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D9.89 - Report on venues, challenges, opportunities and recommendations for stakeholder engagement in the medical field

Lead Authors: Marie-Claire Cantone (UMIL), Christiane Pözl-Viol (BfS), Bieke Abelshausen (SCK•CEN), Sotiris Economides (EEAE), Liudmila Liutsko (ISGlobal), Diana Savu (NIPNE), Caroline Schieber (CEPN), Nadja Zeleznik (EIMV), Benjamin Zorko (IJS)

Reviewer(s): Catrinel Turcanu, SCK•CEN
 and
 CONCERT coordination team

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Abstract

This document reports on case studies carried out in the ENGAGE project, on stakeholder engagement in relation to medical exposures to ionising radiation. It is centred on stakeholder engagement in justification and optimization practice, and in the aspects of informed consent, communication in radiation protection, and on the education and training on ionising radiation in the medical field. Case studies include procedures characterized by different inherent complexities, and pertaining to radiology, radiotherapy, interventional radiology. These cases refer to medical exposures of pregnant women, paediatric CT-scanning, interventional image-guided procedures, use of radiation for cancer treatment, and X-rays use in dental clinics.

The current continuous increase of medical exposure, a matter of concern from a radiological protection point of view, is often accompanied by lack of awareness, about risk, from the members of the public, and in some cases also from the medical professionals. Cooperation among the relevant stakeholders is deemed useful for giving due attention to the justification process, and for engaging the patients in the process of defining the prescriptions of radiological imaging by the family doctors. Awareness for the implementation of stakeholder engagement is, in the view of some professional figures, still poor. The more complex the procedure of medical exposure, the more important is the involvement and consultation of stakeholders, as they enable patient-centred approaches and informed decision making, both in radiotherapy and radiology.

Even if communication with patients is perceived by medical staff as beneficial, it is mainly seen as a one-way approach. The topic of communication is very rarely present as part of education and training courses, for health professionals and practitioners, while communication would help in the practice to introduce to patients both the expected benefits and potential risks of medical exposure. The intrinsic complexity of the nature of radiation risk estimate, and the differences between how the professionals evaluate and the patient perceives the related risk and benefits of the medical exposure, substantiate the significant role in communication. With an improved risk benefit dialogue with patient, the level of information on radiation risk-benefits would be tailored to the different medical exposures and to the attention and respect of patient.

Informed consent is a process, starting with communication, providing adequate information and answers to patient on the risks-benefits and options about the diagnostic, or therapeutic, or interventional procedures, and defining if there is an agreement by the patient about the proposed procedure. Depending on the medical situation and the preferences of patients, there are situations characterised by an increasing expectation by the patient to be involved in the decision process or, the opposite, there are situations where patients consider radiation as their last problem needing attention. In reality, in many instances, the informed consent remains a formality. The use of an adequate informed consent, with a procedure including a higher consideration for patient dignity in decision-making, is still considered a challenge.

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1. Introduction

The ENGAGE project, funded under the H2020 CONCERT, aims at *Enhancing stakeholder participation in the Governance of radiological risks* [1]. It is a two-year project that started on November 20th, 2017, and which seeks to identify and address key challenges and opportunities for stakeholder engagement in relation to medical use of ionising radiation, post-accident exposures and exposure to indoor radon. In all these situations, stakeholder engagement is a key issue for improving the governance of radiological risks and the radiation protection of the exposed individuals.

The ENGAGE project aims are:

- to assess why, when and how stakeholders engage in radiation protection;
- to develop novel approaches to analysing stakeholder interaction and engagement, and provide guidance to meet the challenges and opportunities identified in response to (a);
- to investigate the processes for enhancing radiation protection culture and their role in facilitating stakeholder engagement, and develop guidelines for building radiation protection culture; and
- to build a joint knowledge base for stakeholder engagement in radiation protection.

The ENGAGE project is organized in four main work packages (WPs) coordinated by the management WP, which interact to achieve the objectives as presented on the Figure 1.

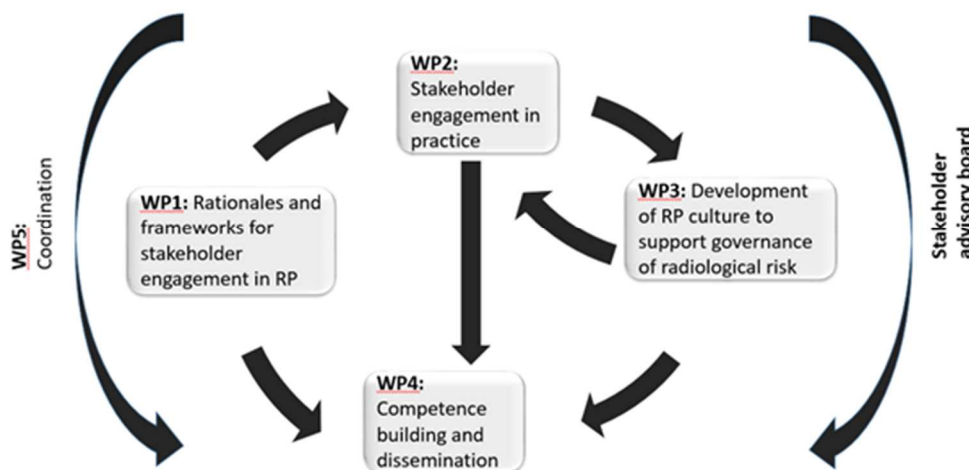


Fig. 1 Interaction between ENGAGE work packages

ENGAGE WP 2 on “Stakeholder engagement in practice” investigates how are legal requirements, guidelines and recommendations for stakeholder engagement implemented in practice. Specifically, it analyses how radiation protection communities respond to the expectations and demands for stakeholder engagement, and what kind of engagements practice, forms and instruments can be found in radiation protection fields, with or without reference to existing requirements.

For this purpose, WP2 is informed by results obtained in WP1 “Rationales and frameworks for stakeholder engagement in radiation protection”, in which the rationales for stakeholder engagement in radiation protection and the related legal or contextual drivers are clarified (how is stakeholder engagement envisaged, who is involved and for what purpose?). The results of WP1 were published in Deliverable 9.85 “Rationales and frameworks for stakeholder engagement in radiation protection in the medical field (Part 1), nuclear emergency and recovery preparedness and response (Part 2) and indoor radon exposure (Part 3)” and Deliverable D9.86 “Report on stakeholder engagement in radiation protection: transversal issues and specifics of different exposure situations”.

The expected outcomes of ENGAGE WP2 are:

1) An evaluation of the impact of past or ongoing participatory activities in radiation protection decision making processes.

2) A comparative analysis of stakeholder engagement practice, identifying broader lessons that can be learned, as well as what is specific to each field and why.

WP2 activities were structured along several tasks.

First step of Task 2.1 was to develop the “Methodology for analysing stakeholder engagement in practice”, which provided the framework for analysing ENGAGE cases studies. Guiding research questions for analysing stakeholder engagement in practice were developed. The list of questions is described in section 2 of this report.

