Medical University
"Prof. Dr. Paraskev Stoyanov" – Varna

Faculty of Public Health
Department of Healthcare

Stanislava Milcheva Mavrodinova

RAISING AWARENESS OF RADIATION RISK IN MEDICAL DIAGNOSTICS AND THERAPY

THESIS SUMMARY

Of a PhD Thesis

For awarding the educational and scientific degree "Philosophy Doctor."
In the field of higher education 7. "Healthcare and Sports"
Professional area 7.4 "Public Health"
Scientific speciality "Healthcare Management"

Research Supervisors:

Assoc. Prof. Anna Georgieva, PhD

Assoc. Prof. Veselina Slavova, PhD

Varna, 2023

The thesis contains 191 pages and is structured in four main chapters. It includes 74 figures, 3 tables, and 4 appendices (the number of figures and tables in the thesis and the thesis summary differs due to the requirements for developing each one). The bibliography includes 279 references, of which 49 are in Cyrillic, and 230 are in Latin.

The doctoral thesis was discussed and referred for defence by an extended departmental council of the Department of Healthcare at the Medical University "Prof. Dr. P. Stoyanov" – Varna on November 8th, 2023. The public defence will take place on February 16, 2024, in Hall A of the Medical University of Varna.

The defence materials are available at the Career Development Centre of MU–Varna and are published on the MU-Varna website.

CONTENTS

LIST OF ABBREVIATIONS

AMA	American Medical Association
BAHP	Bulgarian Association of Healthcare Professionals
CT	Computed tomography
DICOM	Digital Imaging and Communications in Medicine
EU	European Union
HA	Health Act
HIA	Health Insurance Act
IAEA	International Atomic Energy Agency
ICN	International Council of Nurses
ICRU	International Commission on Radiation Units and Measurements
IGRT	Image-guided radiation therapy
IMRT	Intensity-modulated radiation therapy
JSC	Joint Stock Company (Ltd or PLC)
Ltd	Limited Liability Company
MHAT	Multiprofile Hospital for Active Treatment
MMA	Military Medical Academy
MRI	Magnetic resonance imaging
NFC	National Framework Contract
NRA	Nuclear Regulatory Agency
NSCA	Nuclear Safety and Control Act
PACS	Picture archiving and communication system
REC	Research Ethics Committee
RET	Positron emission tomography
SG	State Gazette
SIR	Source of Ionizing Radiation
SNA	Selective coronary angiography
SPECT	Single Photon Emission Computed Tomography
SPECT/CT	Dual source/Dual energy CT
UMHAT	University Multiprofile Hospital for Active Treatment
USR	Uniform State Requirements
WHO	World Health Organisation

INTRODUCTION

The progress of scientific knowledge and technological innovations is driving the implementation of novel approaches for medical treatment and diagnosis. These developments are particularly notable in the field of radiotherapy and diagnostic imaging. The increase in the quality of medical services is associated with administering more and more examinations requiring the application of higher individual doses of ionising radiation, such as computed tomography, positron emission tomography, etc., as well as interventional procedures under X-ray control. Hence, the need to reduce the risk associated with radiation exposure. This is achieved by respecting the basic principles of radiation protection, namely that any medical exposure should be carefully considered and optimised. Therefore, international standards and the Good Clinical Practice Guidelines for Diagnostic Imaging offer several tools to support optimisation. Among them, maintaining periodic monitoring of patient doses is essential, along with the evaluation of doses with relevant diagnostic reference levels.

Concurrently, honouring the patient's rights requires that he/she be recognised as an equal partner in all procedures concerning his/her life and health. This calls for raising awareness among medical professionals and patients involved. Patient awareness is a fundamental rule derived from the principle of autonomy in medical ethics. In order to make a competent decision and consent, he/she must be provided with the necessary information. The issue has not been thoroughly and systematically studied in the scientific literature. Our scientific interest has been triggered by the potential for increasing patients' awareness of the risks of ionising radiation for medical diagnostics and therapy. Comparing the regulatory frameworks of the Republic of Bulgaria and international standards, and analysing the awareness level of medical professionals and patients about radiation risk, will result in streamlining all activities related to the diagnosis and treatment with ionising radiation.

1. RESEARCH METHODOLOGY

1.1. Aim, tasks and hypotheses of the study

Aim: To investigate the possibilities of raising awareness about the risks of ionising radiation in medical diagnostics and therapy.

Tasks

1. To examine and analyse the available literature in order to define the theoretical standing of the issue.

2. To study the practice in other countries regarding the organisation of documentation and systematisation of information related to radiation risk in medical diagnostics and therapy.

3. To conduct a comparative analysis of the regulatory framework of the Republic of Bulgaria and other countries regarding obtaining the patient's informed consent in the course of performing medical activities related to radiation risk.

4. To analyse the need to implement regulatory protocols for obtaining informed consent by radiology laboratory technicians.

5. To clarify the functions of the X-ray laboratory technician in providing information on radiation risk in medical diagnostics and therapy.

6. To explore the need for additional training for all professionals providing patients with information about radiation risk in medical diagnostics and therapy.

7. To develop novel models and tools for organising data collection from patients' X-ray imaging examinations in order to raise awareness and improve the effectiveness of medical professionals involved in medical diagnostics and therapy related to radiation risk.

8. To prepare an expert assessment of the feasibility of the developed innovative models and tools to raise awareness of the risk of ionising radiation for medical diagnostics and therapy.

Research hypotheses

1. There is a lack of a unified system for registration, reporting and control of patients' X-ray examinations, which reduces the ability of X-ray professionals to monitor patients' doses and makes it challenging to inform them about the risks associated with ionising radiation for medical diagnostics and therapy.

2. Patients' awareness of the risks associated with ionising radiation for medical diagnostics and therapy is inadequate, limiting patients’ ability to make an informed decision about consenting to X-ray examinations and procedures.

3. Innovative models and information organisation tools for data collection from patients' X-ray imaging examinations will increase awareness and improve the efficiency of medical professionals performing medical diagnostics and therapy related to radiation risk.

4. The Radiation Passport for registering individual patient radiation doses during X-ray examinations and procedures is a tool that enables X-ray professionals to monitor patient doses.

5. The Radiation Passport for registering the individual patient's radiation dose during X-ray examinations and procedures is a tool for increasing patient awareness of the risk of ionising radiation for medical diagnostics and therapy.

1.2. Subject, object and scope of research

The subject of research is the process of investigating the options for raising awareness of the risk of ionising radiation for medical diagnostics and therapy.

The object of research is the awareness of the risk of ionising radiation for medical diagnostics and therapy.

Scope of research – 370 individuals from the following groups participated in the study:

- Patients who underwent X-ray examinations and procedures in an outpatient medical facility – 152 individuals;
- specialists (general practitioners and specialist physicians) from inpatient and outpatient medical care – 100 individuals;
- X-ray and laboratory technicians from inpatient and outpatient medical care – 103 individuals;
- Imaging specialists – 15.

Each of the patients, radiology lab technicians and specialists completed an anonymous questionnaire, providing prior consent to participate in the study.

A hybrid form of the survey was used by completing online surveys distributed on social networks of patient organisations as well as completing paper surveys.

Imaging specialists were interviewed after declaring their consent.

1.3. Logical units of research

- **First logical unit** – a patient who underwent X-ray examinations and procedures in outpatient medical care;
- **Second logical unit** – a specialist (general practitioner and specialist physician) from inpatient and outpatient medical care;
- **Third logical unit** – a radiology lab technician from inpatient and outpatient medical care;
- **Fourth logical unit** – an imaging specialist.

Logical unit features

Features of Logical Unit I

- Awareness of imaging modalities prescribed to patients.
- Awareness of radiation risk in medical diagnostics and therapy.
- Information needed when prescribing X-rays and procedures using ionising radiation.

- Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
- Functions of the radiology lab technician in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
- Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.

Features of Logical Unit II

- Diagnostic imaging methods assigned to patients.
- Patient awareness of radiation risk in medical diagnostics and therapy.
- Information needs of the patients referred for X-rays and procedures using ionising radiation.
- Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
- Functions of the radiology lab technicians in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
- Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.
- Attitudes and necessity for additional training of professionals involved in informing patients about radiation risk in medical diagnostics and therapy.

Features of Logical Unit III

- Diagnostic imaging methods performed on patients.
- Patient awareness of radiation risk in medical diagnostics and therapy.
- Information needs of patients when referred for X-ray examinations and procedures using ionising radiation.
- Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
- Functions of the radiology lab technician in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
- Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.
- Attitudes and necessity for additional training of professionals involved in informing patients about radiation risk in medical diagnostics and therapy.

Features of Logical Unit IV

- Comments and recommendations on the practical tools we have developed on the effective implementation of innovative models and tools to raise awareness of the risk of ionising radiation and optimise the performance of medical professionals involved in medical diagnostics and therapy related to radiation risk.

Inclusion criteria

- Individuals over 18 years of age;
- Patients who have undergone X-ray examinations and procedures;
- Medical professionals referring and/or performing X-ray examinations and procedures;
- Individuals who have signed an informed consent.

Exclusion criteria

- Individuals under 18 years of age;
- Individuals with contraindications to X-ray examinations and procedures;
- Patients who have not undergone X-ray examinations and procedures;
- Medical professionals who do not refer and/or perform X-ray examinations and procedures;
- Individuals who have not signed an informed consent.

1.4. Sources of information

- Available scientific literature;
- Available national and international regulatory protocols and guidelines;
- Opinions of patients, physicians (general practitioners and specialists prescribing X-ray examinations/procedures), radiology lab technicians and experts (imaging specialists)

The studies were approved by the Research Ethics Committee (REC) of the Medical University – Varna (Protocol № 115/31.03.22).

1.5. Time and location of research

Time of conduct: Jan. 2021 – Sep. 2023

The Research Ethics Committee (REC) of the Medical University – Varna approved the research by Protocol No. 115/31.03.2022.

The study was conducted in inpatient and outpatient medical **institutions with imaging clinics/departments/centres** in Burgas, Varna, Veliki Preslav, Dobrich, Omurtag, Pleven, Ruse and Shumen.

The following establishments meet the criterion:

- St. Marina University Hospital – Varna;
- Military Hospital Varna – Military Medical Academy;
- St. Anna Hospital – Varna;
- Dobrich Hospital;
- Shumen Hospital;
- Kanev University Hospital – Ruse;
- Veliki Preslav Hospital;
- Omurtag Hospital;
- St. Clementina Diagnostic and Consultation Centre 1 – Varna;

- Diagnostic and Consultation Centre 3 – Varna;
- Diagnostic and Consultation Centre – Varna;
- Chaika Diagnostic and Consultation Centre;
- Mladost Diagnostic and Consultation Centre – Varna;
- Mladost Imaging Diagnostics Centre;
- Acibadem City Clinic – Varna;
- Dr. Staykov Medical Centre – Burgas.

The main part of the study was carried out independently by the author. When surveying the opinions of physicians (general practitioners and specialists), X-ray laboratory technicians/technologists, and patients, the cooperation of senior X-ray laboratory technicians/ technologists was also used.

All selected associates were previously familiarised with the purpose and methodology of the study and were trained to use the questionnaires.

Stages of research

The research activities on this thesis were carried out in 5 stages, as described in Table 1.

Table 1. Research stages

Stage	Activity Description	Range (Group – Number)	Place	Tools
I **From Jan. 2021 to May 2022**	✓ Study of the situation, relevance and formulation of the problem; ✓ Formulation of research topic, object and subject of research; ✓ Definition of the aim and objectives of the study. Development of hypotheses. Selection of research methods and tools for conducting the research.		Varna	Review of literature sources on the issue.
II **From April 2022 to May 2023**	Fieldwork: Conducting an anonymous survey to determine awareness of radiation risk in medical diagnostics and therapy and opportunities to improve it. Conducting a semi-structured interview to ascertain attitudes among imaging physicians on increasing awareness of radiation risk and opportunities for introducing novel models into practice.	**1. Patients** who have undergone X-ray examinations and procedures – **152** individuals **2. Medical specialists** who refer and/or perform X-ray examinations and procedures **– 100 individuals** **3. X-ray laboratory technicians** **- 103** individuals**.** **4. Imaging specialists** **- 15** individuals**.**	Burgas; Varna; Dobrich; Pleven Shumen Ruse; Omurtag; Veliki Preslav Burgas; Varna; Dobrich; Pleven Shumen Ruse; Omurtag; Veliki Preslav	Questionnaire No. 1, 2, 3 Semi-structured interview questionnaire (Appendix 4)
III From May 2023 To June 2023	Data processing and analysis.		Varna	SPSS v. 20.0
IV From July 2023 to Sep. 2023	Description of results		Varna	
V Sep. 2023	Drawing conclusions and contributions. Thesis outline		Varna	

1.6. Survey methods

The following methods were used to achieve the aim and objectives:

1.6.1. Documentary method

The documentary method is used to analyse literature sources, protocols, regulations and guidelines outlining the topic being investigated.

1.6.2 Sociological method

- Direct anonymous individual survey on the awareness related to the risk of ionising radiation for medical diagnostics and therapy aimed at:
  - patients who have undergone X-ray examinations and procedures;
  - X-ray specialists (X-ray laboratory technicians);
  - physicians (general practitioners and specialists) prescribing X-ray examinations and procedures.
- Semi-structured interviews with expert imaging specialists to assess the feasibility of innovative tools developed to raise awareness of the risk of ionising radiation for medical diagnostics and therapy.

1.6.3. Statistical methods

To systematise, summarise, analyse and interpret statistical data to reveal the nature of observed phenomena and correlations. The results are analysed and presented using the following statistical methods:

- **Descriptive analysis** to establish the mean levels and variations in quantitative variables and absolute and relative frequencies for qualitative variables;
- **Parametric methods for hypothesis testing** (Student's t-test);
- **Non-parametric hypothesis testing methods**;
- **Correlation analysis** to examine the relationship between observed phenomena (Pearson's r; Spearman's ρ); Statistical significance of results at $p < 0.05$;
- **Tabular and graphical methods of data presentation** – simple and multivariate tables; line and bar charts.

Statistical analysis of data was performed using the professional statistical processing program SPSS v. 20.0.

1.7. Research tools

A proprietary survey tool was developed for the efficient administration of the survey among respondents: questionnaires and a semi-structured interview.

1.7.1. Direct individual anonymous questionnaire

A survey method using a direct anonymous questionnaire was used to investigate the possibilities of raising awareness of the risk of ionising radiation for medical diagnostics and therapy. In order to better process the primary information, the questionnaires are composed of

groups of closed questions with ready-made options and semi-closed questions with formulated options for some of the answers and the possibility of expressing an opinion. Some questions provide multiple solutions within the available options. For the purposes of collecting the information we need on the same issue of interest (for example, the need to provide information to patients about the X-ray doses), each group of respondents was asked a series of questions – patients who had an X-ray examination or procedure, physicians (general practitioners and specialists) prescribing X-rays and procedures, and X-ray laboratory technicians.

The respondents were 18+ individuals from different regions – Burgas, Varna, Veliki Preslav, Dobrich, Omurtag, Pleven, Ruse and Shumen. The respondents fill in the electronic form of the questionnaires manually. Before filling it out, they have been briefed on its purpose and instructions to ensure the reliability of the results. Three questionnaires were developed to achieve the aim of the study.

