

REVIEW

**OF DISSERTATION WORK "OWNERSHIP OF
PATIENT INFORMATION IN THE CONTEXT OF BIG
DATA"**

AUTHOR: MARTIN OGNYANOV MIRCHEV
MENTOR: PROF. Dr. A. KEREKOVSKA, MD
Reviewer: Prof. Dr. ELENA SHIPKOVENSKA, MD

By Order No. R-109-342 / 09.10.2019 of the Rector of the Medical University "Prof. Dr. P. Stoyanov"- Varna I have been appointed as a member of the scientific jury under the procedure for obtaining the educational and scientific degree "Doctor" by Assistant Professor Martin Ognyanov Mirchev, PhD student at Medical university "Prof. Dr. P. Stoyanov "- Varna, Faculty of Public Health, Department of Social Medicine and Healthcare Organization, Professional Field: 7.4. Public Health, Specialty: Public Health Management. By Protocol No. 1 of October 23, 2019, I have been appointed as a reviewer by a meeting of the Scientific Jury.

Career development and qualifications of the doctoral student

Martin Mirchev has graduated as Bachelor in philosophy at Sofia University Kliment Ohridski (2006-2010), Master of Laws (2007-2015) and History of Philosophy (2010-2011). In addition he holds a Master's degree in Public Health from the Medical University "Prof. Dr. Paraskev Stoyanov "- Varna (2017-2018).

Martin Mirchev started his professional development in 2014 in the Department of Social Medicine and Healthcare Organization as a part-time assistant professor in medical ethics. From 2015 until now he has been an assistant at the same department, providing teaching in medical ethics to Bulgarian and English speaking students.

The applicant is a member of the Bulgarian Association for Bioethics and Clinical Ethics (BABKE), the European Public Health Association (EUPHA) and the Bulgarian Scientific Society for Public Health.

He participated in a one-week training course in public health and law at the Open Medical Institute in Salzburg, Austria, 06-12.10.2019. At BABKE, he

participated in one-day training in moral reasoning on case and conflict management. He is fluent in English.

Topicality of the dissertation

The problem of ownership of patient information in the context of Big Data has been poorly researched so far and there is no consensus on the ethical requirement for the privacy of individuals' personal data, the protection, and their use and management. So far, none of the EU Directives and Regulations has addressed directly the ownership status of patient data. Isolated debates exist in different places around the world, but the interest in improving healthcare systems and patient care locally, as well as globally, requires concrete and decisive approaches that address the issues of ownership of patient information not only in theory, but also in practical terms. All this determines the importance of this dissertation.

Structure of the dissertation

The total volume of the work is 257 pages, distributed as follows: Literature review; Aim, tasks and methodology of the research; Results and discussion; Conclusions and Proposal for a fair approach to ownership of patient information. The work contains 4 figures, 11 tables and 2 annexes.

EVALUATION OF THE SEPARATE SECTIONS:

Literature review:

The dissertation's literary review is well structured, with an emphasis on the conceptual apparatus and on the historical overview of the emergence and development of the information revolution and big data.

359 literary sources were analyzed, 4 of them in Cyrillic and 355 in Latin. Particularly valuable sections of the review section are those that address unresolved issues, shared challenges, and potential opportunities for future research.

Aim, tasks and methodology of the study

Defining the purpose and objectives in different areas is appropriate. The aim of the 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 ownership, and to propose a fair approach to ownership of patient information".

As the topic is interdisciplinary and includes legal, ethical, medical, informational, communication and technological aspects, it requires a more complicated search and analyze of the available sources of information. This also defines the applications in the dissertation, a comprehensive research toolkit, including:

- historical method for analyzing the evolution of the information revolution;

- philosophical and ethical analysis of the concept of ownership of patient information;

- a documentary method for analyzing regulatory documents. For the first time in Bulgaria, the methodology for conducting a scoping review on the given problem has been presented and applied. The purpose of the review is to determine the scope of available scientific literature, to summarize it and to identify the main sources of available evidence, as well as the gaps in the area of research. The research protocol was developed by the author.

The study uses an analytical framework including search, evaluation, synthesis and analysis (SALSA) of the main types of reviews, indicating their strengths and weaknesses.

Discussion of the research:

To achieve the goal, the author identifies three focuses of the study: 1. Problem: ownership of patient information. 2. Area: Health (Medicine) and 3. Context: Big data.