The second step within Task 2.1 was a review of selected academic literature, radiation protection research projects connected to stakeholder engagement, current stakeholder engagement practice within radiation protection platforms, as well as past experiences of stakeholder engagement in the three exposure situations and, beyond that, international experiences in stakeholder engagement in radiation protection and connected fields. This review was published in ENGAGE “D9.82 – Report on key challenges, best practices and recommendations for stakeholder engagement.” Based on this review, the initial list of research questions formulated for WP2 was enriched (see section 2)

In Tasks 2.2, 2.3 and 2.4, a deeper analysis was carried out on the role of stakeholder engagement in practice in the three exposure situations considered in ENGAGE, based on the guiding research questions: i) medical exposure to ionising radiation, ii) emergency and recovery preparedness and response, and iii) exposure to indoor radon. Current or recent practices, challenges and triggering factors for engagement were studied specifically by means of case studies for each of these exposure contexts.

The aim of this report is to describe the objectives and results of the case studies carried out with respect to medical exposures to ionising radiation. The report focusses on the detailed description summarized findings of each case study carried out (section 3). A first comparative conclusion is provided (section 4). A deeper comparative assessment regarding the findings of the case studies in the three exposure situations will be carried out in the “Final report of the ENGAGE project” (D9.94, due end of November 2019). Here also the evaluation of findings and formulation of recommendations in the light of ENGAGE project aims will be dealt with.

2. Stakeholder Engagement in Practice -Aim and Methodology of Case Studies

At the outset of the ENGAGE project, the research for WP2 started from the hypothesis that while stakeholder engagement and informed decision-making are nowadays recognized as essential factors for an effective governance of radiological risk, the practical implementation of policy and legal requirements for stakeholder engagement is confronted with multiple challenges. We must therefore understand better why, when and how stakeholders are engaged in radiation protection. This understanding is necessary to facilitate the development of guidelines and a knowledge base for a more robust stakeholder engagement in radiation protection.

ENGAGE defines stakeholders as: actors (individuals or groups, institutional and non-institutional) with a tangible or intangible (yet to be shaped or discerned) interest in the radiation exposure situation and the related radiation protection issues, directly affecting decisions, or affected by the formulation and resolution of a problem or challenge. In this perspective, stakeholders are constructed in interaction with actors, issues, contexts. Various publics are also (potential) stakeholders.

While the overarching question in ENGAGE WP1 was “*What are radiation protection (RP) communities being asked to do? That is, what “external” pressures, mandates, demands, and/or expectations have emerged in public venues commending the engagement of stakeholders (including wider publics) in RP?*”,

in WP2 we analysed “What are RP communities doing?”

- *That is, how are RP communities responding to these pressures, mandates, demands, or expectations and how does this show in practice (e.g. specific cases)?*
- *Which (other) real or potential forms and instruments of stakeholder engagement and public participation can be observed in RP practice, showing no reference to existing requirements?*

More information on how these research questions have been created can be looked up in section 2 of “D9.82 – Report on key challenges, best practices and recommendations for stakeholder engagement.”

In order to operationalise the overarching questions of WP2, these were further explicated in the following derived questions:

- a) What levels of awareness about external prescriptions of stakeholder engagement in radiation protection do researchers and practitioners reveal?
- b) How do researchers and practitioners understand and practice stakeholder engagement (at individual and institutional level)?
- c) What were the rationales for stakeholder engagement, the final objectives? Has there been a critical evaluation of the attainment of objectives and of the impact of stakeholder engagement? Have there been any guided improvement activities?
- d) What forms of acceptance, resistance, denial, or alteration of engagement do you observe or encounter? And how do these forms change over time?
- e) What are radiation protection actors and communities doing that may de facto count as stakeholder engagement (but are not necessarily labelled that way)?
- f) Are there any alignments/misalignments between case practice, on the one hand, and external conceptions and prescriptions, on the other, and if so why? Which challenges and opportunities do you encounter for stakeholder engagement in your specific case?
- g) What else have you found or should we be asking?

The guiding questions a) - g) have informed the analysis reported in D9.82. Following that literature review the following research questions h) – o) were added:

- h) What are the benefits of implementing stakeholder engagement processes (in the situation studied)?
- i) What are the lessons learned for the establishment of efficient stakeholder engagement processes?
- j) Can you identify in official documentation or discourses, or in secondary sources, any references to a “participatory turn” for your field or case? If so, please document and indicate how this turn is understood, why and when it came about.
- k) Can you identify in official documentation or discourses, or in secondary sources, any mention (explicit or implicit) of a shift away from expert-based or technocratic decision making to more inclusive, open, democratic, participatory decision making? If so, please document and motivate, and indicate why and when this shift came about.
- l) Is dealing with emotions one aim of engagement in relation to medical exposure to ionising radiation? And which kind of emotions play a central role?
- m) How can goals and ideals about patient centred communication in radiology be implemented into day-to-day academic and private practice?
- n) How to accelerate the process of bringing together the different disciplines which are necessary to start a stakeholder process in a certain radiation protection field?
- o) How to raise awareness of the need to engage among radiation protection researchers?

Further information on how the guiding research questions were applied are described in each case study.

In the subsequent section 3, the case studies carried out with respect to medical exposure to ionising radiation are presented. The selection of case studies aimed at covering a broad range of participation practices, stakeholders, and settings. The research methods used included desktop research, interviews and observation. More details will be provided in the case study descriptions.

3. National Case Studies

The ENGAGE project aims to contribute to the understanding of what is being prescribed concerning stakeholder participation and what is actually achieved in the aforementioned fields in practice. In this sense ENGAGE will identify and address key challenges and opportunities for stakeholder participation. WP2 analyses how stakeholder engagement in radiation protection is enacted in practice and task 2.2 refers to the medical field. In this environment there is continuous scientific and technological development with a total increment in the exposure of patients, thus emphasising the attention on justification and optimization, and on the requirements regarding the information to patients and involvement of stakeholders, including patients and families, in aspects of decision making

Task 2.2 of WP2 analyses stakeholder involvement at national level in the medical field, which includes a large number of procedures that are characterized by different inherent complexities and levels of radiation exposure. Indeed, taking into account EU Directive 2013/59, medical exposure is recognised as pertaining to radiology, radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes. The implementation of the EU BSS is of great significance ; in particular, the last Directive (2013/59) provides the basis for a comprehensive approach to radiation protection, as it covers in one document the occupational, public and the medical exposure. Indeed, medical exposures was addressed previously in a separate directive. In ENGAGE WP1, the rationales for stakeholder engagement were analysed; these will be further referred to when highlighting the level of transposition in practice.