- **Questionnaire No.1** – explores the opinion of patients undergoing an X-ray examination/procedure. The information was collected through a questionnaire that included 26 questions structured into the following groups (Appendix 1):

✓ Socio-demographic characteristics: gender, age, level of education.
✓ Imaging methods assigned to patients.
✓ Patient awareness of radiation risk in medical diagnostics and therapy.
✓ Information needs of patients when referred for X-ray examinations and procedures using ionising radiation.
✓ Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
✓ Functions of the radiology lab technician in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
✓ Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.

- **Questionnaire No.2** – surveys the opinion of physicians (general practitioners and specialists) prescribing X-ray examinations and procedures working in inpatient and outpatient medical facilities. It includes 29 questions structured in the following groups (Appendix 2):

✓ Socio-demographic characteristics: gender, age, place of work, speciality, work experience in the speciality.
✓ Imaging methods prescribed to patients.
✓ Patient awareness of radiation risk in medical diagnostics and therapy.
✓ Patient information needs when on X-rays and procedures using ionising radiation.
✓ Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
✓ Functions of the radiology lab technician in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
✓ Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.
✓ Attitudes and necessity for additional training of professionals on informing patients about radiation risk in medical diagnostics and therapy.

- **Questionnaire No. 3** – surveys the opinion of radiology lab technicians performing radiological examinations and procedures and working in inpatient and outpatient care facilities. It includes 27 questions structured in the following groups (Appendix 3):

✓ Socio-demographic characteristics: gender, age, place of work, work experience in the speciality.
✓ Imaging methods performed on patients.
✓ Patient awareness of radiation risk in medical diagnostics and therapy.
✓ Patient information needs on x-rays and procedures using ionising radiation.
✓ Role and contribution of medical professionals in the process of obtaining informed consent from the patient.
✓ Functions of the radiology lab technician in the process of providing information on radiation risk in medical diagnostics and therapy and obtaining informed consent.
✓ Informing and obtaining informed consent for X-ray examinations and procedures using ionising radiation.
✓ Attitudes and necessity for additional training of professionals involved in informing patients about radiation risk in medical diagnostics and therapy.

The questionnaires support the study in the following aspects:

Effectiveness of the patient information process: assesses the degree of awareness in preparing patients for X-ray examinations related to: ionising radiation exposure; the risk of ionising radiation; the dose of X-rays (i.e. ionising radiation) received during a radiological procedure.

The necessity for additional training of professionals involved in informing patients about radiation risk in medical diagnostics and therapy.

1.7.2. Semi-structured interview

A qualitative study was conducted through semi-structured interviews with 15 experts on the feasibility of the developed innovative models and tools to raise awareness of the risk of ionising radiation and optimise the performance of medical professionals involved in medical diagnostics and therapy related to radiation risk.

- **A semi-structured interview** – explores experts' views on the feasibility of the developed innovative models and tools to raise awareness of the risk of ionising radiation and optimise the performance of medical professionals involved in medical diagnostics and therapy related to radiation risk.

2. Results and analysis of the survey conducted among patients, radiology laboratory technicians and medical professionals

2.1. Characteristics of the study groups

2.1.1. Patients' characteristics

The survey investigated the opinions of 152 patients who had undergone or were about to undergo medical imaging examinations using ionising radiation sources in outpatient and inpatient care. The survey included 83.0% of all patients in outpatient and inpatient care settings at the time of the survey.

Within the patient group, the gender distribution was uneven, with the majority of participants in the patient group being female, 81.6% (n = 124). Only 18.4% of individuals were male (n = 28) (Fig. 1).

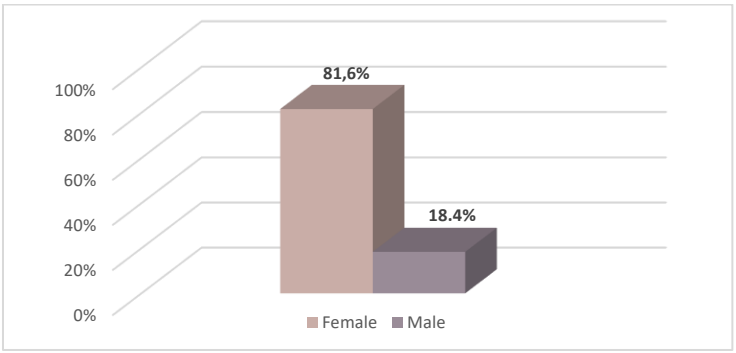


Figure 1. Distribution of patients by gender (%)

Patients aged 19 to 80 years were included. The mean age of the patients was 43.6 years (± 13 years). Most patients were in the age group 36 to 50 years (52.6%), followed by those aged 51 to 65 years (21.6%). The predominance of patients in the 36 to 50 age group indicates an alarming trend of a resurging population of patients affected by diseases about which medical imaging studies using ionising radiation sources have been performed or are to be performed in outpatient and inpatient care. Our data correspond with those of a study by Vassileva and Holmberg (2021) (264) (Fig. 2).

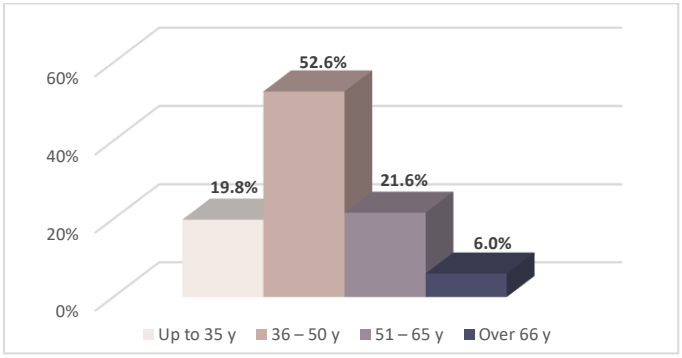


Figure 2. Distribution of patients by age (%)

A question on education was included in the survey because it provides a clue as to whether there is a correlation between education and patient awareness regarding their disease, information needs, understanding of the information provided by medical professionals, and obtaining informed consent regarding diagnostic and therapeutic procedures with ionising radiation, as well as the role and contribution of radiology lab technicians in optimising it. The data showed that the majority of patients were highly educated, 121 individuals (79.6%), and more than one-fifth (20.4%) had secondary (high school) education or 31 individuals. These results indicate a high educational level in the majority of the studied patients, suggesting a higher awareness of the studied problem (Fig. 3).

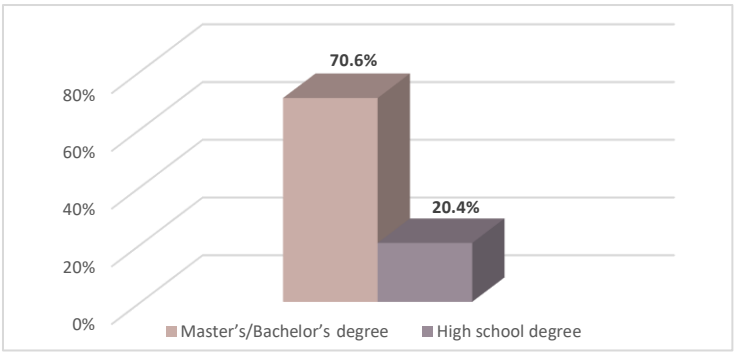


Figure 3. Distribution of patients by education (%)

In this study, the opinions of 103 radiology laboratory technicians were investigated. 78.5% of all working radiology lab technicians at the time of the survey were covered. The majority of the radiology lab technicians were female (67.0%), whereas the number of male radiology lab technicians was twice as low (33.0%) (Figure 4).

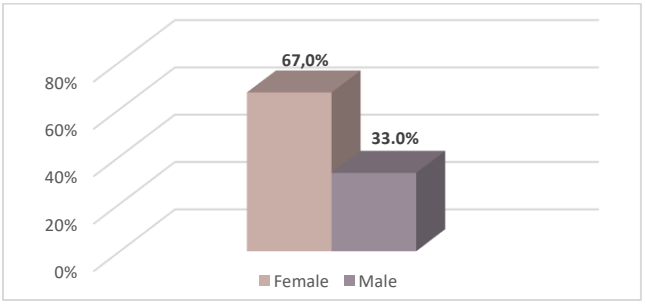


Figure 4. Radiology lab technicians by gender (%)

In terms of age groups, it was found that the mean age of the radiology lab technicians studied was 50 years (± 9 years). The highest proportion of Radiology lab technicians was under 35 years (59.3%), followed by those aged between 36 and 50 years (30%), and one in ten were in the age range 51–65 years (Fig. 5).

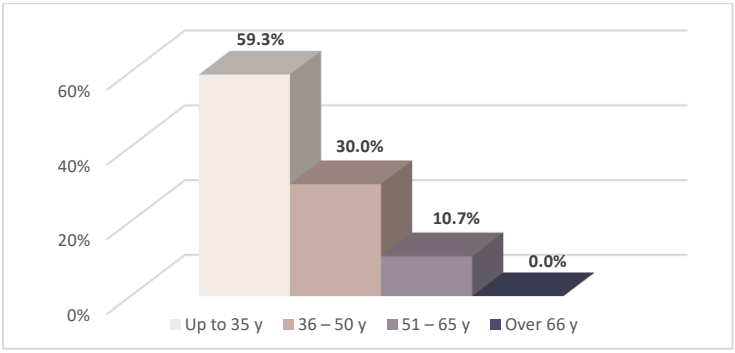


Figure 5: Radiology lab technicians by age (%)

The mean working experience of radiology laboratory technicians was 12 years (± 11 years). The shortest documented period of employment in the radiology lab technician group was less than one year, and the maximum was 40 years.

X-ray laboratory technicians with less than 10 years of experience predominated, followed by those with 11 to 20 years of experience, and one in ten had 21 to 30 years of experience. The

smallest proportion of respondents in this group had more than 30 years of experience. The results can be explained by the young age structure of the X-ray laboratory technicians included in the sample (Fig. 6).

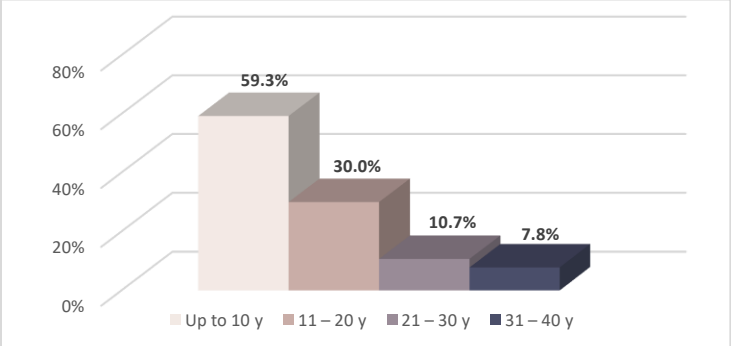


Figure 6: Radiology lab technicians by years of experience (%)

2.1.2. Characteristics of surveyed imaging specialists

The study included 100 physicians-specialists working in outpatient and inpatient care. 70% of all medical specialists working at the time of the survey were covered.

In the group of specialists, there was a slight predominance of male respondents, 56 (56.0%), while 44 respondents were female (44.0%) (Figure 7).

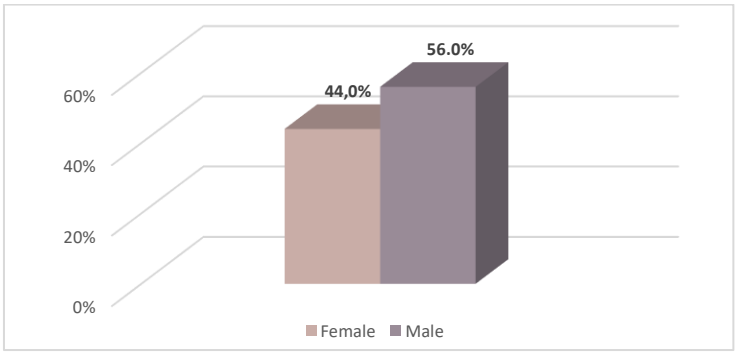


Figure 7. Distribution of physicians-specialists by gender (%)

The mean age of the surveyed physicians was 48.5 years (± 10 years), with a minimum age of 29 years and a maximum age of 69 years. The highest proportion of specialists was in the age group 51–65 years (43.0%), followed by those aged between 36 and 50 years (40.0%) (Fig. 8). These data are in line with the growing concerns of an ageing population, a trend that also affects the medical profession (8).

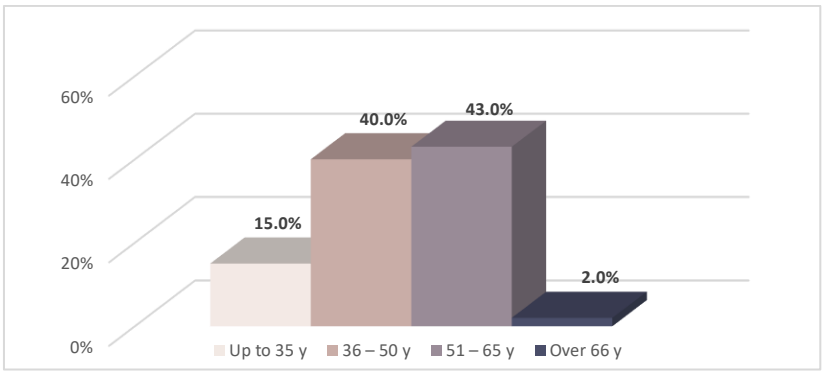


Figure 8: Distribution of physicians-specialists by age (%)

The most significant proportion of medical specialists has 21 to 30 years of experience (40.0%), and one-third of them have 11 to 20 years of experience (Figure 9). These results demonstrate the presence of extensive professional experience and suggest a thorough knowledge of the importance of the role of the radiology laboratory technician in the overall process of radiological diagnosis of patients. This, in turn, is essential to clarify the possibilities of optimising the participation of the radiology laboratory technician in the process of informing and obtaining informed consent from patients for diagnostic and therapeutic procedures with ionising radiation.

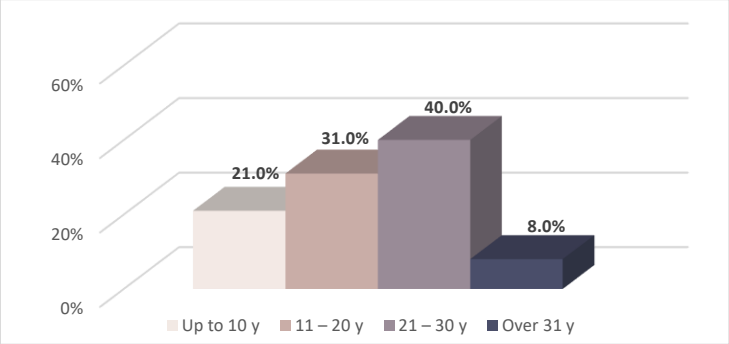


Figure 9. Distribution of physicians-specialists by work experience (%)

In our study, general medicine specialists predominated with 20 individuals (20%), followed by dental specialists with 15 individuals (15%). The proportion of specialists in orthopaedics – 13 individuals (13%), and neurology – 13 individuals (13%) was the same. They are followed by specialists in surgery – 12 individuals (12%) and specialists in paediatrics – 7 individuals (7%). The share of obstetrics and gynaecology, and ENT specialists is identical – 4 (4%) each, as well as the urology and cardiology specialists – 3 (3%) each. The smallest share is of emergency medicine specialists – 2 individuals (2%) and 1 representative for dentistry, endocrinology, imaging diagnostics and radiology, respectively (Fig. 10).