Out of the thousands of Big Data publications, the doctoral student reviews 724 and, after their eligibility assessment, screened 126 full-text publications in English language in the fields of healthcare and medicine.

After categorizing and classifying the publications, the author analyzes 27 of them, which directly address the issue of ownership of medical data. The articles are subject to quantitative analysis and evaluation. The publications are from 2014-2019. These are publications by authors employed by academic institutions, mainly from the United States and the United Kingdom. The author finds that the ownership of medical data is evaluated by different authors with respect to 5 aspects: ethical, legal, political, managerial, and combinations of them. Trends in the perception of patient information in terms of ownership - public or private - are outlined. In most publications, ownership of medical data is presented as a challenge to society and institutions, and no firm stance on the issue is indicated. Therefore, this study can be considered as a first step that initiates future research in this field.

In his dissertation, the author cites a number of examples that access to global databases could have the potential to transform real evidence in medicine and health care and open up unexpected new avenues for disease prevention, diagnosis and treatment. The development emphasizes that unlike structured data, unstructured so-called Big Data does not have a pre-defined organization. Despite the inaccuracy of Big Data, they have the potential to significantly expand knowledge of many clinical conditions, in which the collection of promising, structured data is time-consuming, limited, and more expensive.

The doctoral student proves that the role of patient information in the context of Big Data is fundamental because it becomes a valuable source of

information for the entire field of modern healthcare. A critical philosophical and ethical analysis of the permissibility of the idea of ownership of patient information shows the benefits and risks to humans of accessing and using the titanic amount of medical data that is being generated today. It is emphasized that the use of patient information is both scientifically and commercially important, which makes its regulation at this stage "a complex and almost unsolved problem."

Based on the philosophical and ethical analysis, the doctoral student proposes a fair approach to the ownership of patient information through 3 steps:

- first step - ethical analysis and determination of right / wrong, useful / harmful, fair / unfair;
- the second step - a subsequent public and political debate;
- Third step - a legal framework that reflects the rights of many stakeholders in the health information market, from patients, healthcare professionals to healthcare providers, and the public interest related to the appropriate use and disclosure of medical information.

The conclusions drawn are valuable because they provide a basis for the future proper orientation of the technical and technological ways of capturing and processing the patient's medical information. I agree with the doctoral contribution report. The work has theoretical, cognitive and practical contributions, some of which have original character:

1. For the first time, the issue of protection and ownership of patient information in the context of Big Data is raised and analyzed, and the main challenges, risks, benefits and opportunities of its use are presented.
2. On the basis of a detailed study and analysis of peer-reviewed publications in the specialized scientific literature, the historical development and definitions of the basic elements of eHealth have been traced: Electronic medical record, Electronic health record, Personal health record, Big data, Ownership of patient information;
3. For the first time in Bulgaria, an ethical analysis of the concept of propertization of patient information was carried out on the basis of the basic principles in biomedical ethics - autonomy, non-maleficence, beneficence and justice.
4. A fair approach to ownership of patient information is proposed with two potential options:
 - Patient information and its useful uses should be regulated without established ownership;
 - If a property right is recognized, it should be restricted in view of its potential useful uses for scientific and research medical purposes.

The abstract to the dissertation correctly reflects the structure of the dissertation and contains the most significant results and conclusions of the study. In connection with the dissertation, 3 publications were presented, printed in reputable Bulgarian medical journals and one article in a foreign journal - "European journal of public health". In three of the publications, the dissertation author is a solo or lead author. 2 scientific reports have also been prepared, presented at scientific forums / one - abroad and 1- exported to our country /.

CONCLUSION:

The dissertation presented is innovative in its formulation. This is the first study in Bulgaria to examine the problems of protection and ownership of patient information in the context of Big Data. The study identifies the problem, proposes a comprehensive methodological toolkit for its investigation and outlines concrete steps for its solution. The theoretical and applied contributions presented would deservedly find a place in the search for a future fair approach to ownership of patient information.

Everything in the review gives me reason to vote "positive" and I am confident to recommend to honorable members of the Scientific Jury, to vote positively for the award of the scientific and educational degree "Doctor" to MARTIN OGNYANOV MIRCHEV.

Sofia, 06.11.2019

REVIEWER: 
Prof. Dr. Elen. Shipkovenska, MD