The areas covered in task 2.2 are mainly centred on stakeholder engagement in the justification and optimization practice, the aspects of informed consent, communication in radiation protection, and the education and training on ionising radiation in medical field. Moreover, case studies report on national experiences based on specific practices of medical exposure, such as:

- medical exposures of pregnant women,
- paediatric CT-scanning,
- interventional image-guided procedures,
- use of radiation for cancer treatment,
- X-rays use in dental clinics,

The topics considered in case studies within task 2.2 are the following:

- Stakeholder participation in practice, as experienced by nurse-practitioners in various institutions ranging from private to public hospitals, as well as in public institutions such as prisons – Belgium
- Education and training related to medical exposures to ionising radiation – exploring (international) stakeholders' view and approaches – Germany
- Stakeholders' role in the performance of medical exposures of pregnant women - Greece
- Stakeholders' role in radiological protection aspects in relation to interventional procedures- Italy
- Informed consent in medical use of radiation for cancer treatment - Romania
- Justification, optimisation, education and training at the Institute of Oncology Ljubljana - Slovenia
- Justification, Optimization of IR use and Stakeholders' role in radiation protection: Paediatric CT-Scanning – Spain
- Justification and optimisation of the use of X-rays in dental clinics – Spain

3.1. Belgium

3.1.1. Description of case study

Topic

Stakeholder participation in practice, as experienced by nurse-practitioners in various institutions ranging from private to public hospitals as well as in public institutions such as prisons.

Context

In Belgium, there exists a legally obligatory training course on radiation protection for staff in the medical sector. While the compulsory modules of this training course consist mainly of techno-scientific information about the use of radioactivity in medical applications (e.g. nuclear physics, dosimetry, radiobiology), some schools have also included a module on “communication in radiation protection”. Researchers from SCK•CEN developed this course to explain how science communication and the relation between science, technology and society - and medical care in particular - has evolved over time, and to investigate the notion of risk and risk perception, radiation protection, patient rights and communication. Part of the course consists of an exercise to get students to discuss their experiences and views on understanding, working with and communicating about radiation risks. This course is used as the case study in the field of Medical exposure in Belgium.

Objectives

The objective of the case study is to analyse the role of stakeholder participation in (a) education and training for medical exposures to ionizing radiation, and (b) the application of stakeholder participation in practice. The Belgian case study examines how a specific part of the radiation protection community, i.e. medical practitioners partaking in the course radiation protection respond to pressure, mandates, demands and expectations set on them by national and international prescriptions on radiation protection, and how these are implemented in practice. Furthermore, it will be examined which other forms of stakeholder participation are implemented in practice that are not prescribed or to which no reference is made in existing international and national requirements.

The case study is intended to provide insights in the benefits of stakeholder engagement processes, what the lessons learned are and provide recommendations for the radiation protection community.

Methodology

For the case study, two schools were selected. One school provides education for nurse practitioners in higher education in the fields of Nursing, Home and elderly care, special needs care, dental care assistant, pharmacy assistant, childcare, and dual learning nursing and childcare. The course on radiation protection in which the module “communication in radiation protection” is organised was developed following the 2002 Royal Decree on the use of ionizing radiation, art.53.2¹ in cooperation with expertise in the field and the Belgian Federal Agency for Nuclear Control (FANC). The course is aimed at nurse practitioners and paramedics that work with ionising radiation and contributes to a conscientious dealing with ionising radiation and protection of both practitioners and patients.

The other school provides education in nursing, midwifery, geriatrics, intensive care and emergency medicine, surgery nursing, paediatrics and neonatology, social healthcare, anaesthesiology, diabetic-educators, palliative care, dementia, elderly care, and radiation protection. The course on radiation protection for the second school entails general and practitioner-focussed regulations, basics in ionising

¹ <http://www.jurion.fanc.fgov.be/jurdb-consult/consultatieLink?wettekstId=11666&appLang=nl&wettekstLang=nl>

radiation, radiation and patient dosimetry, knowledge on equipment and communication. The course is aimed at nurse practitioners, paramedics, staff who use ionising radiation for medical purposes in, among others, nuclear medicine, radiotherapy, surgery.

Questions that can be answered in this case study

The Belgian case study is addressed to provide answers to the following questions:

- a) What levels of awareness about external prescriptions of stakeholder engagement in RP do researchers and practitioners reveal?
- b) How do researchers and practitioners understand and practice stakeholder engagement (at individual and institutional level)?
- c) What were the rationales for stakeholder engagement, the final objectives? Has there been a critical evaluation of the attainment of objectives and of the impact of stakeholder engagement? Have there been any guided improvement activities?
- d) What forms of acceptance, resistance, denial, or alteration of engagement do you observe or encounter? And how do these forms change over time?
- e) What are RP actors and communities doing that may *de facto* count as stakeholder engagement (but are not necessarily labelled that way)?
- f) Are there any alignments/misalignments between case practice, on the one hand, and external conceptions and prescriptions, on the other, and if so why? Which challenges and opportunities do you encounter for stakeholder engagement in your specific case?
- g) What else have you found or should we be asking?

For the purpose of this case study, a class discussion was held in the school year 2017-2018 in the first school and year 2018-2019 in the second school. The following questions were projected on the board to guide the discussion:

- a) Are patients worried about ionizing radiation in your experience?
 - a. Is there a need for risk communication/stakeholder participation?
- b) How is radiation risk explained to patients in your field?
- c) What is your opinion on the (scientific) explanation provided for radiation risks?
- d) Provide an (noteworthy) example of stakeholder participation/risk communication that you yourself have encountered within your working environment?
- e) With whom is stakeholder participation/risk communication challenging?
 - a. With whom not?
 - b. Why?
- f) What is for you the most important aspect of stakeholder participation/risk communication?
- g) What are your experiences with the 'informed consent'?

3.1.2. Analysis

The analysis for the Belgian case study entails three different types of analysis. First, the experiences from previous years in the classes are identified for their relevance for the ENGAGE project and summarised. The analysis of the group discussion in School 1, conducted in March 2018, has been transcribed and analysed using coding analysis. And finally, the notes of the self-reporting on the discussions conducted in March 2019 have been analysed using coding analysis.

The results of the aforementioned three steps are analysed according to the aforementioned guiding questions: Awareness on external prescriptions of stakeholder participation; Understanding and practice of stakeholder participation; Rationales for stakeholder participation; Attitudes towards stakeholder participation; and Expressions of stakeholder participation.

3.1.3. Main findings

Awareness on external prescriptions of stakeholder participation

Medical practitioners are very aware of the safety prescription of exposure to ionising radiation for both themselves and their patients. Concerning stakeholder engagement, the awareness of prescriptions for stakeholder engagement is limited. One-way communication on safety measures is common practice, although not without its challenges. Stakeholder participation, including patients is non-existing according to the medical practitioners. When queried about their own experiences as stakeholders in the medical use of ionising radiation the same is true. There seems to be very little awareness on prescriptions on stakeholder participation in the exposure to ionising radiation and the opportunities (and challenges) that might exist to co-decide on issues related to ionising radiation. The only prescription that is currently well known is the informed consent, although the responsibility for this is seen to lie mainly with doctors and less with other medical practitioners. This awareness of the informed consent is however fairly recent as the insight from the discussion with medical practitioners in the course on radiation practices shows that many of these practitioners were unfamiliar with the form and even less familiar with the content of this form.

