peculiar but not atypical human selfishness that could have undesirable effects on social well-being, understood in terms of public health and the overall development and improvement of medical science. The idea of having a "property right" actually protects the individual interest; and if this idea is fully accepted and relevant to certain aspects of public life, then in the case of patient information, propertysation would be at odds with the common interest aimed at the development and refinement of medical science and care.

Social ontology examines the manifestations of the individual and social groups, focusing on the idea of interdependence. Individuals manifest their interests by interacting with others with whom they form social groups and societies. In the context of modern healthcare, which is evolving in exceptional technological and informational circumstances, individuals have the opportunity to contribute and consciously become part of making responsible decisions and making significant positive changes.

Epistemological approach to the problem of ownership of patient information

In the context of this dissertation, epistemology is used, both by its basic function - exploring the possibility of knowledge and in another variety of it - similar to social ontology - as a social manifestation affecting both the individual and the group - social epistemology .

The epistemological analysis of the problem of ownership of patient data in the complex information context reflects on the ability of individuals and groups to truly understand the facts of reality. What is their medical information - just physical data used by medical professionals or original information that constitutes an individual in a unique way? By what methods can it be used and by whom? For what purposes? What is its value, and what claims can an individual have against it?

In this line of thought, epistemology draws attention to the complex nature of patient information, viewing it at the same time as complex because it is not readily recognizable by every human being and unique because it binds it to the body and physical nature of each of us.

Today, big data in health care goes beyond the institutional use of medical information, which means that the subjects of such information need to adapt to a significantly more diverse information environment in which not all possible uses are justified, transparent, or legal. In this sense, the ability to make a true and real idea of how the information industry works, where the border between conscious, unconscious, right and wrong, is of particular importance.

Axiological approach to the problem of ownership of patient information

Values are the foundation upon which all ethics, including bioethics, are established. The values that patients and healthcare providers share or associate with them influence not only current medical knowledge and practice, but also the application of that knowledge. Values basically serve to determine not only what is closest to, but also what appears, as the ultimate value.

There are different values that set the ethical position, both for doctors and patients, such as: concept of health, treatment and prevention of diseases, help, normality, truth, choice, justice. Each of these has a direct or indirect bearing on the demand for a balanced attitude to ownership of patient information in the context of Big Data in healthcare. On one hand, there is the creation and understanding of the concepts of health, prevention and treatment that, even with traditional content and definitions, continue to evolve along technological and scientific advances. In today's information reality, these concepts can be closer to people than ever, which means that we have the opportunity to understand them better and make more responsible and informed decisions about health related behaviors – to be more committed to our health. Our environment in a broad sense makes it easier to form principled positions and clarify values. What does health mean? How to maintain and improve? What should we be prepared to compromise with? In this line of thought, can we associate individual values and understanding of "health" with the public interest in health?

Common phenomenology of values involves determining what can be valued. The main problem is that there are two options for valuation: something is valued because it is valuable (in itself, objective valuation) or it is valuable because it is valued (subjective valuation). In this sense, the moral character of members of society is an important factor in the health and overall well-being of this society. As a result, moral values must be the same and shared by members of society.

Health is valued in many different ways, especially with regard to the biomedical model. Health is chosen as a utilitarian or instrumental value because it promotes or is profitable in order to receive other benefits that one values in the course of his or her social life and interaction with others. It is reasonable to say that individuals have an intrinsic interest in those around them to be healthy and support one another in order for prosperity, provision and exchange of goods to flourish.

Anthropological approach to the issue of ownership of patient information

The issue of ownership of patient information and big data in healthcare implies a variety of relationships. These are relations between people and technology, between people and institutions, between individual and public interests and others. In this respect, technological reality is more of an auxiliary tool, a consequence of the relationships and evolving interests and opportunities unfolded in the amazing information environment.