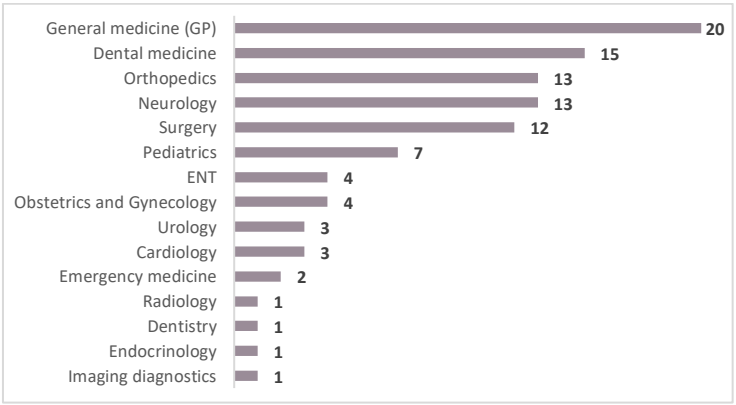


Figure 10. Distribution of physicians-specialists by speciality (%)

The majority of the surveyed specialists, 54 individuals (54.0%), work in an outpatient care facility, and 46 individuals (46.0%) work in an inpatient care facility (Figure 11).

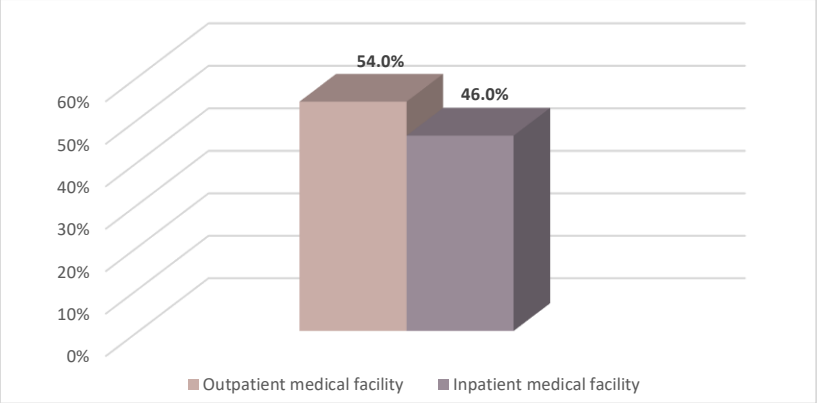


Figure 11. Distribution of physicians-specialists by place of work (%). Comparative socio-demographic characteristics of the survey respondents

Considering the significance of the frequency of X-ray examinations performed and the impact of cumulative doses on a patient's health, we needed to examine how many diagnostic imaging procedures had been performed on patients in the past year. Most patients reported having one procedure performed in the last year (42.8%; n=65). More than one-third of patients surveyed (37.5%; n=57) responded "none," these were most likely patients who had yet to undergo such procedures. Troubling evidence indicated that almost one-fifth of patients surveyed had undergone more than 2 diagnostic imaging procedures in the past year (with no clear information available regarding cumulative dose) (19.7%; n=30) (Fig. 12).

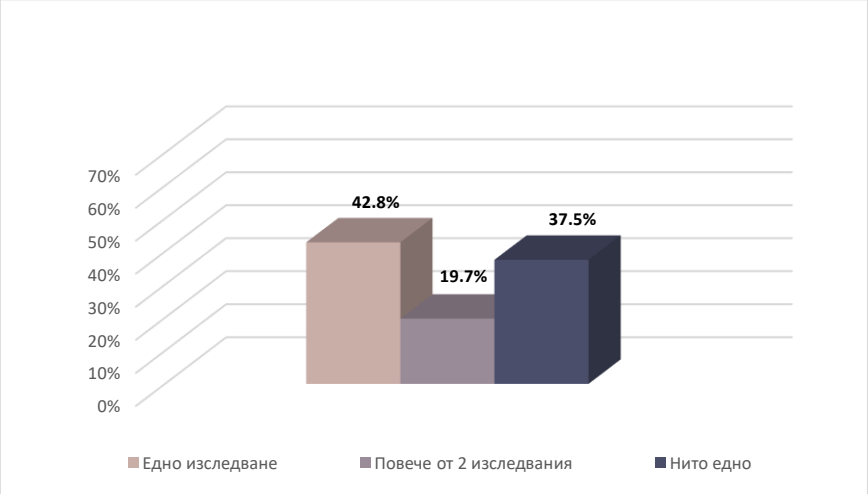


Figure 12. Number of diagnostic imaging procedures performed on patients in the last year (patient opinion, %)

2.3. Patient awareness of radiation risk in medical diagnostics and therapy

Considering the frequent application of diagnostic procedures using ionising radiation, their performance should be preceded by obtaining informed consent. In this regard, we explored the views of the three groups of respondents on whether patients are aware that some diagnostic imaging tests are performed using X-rays (i.e., ionising radiation). Most patients surveyed

(83.6%; n=127) were informed that some diagnostic imaging tests use X-rays. However, a proportion of patients reported that they were not aware of the use of ionising radiation in X-ray examinations (16.4% n=25). The described group of individuals is not large, but its presence confirms the insufficiency of thorough and in-depth information in obtaining informed consent. Of course, the described result focuses solely on one aspect while disregarding the gaps in this two-way process – the presence of uninformed individuals about the performance of diagnostic procedures using ionising radiation in the patient group. The general opinion of the majority of the three groups of respondents (more than 80%) was that most patients were aware of using X-rays in some diagnostic examinations. In this context, logically, there was no statistically significant difference between the responses of the three groups of respondents ($p > 0.05$) (Fig. 13).

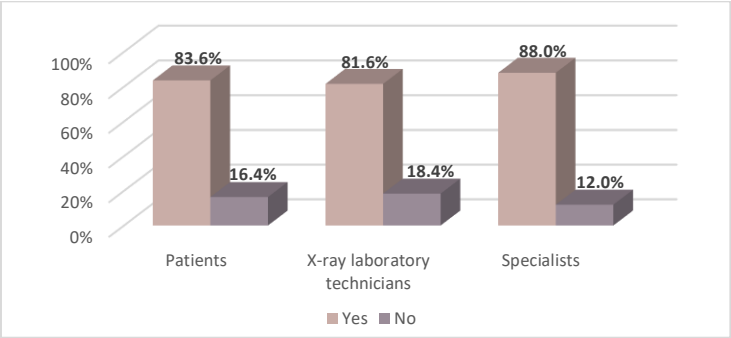


Figure 13. Patient awareness of diagnostic tests using ionising radiation (opinion of patients, radiology lab technicians, specialists, %)

Patients' education was statistically related to their knowledge about using X-rays in some diagnostic imaging ($\chi 2=7.084$, $p=0.008$). The majority of patients with higher education (87.6%) were familiar with the use of ionising radiation in some diagnostic examinations. In comparison, the proportion of informed patients with secondary education was lower – 67.7% (Figure 14).

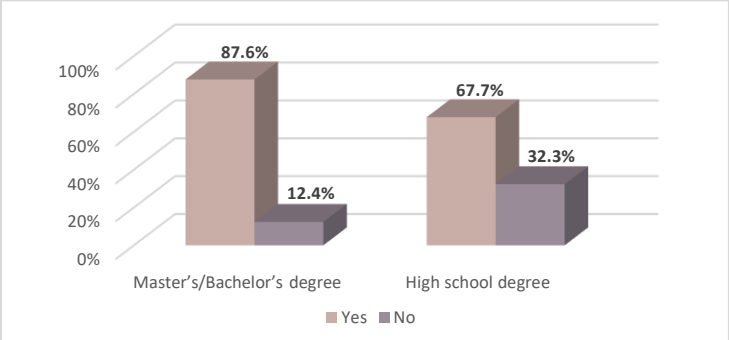


Figure 14. Patients' awareness of diagnostic tests using ionising radiation (Responses of patients by education, %)

There was no statistically significant correlation between the patients' opinion and their age and gender or the radiology lab technicians' view on the issue and the socio-demographic characteristics examined in section 2.1 ($p > 0.05$).

Regarding the obtained findings, we investigated the **baseline knowledge** on diagnostic procedures using ionising radiation in the group of 152 patients. To the question "In your

opinion, which of the mentioned diagnostic imaging procedures use X-rays?" with more than one possible answer, most patients (84.2%; n=128) correctly judged conventional radiography as a method of ionising radiation. The judgment of the majority in the group of patients who associated the performance of mammography and computed tomography with the use of X-rays was also unerring (60.5%; n=91 and 59.9%; n=92, respectively). However, only 32 individuals (20.1%) in the patient group identified osteometry as a diagnostic procedure associated with the use of ionising radiation. There are differences between individual diagnostic bone examinations, with particular types having significant differences in radiation exposure, but the small number of patients who define it as using ionising radiation is substantial. However, 43 individuals (28.3%) in the patient group correctly identified positron emission tomography as a diagnostic test associated with the use of ionising radiation. Comparatively fewer individuals misidentified magnetic resonance imaging and ultrasonography using ionising radiation (24.3%; n=37 and 6.6%; n=10, respectively). Only 13 individuals (8.6%) in the patient group identified all of the procedures described as using ionising radiation, and 6 individuals (3.9%) responded that they were not familiar (Figure 15).

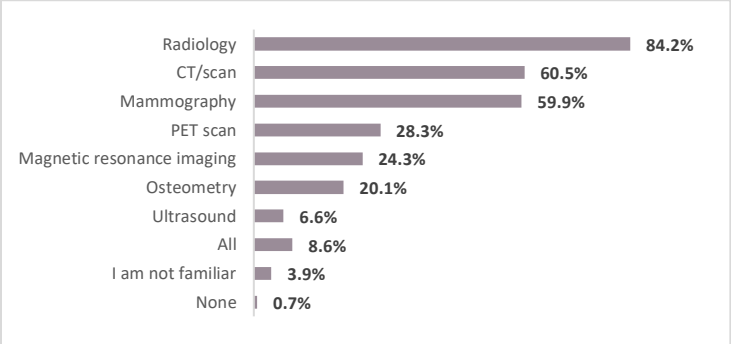


Figure 15. Distribution of patient responses to the question: "Which of the following diagnostic imaging procedures do you think use X-rays?" (%) (Answers exceed 100% as the question is multiple-choice)

Because some patients appear to be unfamiliar with the nature of the most common diagnostic tests using ionising radiation, we must assess how familiar they are with the risks of radiation to humans in general. Mostly, all groups of respondents thought that patients should be made aware of the radiation risks of specific diagnostic tests. However, while this proportion was 100% for specialists and 96.1% for radiology laboratory technicians, it was comparatively less for patients at 76.3%. (Fig. 16).

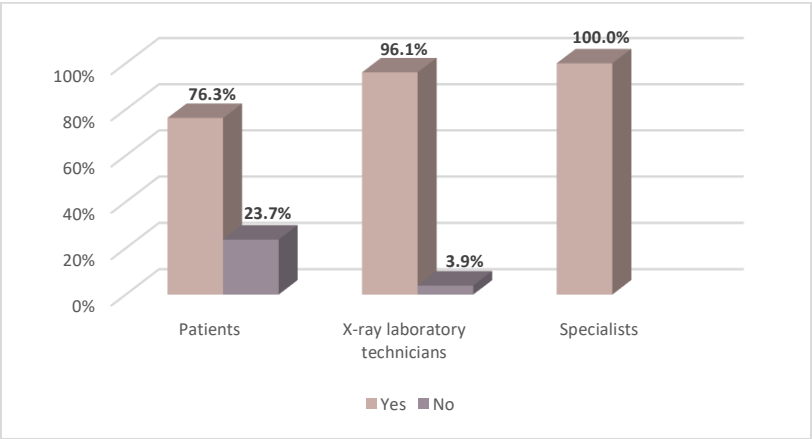


Figure 16. Necessity for patients to be informed about radiation risks related to human health (opinions of patients, radiology lab technicians, specialists, %)

Checking with the $\chi 2$ test for independence (correlation) shows that the answers to this question are significantly dependent on belonging to the group (patients, radiologists, specialists) ($\chi 2$=41.754 p=0.000).

2.4. Patients' information needs when being referred for X-ray examinations and procedures using ionising radiation

In the context of low patient awareness of radiation risks, it is worrying that a significant proportion of patients do not even feel the need to be informed about the reason for an X-ray appointment (13.8%; n=21). However, the majority of patients still wanted to be informed (86.2%; n=131). Along with these, the opinion of specialists and Radiology lab technicians on the need for patients to be aware of the risks and benefits of radioactive exposure related to a person's health (when an imaging study or therapeutic procedure is prescribed) was also investigated. Absolutely all of the responding specialists (100%) and almost all of the responding radiology laboratory technicians (99.9%) strongly endorsed the need for patients to be aware of the risks and benefits of radioactive exposure when they have been referred for imaging tests, as well as the reason why they have been prescribed an X-ray. The responses to this question showed a statistically significant difference between the three groups of respondents ($\chi 2$=26.623, p=0.000) (Figure 17).

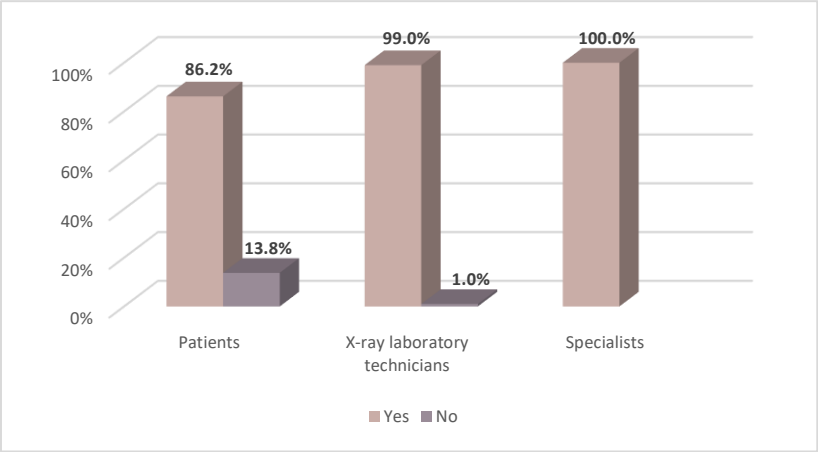


Figure 17. Necessity for patients to be informed about the reason why they have been referred for an X-ray examination (opinion of patients, radiology lab technicians, specialists, %)

In regard to the findings, we also investigated the opinions of patients, radiology technicians and specialists about the need to inform patients about the X-ray doses (ionising radiation) received during a radiological procedure. The majority of patients (74.3%; n=113), radiology lab technicians (66.1%; n=68) and specialists (78.0%; n=78) advocated for increased awareness. Meanwhile, 32 individuals in the patient group (21.1%), one-quarter of the laboratory technicians, and one-fifth of the specialists could not assess the need for prior information regarding the exposure dose received in previous procedures before a specific examination. A minority of patients (4.6%; n=7) and radiology technicians (8.7%; n=9) felt such information would not be helpful. None of the specialists expressed a negative statement on this issue.