Understanding and practice of stakeholder participation

Stakeholder participation and communication are often used interchangeably. Understanding of what stakeholder participation is, is therefore skewed towards communication. One of the comments given is that stakeholder participation is also not realistic because of the higher hierarchical position (although perhaps mainly in an intangible manner) of doctors. For this reason, medical practitioners, other than doctors, have a sense of resignation or defeat. This results in these medical practitioners referring patients to these doctors for any issues related to participation such as for example the informed consent. One illustrative quote from medical practitioners is *"We send them to the doctor as they always want to be right anyway"*. As stakeholder participation is experienced in the same manner by the medical practitioners themselves, there seems to be very little motivation to implement stakeholder participation including patients. There is an obvious (although intangible) threshold to even consider stakeholder implementation.

Rationales for stakeholder participation

Rationales for stakeholder participation are scarce. It is indicated that more decision-making power would be an added value but it appears to be low on the medical practitioners list of priorities. Concerning the informed consent, co-decision making power in relation to medical procedures is a right reserved for the patient. And only in case, other than signing the form, it is requested by the patient themselves. The same is true for other aspects of exposure to ionising radiation; unless the patient asks questions or wants decision making power of the choice of procedure, the idea of stakeholder participation is non-existent.

Attitudes towards stakeholder participation

The aforementioned attitudes towards stakeholder participation highlight further that stakeholder participation in medical exposures to ionising radiation is viewed on a short time scale. More specifically, when a certain exposure is necessary or prescribed. Long-term stakeholder participation, for example in relation to patient organisations or practitioners' unions is not mentioned. Stakeholder participation is viewed within the everyday working activities and not within the overall job or career trajectory of an individual or within the workings of a team or profession. For this reason, the attitude towards stakeholder participation is highly instrumental, serving the purpose of the day-to-day activities. With the

exception of the informed consent form where the understanding exists that patients should have the right to make an informed decision on treatments, procedures and thereby exposure to ionising radiation. The belief that this rather normative motivation is true in practice is however discussed. While this ‘might’ have been the initial reasoning for informed consent, or at least should have been, in practice the informed consent is currently a formality that is not high on the priority list of the medical practitioners.

Expressions of stakeholder participation

Stakeholder participation expresses itself most explicitly in the informed consent. Other expressions include mainly communication activities.

3.1.4 Conclusions

- Stakeholder engagement is (almost) non-existent;
- Very little awareness exists among nurse-practitioners on prescriptions for stakeholder participation – such as Informed Consent;
- Confusion about who is responsible for Informed Consent: nurse-practitioners or doctors;
- Confusion between participation and communication; they are used interchangeably;
- “Real” participation wherein nurse-practitioners and patients have full co-decision-making power is considered impossible;
- Only patients can participate, nurse-practitioners have no opportunities for participation;
- Stakeholder participation is only considered on a short time frame.

3.2. Germany

3.2.1. Description of case study

Topic

Education and training related to medical exposure to ionising radiation – exploring (international) stakeholders’ view and approaches

Context

Education and training with respect to radiological applications in medical issues, take place in different contexts: training of doctors; radiation protection courses; training of radiation protection specialists, medical physicists. Education and training are important elements to build competence and raise awareness on radiation protection in general, and risk communication and stakeholder engagement, in particular.

Objectives

The first aim of the case study was to identify which role does stakeholder engagement play in the process of developing education and training related to radiation protection in medical settings. A second aim was to identify the role of radiation risk communication and stakeholder engagement aspects in training courses as well as the reasons and motivations to include communication and engagement aspects into education and training.

Methodology

The methodological approach included:

- a) Interviews carried out with representatives of international organisations (HERCA, EUTERP, CONCERT) in order to gain an impression about the international importance of communication, risk communication and stakeholder engagement in the medical field.
- b) An unsystematic screening of peer reviewed and grey literature carried out to identify what kind of literature deals with risk communication in relation to medical exposures to ionising radiation.
- c) Investigation of the IAEA approach on education and training, at international level.
- d) At the national level in Germany, the following issues were analysed:
 - i. communication as part of technical radiation protection qualifications for doctors (“Fachkunde Strahlenschutz”);
 - ii. role of information / communication on websites of medical expert associations;
 - iii. analysing trainings for medical specialists (radiology, radiation therapy, nuclear medicine) if risk communication, informed consent is special part of the curricula;
 - iv. unsystematic screening of literature.

The ENGAGE questions listed below were the basis of analysis in this case study:

- What is the level of awareness of the importance of stakeholder engagement (also development retrospective / prospective)? What is the level of awareness about external prescriptions?
- How do researchers and practitioners understand and practice stakeholder engagement (at individual and institutional level)?
- What were the rationales for stakeholder engagement, the final objectives?
- What forms of acceptance, resistance, denial, or alteration of engagement do you observe or encounter?
- What are radiation protection actors and communities doing that may de facto count as stakeholder engagement (but are not necessarily labelled that way)?
- What are the benefits of implementing stakeholder engagement processes?
- How can goals and ideals about patient centred communication in radiology be implemented into day-to-day academic and private practice
- How to accelerate the process of bringing together the different disciplines which are necessary to start a stakeholder process in a certain radiation protection field?

3.2.2. Analysis and results

Interviews:

Three interviews were conducted with representatives of CONCERT, EUTERP and HERCA. As the medical area is only one part in education and training in radiation protection in general, the interviews did not focus only on the medical area.

The interview regarding the development of education and training in the international context showed that there is a broad involvement process going on when IAEA recommendations are developed for training and education in the area of radiation protection. A broad consultancy process is carried out for the standard syllabus that defines the contents of radiation protection training in the training centres. Those training centres are installed in specific regions worldwide. The aim is to ensure that certain standards and certain quality in education and training in radiation protection are complied with even in countries that cannot provide themselves that infrastructure. Together with the steering committee with representatives of national and international radiation protection experts, IAEA develops a 10-year-

strategy for education and training in radiation protection. On a yearly base, the strategy and its implementation are reviewed. Performance indicators serve as landmarks for quality management. Training centres and course institutions regularly report on number of courses, number of participants, form of developed training material. The current strategy ends in 2020 and a continuation for further 10 years is planned. The course contents are discussed in the framework of a technical expert meeting, to which interested Member States can send representatives. According to the interviewed person, communication and stakeholder engagement is part of the IAEA training strategy for a couple of years now. However, communication and engagement is only a visible part in the specifications for emergency preparedness and management, not in the medical area.

On the national level in Europe, approaches to education and training in radiation protection are different. In Germany, the required competences in radiation protection are described very specific and in competence guidelines for (technical) qualification. There it is specified what kind of competences are required in specific working surroundings and jobs. A complex system of laws characterises the system in Germany. However, European countries have different levels of specificity and diversity with regard to the provisions for training goals and contents in professions dealing with radiation. The guidelines for technical qualification, are, as their name suggests, only meant to specify the technical training contents and do not include any demands for communication about radiation risks.

