R E VIEW

Of a PhD thesis on the subject of:

RAISING AWARENESS OF RADIATION RISK IN MEDICAL DIAGNOSTICS AND THERAPY

By

Stanislava Milcheva Mavrodinova

A full-time doctoral student,

Lecturer at the X-Ray Laboratory Assistant Educational Sector at Medical College Varna, Medical University "Prof. P. Stoyanov" – Varna

The doctoral thesis is submitted for awarding the educational and scientific degree Philosophy Doctor in higher education area 7. Healthcare and Sports, 7.4. Public Health – professional field, Scientific Specialty Healthcare Management

Reviewer: Prof. Sonya Koleva Toncheva, PhD, DSc
Deputy Director of the Shumen Affiliate, MU-Varna

1. Biographical data, career profile and thesis subject relevance

Stanislava Milcheva Mavrodinova was born on December 23, 1977 in Varna. In 1999, she graduated from the Medical College in Plovdiv with a degree in X-ray laboratory technician. She consistently advanced her education, acquiring a Bachelor's degree in Social Services from St. Cyril and St. Methodius University of Veliko Tarnovo (2003) and two Master's degrees in Public Health (2008) and Healthcare Management (2014) from the Medical University "Prof. Dr. P. Stoyanov" – Varna. In September 2021, she obtained a degree in Public Health at the Medical University - Varna.

Stanislava Mavrodinova has more than twenty years of experience in various inpatient and outpatient medical facilities in the field of Imaging Diagnostics in the city of Varna – the Naval Hospital and St. Anna's Hospital Varna, etc.

She became an assistant professor in 2009, launching her academic career. Until 2020, Mavrodinova successively held the position of lecturer at the X-ray Laboratory Assistant educational sector at the Medical College of MU–Varna. At present, she is an assistant professor there. She teaches in the following subjects: Radiographic methods – 1, 2, 3, 4 part – academic

exercises; and academic Teaching practice – 1, 2, 3, 4, and 5 parts. St. Mavrodinova is involved in developing and updating the curricula for the mentioned courses.

On June 11, 2020, Stanislava Mavrodinova was enrolled as a full-time doctoral student in the Department of Nursing Care to pursue the educational and scientific degree "Philosophy Doctor" in Healthcare Management.

She has over 14 publications, participated in numerous congresses and international symposiums in the field of imaging diagnostics and radiation protection, and contributed to multiple research projects.

Assist. Prof. Mavrodinova is a member of a number of renowned professional associations – the Bulgarian Association of Healthcare Professionals (BAHP), the Bulgarian Association of Laboratory Technicians in Imaging Diagnostics and Therapy, the Bulgarian Association of Radiology (BAR), the European Federation of Radiographer Societies (EFRS) and the International Society of Radiographers and Radiological Technologists (ISRRT).

In my opinion, the thesis subject is highly relevant to the professional and academic development of the doctoral student.

2. Administration of the thesis defence procedure

Assist. Prof. Stanislava Milcheva Mavrodinova was enrolled as a full-time doctoral student in the PhD program at the Department of Nursing Care of the Medical University – Varna by Order № R -109- 499/04.11.2020 of the Rector of Medical University - Varna. She was given authorisation to defend her doctoral thesis by Order No. 109-50/29.11.2023 of the Rector of MU-Varna. The Rector's order was based on Article 26, paragraph 6 and Article 30, paragraph 3 of the Development of the Academic Staff in the Republic of Bulgaria Act in Bulgaria, the Rules and Regulations for Academic Staff Development of the Medical University Varna (Article 68, paragraph 1) and the Minutes Summary No. 214/22.11.2023 of the Faculty Council of the Faculty of Public Health for successfully passed doctoral examinations.

The candidate's submitted documentation, along with the existing administrative records, demonstrate the procedural validity of the process as per the Development of the Academic Staff in the Republic of Bulgaria Act.

The list of thesis-related publications presents 2 papers. Mavrodinova is the first author of one of them, while in the other, published in Kazan, she is listed as the second author. The publications are presented in full text. They adequately reflect the thesis research subject.

The thesis summary is presented on 77 pages. The content is well-structured and conveys a cohesive summary of the thesis. It contains all the mandatory components for a thesis summary. The most essential parts of the thesis content have been expertly selected. The summary provides a comprehensive understanding of the concept, methodology, structure and results.

