R E V I E W

by Prof. Kancho Trifonov Tchamov, MD. PhD.
member of scientific jury appointed by order No. R-109-508 / 29.11.2023 of Prof. Dr. Svetoslav Georgiev, Ph.D. - Rector of Medical University "Prof. Dr. Paraskev Stoyanov" Varna

Regarding : procedure for defending a dissertation work for obtaining the educational and scientific degree (ESD) "doctor " by the candidate **Stanislava Milcheva Mavrodinova**, a full-time doctoral student in the doctoral program "Health care management" in the field of higher education 7. "Health care and sports" in professional direction 7.4. "Public Health" and the scientific specialty "Social Medicine and Organization of Health Care and Pharmacy" at the "Health Care" Department of the Faculty of Public Health at Medical University - Varna on the topic **"Increasing the awareness of radiation risk in medical diagnosis and therapy"**

Academic supervisors : Associate Professor Anna Georgieva, Ph.D.

Associate Professor Veselina Slavova, Ph.D.

1. Biographical data and career development of the doctoral student

Stanislava Milcheva Mavrodinova was born on December 23.12.1977 in the city of Varna. In the period 1996 - 1999 completed his studies in the Medical College at the Medical University - Plovdiv, acquiring the specialty "X-ray Laboratory Technician". In 2003, she successfully completed a bachelor's program in "Social Activities" at VTU "St. St. Cyril and Methodius" - town of Veliko Tarnovo. She successively acquired a master's degree in Public Health (2008) and Health Care Management (2014) from the Medical University "Prof. Dr. Paraskev Stoyanov" - Varna. In the period 2020-2021, she completed her specialization in "Public Health" at the same university. The candidate began her professional career as an X-ray laboratory assistant in the Department of Imaging Diagnostics of the MMA - Varna in 1999. From 2000 to 2007, she worked for varying lengths of time in health facilities for inpatient and outpatient medical care in the city of Varna. The academic career of Stanislava Mavrodinova began in 2009 with the appointment as a teacher, and later, after winning a competition, as assistant professor in the Department of "X-ray Laboratory Technician" at the Medical College at the Medical University of Varna. In 2020, she was enrolled as a full-time doctoral student at the Department of Health Care at the Medical University of Varna. The presented information about the doctoral student's career development shows a desire for professional development and improvement.

2. Dissertation data

The dissertation work of Stanislava Mavrodinova presented for discussion has a volume of 191 standard pages. The text of the development is illustrated with 74 figures, 3 tables and 4 appendices. The literature reference contains 279 sources, of which 49 are in Cyrillic and 230 are in Latin.

The paper is presented in four chapters and is structured as follows: introduction; literature review; purpose, tasks, methodology and organization of the study; two chapters including, discussion of the results of a survey conducted among medical professionals and patients and analysis of innovative models to increase awareness of the risk of ionizing radiation in diagnosis and treatment; findings, suggestions, contributions, conclusion, bibliography and appendices. The individual chapters of the work are chronologically connected and meet the structural and substantive academic requirements for a similar scientific work. In addition, four applications developed by the doctoral student as a methodological toolkit for researching the problem are presented, including: three questionnaires for assessing the possibilities of increasing awareness of the risk of ionizing radiation in medical diagnosis and therapy among patients, medical specialists and X-ray laboratory technicians; and a structured interview to assess the applicability of the purpose-developed informed consent form and radiation passport. Two scientific publications, printed in authoritative Bulgarian medical publications, are presented in thematic connection with the dissertation work.

2. Actuality of the dissertation work

Medical procedures are the largest man-made source of radiation exposure to the population. According to summary estimates of the "Scientific Committee on the Effects of Atomic Radiation at the United Nations," (UNSCEAR), medical radiation is the main man-made source of human exposure, accounting for over 99% of background exposure and about 21% of total population exposure. In recent decades, radiation exposure continues to increase due to the systematic introduction of new imaging methods and radiation therapy. The national health policy should take into account the possible risks of the spread of new technologies and approve measures to guarantee the legitimacy of radiation for medical purposes. This raises the need for action to reduce the risk of exposure to ionizing radiation by complying with international and national standards and rules of good medical practice. These include: compliance with the basic principles of radiation protection; quality control of medical equipment; specifying the need for justified and optimized methods of medical radiation; and supporting radiation protection through scientific research. Of decisive importance in this direction is the control and traceability of the doses administered by various imaging methods or therapy. *In this sequence, it is also necessary to increase the awareness of patients through targeted information and adequate dialogue with the referring physician, through which to ensure the patient's informed consent for the applied medical procedures.*