Concluding for actions on education and training in radiation protection, on the international level driven by IAEA, a continuous planning, implementing and reviewing process is going on with involvement of interested Member States representatives and national and international radiation experts. This is not specific for the medical area. In Germany, communication is not part of the guidelines for technical qualification which define the contents of education and training courses in Germany.

A second interviewed person expressed the opinion that not only the radiologist should be the one person that knows about good risk and benefit communication, but also the medical technical radiology assistant (MTRA). MTRAs are mostly the persons who are in the first contact with the patient, therefore also they should receive a stronger support for a good communication. According to this interviewee, a strengthened role of informed consent may also lead to overload of the patients and bear the danger that responsibilities are handed over to the patients. This means, that also patients have to learn about the meaning of informed consent, and not only the medical doctors.

Another interview was carried out with a representative of CONCERT. In this interview the view of radiation protection activities in education and training on the overarching European level was reflected, which means that also in this case the medical exposure to ionising radiation was again one of many aspects dealt with in the interview. Generally it can be said that there is no explicit stakeholder engagement process in designing education and training from the radiation protection communities' point of view. Of course, it is a concerted approach in order to ensure high quality in education and training. However it is not a conscious and structured engagement process. According to the interviewee, it can be observed that on the level of European radiation protection experts, at the moment it cannot be managed to ensure enough competencies to counteract the loss of competence throughout the time. In the interviewee's opinion, there is a gap between the academic and the vocational training. On the academic level, training is not driven from the point of view of what is required in practice. Radiation protection experts do not see it as their main objective to search for fields where they can offer their radiation protection expertise and train others, rather it works the other way round that other disciplines realise that they have a lack of knowledge and they approach the radiation protection experts and ask for

training support. The interviewee would prefer approaches from both sides – the academic side and the practical side – with should result in better information and education and a mutual understanding, as well as a better working together. The problem is that different paradigms drive the work in these two levels of action. It would be important to bridge the gap between the scientific worlds and the practical work, for example of practitioners. For them, for example limit value concepts are not of importance. Unfortunately, the need to bridge this gap in order to improve the radiation protection system has not yet been widely realized. The reason for that is seen in the necessary amount of resources and time. Regarding the role of stakeholder engagement for radiation protection education and training, the interviewee expressed the opinion that there is no intrinsic motivation in the radiation protection community itself, but the demand is expressed from the outside, from historical processes as well as from recent years' developments which in general strengthened the perceived need for involvement throughout societal processes. It would be only in recent years that the radiation protection community opened itself to views and reflections from outside. Such social movements came from outside and reached the radiation protection community. The need for bridging the gap is being refused from the academic level, so the wish for a strong differentiation and professionalization contradicts the need for integration, exchange and engagement. The interviewed person would see the implementation of an education and training academy as a good way to integrate different disciplines and action levels. A form where experts have to develop courses together and to see the respective needs and requirements of different fields of actions and expertise. A greater opening to other disciplines and their approaches would be necessary.

With respect to the medical area, the interviewee expressed the opinion that developments that took place in other fields and requirements that were valid for other areas were implemented in medicine only years later. The same is true for radiation protection requirements and aspirations that have been developed in other fields, such as the need for stakeholder engagement.

Unsystematic literature screening

Since, 2001, the German Federal Ministry for Health supports the funding focus “the patient as partner in medical decision making process”. Participative decision making is seen as an interaction process with the aim of a jointly taken agreement, by equal and active involvement of patient and doctor and based on shared information.

Claims to include the topic into the education of students exist since 2004 (e. g. Der Patient als Partner. „Ein zartes Pflänzchen“, Deutsches Ärzteblatt, Jg. 101 Heft 17; 23. April 2004)

In “Partizipative Entscheidungsfindung und Anwendung von Entscheidungshilfen” (Deutsches Ärzteblatt, Jg. 112, Heft 40, 2. Oktober 2015) Härter et al., concludes that despite doctors and patients increasingly aiming at fostering participative decision making, doctors still do not feel educated enough to implement participative decision making into the everyday healthcare. Neither has the efficacy of teaching material been investigated so far. A specific training is proposed in this article. Participative decision making training was integrated in a longitudinal communication curriculum in UKE (University Hospital Hamburg Eppendorf).

Other publications deal with legal consequences of the new patients' rights act related informed consent. They give recommendations which forms and approaches to use in order to meet the legal requirements, but they do not focus on the communication process itself.

In “Current issues and actions in radiation protection of patients”, Holmberg, Malone et al. (European Journal of Radiology 76, 2010, 15–19) point out that “...it is also important that more attention be given

to consent, particularly to the information provided to patients, and that more consideration is given to their dignity as individuals”.

A couple of articles deal with risk communication in the medical area, but not specifically for the field of ionising radiation:

- Risikokommunikation: Risiken und Unsicherheiten richtig verstehen lernen. Dtsch Arztebl 2011; 108(9): A-448 / B-360 / C-360. Wegwarth, Odette; Gigerenzer, Gerd (*“Risk communication: how to learn to understand risk and uncertainties properly”*)
- Risikokommunikation. Ein interaktives Training für Ärztinnen und Ärzte am 5. und 6. February 2016, Köln (*“Risk communication. An interactive training for medical doctors”*)
- MD Medicus: Risikokommunikation Teil 1, und Teil 2, O. Renn,

IAEA

The following IAEA documents were analysed with respect to the role of communication in education and training (see more details in Annex 5.1)

- Building competence in radiation protection and the safe use of radiation sources. Safety Guide No. RS-G-1.4
- AEA SSG 44. “Establishing the Infrastructure for Radiation Safety”
- AEA SSG 46 “Radiation Protection and Safety in Medical Uses of Ionizing Radiation”
- AEA GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

In May 2019, the new IAEA Standard Syllabus Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources was launched. For nuclear or radiological emergency, emergency preparedness and response, communication with the public is part of the standard syllabus. This is not the case for medical exposures. There is no mentioning of informed consent, informed decision making, support for participative decision making or similar.

3.2.3. Main findings

- Risk communication is seldom dealt with in trainings for medical specialists (radiology, radiation therapy, nuclear medicine). Here, patient information / patient education is a small part, but not risk communication per se.
- Risk communication is no – or only seldom a really small – part in courses for radiation protection (technical qualifications).
- Social scientists deal with risk communication in the medical area (for example the Harding center for risk competence).
- Some articles, for example in the German medical journal, deal with doctor-patient communication, participatory decision making or informed consent, but not with risk communication related to ionising radiation.
- The doctor-patient conversation as well as patient education are part of medical education at universities, but no special radiation risk communication skills are trained.
- Patient involvement and participatory decision making are only side issues, in literature more than in education courses themselves. These topics are partly dealt with within the medical community.
- The radiation protection community does not deal with requirements of good risk communication or questions of participatory decision making in the medical field.

