

## REVIEW

**by Prof. Dr. Silviya Aleksandrova-Yankulovska, MD, PhD, DSc,  
Dean of the Faculty of Public Health at the Medical University - Pleven  
for the dissertation work of Assistant Professor Martin Ognyanov  
Mirchev on "Ownership of Patient Information in the Context of Big  
Data"**

According to 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, Scientific specialty: Public Health Management. According to Protocol No. 1 of October 23, 2019, I have been appointed as a reviewer at the meeting of the Scientific Jury.

### **Short information on the career development and qualifications of the PhD 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. Since 2015 he has been an assistant at the same department, teaching medical ethics to Bulgarian and English speaking students in the specialties "medicine" and "dental medicine" and to students in the specialties "health care management", "speech therapy" and "preservation and control of public health". His workload was 437 hours for the last academic year.

The applicant is a member of the Bulgarian Association of Bioethics and Clinical Ethics (BABCE), 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 Society Institute in Salzburg, Austria, 06-12.10.2019. At BABCE, he participated in one-day training in moral case deliberation and conflict management. He is fluent in English.

### **General characteristics of the dissertation**

The dissertation comprises of 257 pages (without the bibliography). It is structured as follows:

- Introduction - 3 pages;
- Aim and objectives - 2 pages
- Material and methods - 31 pages;
- Literature review - 26 pages;
- Analysis (Results and Discussion) - 171 pages;
- Proposal for a fair approach to ownership of patient information in the context of big data - 9 pages;
- Conclusion - 2 pages;
- Inferences - 4 pages;
- Contributions - 2 pages;
- Appendices - 6 pages.

The dissertation includes a total of 11 tables, 4 figures and 2 appendices.

### **Topicality of the dissertation**

The selected subject of the dissertation is undoubtedly topical against the background of the already accumulated and accumulating masses of information in healthcare, which is of interest to different parties and it is significant for the realization of specific public health goals. By prioritizing the principle of respect for autonomy in bioethics and its formalization as an absolute requirement for obtaining informed consent from the patient not only for medical actions, but also for the use of patient information, practical dilemmas become a daily matter for healthcare professionals, both in patient care and research. This reality and the expected increase in the importance of Big Data in the delivery of healthcare are presented in the introduction of the dissertation.

## **Assessment of the structural parts of the dissertation**

The dissertation is innovative in many ways, including its structure. The applicant does not follow the traditional structure of: literature review; aim, objectives and methodology; results; inferences, recommendations, contributions, bibliography. Instead, the aim, objectives, research hypotheses are presented first, followed by material and methods, and only then the literature review and analysis (results and discussion) are presented. The proportions of the individual parts also differ from the traditional ones, with the literature review covering 26 pages out of the total 257 pages, which is only 5 pages less than the Material and Methods section. It should be noted, however, that in the Analysis section there are another 30 pages of results from the scoping review, which placement is controversial. Personally, I accept the categorization of the scoping review in this section, but it could be part of the literature review regardless of the issue with the terminology (the literature review is a separate type of review according to the classification of Grant and Booth).

As for the other sections of the structure, I accept the shift of the traditional structure as justified given the use of less popular in the field of medicine in general and social medicine in particular research methods and the need to present them adequately from the outset. Nevertheless, I believe that the texts that are distinguishing the systematic review from the so-called scoping review can be shortened in the parts where they resemble too much a scholar style.

**Purpose and Tasks.** Heterogeneous sources are used and not all of them (lectures, presentations) are widely accessible and could be independently evaluated. The difference between the second and third task is not clear. A task has been formulated to identify regulatory issues. Thus it would be appropriate to combine this task with a task to investigate the regulatory framework.

The formulation of the hypotheses can be specified. The first hypothesis combines two statements, and its proof would be easier to trace if they were separated.

**Material and Methods.** Overall, the section is very precisely described, with particular emphasis on the methodology of the scoping review. The steps are adequately described and allow for repeatability. The PRISMA diagram is correctly drawn up.

The documentary method is described generally. The objectives of this method listed in one sentence would be more specific if presented in a questionnaire for extraction of information from documents.

The Philosophical schools of thought are well placed in the context of the tasks of the scientific inquiry.

In the ethical analysis section, the PhD student deviates from the well-established terms in our ethics literature on the basic principles of bioethics by introducing a no-harm principle as a "substitute" for the principle of non-maleficence. I do not regard the replacement appropriate, although this does not change the substance of the text.

