

STATEMENT

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Subject: Thesis for Doctoral degree
in the field of higher education 7. "Health and sport",
Professional field 7.4 "Public health"

Theme of the thesis: "Ownership of patient information
in the context of big data"

Author: Martin Ognyanov Mirchev

I submit this statement as a member of the Scientific Jury, appointed by Order No. R 109-342 / 26.09.2019 of the Rector of the Medical University "Prof. Dr. Paraskev Stoyanov" - Varna based on a decision of the Academic Council of the Medical University - "Prof. Dr. Paraskev Stoyanov" (Protocol №143 / 27.09.2019) for evaluation of the dissertation work of Martin Ognyanov Mirchev - doctoral at the Department of Social Medicine and Health Organization, Faculty of Public Health, University of Medicine - Sofia. Varna with scientific mentor Prof. Dr. Albena Kerekovska, MD. The dissertation work was discussed and proposed for defense by the extended departmental council of the Department of Social Medicine and Health Organization, Faculty of Public Health at the Medical University "Prof. Dr. Paraskev Stoyanov" - Varna.

1. Brief information on the doctoral student's career development

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.

2. Relevance of the topic

The title of the dissertation submitted for review clearly speaks of its relevance and innovation, which have the following basic aspects: first, it is the given context of Big Data. The author traces the roots of the information revolution back in antiquity, but its culmination, the Big Data phenomenon, has only been reached in recent decades. Due to their highly dynamic development, Big Data today is considered to be the norm in healthcare, especially in the European context, but has not yet been uniquely defined and has not been thoroughly examined in relation to its relationship and role in health and healthcare.

The second up-to-date aspect of the topic is its exceptional legal and philosophical and ethical focus, which is related to the ELSI (Ethical Legal and Social Implications Program) program in human genome research. Scientific discussion recognizes that studies with similar ethical, legal and social focus are necessary for the needs of adequate public health policy, but are still very scarce, especially in the field of innovation in medicine.

3. Descriptive characteristic of the dissertation

The dissertation is presented in a total volume of 257 pages, including 4 figures, 11 tables and 2 annexes.

Its structure differs from traditionally established in the field of health sciences, but follows the usual approach to social sciences, which corresponds well with the specifics of the methodology used and the philosophical and ethical focus of the theoretical analyzes.

After a brief introduction to the research problem, the aim, tasks and research hypotheses are formulated. The following structural parts of the dissertation consistently present the study methodology, the literature review, the analysis (integrating results and discussion), their own proposal for a fair approach to ownership of patient information, conclusions, and contributions.

The author refers to 359 sources, 4 of which are in Cyrillic and 355 in Latin. The book illustrates the author's current awareness of contemporary scientific production on the problem and enviable awareness of the legal aspects of the topic and a wide range of classical and contemporary philosophies, social and ethical theories on which the individual theoretical studies are based.

4. Research methodology

The purpose 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 property, and to propose a

fair approach to ownership". Eight research tasks were set out in a logical sequence and four working hypotheses for its implementation.

Undoubtedly one of the greatest strengths of Martin Mirchev's dissertation is the use of a diverse, complex methodology for achieving the goal and objectives, combining a systematic preliminary review of the scope of scientific publications on the research problem, with a series of in-depth theoretical analyzes based on a historical, philosophical and ethical approach.

I highly appreciate the methodology of a preliminary review of the scope of research on the problem, which, in addition to being presented and applied for the first time in Bulgaria, can serve as a benchmark for accurately describing this extremely important part of any scientific study.

The historical method considers the origin and development of the Information Revolution and Big Data as products of historical regularity and social relations.

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. A comparative analysis of the scope and some of the specifics related to the protection and use of patient information, between the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the European Data Protection Regulation GDPR is presented.

The philosophical method itself is complexly applied and includes ontological, epistemological, axiological and anthropological aspects.

Ethical analysis has been made in depth through the prism of the four fundamental principles in contemporary biomedical ethics: autonomy, non-maleficence, beneficence, and justice.

5. Evaluation of the analysis and contributions of the dissertation

This dissertation is the first of its kind, focused, in-depth study of the problem of "ownership of patient information in the context of Big Data" and its ethical, legal and socio-philosophical aspects.

The results of the dissertation and their discussion are well structured and set out in the Analysis section following the tasks.

The analysis begins logically with the results of the specific and extremely appropriately selected method for scoping review, given the scarce information on the specific topic of "patient information ownership" among the otherwise abundant publications on Big Data.

The review confirms the hypothesis that the issue of ownership of patient information in the context of Big Data has been poorly studied and has not been addressed consistently and in its entirety - with respect to the ethical, political and regulatory aspects relevant to its resolution. Numerous proposals for resolving the

problem of property ownership highlight the technological potential and the need for political and regulatory solutions that imply a prior ethical, political, and rule-making debate.