- The gap between radiation protection activities on the academic level and requirements from the vocational level does not support stakeholder engagement activities and a penetration of the radiation protection community with the consciousness of the importance of risk communication skills in other areas than emergency management.

3.2.4 Conclusions

- Risk communication and participatory decision making elements have to be included into medical education, technical radiation protection courses, trainings for specialists and assistants.
- The radiation protection community should encourage good risk communication approaches.
- Guidance for radiation risk communication should be provided for – or be co-developed with – medical expert associations.
- The SSH platform SHARE should seek to approach important medical actors to develop a joint strategy.
- The gap between the academic level and the vocational level of radiation protection should be bridged by common efforts from all sides.

3.3. Greece

3.3.1. Description of case study

Topic

Stakeholders' role in the performance of medical exposures of pregnant women

Context

The risk for the unborn child associated with the in-utero irradiation is well presented in the literature, as many guidelines and reports on the issue have been published by various scientific organizations and committees. Additionally, Council Directive 2013/59/Euratom, that has been transported to the Greek legislation, imposes specific requirements for the performance of medical exposures during pregnancy and for the minimization of the likelihood of inadvertent exposures. In this respect the identification of the roles and the level of engagement of the stakeholders involved in these procedures is considered crucial.

The stakeholders involved in the medical exposures of pregnant women include: Referral physicians, gynecologists, radiologists, nuclear medicine physicians, radiotherapists, technologists, medical physicists, health authorities, professional associations, patients, patients' representatives and regulatory authorities.

Objectives

The case study concerns the engagement in practice of stakeholders involved directly or indirectly in medical exposures of pregnant women which may result to the exposure of unborn children. The role of stakeholders engaged in these exposures are crucial since they are related to the proper implementation of the justification and/or the optimization principle.

Methodology

For investigating the stakeholders' roles and engagement in the performance of medical exposures of pregnant women the following methodology was used:

1. Collection of information found in literature on the role of the involved stakeholders (publications, guidelines, reports, legislative documents).
2. Use of data collected by the EEAE from communications with pregnant women undergone medical exposures and during the authorization procedure.
3. Analysis of the related information and data.

The interviews were carried out as part of the on-site inspections of the EEAE to medical facilities. One senior manager of a medical clinic and the heads of two radiology departments of large hospitals were interviewed in order to identify their role and involvement as stakeholders as well as their awareness about how other stakeholders are engaged in medical exposures performed to pregnant women.

Questions that can be answered in this case study

Questionnaire used during interviews for the purposes of the case study

1. What is your role in the institution?
2. What is the role of the institution in relation to the exposure of pregnant women to ionising radiation?
3. What did you experience regarding the awareness of and acceptance/resistance to stakeholder engagement by different actors in the performance of medical examinations to pregnant women?
4. What are the motivators for stakeholder engagement in practice?
5. What is the role of external prescriptions or recommendations?
6. What are the benefits of efficient stakeholder engagement in the performance of medical exposures to pregnant women?
7. What are the challenges related stakeholder's engagement in the performance of medical examinations to pregnant women?

3.3.2. Analysis and results

Greek Atomic Energy Commission (EEAE) has established a special committee to provide consultation to pregnant women undergone medical exposures. From information collected during communications with these women it was identified that in many cases they were not aware of their pregnancy and no investigation of such a possibility took place (by the referrer or the radiologist) before the medical exposure. Moreover, in some other cases, the information provided to them after the exposure regarding the risks for the unborn child and the actions needed was not correct. These findings underline the significance of engaging stakeholders (referral physicians, radiology physicians, technologists, etc.) properly educated and trained on radiation protection. In this respect, universities, scientific and professional societies as well as regulatory authorities have to play a key role.

With regard to the interviews, they were carried out as part of the on-site inspections of the EEAE to medical facilities. One senior manager of a medical clinic and the heads of two radiology departments of large hospitals were interviewed in order to identify their role and involvement as stakeholders as well as their awareness about how other stakeholders are engaged in medical exposures performed to pregnant women.

Despite the small number of the interviewees the conclusions derived from the answers received could be considered representative of the current situation. More specifically:

The answers to Question 1 indicated that all interviewees were aware about:

- their key role either at the level of institute or department and their responsibilities regarding the management of personnel involved in medical exposures;
- the roles and responsibilities of the personnel in the radiology department according to the management system implemented;

They were also aware of the particularities related to the performance of medical examinations to pregnant women (Question 2) as well as the procedures which have been applied in terms of justification and optimization. Medical physicists with the responsibility to supervise and ensure radiological safety as Radiation Protection Experts (RPEs), Medical Physics Experts (MPEs) or Radiation Protection Officers (RPOs) were identified as main source of information and advice.

Moreover, interviewees pointed out the issue of patients requesting to undergo medical examinations, such as CT, even if these examinations are not justified. This attitude indicates lack of awareness about the risks associated to ionizing radiation as well as about the requirement for the justification of medical exposures.

As far as Question 4 is concerned, according to the answers received, the main motivators for the engagement of the stakeholders is the need for compliance with the legislation requirements and their commitment to safety. Moreover, recommendations and suggestions of scientific or professional organizations as well as regulatory authorities play a significant role to the level of their engagement (Question 5).

According to the answers to Question 6, main benefits of the effective engagement of the stakeholder's in medical exposures of the pregnant women are: a) the prevention of unjustified medical exposures, b) the optimization of the doses received by the unborn child during the medical exposures of the mother, and c) the prevention of inadvertent exposures.

Finally, the main challenges related to stakeholders' involvement (Question 7) are the lack of awareness regarding the risks associated with the exposure of unborn child to ionizing radiation as well as a lack of safety culture.

3.3.3. Main findings

- Senior managers and heads of radiology departments showed a satisfactory level of awareness regarding the particularities of medical exposures of pregnant women. This is encouraging, as they have to play a key role as far as the effective engagement of the personnel is concerned.
- Main motivators for the engagement of the stakeholders seem to be the compliance with the legislation requirements and their commitment to safety.
- Main benefits of the effective engagement of the stakeholders in medical exposures of the pregnant women are: a) the prevention of unjustified medical exposures, b) the optimization of doses received by the unborn child during the medical exposures of the mother, and c) the prevention of inadvertent exposures.
- In some cases the personnel involved in medical exposures of pregnant women, as well as members of the public, show a lack of awareness regarding the risks associated with ionizing radiation and of a safety culture.
- The provision of education and training to stakeholders is necessary in order to ensure their effective engagement in procedures related to the medical exposures of pregnant women. In this respect, universities, scientific and professional societies as well as regulatory authorities have to play an important role.

3.3.4 Conclusions

The provision of education and training to stakeholders is necessary in order to ensure their effective engagement in procedures related to the medical exposures of pregnant women. In this respect, universities, scientific and professional societies as well as regulatory authorities have an important role to play.