**Literature review.** In a narrative style, the PhD student gives a brief overview of the emergence of the information revolution; he attempts to define the concept of "big data", to define its meaning in healthcare, and ends the review with the concept of "ownership" in the context of patient information. I believe that a section, regarding the use of patients' information for scientific purposes, may be added to summarize the available positions in the European regulations and national legislation.

**Analysis (results and discussion).** In the next section, the PhD student begins with the results of the scoping review. In a separate appendix PRISMA checklist is provided. However, some sections are difficult to trace. For example, it is not clear whether the review protocol has been formally published, as such practice exists for the systematic reviews. The review covers English-language publications made after 2014, mainly by authors employed by academic institutions. It is visible that very few articles are published in ethics, law and policy journals. These were dropped due to the specific inclusion criteria of the review, namely the impact factor and the citations, which are rather low for such specialized publications. I believe that these two criteria should have been dropped precisely because they limit valuable publications - those whose authors are close specialists and represent the ethical, deontological and philosophical debate that Martin Mirchev's research interest is focused on. The perspectives on the propertization of personal data, especially the perspective that it may prove to be a valuable alternative to the difficult task of making the existing healthcare system effective, are interesting (p.78). A reference could be made here, to such a mechanism introduced by the National Health Insurance Fund with the provision of a unique access code for health insured persons to enable them to monitor their data in the system and to control the activities

reported by health care providers (<https://pis.nhif.bg/main/>). The part "Limitations of the Study" honors the work by following the international standards for such publications. When reviewing scientific works employing qualitative research methods, such as those submitted to the scoping review, it is not necessary to seek statistical significance. Therefore, I do not find this to be a limitation of the review. Rather, I would add the coverage of only English literature as a limitation (which is often a problem in systematic reviews in general).

The next section of the analysis, "Big Data in Healthcare and the Place of Patient Information - Challenges, Risks and Benefits, Potential Opportunities" is, in essence, a critical analysis of the literature, but there is no clarity on the applied methodology, and it is difficult to distinguish the student's own reflections from the summaries based on other authors. What I find most interesting in this section, is the comparative analysis of GDPR and HIPAA, which is prepared exhaustively and competently. In case of publication of this material in the future, I recommend systematizing the benchmarks and the positions of the two documents in the form of a table.

In the expanded arguments regarding public versus personal ownership of patient data on page 152, it is also worth discussing the "reverse side of the coin", namely the cases in which, based on the application of new diagnostic methods on archives of patients' materials, important patterns that may influence the therapy are established, but no proper feedback mechanisms and mechanisms of provision of this new information to the patient and physician are available.

*The philosophical analysis* begins with a brief and appropriate explanation as to why this method of inquiry will be applied to the problem under study. An ontological, epistemological, axiological and anthropological approach has been consistently developed in regard to the problem of the ownership of patient information. The text is consistent, without digression and with appropriate references to key authors and concepts.

*The ethical analysis* is based on the classical four principles of bioethics, known as the principles of Beauchamp and Childress, but with the above mentioned substitution of the names recognized in the Bulgarian ethics literature. However, interpretations of the principles are deepened by the incorporation of more than one dimension. The positions of Ass. Mirchev on each of the principles are well reasoned and written in an appropriate scientific style. Appropriate analogies are chosen, such as between organ

donation and patient information regarding trade opportunities and the risks of harming the patient (p. 206). Internal comparisons and attempts have been made to balance the principles. The fundamentality and inviolability of the principle of non-maleficence, in accordance to the classical concept of Beauchamp and Childress, have not been emphasized. In addition, the discussion in this section would benefit from a clearer structuring with a separation between utilitarianism and principlism, where the latter has an individual focus. It is also appropriate to separate the patient rights perspective in a separate part of the ethical analysis and to identify it as a separate methodology.

**Proposal for a fair approach to the ownership of patient information in the context of Big Data.** This part of the dissertation begins with a summary of the analysis with the different research methods, which creates good prerequisites for coming up with a specific practical proposal. However, it is rather blurred and, instead of creating a completion of the work, it gives the impression of avoiding to take a clear stand, especially when Martin Mirchev proposes to “put aside the possible alternatives of propertyzation” (p.241), what seems to return us at the starting position. This impression is only cleared up in the next section of inferences and contributions. Thus, the realization of the last task of the dissertation remains unconvincing. In addition, the proposal to view patient information as socially relevant in regard to its easier use for scientific purposes, while being in the interest of public health, does not contribute to other current tasks at the European Union level, namely reducing unnecessary research on issues with accumulated sufficient evidence-based data. Despite everything, if researchers have to justify their need for access to protected patient information, only high value and really necessary research would be held. I leave the latter for reflection and an opportunity for further scientific development of Martin Mirchev.