Thus, an overview of the scope of available scientific research naturally leads to the next part of the analysis examining the place of patient information among the big data in healthcare, the challenges, risks, benefits and potential health benefits associated with their use. This section relates to the important comparative analysis between the US Federal Law on Health Insurance Portability and Accountability (HIPAA) and the European General Data Protection Regulation - (GDPR, applied since 25.05.2018). Both regulations have been found to relate to more specific health information and suggest protection without addressing the ambiguity about ownership. The differences and points of contact between the two documents are noted.

The benefits and risks associated with the ideas of public and private ownership of PI are analyzed, and it is strongly demonstrated that, regardless of the type of ownership (public or private), adequate legal tools are in place to ensure the confidentiality of information. It is pointed out that in reality, today, various legal acts regulate the right for the protection of personal data of people without indicating whether they are the data owners or only their physical sources.

Through the application of philosophical analysis, the author seeks to achieve an ethically justified perspective in the investigated problems of dissertation work and successfully realizes it. The ontological view shows that "ownership" serves the individual interest, which in the case of PI would be contrary to the public interest.

Epistemological analysis of the problem of ownership of patient information focuses on the ability of individuals and groups to authentically understand what their medical information is, through what techniques it can be used and by whom. For what purposes? What is its value. The following is an axiological and anthropological view of the problem, and the complex analysis thus achieved rejects the hypothesis that the existence of a legally recognized ownership of patient information would be justified in the light of individual and public interests focused on developing and improving medical services and science.

Alternatively, a limited ownership option is offered, given the possible useful uses of patient information for the development of medical science and research.

The following is the part of the ethical analysis that looks at the issue of ownership of patient information and the context of Big Data, in the light of the principles of autonomy, non-maleficence, beneficence and justice. Its purpose is to critically examine whether the idea of the identity of medical information meets the ethical requirements enshrined in these principles.

16 conclusions have been formulated, which follow logically from the broad multidisciplinary analysis of the scientific literature under consideration and follow the research tasks. I agree with the doctoral contribution report. I would like to point out once again the innovative nature of the study and its three original theoretical and cognitive contributions:

1. For the first time in Bulgaria, a philosophical analysis of the concept of propertization of patient information was carried out through the application of basic philosophical techniques and teachings - ontology, epistemology, axiology

and anthropology and ethical analysis based on the basic principles in biomedical ethics - autonomy, non-maleficence, beneficence and justice.

2. For the first time, the regulatory framework for the ownership and protection of patient information in Europe and the US has been analyzed for comparative purposes.

3. For the first time in Bulgaria the methodology for conducting scoping review is presented and applied in general as well as on a specific topic.

6. Assessment of publications and personal contribution of the doctoral student

In connection with the dissertation, three full-text publications and one extended summary were published in international journal with Impact Factor: European Journal of Public Health.

The doctoral student also presents two participations in scientific forums, one at a national ethics forum in Bulgaria and the other at the International Conference of the European Public Health Association - the most important forum in the field of public health in Europe.

In all publications and contributions related to the dissertation, Martin Mirchev is a sole or first author, which proves his personal involvement in the research and their contributions.

7. Abstract

The abstract is prepared according to the requirements and reflects the most important points of the dissertation. Structurally, he follows the thesis, is well illustrated with appropriate tables and a PRISMA diagram.

8. Critical notes and recommendations

I have had the opportunity to share my critical notes at earlier stages and I find that they have been taken into account. I recommend the author to publish at least two more articles: reviewing the scope of literature and ethical analysis in relevant scientific journals.

CONCLUSION

The dissertation presented is the first of its kind, purposeful, in-depth theoretical and with a philosophical-ethical focus research on the topic, meticulously conducted with complex methodology. It is a complete scientific product with undoubted theoretical contributions that make it relevant and valuable for any future research on the subject of patient ownership and broad types of health-related data.

The dissertation shows that Martin Mirchev possesses deep theoretical knowledge and professional skills, demonstrating qualities and skills for independent research.

The above said, along with the qualities of the dissertation and its full compliance with the requirements of the Law for the Development of the Academic Staff in the Republic of Bulgaria (ZRASRB), the Regulations for the implementation of the ZRASRB and the Rules of the MU – Varna, are the grounds for my positive assessment

and a definite proposal to the respected scientific jury, to awarded the educational and scientific degree "doctor" by Martin Mirchev in the doctoral program and specialty "Public Health Management", professional field 7.4 "Public Health", Higher Education Area 7. Healthcare and Sports.

11.10.2019 r.



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