3. General characteristics of the thesis

3.1. Relevance of the thesis research

The advancement of scientific knowledge and technology has facilitated the implementation of innovative treatment and diagnostic techniques in medicine. These developments are

particularly noticeable in the field of radiotherapy and diagnostic imaging. Hence, there is a need to reduce the risk associated with ionising radiation exposure. This can be achieved by respecting the basic principles of radiation protection, namely that any medical exposure should have a valid reason and be optimised for maximum benefit. Therefore, international standards and the Good Clinical Practice Guidelines for Diagnostic Imaging offer a number of tools to support the optimisation process. One of the key elements is conducting periodic monitoring of patient doses and comparing them with appropriate diagnostic reference levels. All of this, together with respect for the patient's right to informed consent for all procedures affecting patient life and health, necessitates raising the awareness of both the medical professionals involved in this process and the patients themselves.

In today's world, mastering a profession requires a significant volume of knowledge and skills. This calls for the implementation of both conventional but also innovative interdisciplinary methods and techniques. The author has convincingly established the significance of the topic through the literature review. The inadequate progress of research and identified gaps in the problem in our country have motivated the selection of the proposed thesis subject. It is indisputable that a serious issue, such as the participation of the radiology laboratory technician in the diagnostic imaging team, deserves its detailed study. Professional communication and cooperation with other medical team members allow the radiology lab technicians to effectively apply their training. The elected subject is important in constructing a present-day profile of the regulated profession of X-ray laboratory technicians.

3.2. Expertise in the issues demonstrated by the doctoral student

Assist. Prof. Mavrodinova has over 20 years of experience in Diagnostic Imaging for both inpatient and outpatient care. Since 2009, Mavrodinova has been actively incorporating her accumulated experience into her teaching, projects, and research for her thesis. The thesis subject was selected due to the significance of the topic, taking into account the limited scientific progress in our country and its impact on the professional competency and responsibilities of radiology lab technicians.

3.3. Existence of a research issue (suitable for thesis research)

The scientific literature lacks a comprehensive and systematic study of the problem under consideration. The attention of scientists is naturally drawn towards investigating methods to promote understanding of the risks associated with ionising radiation in medical procedures. Comparing the regulatory frameworks of the Republic of Bulgaria and international standards, as well as the study of the level of awareness of medical professionals and patients about the radiation risk, creates opportunities for raising awareness about radiation exposure and optimisation of activities related to diagnostics and treatment with ionising radiation.

The self-developed **Model for Informed Consent Form for Mammography** (an X-ray examination that images the structure of the breast and in which a source of ionising radiation is used) is an original document with a structure and content reflecting all the necessary requisites of a written form for obtaining a patient's informed consent. The form brings together three main sections adapted to the needs of patients and health professionals.

The proposed **Patient Radiation Passport Model** projects the PhD student's views on patient dose reporting in imaging studies. The rationale is that according to Bulgarian legislation, there are no defined limits on patient doses, and the application of X-rays in imaging studies is guided

by the ALARA principle. The developed Patient Radiation Passport Model aims to create accountability in patient exposure doses to prevent unnecessary and unregulated application of X-ray examinations leading to radiation dose load.

The topic is effectively conveyed in the content of the work through a precise conceptual approach. The formulated and research-backed aim effectively showcases the study's objectives, sub-objectives, working hypotheses, methodology, organisation, objects, and volume. The technical and logical units of the study are precisely defined. The inclusion criteria for the study and its stages are described.

Undoubtedly, the work submitted by Assist. Prof. Mavrodinova can be the subject of a thesis research. By combining her professional expertise, unique teaching style, and awareness of global best practices, the author has identified niches in Imaging Diagnostics. Based on all of this, I am convinced that both the selected topic and the method of addressing it in a research project are realistic, pertinent, quantifiable, and feasible.

3.4. Thesis structure

The thesis contents are structured in four chapters. Following the review, a summary is provided that supports the research focus and highlights the author's concept. The author's general conclusions and recommendations, contributions and conclusion are not separated in a separate Chapter V of a thesis, which would have followed the classical structure of a thesis. The methodological framework and the organisation of the study are set out in Chapter II, and Chapters III and IV substantively and evidentially fulfil the aim and tasks of the thesis research.

The thesis is presented on 191 standard pages. There is a good balance between the individual sections/chapters in terms of length and content: introduction – 1 page; chapter one – 53 pages; chapter two – 11 pages; chapter three – 51 pages; chapter four – 23 pages; and conclusions, recommendations, contributions and conclusion – 7 pages. The references are presented on 18 pages, and the sources are properly cited in the reference list. All the study chapters are linked by a logical connection, resulting in a cohesive methodology. The necessary evidence accompanies the content of each chapter. The appendices run to 18 pages.

3.5. Thesis contents

While the methodological framework structures the thesis, the content is subordinate to the research hypothesis.