Big data, on one hand, provides a vast field for exploiting information (in any form and for any purpose, including medical), which we are witnessing; on the other hand, many people are skeptical, despite the medical benefits. Those who fall into the "skeptical" category are far more likely to support the idea of propetisation of the information, drawn mainly from two things: the idea of more secure control, and also the potential opportunity to profit from their medical data.

The field of public health - and more generally, the development of policies and strategies - requires contributions to research from multiple disciplines and sources, which supports the idea of creating means and informed environment in which people are predisposed to share their medical information in view of the objectives already mentioned. Moreover, a multidisciplinary approach could best meet the public health needs of the population. A problematic moment is related to the consideration of cultural and social diversity, which can lead to divergence in the concepts of health, illness and well-being.

By sharing their medical information, people will cause less harm than they would gain benefit and help for themselves and others. The act of informed consent for such a purpose would be much more than a mere consent to something; over time, it would help the social consolidation of people united by a strong incentive - to contribute, but as mere separate units, but together - because it is shared.

ETHICAL ANALYSIS

Since its formation in the 1960s, modern medical ethics has been confronted with a number of challenges due in part to dynamic information and technological developments. Today, the development of information technology, the information environment, science, as well as the potential for improving not only personalized health but also services in the healthcare sector, are more than ever complying with fundamental principles in biomedical ethics.

The principle of Autonomy and the ownership of patient information

The problem of ownership of patient information in Big Data is affecting the ethical principle of respect for autonomy, primarily because of the very use of personal patient data. An important point here is to clarify the role of the medical data subject (patient) and the desire or claim to own and control this information, the need to be aware of its primary or subsequent use, and the ability to exercise autonomous choice.

Even autonomous individuals, who are generally able to manage their health and behavior, may sometimes fail in some of their choices for various constraints.

Because the possibilities for using patient information are almost unlimited, and for the vast majority of them, transparency is lacking, to what extent it can be expected that any potential or current patient can autonomously judge them, make informed choices, and everything to be subordinated to his rational choice?

When such a choice is made, it may be in conflict with the interests of others, so - is it possible to compromise the principle of individual autonomy with those of beneficence and non-maleficence and, ultimately, justice, in favour of a greater interest, like the public one?

One possible perspective is that anything that directly affects the autonomous individual should be subject to informed consent. Consent derives its importance from the fact that law and conventions place a circle of inviolable integrity on people. Of course, there is an infinite difference of opinions as to how wide and how insurmountable this circle should be, and societies differ in their judgments as to where the rights of the individual should end and where the rights of other individuals or community should begin.

The right to confidentiality in medical practice is an example by which justified exceptions to the rule can be indicated.

The principle of nonmaleficence and the ownership of patient information

The principle of nonmaleficence is also relevant to the issue of ownership of patient information in the contextual information environment, as different individual and collective interests and rights may be affected. In the case of patient information, there are several possible perspectives: if patients own their medical information, could this be potentially direct or indirect harm to others? Conversely, are they harming the data subjects by not recognizing their property rights?

With regard to patient information, we consider harms in the prevention or suppression of one's interests, taking into account that the harmful action is not necessarily wrong or unjustified. Malicious acts that involve justified interference with or preventing one another's interests are not wrong, as in some circumstances the admission of certain harm prevents a greater harm, or when one suffers harm because of one's actions that harmed another - that is, justified. This justification may come from the fact that malicious acts do not affect specific nonmaleficence obligations, or even if they affect them, they are in the light of transcendental or priority ethical principles or rules.

Considering that in cases where it is possible to dispose of important medical information, the public interest is actually protected, certain harms might be justified.

The principle of beneficence and the ownership of patient information

The principle of beneficence, in a sense, complements that of nonmaleficence, and in addition, beneficence also implies provision of benefits. The term beneficence connotes certain actions or personal qualities such as clemency, kindness, generosity and charity. This involves altruism, love, humanity and the promotion of good for others. In ordinary language, the concept is broad, but in ethical theory it is understood even more broadly to effectively include all norms, orders, and actions in order to benefit or promote the good of others.