The Chi-square test for independence does not provide us with a conclusive statement that the answers to this question are significantly related to a particular group of respondents ($\chi 2=17.121$; $p=0.002$), since the test is liberal: more than 20% of the cells contain theoretical frequencies less than 5 (Fig. 18).

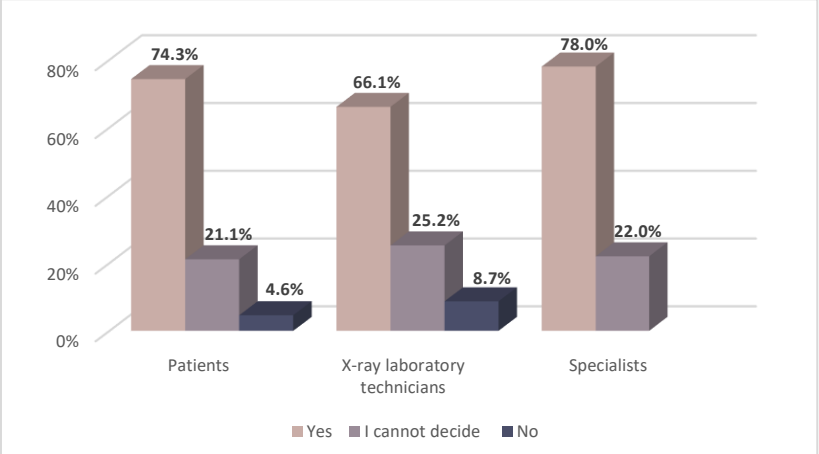


Figure 18. Necessity for patients to be informed about the X-ray dose (ionising radiation) received during a radiological procedure (opinion of patients, radiology lab technicians, specialists, %)

When asked if it is helpful to know what dose of X-rays they have received during a radiological procedure, 79.3% of the patients with higher education answered “yes”, and 15.7% could not judge. For patients with secondary education, 54.8% rated the information as useful, and 41.9% could not judge. There was a significant correlation between the respondents' education and their judgment of needing such information ($\chi 2=10.220$, $p=0.006$) (Figure 19).

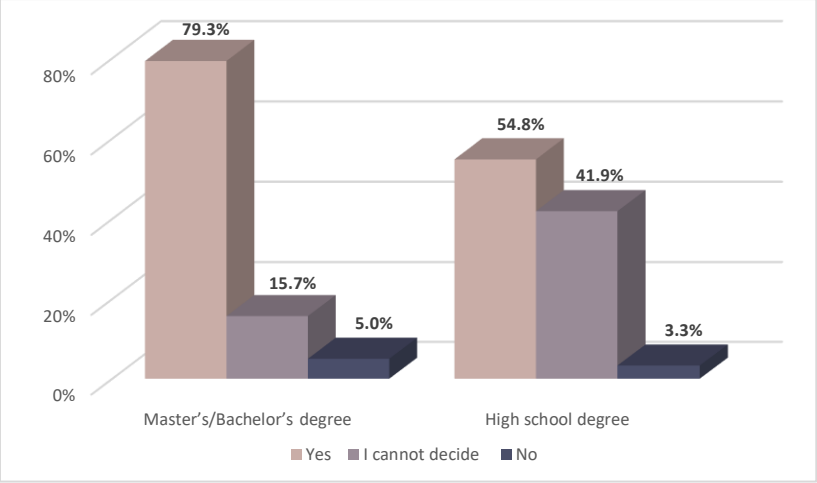


Figure 19. Distribution of responses by patient education to the question "Do you find it helpful to have information about the dose of X-rays received during your radiology procedure?"(%)

It was also essential for us to explore the attitudes of patients, radiology technicians and specialists involved in this study regarding the concept of introducing an electronic patient record/radiation passport in which the exposure dose would be recorded after each radiological examination. Therefore, we asked the three groups of respondents, "Do you think that the dose

received from X-rays during diagnostic and therapeutic procedures (i.e. from administered ionising radiation) should be recorded in an Electronic Patient Record/Radiation Passport?". A large majority of patients (79.6%; n=121), X-ray laboratory technicians (70.9%; n=71) and specialists (72.0%; n=72) believed that X-ray doses should be tracked and included in the data required to create a patient radiation passport. Relatively small proportions of patients (2.0%; n=3), radiology lab technicians (11.7%; n=12), and specialists (9.0%; n=9) felt that this information did not need to be tracked and documented. Almost the same proportion of all three groups of respondents expressed uncertainty on this issue: patients – 18.4%; radiology lab technicians – 17.4%; and specialists – 19.0%, respectively. A statistically significant correlation was established between the responses to the need for an Electronic Patient Record and the surveyed groups – patients, radiology technicians and specialists ($\chi 2$=10.387, p=0.034) (Fig. 20).

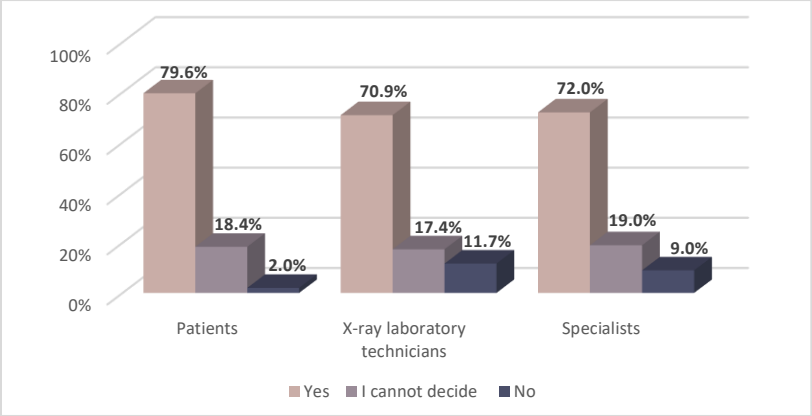


Figure 20. The need for documenting the exposure dose in an Electronic Patient Record/Radiation Passport (opinion of specialists, radiology lab technicians and patients, %)

2.5. Role and contribution of medical specialists in the process of obtaining informed consent from the patient

An essential requirement for obtaining valid informed consent from the patient is that healthcare professionals provide information and discuss with the patient the risks of the diagnostic or therapeutic X-ray procedure, based on which the patient can make an informed choice. With regard to the information discussed with health professionals about the risks arising from X-rays (ionising radiation), the patient group was divided into two subgroups, one of which responded positively (47.4%; n=72) and the other (52.6%; n=80) negatively. **Almost every second patient had not discussed the risks of ionising radiation with a health professional.** The fact that the two groups were relatively equally represented and the positive responders were even fewer in absolute number highlighted again the presence of a large number of patients who, despite exposure to ionising radiation procedures, had not received sufficient information about the risks to their health and these risks had not been discussed with a health professional.

In contrast to patients, most specialists and radiology lab technicians surveyed strongly emphasised that they had discussed information about the risks of ionising radiation procedures in detail with their patients, 78.0% (n=78) and 79.6% (n=82), respectively. Only 22 individuals,

or 22.0% in the specialist group and one-fifth of the radiology laboratory technicians (20.4%; n = 21), reported not discussing such information with patients (Fig. 21).

There was a statistically significant difference between the opinions of the three groups of respondents on the question at hand ($\chi 2$=38.024; p=0=000).

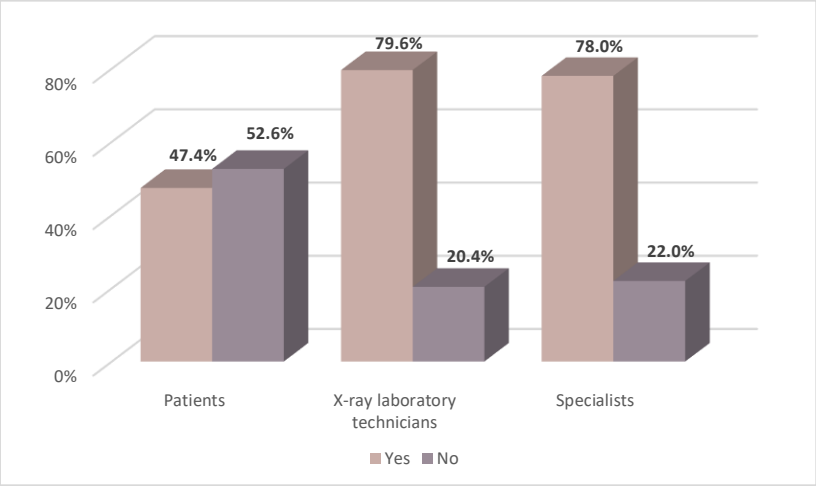


Figure 21. Discussion between health professionals and patients on the risks from X-rays/ionising radiation (opinion of specialists, radiology lab technicians and patients, %)

The object of our research interest was also with which of the health professionals, patients most often discuss information about the risks from X-rays/ionising radiation. The radiology technologist was the health professional with whom more than one-third of patients confirmed discussing information (38.8%; n=59), and one-fifth discussed such information with a radiologist (21.7%; n=33). With the family physician (GP), 15.8% (n=24) of patients had discussed the risks of X-rays, and twice as many (7.2%; n=11) had discussed with the attending physician. There were few patients who consulted information with a medical physicist (2.6%; n=4) and friends (0.7%; n=1). **Most patients did not discuss such information (52.6%; n=80).** These negative statements are cause for concern as they evidence that the patients who indicated them, despite exposure to ionising radiation procedures, were unaware of and had not discussed the potential risks to their health with a health professional (Fig. 22).

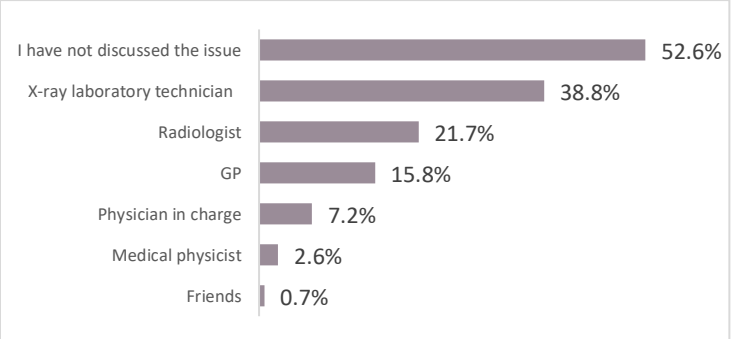


Figure 22. Health professionals with whom patients most frequently discuss information about risks from X-rays/ionising radiation (patients' opinion, %)

2.6. Functions of the radiology lab technician in providing information on radiation risk in medical diagnostics and therapy

Regarding the need to inform patients about the risks from ionising radiation, the opinions of patients, radiology lab technicians and specialists were compared on the question of which specialist should present such information. Most of the surveyed medical specialists and Radiology lab technicians identified the imaging specialist as the most appropriate physician to explain the risks of ionising radiation (51.0%; n=51 and 47.6%; n=49, respectively). A quarter of the specialists and a third of the radiology lab technicians considered that the above information should be given by the radiology lab technician (26.0%; n=26 and 33.0%; n=34, respectively). A relatively smaller proportion of the two groups of respondents considered that such information was the responsibility of the medical physicist (specialists – 17.0%; n=17 and radiology laboratory technicians – 16.5%; n=17, respectively).

Patients' opinions on this issue varied, with the majority expecting to receive information from a radiology laboratory technician (42.1%; n=64), and a relatively smaller proportion – from an imaging specialist (34.9%; n=53). These findings can be fully accounted for by the differences in education between the group of specialists and radiology lab technicians on the one hand, and patients on the other. The claims of the first two groups of respondents are derived from their professional competence in imaging diagnostics. In contrast, patients' claims are derived from their life experiences, perceptions and expectations. Conversely, radiology lab technicians are in closer contact with patients, which also explains patients' expectations to receive information mainly from radiology lab technicians (Fig. 23).

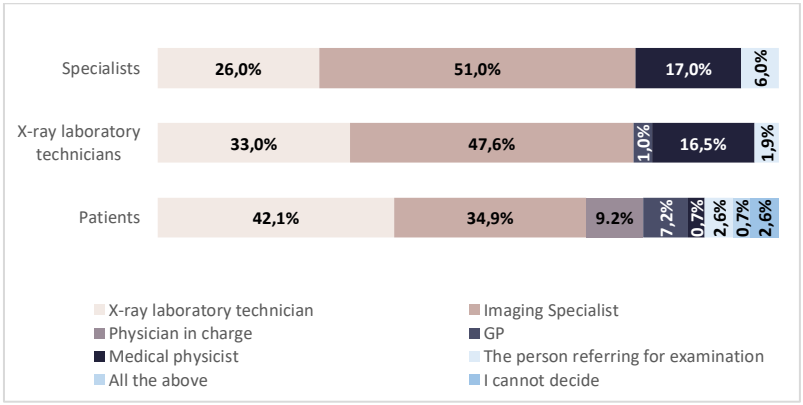


Figure 23. Best-suited medical professional to provide information on the risks from X-rays/ionising radiation (opinion of specialists, radiology lab technicians and patients, %)

Based on the analysis, no statistical significance was found in the responses of the three groups of respondents presented in Figure ($\chi 2=2.35$; $p>0.05$).

With regard to the results we achieved, we were interested in the opinion of radiology lab technicians and specialists on the most appropriate health professional who should obtain informed consent, certified by signature, from patients before performing imaging examinations with X-rays (ionising radiation). Most radiology lab technicians and specialists expressed the opinion that informed consent should be obtained from the radiology lab technicians (65.0%; n=65 and 53.4%; n=55, respectively). More than one-third of specialists and one-third of radiology lab technicians indicated that an imaging specialist was the most appropriate person to obtain informed consent. More than half of the specialists and one in ten

radiology lab technicians credited their preference to the medical physicist. The remaining minority of participants from both respondent groups indicated the most appropriate person to be the one who prescribed the examination (respectively: specialists – 9.0%; n=9 and radiology lab technicians – 5.8%; n=6). Four of the specialists and two of the radiology lab technicians considered the family physician to be the most appropriate person to obtain consent. The results highlight the critical function of the radiology lab technician in obtaining informed consent from the patient before performing imaging tests with X-rays (ionising radiation). The data analysis proved that the differences in the responses of the two surveyed groups were not statistically significant ($p > 0.05$) (Fig. 24).

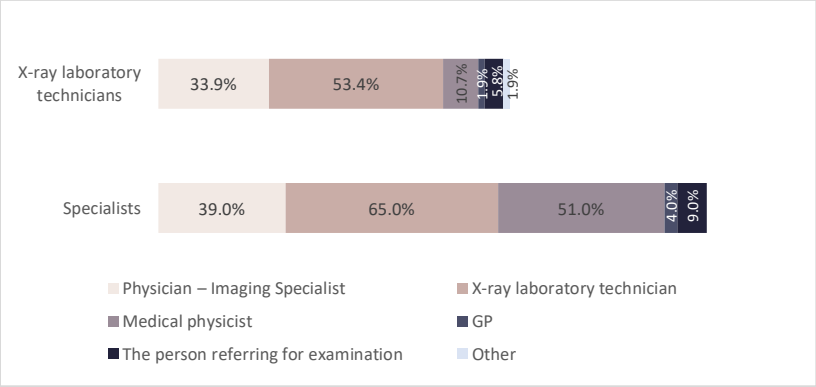


Figure 24. Best-suited medical professional to obtain informed consent from the patient prior to performing imaging tests with X-rays (opinion of specialists and radiology lab technicians, %) (Responses exceed 100% because the question is multiple choice)

In the context of the results, we asked patients and radiology lab technicians if they had discussed the risk of a particular type of X-ray test. It appears that 47 out of 152 patients (30.9%) had discussed the risk with a radiology lab technician. **Most patients, 105 (69.1%), did not discuss the risk assessment with a radiology lab technician before an upcoming procedure.** In contrast to patients, only 7 individuals (6.8%) in the radiology lab technician group reported discussing it in detail. The majority, or 69 individuals (67.0%), reported discussing the risk in general before a procedure. There were 27 persons (26.2%) in the radiology lab technician group who did not discuss the risk. Again, the outcome reveals a deficiency in the overall understanding of ionising radiation procedures performed and health risks.