In this context, the dissertation work presented by Stanislava Mavrodinova treats an actual, but poorly studied in our country, medico-social problem, related to raising awareness about the radiation risk in medical diagnosis and therapy. The relevance of the presented study is also supported by the almost missing scientific studies and publications on this issue in our country.

3. Awareness of the issue

The literature overview in a volume of 53 pages includes 279 literary sources, the majority of which were published in the last 10 years. The analysis of scientific publications is structured in two sections, which chronologically analyze the main aspects of the researched problem, including: a historical overview of the use of ionizing radiation in medical diagnostics and therapy;

diagnostic procedures using ionizing radiation; international standards and good practices related to radiation risk; the process of informing and obtaining informed consent from the patient in Bulgaria and other countries; legal and regulatory framework related to the organization and documentation of radiation risk information during medical diagnosis and therapy in the Republic of Bulgaria.

The PhD student demonstrates good literature awareness and analytical abilities to place the right emphasis on current issues related to the study of the level of awareness of medical professionals and patients regarding radiation risk in diagnosis and treatment with ionizing radiation. The role of medical specialists in the process of informing the patient about the radiation risk as a basis for obtaining informed consent is also analyzed. The synthesis of the literary sources shows a thorough knowledge of the problem, good professional and terminological competence. The conclusions of the literature review served as a basis for formulating the goals and structure of the dissertation work. The obtained summaries convincingly substantiate the necessity and relevance of the study, supporting the chronological selection of its tasks and the approaches to their implementation.

4. Purpose, tasks and methodology of the study

The aim and the set eight tasks of the dissertation development are clearly formulated, specific and justified. The subject, object and scope, logical units and features of the study are defined in detail. It included 370 persons, divided into the following four groups of respondents: patients who underwent x-ray procedures in outpatient medical care (n =152); General practitioners and specialist doctors from hospital and outpatient care (n =100); practicing X-ray laboratory technicians (n =103) and imaging specialists (n=15) . The logical units of observation include representatives of the above-mentioned four groups of respondents selected on the principle of voluntariness and random selection. The methods for selecting the logical units, the criteria for their inclusion and exclusion, and the stages of the study are precisely defined. The study was conducted in 8 inpatient and 8 outpatient health facilities located in five administrative regions of the country.

The chosen methodology of the study allows to successfully achieve the set goal and adequately solve the tasks in the dissertation work. Research methods are successfully selected , comprehensively described and statistically validated. The study is multi-layered and time-consuming to implement, due to the diverse elements of the tools used, which increases the cumulative effect of the quality of the scientific and practical contributions. A combined methodology was applied to collect the information by means of: three questionnaires for patients, for GPs and specialists and for X-ray laboratory technicians; semi-structured interview questionnaire with radiation risk experts. A high degree of correspondence was achieved between the 8 tasks set, the number of scientific interventions undertaken and the results obtained.

I should point out the high quality of the methodological tools, the precision of the conducted research and the reliability of the results obtained. In this regard, I should emphasize the merit of the scientific supervisors.

5. Evaluation of the obtained results

The results of the study are presented in the third and fourth chapters of the dissertation with analyzes and assessments of: the socio-demographic characteristics of the respondents; of the imaging methods used; on the level of awareness of patients and the need for additional information about the radiation risk in medical diagnosis and therapy with ionizing radiation; the role of medical specialists - doctors and X-ray laboratory technicians in obtaining informed consent from the patient; the need for additional training of specialists for this purpose; of innovative tools and models to increase the awareness of patients and medical professionals about the risk of ionizing radiation in diagnostic and therapeutic procedures.