In this sense, the actual utilization of patient data occurs through the act of sharing the information that can be viewed and as an act of beneficence. This act is a form of positive beneficence because it is the first step to contributing a benefit. In the case of patient information, given the lack of established ownership and the lack of regulation, it seems that the act of patient sharing can be characterized as a moral imperative that does not require a grand sacrifice. The problematic moment here is that there is a discrepancy between the moral act of sharing valuable medical information for research and development of science, and that it is exploited by third parties.

If we look at the issue of patient information through the second principle of beneficence - that is, as a utility, we come to the search for a balance between the possible risks, benefits and harms. Usually, when it comes to researching and evaluating beneficial health policies, tools are used to analyze and evaluate the right benefits in terms of costs and risks. These considerations take into account whether the likely ultimate benefit, usually to society, is greater than the potential harm to individuals. The balance of costs, risks and benefits implies that prices include the resources needed to reap the benefits, as well as the negative effects of the pursuit and realization of those benefits. Risks are potential future harms that can vary, both in type and effect - they can be physical, psychological, financial, legal. The term 'benefit' sometimes refers to avoiding or reducing risks, but in the biomedical sense it represents something of positive value, such as preserving life, maintaining or improving health.

The principle of justice and the ownership of patient information

Given the problem of ownership of patient information and the complexities of Big Data, ethical reflection on justice is of particular importance as it examines the possibilities of fair use of specific medical information in the light of individual and social interests and claims. On the one hand, this implies an analysis of the concepts of 'justice' and 'distributive justice' in the contemporary context under consideration, as well as taking into account issues affecting national and international health policies as well as other sustainably problematic areas of social justice, such as access, vulnerability and exploitation.

The focus shifts to the potential benefits, not so much to the possible risks, without of course ignoring them. It is understandable that risks and benefits run in parallel, and as one increases, so does the other, but this fundamental change in perspective - to the potential benefits - rather than to the potential risks, is an important prerequisite for considering the useful options. Obviously, this is about fair access and distribution of essential medical information that is potentially important to an indefinitely large number of individuals. We can say that this is a principle of need according to which key social resources, including health care, must be allocated as needed.

The idea is that everyone's well-being depends on cooperation between people, without which no one would have a satisfactory life. The sharing of goods must be such that it encourages the voluntary cooperation of all. There is also a fundamental difference with the theory of utilitarianism, where the main idea is the greatest good for the greatest number of people, while in the case of utilization of patient data we are talking about the pursuit of potential benefits for all.

In relation to the issue of patient information under consideration, improving social conditions implies the need to be more aware of the benefits (without neglecting the risks) of providing and handling patient information. In this sense, understanding the environment and opportunities can drastically change or support a health behavior, but this should be an informed process and part of a purposeful health strategy. This implies that, for the sake of social justice, we should optimally facilitate the process of sharing important medical information for scientific purposes, and to create the best possible environment for it - an environment that is credible for the goals of the initiative, an environment of security to ensure, as far as possible, the protection of the subjects.

PROPOSAL FOR A FAIR APPROACH TO OWNERSHIP OF PATIENT INFORMATION IN THE CONTEXT OF BIG DATA

With the mass collection of 'personal' health and personality data, a policy for that data becomes an unavoidable necessity. And debates we have, with protection being an absolute priority, while property, though implicitly linked, remains out of direct focus for the time being.

No one doubts that patient data is of economic value, but the question is rather how it is exchanged and shared. We must also consider the potential social value of health data, and how it can change the nature of the society in which we live. Patient data is both commercially and competitively relevant, and the principle of free sharing is not easy to put in a dialogue.

There is a concept that data for this century is what oil was for the previous, namely the engine of change. This is also true of Big Data in healthcare - it can be a driving mechanism for a fundamental reorientation and change of mind about how we treat and how we can influence health, healing and disease.

This is directly related to how we choose to manage this data resource, which, at least unlike oil, is not limited.