There was a statistically significant difference in the opinions of patients and radiology laboratory technicians on the issue at hand ($\chi 2=4.691$; $p=0.021$) (Fig. 25).

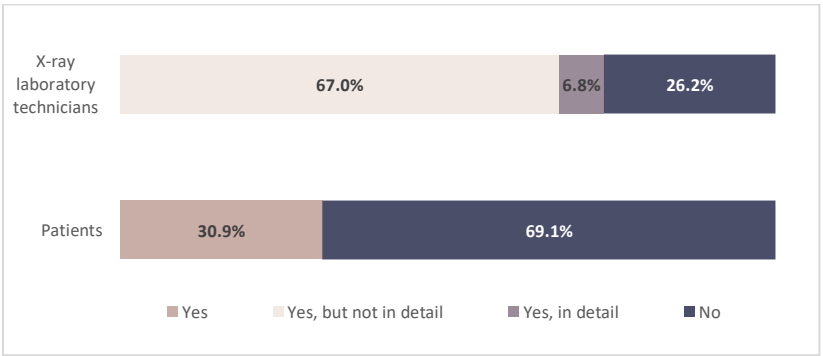


Figure 25. Discussion on the potential risks of ionising radiation in a specific X-ray procedure (opinion of patients and radiology technicians, %)

In order to investigate further, we decided to focus our study on whether detailed information was discussed between patients and radiology lab technicians. We aimed to specify precisely what detailed information about the risk of a particular type of X-ray examination was discussed between patients and X-ray lab technicians and whether only information that there is a potential risk in principle for a specific type of X-ray examination was discussed. Only 12 patients who communicated with a radiology lab technician about the risks of their examination received detailed information about the risks of a particular type of X-ray examination (7.9%). Meanwhile, the remaining 36 individuals received information about an existing risk in principle (26.3%). **It is alarming that 100 persons, or more than two-thirds of patients (65.8%), did not discuss the potential risk of a particular type of X-ray.**

In contrast to patients, 90 individuals (87.4%) from the radiology lab technicians group verified that a conversation occurred with the patient before the X-ray procedure. However, the findings revealed that most of the discussions with the patient revolved around information about the examination and risks involved rather than a detailed discussion about the risks. Only 17 individuals (16.5%) in the X-ray lab technician group confirmed discussing risk in detail before performing X-ray examinations. In contrast, the majority – 73 individuals (70.9%), reported discussing information about the type of imaging examination given, where risk exists in principle. Of those who indicated otherwise as a response, 11 persons (10.7%) indicated discussing information that there is a risk in a given type of imaging test in a possible pregnancy. Only two persons in the X-ray lab group chose the answer "no" (1.9%). Based on the data presented, the conclusion is again confirmed that when performing imaging examinations based on ionising radiation, the vast majority of patients do not receive information about the risk. Even if they do, it is related to a general explanation that there is a risk with the applied method but not to a detailed explanation about the extent and parameters of the risk, which should be the basis for obtaining informed consent. **From the results obtained, it can be stated that, without any discussion of only fragmented information about the nature of the procedure or the risks associated with it, informed consent is obtained from patients who, for the most part, have no knowledge of the field and no realistic ideas about the short- and long-term risks that may be associated with the diagnostic and therapeutic procedures to which they are subjected** (Figure 26).

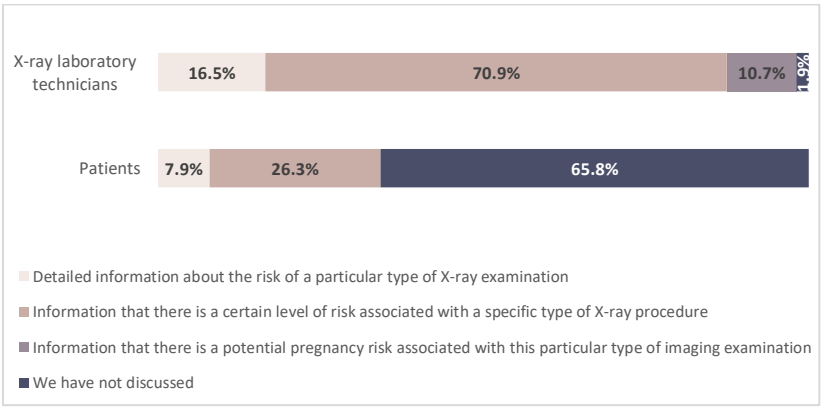


Figure 26. Information discussed between patients and radiology lab technicians (opinion of patients and radiology lab technicians, %)

The differences in the views expressed by radiology lab technicians and patients, presented in Figure 43, regarding the type of information discussed were statistically significant ($\chi 2$ = 84.882; p = 0.000).

2.7. Information to be provided to patients in the process of obtaining informed consent for x-ray examinations and procedures using ionising radiation

The information that should be provided to patients in the process of obtaining informed consent for X-ray examinations and procedures using ionising radiation is essential. It determines to a significant extent whether the patient's choice is genuinely informed, based on reliable information, understood and meaningful to the patient. Therefore, it was essential for us to investigate the opinions of the three surveyed groups regarding the sources from which patients seek information about medical imaging tests in general, which is the best source of information and what information is discussed between patients and medical specialists. Regarding the question of the most frequently used source of information by patients about medical imaging studies, there was disagreement between the three groups of respondents. The majority of X-ray technicians (75.7%) and specialists (64.0%) believe that the main source of information for patients is the Internet, and the patients themselves put it in second place (39.5%). The most preferred sources of information by patients are imaging specialists (55.3%, n=84). At the same time, the fact that 60 persons (39.5%) of the patients indicate the Internet as a reliable source for such specific medical information is alarming, which as an absolute number exceeds the number of persons who indicated a treating doctor - 40 persons (26.3%). The fact that every tenth of the patient group claims that they did not receive any information (10.5%) is alarming.The relationship between sources of information and groups of individuals surveyed was statistically significant ($\chi 2$ = 149.483; p = 0.000), and the results are presented in Figure 27.

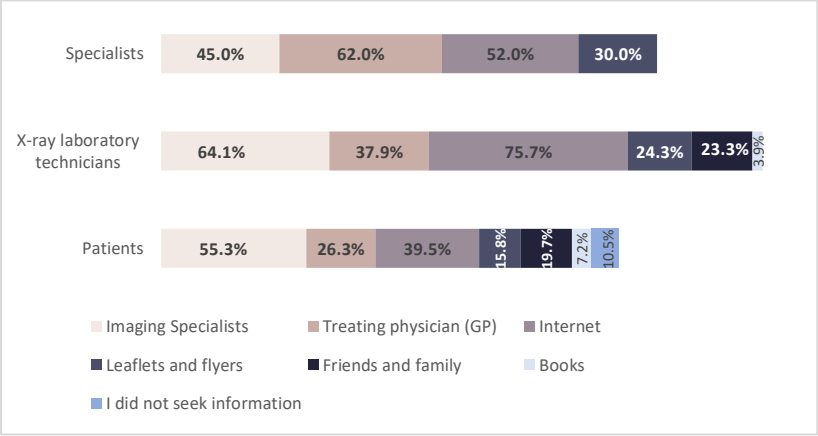


Figure 27. Patients' sources of information about medical imaging tests (opinion of patients, radiology lab technicians, and specialists, %) (Responses exceed 100% because the question is multiple-choice)

When asked about the most appropriate source of patient information for an upcoming imaging test, the vast majority of patients, radiology lab technicians, and specialists surveyed unanimously indicated "by talking to a medical professional" (patients – 84.9%, respectively; n=129, X-ray lab technicians – 59.2% and specialists – 34.0%; n=34) More than half of the specialists (62.0%; n=62), X-ray lab technicians (51.1%; n=53) and a relatively small number of patients (15.8%; n=24) preferred to be informed using an information leaflet. (Figure 28).

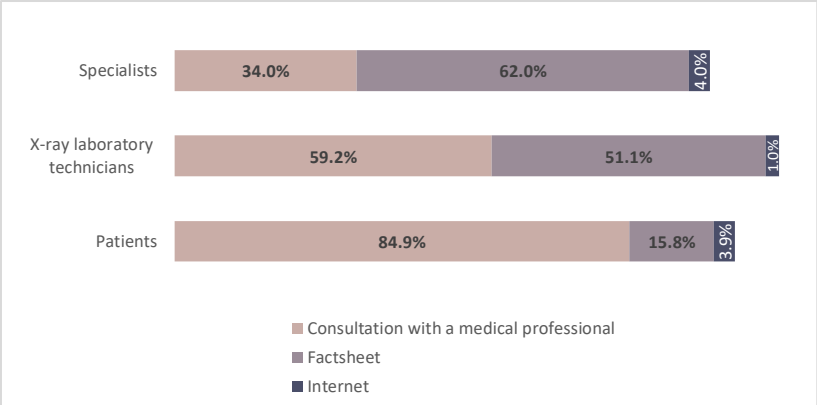


Figure 28. Most relevant source of patient information regarding an upcoming imaging test (Responses exceed 100% as the question is multiple choice)

There was no statistically significant difference between the answers of the three groups of respondents ($p>0.05$).

Age has been shown to influence patients' opinion on the most appropriate health professional to provide information on the risks from X-ray tests ($\chi 2= 62.977$; $p= 0.004$). With increasing age, the proportion of patients considering the radiology lab technician and the imaging specialist as the most appropriate source of information on the risks from X-ray tests (ionising radiation) increased. In contrast, the number of respondents indicating the family physician decreased.

In the context of the results, we were interested in whether there was any discussion between patients and physicians about the dose of ionising radiation in a given type of X-ray examination. The results show that the radiation dose received in a particular type of X-ray examination was discussed with the physician according to a relatively small proportion of the surveyed patients – only 24 persons (15.8%) discussed the dose received in an examination. Only a third of the specialists reported such a discussion. It is alarming that the majority of patients (84.2%; n=128) and specialists (68.0% n=68) did not report a discussion of the radiation dose received during examinations (Figure 29)

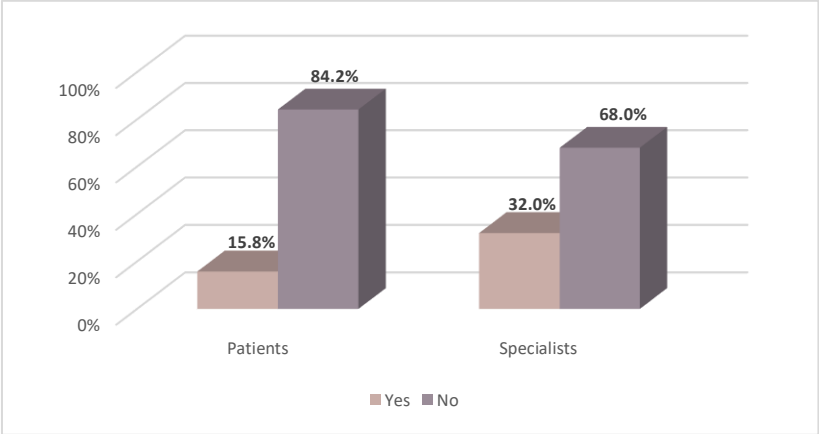


Figure 29. Discussion between patients and specialists on the dose of ionising radiation in a specific type of X-ray examination (patients' and specialists' opinion, %)

The findings once again validate the lack of adequate medical data provided to the patient regarding the radiation dose received during different types of diagnostic procedures with ionising radiation. The Chi-square test revealed a statistically significant correlation ($\chi 2$=9.171; p=0.002) between the variables. However, the test was liberal: more than 20% of the cells contained theoretical frequencies less than 5.

Age is a factor predetermining patients' discussion of radiation dose from X-ray examination with a physician ($\chi 2$=16.437; p= 0.002). As age increases, the proportion of patients who have discussed with a doctor the radiation dose received during a given type of X-ray examination increases. Among patients and specialists who discussed the dose of ionizing radiation for a given type of X-ray examination, two groups were formed depending on the information discussed - basic information about the presence of a dose burden due to the application of ionizing radiation or detailed information about the dose for the patient in the specific planned examination. The majority of the specialists shared about discussing basic information about the existence of a dose load as a result of the application of ionizing radiation (20%), and a smaller part discussed in detail (12%). Of patients who discussed radiation dose with a physician, only seven judged detailed information about the patient's dose for a given type of examination to be key to obtaining informed consent (4.6%), and a greater proportion of patients actually were informed that with the given imaging method there is a dose load in principle due to the application of ionizing radiation, which is a fundamental principle in the majority of imaging studies (11.2%). The Z score test for 2 independent samples - patients and specialists regarding discussion of detailed information about the dose in a given type of examination is Z = -2.1752, p = 0.0292, and for the answer "we have not discussed" - Z = 2.1209, p = 0.034. Therefore, there is a statistically significant difference between the responses of patients and professionals for discussing detailed information (7.4 points) and for non-discussers (11.9 points) (Fig. 30).

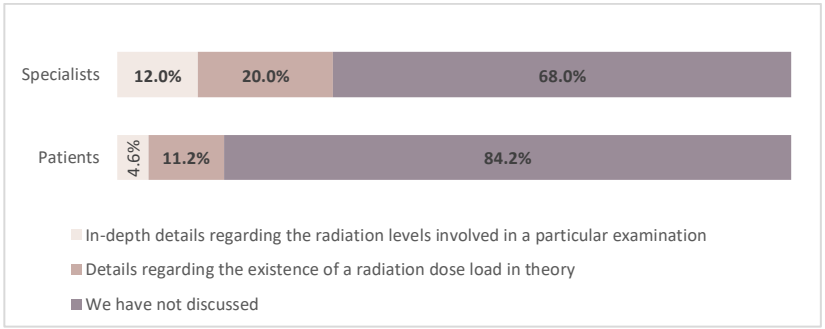


Figure 30. Information on ionising radiation dose for a specific type of X-ray examination discussed among patients and specialists (patients' and specialists' opinion, %)

In the group of patients and specialists, the question related to the physician and patient discussion about the risk of an imaging method was analysed. Such a discussion should be the basis for obtaining valid informed consent. Detailed discussion was present in a tiny proportion of both groups of respondents. Of all 152 patients surveyed, only 4 individuals (2.6%) had such a detailed discussion with a physician. Results were similar in the specialists' group, with only three specialists (3.0%) mentioning a detailed discussion with the patient before an ionising radiation procedure. **Most patients (65.8%; n=100) and approximately half of the physicians (45.0%; n=45) did not discuss the risk of using imaging modalities with ionising**

radiation, which should be the starting point for obtaining informed consent. Most specialists (52.0%; n = 52) and nearly one-third of patients claimed to have discussed the risk of a particular imaging method, but the discussion was not conducted in detail. (Fig. 31).