3.4. Italy

3.4.1. Description of case study

Topic

Stakeholders' role in radiological protection aspects in relation to interventional procedures

Context

Interventional image-guided procedures/treatments include ablation, embolization, biopsy and other procedures. Radiological Protection is a part of great importance in the treatment quality in practice and there are cases, very specific in these procedures, with possible link between the dose to the staff and dose to the patients. It is important to protect staff without impairing the clinical outcome and without increasing patient exposure. Justification, optimization, dose limits (for the workers and/ or members of the staff), education and training, and attention to new techniques development are points of particular interest in the interventional procedures. Different professional associations and patient organizations have given their contribution, together with industry and standard organizations, to continuously improve the safety and the quality of the procedures. The best results would be when all the stakeholders are working together.

Objectives

The objectives of this case study are as follows:

- to evidence in practice the significance for stakeholder involvement in the field of one of the most complex procedure, as image guided intervention.
- to analyze which stakeholders are in general enrolled, the different levels of their involvement, and examples of possible links, exchange of views and experience.
- if possible, to trace a trend in relation with the practice of stakeholder involvement.

Methodology

This case study is based on the analysis of documents recognised at national level ^{1,2,3} and on the interviews conducted with professional experts in radiological protection dedicated to interventional procedures for a long time. This included one eminent radiologist operating in interventional radiology and having an important role in the Italian Society of Medical Radiology, and a medical physicist expert in a national health care structure, operating as radiation protection expert, engaged in different departments of the same structure, including interventional radiology, and also involved in education and training in radiological protection.

Questions that can be answered in this case study

With attention to the objectives of this study the following questions have been considered.

1. What levels of awareness about external prescriptions of stakeholder engagement in relation to the medical field can be revealed?
2. How stakeholder engagement is understood and practiced stakeholder (at individual and institutional level)?
3. What were the rationales for stakeholder engagement, and it was implemented? Has there been a critical evaluation of the achievement of objectives and of the impact of stakeholder engagement? Have there been any guided improvement activities?

4. What forms of acceptance, resistance, denial, or alteration of engagement do you observe or encounter? And how do these forms change over time?
5. What are the medical actors and communities doing that may *de facto* count as stakeholder engagement (but are not necessarily labelled that way)?
6. Are there any alignments/misalignments between case practice, on the one hand, and external conceptions and prescriptions, on the other, and if so why? Which challenges and opportunities do you encounter for stakeholder engagement in your specific case?
7. What else have you found, or should we be asking?
8. What are the benefits of implementing stakeholder engagement processes (in the situation studied)?
9. What are the lessons learned for the establishment of efficient stakeholder engagement processes?

3.4.2. Analysis and results

Awareness of stakeholder involvement

Awareness about the stakeholder involvement is very poor, with attention mainly to the involvement of some professional figures, manufacturers and with only a basic instrumental involvement of patient. Attention to the patient is devoted to the technical aspects of radiological protection in view of the interventional procedure, more than his/her involvement in the decision process. In this sense this procedure has a specificity since it can be seen a link between the patient dose and the dose to the interventional radiologist.

The specialist in radiation diagnostics is the person responsible for the radiological implant, however the procedure is carried out by a radiology technician or by the non-radiologist specialist, as a complementary method to his activity. For instance, the cardiologist operating for inserting a pacemaker, is not under the control of the RP managed by the radiologist, but it is managed by the person in charge of the RP. There is a clear lack of collaboration between the professionals in the same structure that should be involved in the use of ionizing radiation.

The interventional procedure requires that the patient informed consent is accompanied by explaining information. Note that an interventional procedure is determined by a complex pathology, and from the interviews the vision emerged that for the patient the most important thing is "healing", improving her/his situation, and that 'radiation is the last of her/his problems'.

Obviously, there are different levels of attention by the patients. Women of childbearing age worry about radiation and request information on the dose level.

In the new European BSS 2013/59 there is the commitment to indicate the dose of the patient for the radiological procedure and this would help the user and lead to a greater awareness.

For healthcare professionals, the preparation of written procedures, by national institutions and professional associations, addressing many aspects of RP is very useful, since the professionals are involved in reading these documents, and frequently ask for other information, and make requests. In this sense the participation has increased compared to the past.

In any case, the reasons for the involvement of interested parties are related to regulatory obligations, even if some efforts are present to go beyond these settings that come from above.

Overview of the practice in stakeholder involvement

In the practice of interventional procedure, there is the cooperation among different professionals, such as interventional radiologist, radiology technician and nurses, operating at the same time on the patient

with different role, and in addition there is cooperation with the doctor of preventive medicine responsible for RP.

The professional sector suffers from a lack of attention at the level of drawing up regional nomenclatures, in the sense that there is no full update of the nomenclatures of diagnostic tests. Some names refer to obsolete tests and new tests do not yet have a nomenclature record. This fact recalls a misalignment between the professional parts and the part that administers and legislates. The interventional radiology procedures do not yet have a national codification, efforts are supported by professionals towards an improvement, but "the doors are closed". A note emerged in the interviews: "if an association of 11,000 professionals is not heard, who are you listening to?"

An active involvement in the practice is evident among the scientific associations, e.g. Association of Medical Physicists and Society of Radiological Physicians, and also with Patients' Rights Court representing patients.

What emerged on the rationale of stakeholder involvement

The need to involve interested parties is recognized in order to be able to see some specific operational procedures implemented, which are already included in specific documents, such as the ISS report on interventional radiology. However, this comprehensive document is not a legal obligation. In healthcare facilities it is very difficult to start implementing new approaches - only legal obligations have to be implemented. The involvement of the various professional figures and their recognition at the level of the healthcare company manager may be considered as a possible way. This message tells us that we need to go through an obligation, through legislation rather than raising awareness, to make this decision about protection.

Proposals and prospect for active improvement

The expert in medical physics is a figure seen as part of the team, and not only to fulfill the protocols, but to which other professionals can turn to for more information on the RP.

As emerged in the interviews, it is important that the medical physicist is a figure that is present, that after having done so many measurements she/he does not keep the data only in the computer, but proceeds to translate them into the language of those who work, in a simple and constructive way. So that RP measurements are perceived as an opportunity to improve.

The vocational training phase is represented in the interviews as an opportunity to improve the involvement of the professional figures, considering a training in the field of work, which includes discussion of the commitments of the various figures, an exchange of experiences and points of view in practice. Beginning, during training, a true collaborative approach, in which each part integrates its knowledge and competence, is evaluated as a basis for both subsequent updates and openness to discussion and a path to the idea of not only responding to obligations.

3.4.3. Main findings

- Awareness about stakeholder involvement is very poor, with attention focused on some professional figures, and manufacturers. The need to involve interested parties is recognized in order to be able to see some specific operational procedures implemented. At the moment, it emerged that the interested parties still need to go through an obligation.
- There is a recognized lack of collaboration between the professional figures, even considering figures of the same structure that should be involved in the use of ionizing radiation. The vocational training phase is mainly centered on scientific and technical aspects; however, it is also an opportunity to

exchange experiences, concerns and points of view in practice and provides the possibility to start a true collaborative approach, in which each part can integrate knowledge and competence.