In the light of the research and analysis that has been conducted, our proposal for a fair solution to the question of how to treat patient information ownership in the complex Big Data information context *is to leave aside the possible variants of propertisation* - both in the form of public and private ownership of medical information.

Although ideas and suggestions for ownership of information have some serious merits related to the ability to publicly monitor and exercise centralized control over public property, or to recognize the unique relationship between a person and the information obtained from him and the personal control over that information in private property, they give rise to particular problems coming precisely from the fact that *one* or *some* own personal data.

In this line of thought, an alternative involving a property regime suggests that if the right is to be recognized, it should be limited: patients own their information, they can control it, and know who, when, and for what has access, to make it a commercial commodity and to benefit materially from it, *but* if it is a valuable artifact for medical science, research and practice, their right to impede such use in one way or another must be restricted. This, in turn, shows that, while it may be difficult to find a universal path to solving the problem of ownership of specific patient information, it is most reasonable to assume the Occam`s Razor as a guiding principle: to seek an approach along the path of the lowest resistance.

CONCLUSIONS

1. The information revolution is not a modern phenomenon, but a process, a historical practice, which, thanks to technological development and global processes, has reached a remarkable culmination with Big Data today.
2. Big data in healthcare is above all an immense opportunity to utilize masses of medical information whose potential, given its scientific potential, can literally transform the healthcare paradigm, drawing attention to ever more precise, personalized care, prevention and promotion of health information. health.
3. The role of patient information in the context of Big Data is fundamental because it is becoming a valuable source of Big Data for the entire field of modern healthcare. Its use is both scientifically and commercially important, making its regulation complex but not impossible to solve.
4. The specific analysis of the scope of the scientific literature on the problem under study has shown that it has not been considered consistently in its entirety - as ethical, political and rulemaking. The issue of ownership of patient information remains purely theoretical, and there is no formal practical solution to it.
5. The concept of 'ownership' in the context of patient information needs to be redefined. It can be explained by the property that each person has over himself; this includes data that is inalienable to the person to whom it relates. They cannot exist independently and at the same time they exist regardless of whether one describes or extracts them.
6. On the basis of philosophical and ethical analysis, it has been established that major moral and ethical problems arise in conflicts between individual and public interests regarding access to and use of patient information. These problems relate to autonomy and the right to choose, on the one hand, and the protection of the public interest, which in this case prioritizes it against individual claims.
7. The regulatory difficulties stem from the fact that patient information is unique in nature, which makes it impossible to explain it through the prism of traditional ownership concepts. It does not fit into the conventional notion of intellectual property and cannot be the subject of copyright under existing law.
8. Despite the limited academic debate on ownership of patient information, three major trends for potential regulation emerge - by making the information public or private, and by other regulations that are not based on ownership.
9. The disclosure of patient information would complicate the processes of data acquisition and their subsequent use for scientific and research purposes. A serious factor in this is the commercialization of the data and the inability to draw a line between scientific and commercial use, as well as the possible claims in establishing a proprietary regime.
10. Our study affirms the hypothesis that the issue of ownership of patient information in the context of Big Data is poorly researched in academia, and

there is no consensus on the ethical requirement for justice and the necessary legal regulations.

11. Our study affirmed the hypothesis that the problem posed is not addressed consistently and in its entirety - with regard to ethical, political and regulatory steps.
12. Given the philosophical and ethical analysis that has been carried out, our study has rejected the hypothesis that the issue of ownership of patient information may find a universal solution. It remains a reasonable view that the perspective of this problem and its solution takes into consideration the need to identify trade-offs between claims, rights, effectiveness and fairness - a position that reflects the acceptance of possible conflicts and the drawing up of a balance and compromise strategy of political and law-making level.
13. Given the philosophical and ethical perspective presented on the problem of ownership of patient information in the information context of Big Data, our study rejected the hypothesis that having a legally recognized right to own patient information - as we know it in the existing legal world - would be justified in the light of individual and public interests aimed at developing and improving medical services and science.
14. Alternatively, a limited proprietary right may be offered to guarantee the possible useful uses of patient information for the development of medical science and research. That would be a compromise.
15. A fair approach to the regulation of patient information in the context of Big Data is non-proprietary regulation as a matter of law. Patient information is socially relevant and its use for scientific and research purposes, as a matter of priority, protects the public interest.
16. The absence of property rights does not mean that the issue must be ignored. It needs a debate and a reasoned position as to why it is better to have or not to establish such a right. A possible fair option is regulation without ownership, but with the right of access and maximum protection given the capabilities of modern technology.