The analysis of the results in the III-rd chapter begins with a detailed socio-demographic characteristic of the surveyed groups of patients and medical specialists, according to the following indicators: gender, age, work experience, specialty and workplace. The results obtained from the analysis of the responses of the individual target groups are presented and interpreted in 8 thematic sections corresponding to the tasks set. The targeted set of signs of observation in the survey questionnaires and the precise statistical processing ensure reliability, quality and credibility of the results obtained and the conclusions drawn.

The characteristics of the examined patients show a predominance of women - 81.6%, from the age group 36-50 years - 52.6% and those with higher education - 79.6%. The information obtained shows a tendency to rejuvenate the population of patients in need of diagnostic and treatment procedures using sources of ionizing radiation. The high educational qualification of the examined patients implies their higher awareness of the investigated problem. The high relative share of medical specialists with work experience from 11 to 30 years among specialist doctors (71.0%) and X-ray laboratory technicians (34.9%) presupposes the presence of extensive professional experience and a good knowledge of their role in the process of informing patients upon obtaining their informed consent when conducting procedures with ionizing radiation.

The results of the survey of awareness of the radiation risk in medical diagnosis and therapy show that the majority of patients (83.6%) are aware of the diagnostic tests conducted using ionizing radiation. The predominant number of patients with higher education (87.6%) and those with secondary education (67.7%) are aware of this fact. The relative share of uninformed patients (16.4%) establishes the lack of complete and thorough information, which is a problem in obtaining informed consent. Examination of the basic knowledge of the specific diagnostic procedures using ionizing radiation showed a good knowledge of the most widely used procedures such as radiography, (84.2%) mammography, (60.5%) and CT (59.9%), with only 4 .6% of respondents indicated a lack of knowledge.

When examining the need for information regarding the reason for the appointment of procedures using ionizing radiation, 86.2% of patients express a desire to be informed, while 13.8% of them do not feel such a need. 74.3% of patients, 66.1% of X-ray laboratory technicians and 78.0% of doctors - specialists expressed a desire to be informed about the dose of X-rays taken during a radiological procedure. These results, albeit indirectly, provide insight into the health and medical literacy of the three groups of respondents. A statistically significant relationship was established between the education of the surveyed patients and the stated need for such

information. The results obtained for positive attitudes of patients, (79.6%) X-ray laboratory technicians (70.9%) and medical specialists (72.0%) regarding the introduction of an electronic file / radiation passport of the patient to track the received dose of ionizing radiation have a positive character. radiation.

Analysis of the role of medical professionals in obtaining informed consent from the patient found that one in two patients did not receive sufficient information from a health professional about the risks of ionizing radiation to their health. More than half of the patients (52.6%) indicated that they had not discussed such information. In contrast to patients, 78.0% of medical specialists and 79.6% of radiologists claimed to have discussed in detail with their patients the existing risks of ionizing radiation interventions. A statistically significant difference was demonstrated in the opinions of the three groups of respondents on this issue. Of interest are the established preferences of the patients for receiving information about the risks of ionizing radiation mainly from an X-ray laboratory technician (42.1%) rather than from an imaging specialist (34.9%). Representatives from all three groups of respondents considered the X-ray laboratory technician to be the most appropriate healthcare professional to obtain signed informed consent prior to performing imaging interventions.

The results of the conducted survey of the opinion of the three groups of respondents regarding the information that should be provided to patients to obtain informed consent for procedures using ionizing radiation are of scientific applied importance. The majority of medical specialists (64.0%) and X-ray laboratory technicians (75.7%) consider the Internet as the main source of information for patients, while patients consistently choose imaging specialists (55.3%) and the Internet (39 .5%) as the most preferred sources. The doctoral student also receives additional information regarding: the most appropriate source of information for the patient for an upcoming imaging study; the influence of age on the patient's opinion of this choice; discussion of the received radiation dose during a given type of X-ray examination; the opinion of the patient and the specialist about the risk of a given imaging method. The need for additional training of all specialists related to informing patients about the radiation risk in medical diagnosis and therapy was also studied. A significant part of doctors (89.0%) and more than half of X-ray laboratory technicians (61.2%) indicated a need for additional training. The opinions expressed by the two groups of medical specialists are ambiguous, indicating the following preferences: specialist doctors for distance learning (70.0%) and for workplace courses (16.0%); radiologists to on-the-job courses (47.6%) and to distance learning (28.2%).