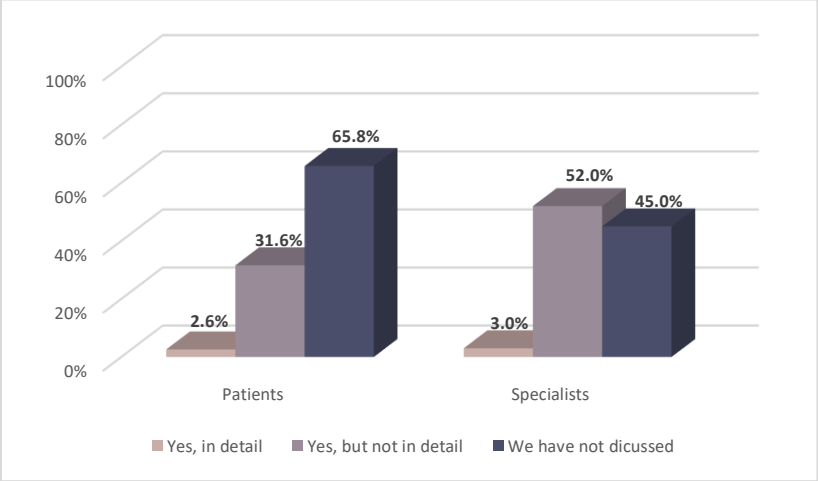


Figure 31. Discussion between patients and specialists on the potential risks associated with imaging tests (patient and specialists' opinion, %)

According to the data from the statistical analysis, the Chi-square test revealed a statistically significant association ($\chi 2=10.9$; $p=0.004$) between the variables. However, the test was liberal: more than 20% of the cells contained theoretical frequencies less than 5. Therefore, it cannot be stated with certainty that there is a correlation between the presence of a discussion on the potential risks associated with imaging exposure in the treatment process and the role of either the patient or specialist.

A significant difference between the opinion of patients and professionals was observed on the question of patients' attitudes about dose and risk awareness and decision-making about the application of a given medical test. The majority of patients preferred to be informed about the dose and risk and to make a decision together with the doctor (80.3%), a result that contrasts sharply with the data reflecting the lack of discussion between patients and doctors about the dose and risk of ionizing radiation in a given type of X-ray examination presented in Figure 30 and Figure 31, according to which a very small proportion of patients claim to receive detailed information from a specialist. It is worth noting the fact that the share of specialists who believe that patients prefer to be informed and make a decision together with the doctor is twice as small as that of patients who indicated the same statement (43.0%). It turns out that 16.4% of patients prefer to be informed, but for the doctor to make a decision himself, and five of the persons or 3.3% do not want to be informed and are ready to give the doctor the opportunity to make a decision himself. That is, less than a fifth of the surveyed 152 individuals from the patient group or 19.7% preferred that the doctor himself decide on an upcoming procedure with the use of ionizing radiation with/without receiving information about the dose and the risk with which it will be associated. In contrast to patients, the largest part of specialists (54.0%) confirmed the attitudes of patients to be informed, but for the doctor to make a decision himself, and only three of the doctors (3.0%) believe that patients prefer not to be informed and not participate in the decision-making process (Fig. 32).

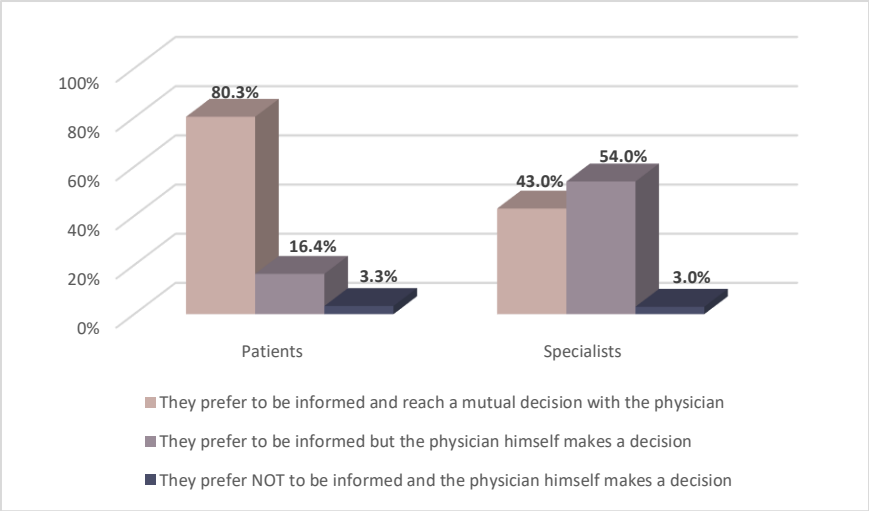


Figure 32. Patients' attitudes to receiving information about the dose load and the potential risks and decision-making about the use of a specific medical test (patients' and specialists' opinions, %)

The results obtained confirm the attitudes in the patient group – **regardless of the wish to be informed about the dose load and potential risks accompanying a specific procedure, the vast majority of patients prefer the decision to be made by the physician**. According to the statistical analysis, the difference in proportions was significant for the first two responses of the respondents, $p < 0.00001$ (for the first response, $Z = 6.087$ and for the second, $Z = -6.2867$). The results of the analysis demonstrate that statistically significant factors determining patients' preferences for information on the dose load and potential risks and the decision-making before medical examination were age ($\chi2=8.324$; $p=0.016$) and gender ($\chi2=10.800$; $p=0.020$). With increasing age, the proportion of patients preferring to be informed but for the physician to make the decision increased, as did the proportion of patients not wishing to be informed and leaving the decision to the physician. At the same time, the share of women (84.7%) preferring to be informed and decide with the physician is relatively higher than that of men (60.7%). In those willing to be informed but for the physician to make the decision alone, men were twice the number of women. Male patients refusing to be informed and make decisions were three times more than females.

Of interest is the analysis of patients, radiology lab technicians, and specialists rated the statement "The dose from lung X-ray is commensurate with the dose received from natural background radiation on a single Varna-Sofia flight" as easy to understand (patients – 63.1%; n=96, radiology lab technicians – 83.5%; n=86, and specialists – 91.0%; n=91, respectively). Notably, the proportion of patients indicating this answer is lower than the other two groups of respondents. This is easily understandable and explicable, given the availability of professional training of specialists and radiology lab technicians in the matter. At the same time, a fifth of patients and a minor identical proportion of X-ray lab technicians (8.7%; n=9) and specialists (9.0%; n=9) expressed hesitation. The statement was defined as difficult to understand by one in ten patients, one in eight X-ray lab technicians and none of the specialists. There was a significant correlation between clarity of explanation and the respondent group indicator ($\chi2=32.987$, $p=0.000$). For all three groups, the responses were graded in decreasing order as follows: 'Easy to understand', 'Cannot judge', 'Difficult to understand' (Figure 33).

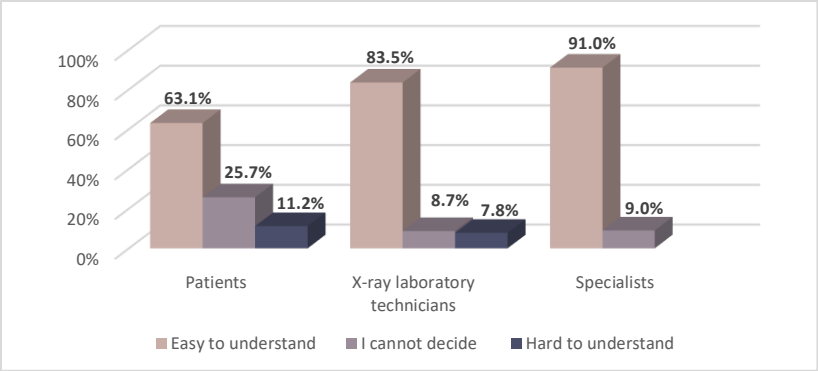


Figure 33. Comprehension of the statement: "The dose during lung x-ray is comparable to the dose received from the natural radiation background during a single airplane flight Varna - Sofia" (opinion of patients, radiology lab technicians and specialists, in %)

The statement was rated as difficult to understand by one in ten patients, one in eight radiologists and none of the specialists. A significant relationship was established between the clarity of the explanation and the indicator for the group of respondents ($\chi 2$=32.987, p=0.000). There is a gradation of answers in patients with higher education, while in those with secondary education, the proportion of those unable to judge is the highest ($\chi 2$=14.752, p=0.001) (Fig. 34).

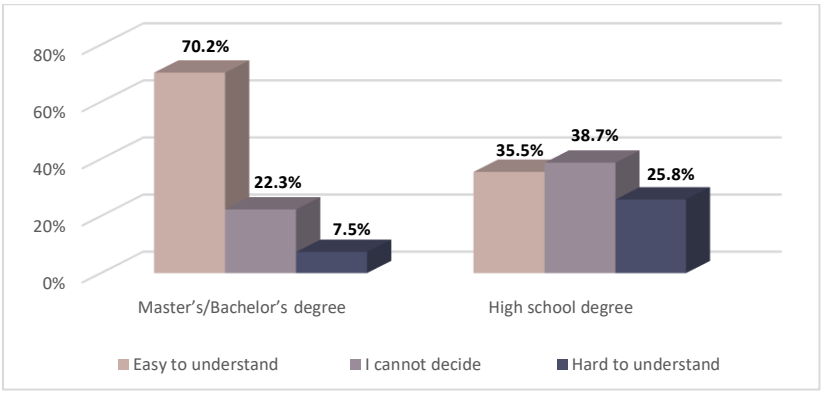


Figure 34. Comprehension of the statement: "The dose during lung X-ray is comparable to the dose received from the natural radiation background during a single airplane flight Varna - Sofia" (distribution of patients' responses by education, in %).

2.8. Need for additional training of all specialists involved in informing patients about radiation risk in medical diagnostics and therapy

Investigating the need to adequately inform patients about radiation risk in medical diagnostics and therapy, it was important for us to investigate to what extent medical specialists and radiology lab technicians are prepared for this critical function by updating their professional competence through continuing education. Therefore, we asked the medical specialists and radiology lab technicians, "Have you received any training (beyond basic training) regarding the application of ionising radiation related to medical diagnostics and therapy?". Notably, only 18 persons or 18.0% of the specialists, had received training regarding the application of ionising radiation related to medical diagnostics and therapy. In contrast, most radiology lab

technicians (61.2%; n=63) have permanently updated their knowledge in this direction through training. Most of the specialists' group (82.0%; n=82) and just over a third of the X-ray lab technicians reported that they had not received any training beyond the basic training related to ionising radiation in medical diagnostics and therapy. There was a statistically significant difference between the responses of radiology lab technicians and specialists, both for those who answered "yes" (61.2%/18%), Z = 6.2788, p < 0.00001, and those who indicated "no" (38.8%/82%), Z = –6.2788, p < 0.00001 (Fig. 35).

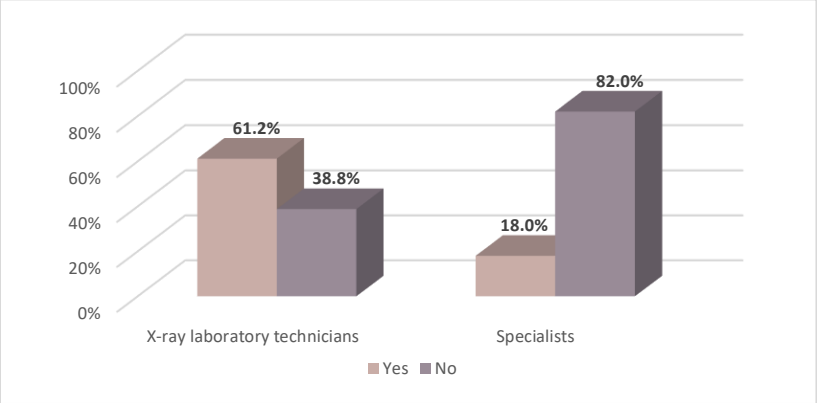


Figure 35. Conducting continuing education regarding the application of ionising radiation related to medical diagnostics and therapy (opinion of radiology lab technicians and specialists, %)

In response to the question, "Do you think you need further training regarding the application of ionising radiation related to medical diagnostics and therapy?", a significant proportion of specialists (89.0%; n=89) and more than half of radiology lab technicians (61.2%; n=63) expressed a need for further training regarding the application of ionising radiation related to medical diagnostics and therapy. At the same time, it is alarming that more than one-third of radiology lab technicians and one-tenth of specialists do not feel the need to update their knowledge and skills on the subject (Figure 36).

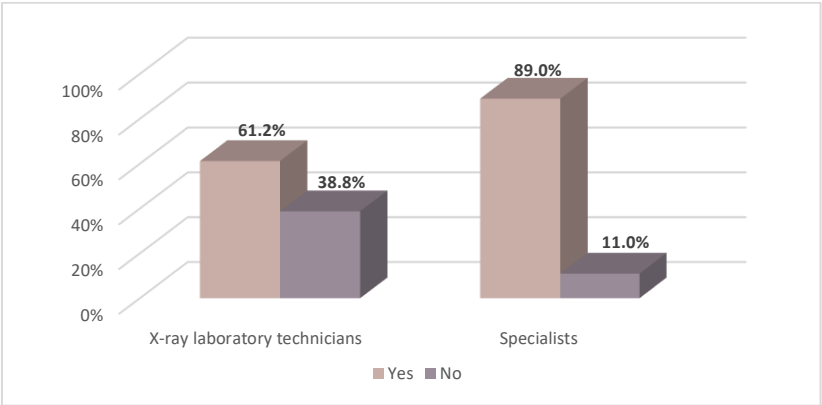


Figure 36. Need for additional training on the application of ionising radiation related to medical diagnostics and therapy (opinion of radiology lab technicians and specialists, %)

The statistical analysis showed a significant difference between the statements of the radiology lab technicians and specialists, both in those who answered "yes" (difference 28 points), Z = –4.5714, p < 0.00001, and those who answered "no" (difference 28 points), Z = 4.5714, p < 0.00001.

Worth noting is the comparative analysis of the responses of the two groups of respondents to the questions regarding the conduct and need for additional training regarding the administration of ionising radiation related to medical diagnostics and therapy. Notably, the proportion of radiology lab technicians attending additional training regarding the application of X-ray radiation in medical examinations and procedures (61.2%; n=63) and those expressing a need for such training (61.2%; n=63) was identical. In contrast, the proportion of specialists wishing to receive additional training regarding the application of X-ray radiation in medical examinations and procedures (89.0%; n=89) was higher than those confirming the mentioned training (82.0%; n=82) (Figures 65 and 66). The above data indicate a perceived need for training – both by radiology laboratory technicians and specialist physicians in the application of ionising radiation related to medical examinations and procedures.

In the context of the results, our research interest focuses on the preferred forms of additional training for the application of ionising radiation related to medical diagnostics and therapy by radiology lab technicians and specialists. A majority of the surveyed specialists (70.0% n=70) expressed a preference for distance learning, and the majority of radiology lab technicians were more likely to attend an on-the-job course (47.6%; n=49) (Fig. 37).