CONTRIBUTIONS

Scientific and theoretical:

1. For the first time the issue of patient information ownership in the context of Big Data is discussed in the Bulgarian scientific field;
2. A historical review on the origins and evolution of Information Revolution and Big Data has been done;
3. The importance of Big Data for the healthcare sector is analyzed and key suggestions, risks, benefits and results are presented;
4. The role of patient information has been analyzed in the context of Big Data;
5. The concept of "ownership" is defined and its contents are stated in a specific context of patient information;
6. The legal framework for the ownership and protection of patient information is presented and a comparative analysis of their regulation in Europe and the USA is carried out;
7. Trends in the perception of patient information in terms of ownership - public or private - are presented and an analysis of their advantages and disadvantages is done;
8. For the first time in Bulgaria, a philosophical analysis of the concept of patient information owneship has been made, which applies to basic philosophical techniques and studies - ontology, epistemology, axiology and antropology;
9. For the first time in Bulgaria, an ethical analysis of the concept of propertisation of patient information was used, based on the fundamental principles in biomedical ethics - autonomy, nonmaleficence, beneficence and justice.

Applied and Practical:

1. For the first time in Bulgaria, a methodology for scoping review on the focal problem is suggested and applied;
2. For the first time in Bulgaria, a study is being conducted to determine the scope of the scientific literature on the issue of ownership of patient information in the context of Big Data;
3. Major moral, ethical and regulatory issues in relatition to patient information ownership and Big Data are identified;
4. On the basis of the considered philosophical and ethical analyzes, a fair appoach to the ownership of patient information has been proposed.
5. There are two potential solutions provided: 1. Patient information and its useful uses are regulated without established ownership right; 2. If a property right is

recognized, it should be restricted in view of its potential useful uses for scientific and research medical purposes.

SCIENTIFIC PUBLICATIONS AND PARTICIPATIONS IN SCIENTIFIC CONGRESSES AND FORUMS IN RELATION TO THE DISSERTATION WORK

Publications:

1. **Mirchev M**. Patient data - between private and public ownership, European journal of public health, 2018, Volume 28 Supplement 4, p.507; https://academic.oup.com/eurpub/article/28/suppl_4/cky218.286/5192656
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3. **Мирчев М**, Кереховска, А. Тенденции относно собствеността върху пациентската информация, Социална медицина, 2018, 3/4, 77-79 http://journals.mu-varna.bg/index.php/sm/article/view/6009/5298
4. **Мирчев М.** Кой притежава пациентската информация? Перспективи пред моралната претенция за собственост, „Етически изследвания“, брой 3, кн. 2-3, 2018; https://jesbg.com/mirchev-koy-pritezhava-patsientskata-informatsia-perspektivi-pred-moralnata-pretentsia-za-sobstvenost/

Participations in Congresses and Forums in relation to the dissertation work:

1. **Mirchev M.** Patient data - between private and public ownership, 11th European public health conference Winds of change: towards new ways of improving public health in Europe, Ljubljana, Slovenia 28 November –1 December 2018
2. **Мирчев М.** Кой притежава пациентската информация? Перспективи пред моралната претенция за собственост. Четиринадесета национална конференция по етика „Етиката в българия – традиции и хоризонти” 15 – 16 Ноември 2018, София

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