The fourth chapter of the dissertation synthesizes the results of the conducted research, finding practical implementation in the formulation of innovative tools and models for increasing the awareness of medical professionals and patients regarding the diagnostic and treatment risk of ionizing radiation. The scientific results obtained in the previous chapter find their application in the following fully developed models of scientific applied tools:

- A multifactorial framework of the informed consent process;
- Model uniform form for obtaining informed consent from the patient to perform an X-ray / mammography examination;
- Model of the Patient's Radiation Passport.

The PhD student notes that good practices for obtaining informed consent must consider the impact of multiple factors to allow for the introduction of unified patient informed consent forms for radiological examinations and procedures. To achieve this goal, Stanislava Mavrodinova uses a multifactorial framework of the informed consent process adapted by her. Scientific applied contributions have the following presented innovative tools: developed a unified model of a form for obtaining informed consent in X-ray examination / mammography; the presented model for the patient's radiation passport with instructions for its use. The conducted expert evaluation of the above-mentioned innovative models aims to validate and confirm the proposed good practices in accordance with the existing legal and regulatory framework in the field of health care. The obtained summary results from the evaluation of the medical specialists support: the proposed unified model for obtaining informed consent; approve the proposed patient radiation passport model. The innovative models proposed above create reasonable opportunities to reflect modern good practices in Art. 87 and Art. 92 of the Health Act.

6. Assessment of Contributions

I believe that the dissertation work presented by Stanislava Mavrodinova has contributions of a theoretical-cognitive, scientific-applied and informative nature, the main of which are:

- An original survey of the opinion of patients, doctors and X-ray laboratory technicians was conducted regarding the possibilities of increasing their awareness of the radiation risk in medical diagnosis and therapy.
- The role of medical specialists (doctors and X-ray laboratory technicians) in the process of informing the patient about an existing radiation risk and obtaining informed consent for medical diagnosis and therapy has been studied.
- An in-depth analysis of the role, place and normative regulation of the participation of the X-ray laboratory technician in the process of informing and obtaining informed consent of the patient was made.
- The following original innovative tools and models have been developed:
  - ✓ a multifactorial framework of the process for obtaining informed consent from the patient in accordance with the legislation in force in our country;
  - ✓ a model of the "Unified Form" for obtaining informed consent from the patient is proposed;
  - ✓ a "Radiation Passport" model was developed for registration of the patient's individual radiation dose.

In conclusion, I should emphasize that the analysis of the respondents' answers is precisely presented with numerous figures and tables that reveal existing correlational dependencies, detailed in the conclusions. The main conclusions, 10 in number, are systematized in the main thematic directions, accurately reflecting the obtained results, respectively, the purpose and tasks of the dissertation work. The proposals made are exhaustive and of a recommendatory nature. They are institutionally addressed to the Ministry of Health, the Bulgarian Association of Health Care Professionals and the Medical universities in the country.

The content and quality of the abstract meets the requirements of the Regulations of the Ministry of Education - Varna, as it faithfully and adequately reflects the main results of the study.

In conclusion, I believe that the dissertation presented by Stanislava Milcheva Mavrodinova on the topic "Increasing awareness about radiation risk in medical diagnostics and therapy" in terms of relevance of the problem, precision of the methodology, quality of the obtained results and scientific contributions meets the requirements of the Law on the Development of the academic staff in the Republic of Bulgaria and the Regulations for the development of the academic staff of the MU-Varna.

In this regard, I will vote positively and strongly recommend to the members of the Scientific Jury to award Stanislava Milcheva Mavrodinova, a full-time doctoral student in the doctoral program "Health Care Management " at the Medical University of Varna, the educational and scientific degree "Doctor" in the field of higher education 7. "Health care and sports" in professional direction 7.4. "Public Health" and the scientific specialty "Health Care Management".

20.01.2024

Sofia

Reviewer:

Заличено на основание чл. 5, §1, б. „В“ от Регламент (ЕС) 2016/679

Prof. Dr. Kancho Tchamov, PhD