The thesis includes 3 tables and 74 figures. There are 4 Appendices. A total of 279 literature sources were used, with 48 written in Cyrillic and 230 written in Latin. The literature sources in Cyrillic are considerably fewer, as there are few studies and publications on the chosen subject. The literature review focuses on recent information, with most sources being from 2018 or later. The thesis begins by listing the abbreviations, simplifying the reading process.

Literature review

The first chapter is LITERATURE REVIEW – RELEVANCE OF THE ISSUE OF IONISING RADIATION IN MEDICAL DIAGNOSTICS AND THERAPY. The review is developed in two sections. A ***Historical Review of the Emergence of the Concept of Ionizing Radiation in Medical Diagnostics and Therapy*** examines the fundamental scientific discoveries related to

ionising radiation and the evolution of ionising radiation in medical diagnostics and treatment. The other main section is ***the Current status of the problem of X-ray examinations and diagnostic procedures using ionising radiation sources***. This part of the review clarifies basic concepts in imaging diagnostics and medical physics, X-ray examinations and diagnostic procedures using ionising radiation sources in modern healthcare – types, effectiveness, and challenges in their selection and application. International standards and best practices are presented to support the process of organisation, documentation and systematisation of information related to radiation risk in medical diagnostics and therapy and the experience of other countries and Bulgaria on the process of informing and obtaining informed consent from the patient for X-ray examinations and diagnostic procedures using sources of ionising radiation.

The doctoral student has addressed the topics of organisation, documentation and systematisation of information related to radiation risk in medical diagnostics and therapy in Bulgaria and has examined ways to optimise the involvement of radiology technologists in the process.

In her concluding remarks for this chapter, Mavrodinova presents significant summary conclusions: the need to optimise the organisation, documentation and systematisation of information related to radiation risk in medical diagnostics and therapy in the Republic of Bulgaria; the presence of gaps in the informed consent forms in the imaging departments, which may lead to compromising the process of informing and obtaining informed consent – lack of standardisation, incomplete information, different language approach, as well as limitations regarding the right to consent.

The author effectively analysed various sources to develop the literature review, demonstrating a comprehensive understanding of other authors' perspectives on the issue. The structure of the literature review and the stylistic layout lead to the conclusion that Assist. Prof. Stanislava Mavrodinova can handle literature sources and express her own opinion on the thesis subject.

Methodology and organisation of the study

Chapter two – **AIM, TASKS, METHODOLOGY AND ORGANISATION OF THE STUDY**, is based on the thoroughly developed literature review and the conclusions drawn. The aim has been clearly established, 8 objectives have been outlined, and the study's object and subject have been identified. The technical and logical units of the study are specified. The author has formulated 5 working hypotheses, probably due to the fact that there are not many studies and publications on the selected subject of the thesis. The general and specific characteristics of the inclusion and exclusion criteria in the study are specified. The scope of research is defined – 370 individuals divided into 4 groups and location of the study. The methodology is presented with the stages of conducting the study and the methods of collecting and processing the information. The whole methodology and organisation of the study are described in a very precise way.

Results

Chapter Three – **RESULTS AND DISCUSSION OF THE SURVEY CONDUCTED AMONG MEDICAL PROFESSIONALS AND PATIENTS**, and ***Chapter Four*** – **INNOVATIVE TOOLS AND MODELS TO RAISE AWARENESS OF MEDICAL PROFESSIONALS AND PATIENTS ABOUT THE RISK OF IONISING RADIATION DURING MEDICAL DIAGNOSTICS AND THERAPY**, focus on the research findings. They are based on the opinions of 4 groups of respondents and precise analyses of the results. The author concludes that despite the advancements of science regarding X-ray tests and diagnostic procedures using ionising radiation sources and the numerous scientific studies, the effective practical implementation of the process of informing patients and medical professionals about these procedures still faces a number of challenges and unsolved problems. The analysed legislative framework regulating this type of medical activity in the Republic of Bulgaria lacks a unified system for registration, reporting and control of X-ray examinations of patients. This, in turn, reduces the possibility of X-ray specialists to monitor patient doses and makes it challenging to inform patients about the risks associated with ionising radiation for medical diagnostics and therapy. The analysis identified gaps in informed consent forms in the different imaging departments, such as lack of standardisation, incomplete information, different language and approach, and limitations on the right to consent and refusal, which may compromise the process of informing and obtaining informed consent. The forward-thinking and the results outline the need to optimise the organisation, documentation and systematisation of information related to radiation exposure in medical diagnostics and therapy in the Republic of Bulgaria. The author investigates how other countries have effectively tackled the issue of obtaining informed consent from patients during medical procedures involving radiation risks and how this can be tailored to suit the conditions in Bulgaria. The issue of the radiology lab technician's involvement in securing informed consent is being discussed. Research indicates that patients are not adequately informed about the potential risks of ionising radiation used in medical diagnostics and treatment. This limits their ability to make an informed decision about consenting to X-ray examinations and procedures. Radiological lab technicians and specialist physicians have important roles in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent for imaging procedures and examinations. According to the majority of X-ray laboratory technicians and specialists, additional training is needed for all healthcare professionals responsible for discussing radiation risk with patients during medical procedures and treatments.