**Inferences and Contributions.** Systematically in the course of the presentation of the text of the dissertation Martin Mirchev draws intermediate conclusions, which helps the reader to follow this principally difficult matter. The final inferences are well elaborated and sufficient in number. I think the first three can be reduced. The fourteenth inference deserves more substantive argumentation and focusing in this direction would be beneficial.

I fully accept the scientific-theoretical contributions and most of the applied science contributions. I have reserves only towards the fourth contribution, which I justified in the previous section of the review.

**The bibliography** contains 355 foreign literature sources and only 4 sources in Bulgarian. Undoubtedly, the research question is new to our scientific school, but more sources in Bulgarian could still be found. For example, one suitable work, that is not referred by M. Mirchev, is the publication of Miteva-Katrandzhieva Ts. and Stefanov R. Ethical issues related to epidemiological registers of rare diseases. *Rare Diseases and Orphan Drugs*, 2016, 7 (1): 18-22, which comes out in a simple google search, it is available in full text, and the ownership is one of the four major ethical issues identified and analyzed by the authors. A suitable place to refer to this article is on page 87, where the PhD student discusses policy decisions with more flexible access to different registers. The inclusion of the so-called 'Gray literature', which is invisible in standard databases, often is written in a language other than English and it is manually searched by the researcher, not only is permissible but it is also encouraged in the systematic reviews. There is a potential for increasing the sources in Bulgarian in the description of the methodology, where references to established authors could be made regarding the historical and documentary method, as well as the philosophical and ethical analyses. Additionally, on page 129, the Law on Copyright and Related Rights is cited without being included in the bibliography. Pages 150-151 comment on the use of patient data for scientific purposes and for identifying public health problems. Reference could also be made here to the Personal Data Protection Act, in particular Art. 25n, which refers to the use of personal data originally collected for another purpose, for research purposes. On page 153 there are cases where the law requires disclosure of patient information supported by a reference to Nesbitt 2013, but the Bulgarian Health Act under Art. 28, which regulates exactly the same framework at national level is not mentioned.

**The summary of the dissertation** corresponds to the structure of the generally accepted requirements and fully reflects the content of the dissertation, but the length can be further reduced. The proposal for a fair approach to ownership of patient information lacks the key idea of identifying patient medical information as a socially relevant type of data.

In relation to the dissertation, 3 full-text articles in Bulgarian were stated as well as 1 abstract of participation in an international scientific event and 2 participations in conferences in Bulgaria. The scholarly journals for the three publications are well-chosen to address a diverse audience of public health specialists, ethicists and philosophers. The international scientific event where the candidate was able to present his work as a sole author, was the annual EUPHA conference, which is the most respected public health conference with the most difficult selection procedure.

In addition, it is worth mentioning that the PhD student authored and co-authored another scientific paper in an EUPHA conference as well as 1 full-text publication and 1 participation in a conference in Bulgarian, what represents him as a prospective researcher.

### **Conclusion**

The constructive remarks that were made on the dissertation work "Ownership of patient information in the context of Big Data" does not diminish its value. On the contrary, the work has made an indisputable contribution to our medical-ethics literature, where theoretical contributions and attempts to apply sociological methods of study have prevailed in the last two decades without taking into account the specific characteristics of this scientific field. Thanks to his training in philosophy, law and public health, Martin Mirchev has successfully applied philosophical and ethical analysis to his research question, what makes the dissertation corresponding, in style and content, to the requirements of the modern bioethics works.

The dissertation meets the requirements of the Regulations for the development of the academic staff at the Medical University of Varna, that makes me confident in suggesting to the honorable members of the Scientific Jury to vote positively for awarding Doctorate degree in the scientific specialty "Public Health Management" to Assistant Professor Martin Ognyanov Mirchev.

13<sup>th</sup> of November 2019

Reviewer:

  
**Prof. Dr. Silviya Aleksandrova-Yankulovska, MD, PhD, DSc**