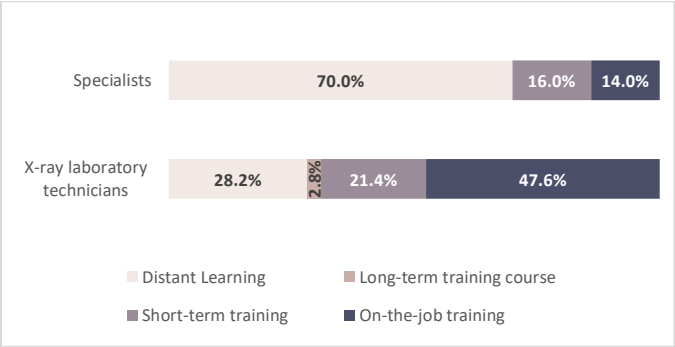


Figure 37. Preferred forms of additional training on the application of ionising radiation related to medical diagnostics and therapy (opinion of radiology lab technicians and specialists, %)

The liberal Chi-square test ($\chi 2 = 40.336$, $p = 0.000$) indicates that there may be a correlation between the preferred forms of additional training and the type of medical professionals.

3. INNOVATIVE TOOLS AND MODELS TO RAISE AWARENESS OF MEDICAL PROFESSIONALS AND PATIENTS ABOUT THE RISK OF IONISING RADIATION FOR MEDICAL DIAGNOSTICS AND THERAPY

3.1. A multifactorial framework of the informed consent process

Based on the literature reviewed regarding the overall informed consent process, it was concluded that informed consent practices in radiology, both globally and nationally, need improvement and standardisation. Experience has shown that good practices consider multiple factors to ensure the optimisation and quality of the process of informing and obtaining informed consent from patients for radiological examinations and procedures. Based on previous studies, a **Multifactorial Informed Consent Process Framework** was developed (Figure 38).

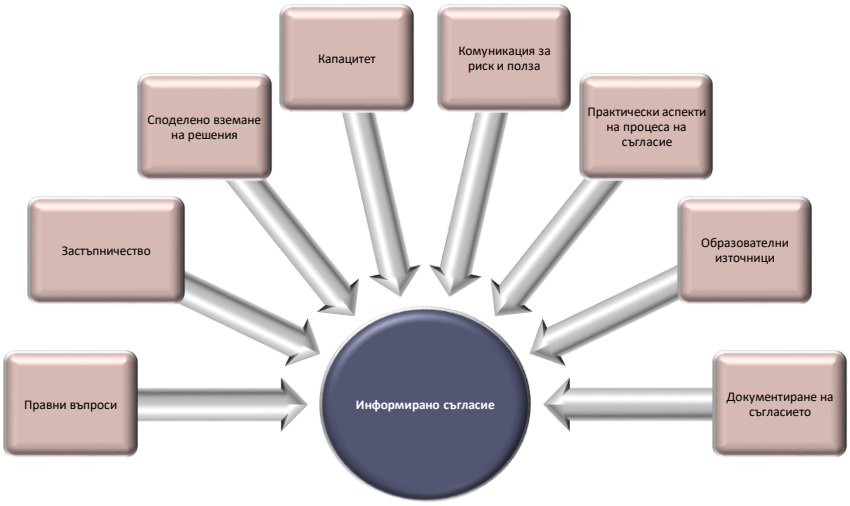


Figure 38. Multifactorial framework of the informed consent process. Adapted from policies and guidelines by the Society and College of Radiographers, European Society of Radiology (ESR), and the World Health Organization.

The introduction of a unified informed consent form into the practice of imaging specialists has several main reasons and advantages:

- **Protection of patient rights:** Unified informed consent forms ensure that patients receive the necessary information about imaging procedures, including the benefits, risks and alternative options. This helps patients make informed decisions about their treatment and participate actively in the healthcare process.
- **Standardisation and uniformity:** Unified informed consent forms ensure that imaging specialists provide the same information to patients and follow the same standards and procedures to inform them. This improves the quality of communication between specialists and patients and ensures a unified approach to informing patients across medical institutions.
- **Strengthening trust:** Unified informed consent form helps to strengthen trust between specialists and patients by demonstrating responsibility and respect for patients' rights and interests. Patients can be reassured that they have received the necessary

information, the opportunity to ask questions, and fully understand the risks and benefits.

- **Compliance with legal and ethical requirements:** The introduction of unified informed consent forms showcases the compliance of imaging specialists with legal requirements to obtain patients' informed consent. This is important for meeting ethical standards and ensuring patients' rights.
- **Adapting to change:** Unified informed consent forms reflect advances in imaging technology and procedures, providing up-to-date and relevant information for patients.
- **Improving communication:** Unified informed consent forms help imaging specialists communicate more effectively with patients. These forms support a better understanding of the information by using clear and systematic language that patients can understand, regardless of their educational or cultural level.

All of this helps advance healthcare and establish trust between specialists and patients. Additionally, it aids in improving the quality of healthcare and protecting patients' rights.

3.2. Model of a unified form for obtaining informed consent from the patient for an X-ray examination (mammography)

The existence of various medical centres and medical institutions in Bulgaria, respectively, in Varna, has led to the development of different forms for the same X-ray examination conducted in each of the medical institutions for outpatient and inpatient care.

We investigated the content of the available forms for obtaining patient-informed consent for mammography in the facilities where the present study was conducted. We established variations in parts (requisites) of the document itself and the information contained in it. For this reason, developing a unified model document for obtaining informed consent for mammography in inpatient and outpatient settings is imperative. It would facilitate a unified approach to informing the patient and respecting the patient's right to written informed consent to mammography within the professional competence of radiologists and radiology technicians.

The proposed Model (Unified) Form for obtaining informed consent from the patient for an X-ray examination (mammography) is based on the current legislation of the Republic of Bulgaria (Art. 87 – 89, p. 1 of the Health Act and Ordinance No. 9 of July 13th, 2018, regulating Diagnostic Imaging medical standard, issued by the Minister of Health, published in the SG No. 61 of July 24th, 2018). The Model Unified form acknowledges the patient's right to informed consent. It will contribute to the professional comfort and security of medical professionals performing professional tasks in imaging diagnostics (radiologist, radiology lab technician).

The model of the technical slip ((‘permission slip’) for obtaining informed consent proposed by S. Toncheva (2004), the model of informed consent protocol proposed by N. Vassilev et al. (2001) and the technical slip for obtaining informed consent by A. Georgieva (2015) served as the basis of the developed author's Model document for obtaining informed consent from the patient for X-ray examination (mammography). Demonstrating the need to introduce a document for obtaining informed consent in the context of the nursing practice, S. Toncheva (2004) stresses that "the introduction of an informed consent slip does not replace the personal contact of the health professional with the patient, but it saves him/her technological time. The proposed model of a technical informed consent slip will create a partnership relationship and

shared responsibility between specialists and patients regarding health". S. Toncheva (2004) also considers the said document as part of the psychological preparation of the patient. All of the above fully applies to radiology professionals (radiologists, radiology laboratory technicians).

Based on the model informed consent form for mammography presented below, forms can be developed for all other examinations and procedures using sources of ionising radiation.

The self-developed model 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 first section includes the personal contact information of the patient and his/her relatives, which the healthcare facility processes and stores for reporting purposes.

The second section contains information provided to each patient due to undergo mammography. The information includes: an explanation of the mammography method; a description of the test's purpose; instructions on how to behave before, during and after the procedure; and an explanation of the advantages, disadvantages and risks of mammography. In addition, the section provides information about the team working at the specific medical facility and the equipment used to perform the examination. Finally, the second section provides a free space for the patient to ask additional questions or express concerns about the procedure, as well as a section where the physician can answer the patient's questions and provide additional information.

The third section is an Informed Consent Statement, in which the patient acknowledges that he/she has received sufficient information about mammography, understands the purpose and risks of the test, and grants permission for the test to be conducted.

The first and third sections (patient details and patient’s statement) will be printed on both sides of one A4 sheet. In this way, the processing and archiving of the patient informed consent obtained will be easier for the medical facility administration. The second section – the mammography information, will be printed on separate sheets so the patient has the option to take them elsewhere and read the contents in privacy if needed.

Model (unified) form for obtaining informed consent from the patient for an X-ray examination (mammography)

PATIENT DATA		
Name:	**Middle name:**	**Surname:**
Personal identity number:		
Address:		
Contact phone number:		

Dear Madam,

In the course of your medical diagnostic process, your attending physician has ordered a mammogram.

Your consent and, if possible, active participation and cooperation are required before any mammography is performed.

Prior to obtaining your consent for mammography, we will provide you with information regarding:

- The nature of mammography;
- Indications for mammography;
- Advantages and disadvantages of mammography;
- Your preparation and behaviour before, during and after mammography;
- Possible unpleasant sensations, risks and complications;
- Equipment and team for performing mammography.

➢ What is a mammogram?

Mammography is a specific imaging method that uses a relatively low dose of X-ray radiation to visualise the structures that make up the breast. It is the only certified method in the world for breast cancer screening.

➢ Indications for mammography

Mammography can detect the presence of a number of pathological changes – cystic transformation, calcifications, and tumours. With this method, small lesions that cannot be palpated can be visualised. Mammography is used both for diagnostic purposes – in patients with clinical complaints (diagnostic) and for preventive purposes – for early detection of breast cancer (screening).

Screening mammography

Mammography is a crucial element in the early detection of breast cancer, as it can show changes in the breast years before the patient or physician detects them. Screening mammography is recommended every year for women, starting at age 40. Research shows that annual mammograms lead to early detection of breast cancer when most curable and breast-preserving therapies are available.

Women who have had breast cancer and those who are at increased risk because of a family history of breast or ovarian cancer should seek expert medical advice about whether they should begin screening before age 40 and the need for other types of screening. If you are at high risk for breast cancer, you may need to get a breast MRI in addition to your annual mammogram.

Diagnostic mammography

Diagnostic mammography is used for assessing a patient with unusual clinical findings – such as a breast lump or nipple discharge – that the woman or her physician has detected. Diagnostic mammography may also be done after an abnormal mammogram to evaluate the area of concern at the screening exam.

- **Advantages and disadvantages of mammography**

Although mammography is the best breast cancer screening tool available today, mammograms do not detect all breast cancers. This is called a false negative result. On the other hand, when a mammogram looks abnormal and there is no cancer, this is called a false positive result.

Screening mammography images alone is often insufficient to establish the presence of benign or malignant disease. If abnormalities are present, your radiologist may recommend additional diagnostic imaging tests (ultrasound, MRI).

It is essential to understand that not all breast cancers can be seen on mammography. Interpretation of mammograms can be difficult because the normal breast looks different for each woman. In addition, the x-ray image may be compromised if there is powder or ointment on the breasts or if you have had breast surgery. Because some breast cancers are difficult to visualise, the radiologist may want to compare the image with mammograms and ultrasounds from your previous exams. For these reasons, you may be called in for an additional x-ray or breast ultrasound, but this is done routinely to give the patient a more accurate result and should not be a cause for concern. Increased breast density also has a significant impact on the reading of mammograms.

The radiologist who reads your mammogram determines your breast density and reports it to your physician. Breast implants can also interfere with accurate mammogram readings because silicone and saline implants are not transparent to X-rays and can block a clear view of the surrounding tissue, especially if the implant is placed in front of rather than under the chest muscles. Experienced technologists and radiologists know how to gently compress the breast to improve image quality without tearing the implant.

- **Your preparation and behaviour before, during and after mammography**

Before your mammogram is scheduled, it is recommended that you discuss any new findings or problems in your breasts with your physician. In addition, inform your physician of any previous surgeries, **hormone use**, and family or personal history of breast cancer.

Do not schedule your mammogram for the week before your menstrual period, when your breasts are usually painful. The best time for a mammogram is one week after your period. Always inform your physician or radiologist if there is any possibility that you are pregnant or breastfeeding.

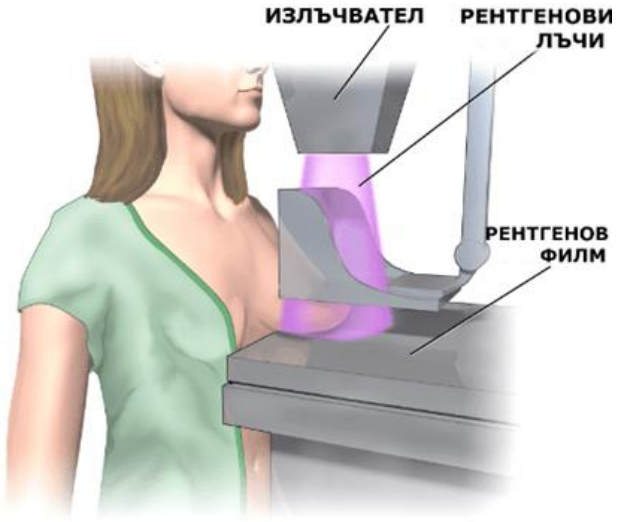
Do not wear deodorant, talc or lotion under your arms or breasts on the exam day. They may show up on the mammogram as calcium spots.

Inform the x-ray technician before your mammogram if you have breast implants, a pacemaker, or a Port-a-Cath.

Describe any breast symptoms or problems to the x-ray technologist performing the exam. Also, let him or her know if your breasts are very painful on the day of the exam. Before the examination begins, it is necessary to remove clothing and jewellery in the neck and chest area.

Bring your previous mammograms, which may also be on CD (disc), and provide them to the radiologist if taken elsewhere. This is necessary for comparison with your current examination. Ask when your results will be ready.

Mammography is performed on an outpatient basis. A specially qualified radiology technician will position your breast on the mammography machine (tripod) on a special plate during the mammogram. The technologist will gradually compress your breast with a clear plastic paddle.



Breast compression is necessary to flatten and reduce the thickness of the breast so that the entire mammary gland can be visualised. When a breast is well compressed, the overlying breast tissue is less likely to hide minor abnormalities. This allows a lower dose of X-rays as a thinner amount of breast tissue is imaged.

It would help if you keep the breast still to minimise the deterioration of the image caused by movement. X-ray scatter is reduced, and image quality is increased.

You will be asked to change positions between images. The routine views are the top-down view and wide-angle view. The process will be repeated for the other breast.

It would be best if you remained still. You may need to hold your breath for a few seconds while the lab technician takes your X-ray. This helps to reduce the possibility of blurring the image.

The lab technician will go behind a wall or into an adjacent room to activate the X-ray equipment.

When the examination is finished, the lab technician may ask you to wait until the radiologist confirms that he or she has all the necessary images.

The examination process may take about 30 minutes.

- **Possible unpleasant sensations, risks and complications**

During the examination, you will feel pressure on your breast as the compression paddle squeezes it. Some women with sensitive breasts may experience discomfort and pain. If this is the case, schedule the procedure when your breasts are least sensitive. Be sure to inform the lab technician if pain occurs when increasing compression. If the discomfort is significant, less compression will be used. Always remember that compression allows for higher-quality mammograms. Another discomfort can sometimes be experienced from cold plates and the tripod shoulder blades (scapula) where the breast is placed.

- **Mammography equipment and team**

Our mammography is a new-generation system equipped with a computer that allows us to establish the lowest and best radiation dose for each breast. The dose of each mammogram is usually recorded. Regular tests are carried out to check the quality of the mammograms and the dose delivered.