I appreciate the original approach to developing a Radiation Passport for the registration of the individual patient's radiation dose during X-ray examinations and procedures. It has been proposed as a tool to create opportunities for X-ray specialists to monitor patient doses and to increase patient awareness of the risk of ionising radiation in medical diagnostics and therapy. The author's approach is accurate as she validates the application of the developed author models through the expressed opinion of experts. According to the results, the expert evaluation proved the applicability of the developed innovative models and tools to increase the awareness of the risk of ionising radiation. They would additionally optimise the performance of medical professionals involved in medical diagnostics and therapy related to radiation risk.

The conclusions and the recommendations to the responsible institutions demonstrate a high level of competence and synthesis. This part of the thesis is a theoretical summary of the

methodology, design decision, process and results to substantiate thesis hypotheses and contributions.

4. Contributions

The research results, formulated conclusions, and recommendations outline the theoretical and practical contributions. The list of contributions presented in the thesis objectively shows the actual achievements of the author. From the contributions presented by the author, I acknowledge the following:

Theoretical contributions

- The first-of-its-kind comprehensive, focused and in-depth study of the possibilities for raising awareness of radiation risk in medical diagnostics and therapy has been made.
- The opinion of radiology lab technicians, physicians and patients was studied regarding the role and contribution of the radiology technician in the process of informing and obtaining consent from patients and the need for legal regulation of his participation.
- For the first time, a study and analysis of the current regulations regarding the participation of radiology technicians in the informed consent process of patients in the Republic of Bulgaria has been carried out.
- Several specific proposals have been made to optimise the organisation, documentation and systematisation of information related to radiation risk in medical diagnostics and therapy in the Republic of Bulgaria.
- Proposals and recommendations have been formulated for the institutions responsible for optimising the organisation, documentation, and systematisation of information related to radiation risk in medical diagnostics and therapy in the Republic of Bulgaria in the process of obtaining patient informed consent.

Practical contributions

- An author's model of a unified form for patient-informed consent for x-ray examination (mammography) has been developed. The Model assists in complying with patients' right to informed consent in accordance with the current regulations of the Republic of Bulgaria (Health Act, Article 89. p. 1, 33). The Model facilitated partnerships and shared responsibility between radiology technicians and patients. Based on the proposed informed consent form for mammography, forms for other X-ray examinations can be developed.
- A multifactorial framework of the informed consent process has been developed in accordance with the regulations of the Republic of Bulgaria. It is applicable to all X-ray examinations and diagnostic procedures using ionising radiation sources.
- For the first time, a Radiation Passport was developed for registration of the patient's individual radiation dose during X-ray examinations and procedures, which is a tool for radiation risk management and for increasing patient awareness of the risk of ionising radiation for medical diagnostics and therapy.

5. Recommendations and questions

- The doctoral student should continue her research into **awareness, radiation risk in medical diagnostics and therapy**, and methods to increase the effectiveness of training for radiology laboratory technicians;

- The comprehensively developed literature review should be expanded and published as a ***Guide for Radiology Laboratory Technicians***;
- The doctoral student should patent the **Radiation Passport** for registration of the patient's individual radiation dose during X-ray examinations and procedures;
- The doctoral student should broaden the scope of her publication activity in specialised Bulgarian and international journals and proceedings.

I have no questions for the PhD student.

6. Personal impressions

I have known Stanislava Mavrodinova for more than 10 years as an assistant professor at the Medical College – Varna, as my student in the Master's program in Healthcare Management and since the state examinations for the Public Health speciality. She is highly positive, ethical and responsive to colleagues and other university faculty. Thanks to her innovative thinking, strong organisational skills, and effective communication, she has become a highly respected teacher with excellent teamwork abilities. She possesses critical self-awareness, a curious mind, and a determined approach towards asserting herself.

7. Conclusion

Having carefully examined the extensive and valuable research work, I give a very good assessment of the thesis and the results achieved. I confidently recommend to the esteemed jury to award Assist. Prof. Stanislava Milcheva Mavrodinova with the educational and scientific degree Philosophy Doctor in Healthcare Management for the needs of the X-Ray Laboratory Assistant Educational Sector at the Medical College of MU-Varna.

18/01/2024

Prepared by

Prof. Sonya Toncheva, MD, PhD