Our team, consisting of certified radiologists and x-ray lab technicians, is specially trained and kept up-to-date with modern breast imaging.

Space for additional information if needed.

If you need more information or have additional questions, please record them here:	*We are ready to answer all your questions here:*

Keep in mind that information about the reasons and purposes for the physician's decision to order a particular mammogram and the benefits and risks of mammography are solely within the physician's competencies.

STATEMENT OF INFORMED CONSENT

IMPORTANT: Before performing any mammography, it is necessary to obtain your consent and, if possible, active participation and cooperation.

If you consider that the information you have received about the test is sufficient and you do not need further clarification, please mark your agreement with "YES" or disagreement with "NO" and sign here:

I hereby declare my consent to have a mammogram performed.

YES / NO

Date: **Signature:**

(patient/guardian)

PATIENT'S LEGAL REPRESENTATIVE / GUARDIAN

Name: Surname: Family name:

Personal ID number:

Contact details/guardian's contact details:
Telephone: Address:

The patient cannot give her consent because:

Date: **Physician:**

City: (Name, Family name, signature)

3.3. Patient radiation passport model

According to Bulgarian legislation, there are no defined patient dose limits, and the application of X-rays in imaging studies is guided by the ALARA principle. The current development aims to create accountability for patient doses, with the aim of preventing unnecessary and unregulated application of X-ray examinations leading to dose loading by introducing a radiation passport.

During development, particular cases should be clarified and taken into account, such as imaging studies of persons living outside the Republic of Bulgaria, temporary residents, etc.

REPUBLIC OF BULGARIA

RADIATION PASSPORT

OF A PERSON NOT DIRECTLY INVOLVED IN ACTIVITIES WITH SOURCES OF IONISING RADIATION IN ACCORDANCE WITH THE PROVISIONS OF NSCA

- **NSCA – NUCLEAR SAFETY AND CONTROL ACT**

- **SIR – SOURCES OF IONISING RADIATION**

(Name)

(Middle name)

(Surname)

/ (Date and place of birth)

(Personal ID number) / (ID card)

/ (Residence)

(Profession/Job)

Phone: _____

(Date of Issue): _____ Signature/Stamp):

RADIATION PASSPORT OF A PERSON NOT DIRECTLY INVOLVED IN ACTIVITIES WITH SIR, ACCORDING TO NSCA

Date	Type of X-ray examination	Physician who ordered the test	Patient dose from the X-ray examination	Patient	
			…….. (µGy.m2)	Accompanying person	

Date	Type of X-ray examination	Physician who ordered the test	Patient dose from the X-ray examination	Patient	
			…….. (µGy.m2)	Accompanying person	

Date	Type of X-ray examination	Physician who ordered the test	Patient dose from the X-ray examination	Patient	
			…….. (µGy.m2)	Accompanying person	

Annual cumulative dose: ..... (µGy.m2) **For 20.....**

GUIDELINES FOR COMPLETING THE RADIATION PASSPORT FOR A PERSON NOT DIRECTLY INVOLVED IN ACTIVITIES WITH SIR, IN ACCORDANCE WITH NSCA

1. The passport shall be filled in with the person's current data according to the identity document and place of work at the time of issue.

2. The passport shall be used only by the person in whose name it is issued.

3. The passport shall be considered invalid if the signature and stamp of the issuing organisation do not authenticate it.

4. The purpose of the Radiation Passport is to collect and store data on the individual exposure of the person.

5. The passport shall be presented to the person carrying out the X-ray examination, who alone shall record details of the type of examination, the date of the examination, the person who ordered the examination, and the dose received by the person as staff or accompanying person during the examination.

6. The value of the dose load received shall be obtained according to the reading of the DAP meter – the immediate reading of the dosimeter shall be provided to the attendant person by the medical establishment at the time of the examination.

7. No corrections or adjustments to the data entered in the passport are allowed.

8. If the radiation passport is completed up to and including the last page, it shall be closed, and the person shall be issued a new radiation passport.

9. The issue date shall be entered on the first page, and the closure date on the last page.

10. The holder shall keep the closed radiation passport until the age of 75 years and shall be presented to the control authorities on request.

11. The patient's radiation passport shall also be closed in the following circumstances: if it is damaged, if it is completed to the last page and in the event of the death of the person.

_____ (Signature/Seal)

(Date of closure)

If you find the current radiation passport, please call .....

or return it to the address:.....

3.4. Expert evaluation of proposed innovative tools and models to raise awareness of medical professionals and patients on the risk of ionising radiation for medical diagnostics and therapy

The unified model we have developed for obtaining informed consent from the patient to undergo mammography and the patient radiation passport model is not an aim in itself but an initiative to improve the quality of healthcare and protect patients' rights. The literature review and our survey results listed above justify the need for these documents. The documentation reflects current good practices and aligns with legal regulations and standards in healthcare. It has been developed considering the technological advances and current imaging procedures, thus providing up-to-date and relevant information for patients.

Seeking experts' perspectives on the unified model we have created for obtaining informed consent from patients for mammography, we interviewed 15 physicians who work in medical facilities for imaging diagnostics.

Starting the interview, we asked for the experts' opinions on the applicability of the proposed unified form for obtaining informed consent from the patient for mammography in the practice of imaging specialists. The vast majority of interviewees (n=11) felt that the proposed form would be adopted for use in their practice, had no comments on the document and made no further recommendations for optimising the model. On the other hand, only four specialists gave a negative opinion on the applicability of the proposed form (Figure 39).

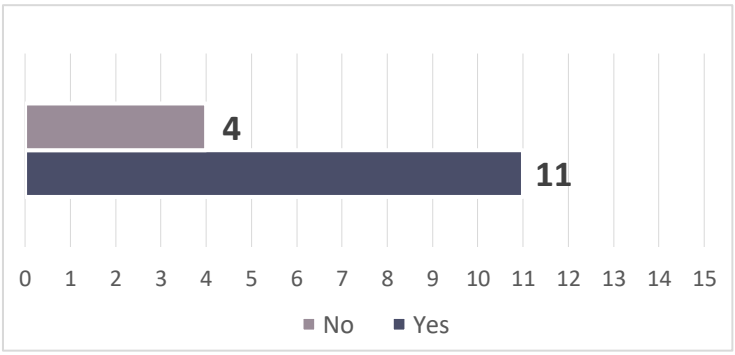


Figure 39. Interviewed physicians' views on the feasibility of the proposed unified form for obtaining patient-informed consent

Both groups justified their opinions by sharing their reasoning. Among the specialists with a favourable opinion, 10 indicated that the form helps to ensure patient informed consent, an essential ethical and legal aspect of medical practice. In total, 9 interviewees emphasised that the proposed model form improves the professional comfort and safety of specialists when prescribing imaging tests using ionising radiation sources, and six considered that the document optimises the involvement of specialists in taking informed patient consent for imaging tests and therapeutic procedures.

The opposing arguments were significantly fewer than the positive ones. They were related to the complexity of the detailed patient information in the form (n=3), shortage of medical staff (n=2) and lack of time (n=2). The recommendation to synthesise the information in the form provided by one of the specialists can be considered an alternative to improve the document and overcome the identified challenges.

The results of the aggregated positive and negative arguments exceeded the number of interviewees, as experts indicated more than one answer (Figure 40).

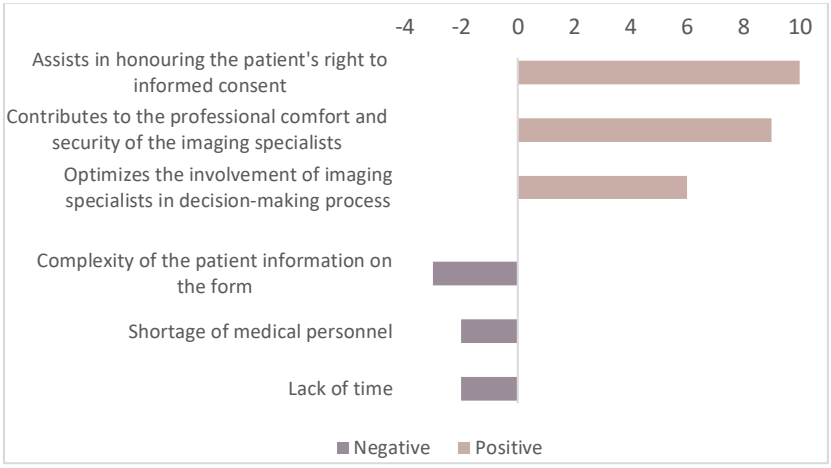


Figure 40. Physicians' positive and negative arguments for implementing the proposed unified form for obtaining patient-informed consent

Since the informed consent form is an integral part of the work of imaging physicians, it was essential for us to have the opinion of the experts regarding the possible difficulties that the proposed model might cause.

Most experts (n=10) believed that the proposed model of a patient-informed consent form would not cause difficulties for imaging specialists. Five physicians highlighted certain circumstances where healthcare professionals might experience difficulties using the proposed form. For example, two of them felt that determining a patient's capacity to consent could be challenging and, in some cases, require contacting the patient's legal representative. Three of the experts' concerns related to possible difficulties or special efforts in determining whether the patient has received all the necessary information. Another concern related to information and additional effort on the part of the health professionals was expressed by five respondents, who stressed the importance of establishing to what extent the patient understood the information provided and whether they could make sense of it (Figure 41).

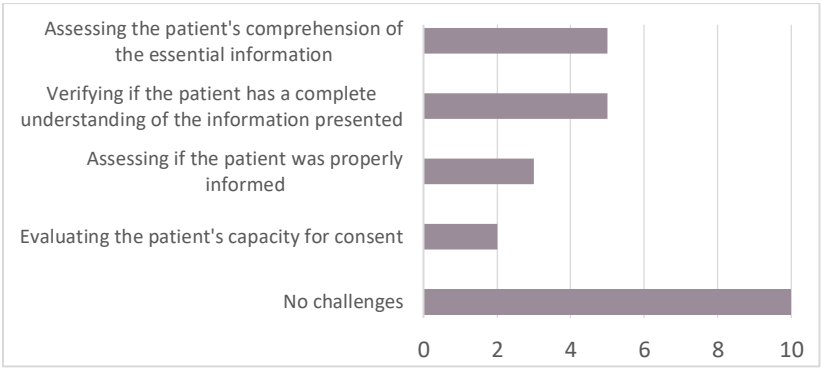


Figure 41. Interviewed physicians' views on the possible difficulties that the proposed model may cause

In summary, most specialists support implementing the proposed unified model for patient-informed consent forms for mammography, but some express concerns regarding the complexity of the content and provide recommendations for improving the

process. In addition, they suggest including details of specific risks and instructions for patient protection. This helps patients to give informed consent and exercise free choice. Experts call for careful information balancing and accurate determination of patients' capacity and confidence in their decision-making competence. These factors are essential to ensure reliable and ethical performance in imaging diagnostics departments.

The interviewed imaging physicians also gave their opinions on our proposed model for a patient radiation passport.

The experts' assessment of the extent to which the patient's radiation passport would assist the radiologist in making an informed choice when selecting the most appropriate examination method was of utmost importance to us. Considering the accumulated radiation exposure from previous examinations was vital. This is essential in terms of reducing the radiation risk to the patient. In this context, the positive responses of 14 experts, according to whom the radiation passport would be helpful to them in the choice of modality, are satisfying. Their recommendations on the information in a radiation passport include: name and personal data of the patient - basic information for identifying the patient and linking the passport to a specific person; history of previous radiological examinations; information about the radiation dose received from the patient's previous radiological examinations, as well as information about previous health problems that may affect the patient's radiological examination (allergies, previous health conditions or treatment that may affect the patient's radiation sensitivity) .

The experts unanimously endorse the patient radiation passport model we have developed and have no suggestions for refinement. In a free text, they recommend including it in the future in the electronic patient record.

CONCLUSIONS

Based on the results of the research, we can draw the following conclusions:

1. Regardless of the advancements in scientific technology for X-ray examinations and diagnostic procedures using sources of ionising radiation and numerous scientific studies, the effective practical implementation of the process of informing patients and medical specialists about these procedures still faces many obstacles, challenges, and unresolved issues.

2. In the Republic of Bulgaria, there is no unified system for registration, reporting and control of X-ray examinations of patients, which reduces the possibility of radiology specialists monitoring the patient doses and makes it challenging to inform the patient about the risks associated with ionising radiation for medical diagnostics and therapy.

3. As a result of the analysis, gaps in the informed consent forms in the imaging departments were identified, such as lack of standardisation, incomplete information, different language and approach, as well as restrictions on the right to consent and refusal, which could compromise the process of informing and obtaining informed consent.

4. It is necessary to optimise the organisation, documentation and systematisation of the information related to the radiation risk in medical diagnostics and therapy in the Republic of Bulgaria, applying the good practices in other countries in terms of obtaining the informed consent of the patient when performing medical activities related to radiation risk.

5. Patients' awareness of the risks associated with ionising radiation for medical diagnostics and therapy is unsatisfactory, limiting the patient's ability to make an informed decision about consent to perform X-ray examinations and procedures.

6. The radiology lab technician and medical specialists are essential in providing information about the radiation risk in medical diagnostics and therapy and obtaining informed consent for imaging procedures and examinations.

7. According to the majority of radiology lab technicians and specialists, there is a need for additional training for all specialists involved in informing patients about the radiation risk in medical diagnostics and therapy.

8. The radiation passport for registration of the patient's radiation dose load during X-ray examinations and procedures is a tool for creating opportunities for X-ray specialists to monitor patient doses.

9. The radiation passport for registration of the patient's radiation dose during X-ray examinations and procedures is a tool for increasing patients' awareness of the risk of ionising radiation during medical diagnostics and therapy.

10. The expert evaluation proved the applicability of the developed innovative models and tools for raising awareness of the risk of ionising radiation and optimising the work efficiency of medical specialists performing medical diagnostics and therapy related to radiation risk.

RECOMMENDATIONS

1. To the Ministry of Health:

To further develop and specify the current legal framework in the Republic of Bulgaria, referring to the participation of the radiology lab technician in the process of obtaining informed consent from the patient, by introducing:

- unified approach in informing and obtaining informed consent from patients for X-ray examinations;
- unified form for obtaining informed consent for imaging tests and procedures;
- a unified system for registration, reporting, and control of patients' X-ray examinations, which allows X-ray specialists to monitor patient doses and informs them about the risks associated with ionising radiation for medical diagnostics and therapy.

2. To the Bulgarian Association of Healthcare Professionals:

- The Chairman of the National Advisory Council of Radiology Technicians to the Bulgarian Association of Healthcare Professionals to initiate legislative regulation and introduction into the practice of radiology technicians of effective approaches to optimise the participation of the radiology lab technician in the patient-informed consent process.
- To stimulate and support the professional development of radiology lab technicians in matters related to informing and obtaining consent from patients through training in continuing education.

3. To the Medical Universities:

- To promote the implementation of post-graduate training for radiology lab technicians and medical specialists involved in the organisation, documentation and systematisation of information related to radiation risk in medical diagnostics and therapy in the Republic of Bulgaria, as well as informing patients on radiation risk in medical diagnostics and therapy.

CONTRIBUTIONS

Theoretical contributions

A first-of-its-kind complex, targeted and in-depth study of the possibilities for increasing awareness of radiation risk in medical diagnostics and therapy was conducted.

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.