- There is in general no attention dedicated to patients' involvement in decision processes; the patient is seen as care receiver and attention is dedicated to technical aspects of radiological protection for patient care, in view of the specific interventional procedure.
- The state of art of patient and staff protection in interventional procedures is in continuous evolution and changes have to be introduced, e.g. the attention to dose to the eye lens. An Italian dedicated IWGIR on interventional radiology is active in preparation of national recommendations with attention to optimization of patients and operators.
- The vision is that for the patient the most important thing is "healing", improving her/his situation, and that "radiation is the last of her/his problems". Moreover, with the idea that patient has low knowledge in RP, the attention to patient information may be seen as of poor interest.

3.4.4 Conclusions

- There is a need to recognize the involvement of the interested parties in order to be able to see some specific operational procedures implemented. At the moment, it emerged that the involvement of interested parties still needs to go through an obligation.
- A specific vocational training phase is indicated in consideration to technical aspects, and as an opportunity to exchange experiences and points of view in the IR practice and to start a true collaborative approach, in which each part integrates its knowledge and competences.
- It is suggested that the informed consent should be defined for the specific interventional procedures, including information on potential skin tissue reactions and with related recommendations.
- Risk communication is recognised, in documents dedicated to interventional procedures, as a fundamental support for the level of quality in the health care structures and characterised by the link between the structures and e.g. the associations of the patients.

3.4.5 References:

- 1) Istituto Superiore di Sanità. Linee guida per l'elaborazione di un manuale di qualità per l'utilizzo delle radiazioni ionizzanti in diagnostica per immagini e radiologia interventistica. National Institute of Health. Guidelines for the development of a quality manual for the use of ionizing radiation in imaging and interventional radiology. 2010, vi, 49 p. Rapporti ISTISAN 10/41 <http://www.tsrn.org/wp-content/uploads/2012/10/Rapporti-Istisan.pdf>
- 2) Istituto Superiore di Sanità. Indicazioni operative per l'ottimizzazione della radioprotezione nelle procedure di radiologia interventistica. National Institute of Health. Operational indications for radiation protection optimization in interventional radiology procedures. 2015, viii, 99 p. Rapporti ISTISAN 15/41 http://old.iss.it/binary/publ/cont/15_41_web.pdf
- 3) G. Compagnone, R. Padovani, M.A. D'Avanzo, S. Grande, F. Campanella, A. Rosi. Summary of the Italian inter-society recommendations for radiation protection optimization in interventional radiology. La radiologia medica, 2018, 123:378-384

3.5. Romania

3.5.1. Description of case study

Topic

Informed consent in medical use of radiation for cancer treatment in Romania

Context

According to the EU BSS, the medical practitioners have the clinical responsibility to communicate about the risks of radiation-induced effects of diagnostic and therapeutic procedures to the patients and other involved individuals, and obtain consent for exposing them to radiation. Informed (radiation) consent as

an important ethical and practical part of engaging with patients, is not simply an act of signing a formal document but a communication process between the patients and a health care provider. The interpersonal component, the patient's involvement in a communication process with medical practitioners together with the technical aspects of care defines the quality in radiotherapy. In this preliminary study, 50 cancer patients undergoing radiotherapy filled in the questionnaires (with closed and open questions) concerning the different aspects of informed consent.

Objectives

The case study focused on patients' perception of information provided in the framework of informed radiation consent.

Methodology

A questionnaire was distributed to cancer patients undergoing radiotherapy in order to evaluate their satisfaction with information about ionizing radiation and opportunities for participation in related decision making.

The questionnaire was distributed in the Coltea Hospital from Bucharest. Ethical approval for distribution of the questionnaires was obtained prior to the study from the Ethical Committee of the hospital. The questionnaire was filled on a voluntary basis –so far- by 50 patients undergoing radiotherapy procedures. Questionnaires were filled in on paper and fully anonymized.

The questions to patients (see full questionnaire in Annex) addressed the perceived importance of various information concerning the radiotherapy; the level of satisfaction with the various information; what is considered as the best moment to receive the information about ionizing radiation: the preferred way to receive the information (written or oral); any suggestions for improving the dialogue between medical staff and patients (open).

Questions that can be answered in this case study

The study considered the following questions included in ENGAGE WP2:

- What level of awareness of stakeholder engagement in medical field can be revealed?
- How stakeholder engagement is understood and practiced?
- What are the main problems, which challenges, and opportunities do you encounter for stakeholder engagement in your specific case?
- What else have you found, or should we be asking?

3.5.2. Analysis and results

Data for this study was collected in an important radiotherapeutical centre from Romania. The clinical responsibility of the medical staff includes ensuring that patients have heard and understood what they are consenting to. The responsibility for obtaining informed consent lies with the radiotherapist. According to the medical staff, information is given in written form and verbally two days before the radiotherapy procedure.

Patients responding to the questionnaire highlighted that information about the risks and benefits of the procedure, as well as possible alternatives and general information about the procedure are all important; 10% think that technical details about the procedure are less important.

Most patients consider that, in general, the information they received about ionizing radiation satisfied their needs; however only 1 in 4 patients considered that the information was easy to understand.

One in two patients consider that information should be given some days before therapy, while the others think that the information should be given immediately before the procedure.

Among patients, 40% of the respondents recommend that information should be given both orally and in writing, while others suggest either oral or written information.

None of the patients provided additional suggestions for improving the dialogue with the medical staff showing the limits of quantitative data collection through questionnaires.

3.5.3. Conclusions

Communication between the patients and medical staff may be improved by providing clearer information, both orally and written, sufficiently in advance before the procedure, including general information, information about risks benefits and potential alternatives. The need to improve communication with patients is also recognized by medical staff.

3.6. Slovenia

3.6.1. Description of case study

Topic

Justification, optimisation, education and training at Institute of Oncology Ljubljana (OI)

Description

As a principal national institution, the Institute of Oncology Ljubljana (OI) supervises programmes on the comprehensive management of cancer diseases in terms of prevention, early detection, diagnostics, treatment and rehabilitation, research and education. In their daily work they use extensively radioactive substances and also ionizing radiation. The case study investigated the practical approaches used at the Oncology Institute in relation to:

- Justification and optimisation of Ionizing Radiation (IR) use by practitioners for individual medical exposures,
- Information on the risk of ionising radiation to patients and other individuals involved (technical staff, nurses, carers and comforters),
- Education and training for staff and for patients (and others) involved in use or applications of IR.

Objectives

The objective of the case study was to highlight what are the practices of stakeholder engagement in place related to the use and application of IR at the Oncology Institute in order to identify any differences between requirements and practice, and what recommendations and/or lessons learned can be pointed out.

Methodology

The analysis of available information on webpages or some other channels was performed, and a series of interviews was conducted (with a radiation protection officer, doctors, other staff and patients' associations) to obtain information about justification and optimisation during different IR applications in practice. The aim was also to highlight what information is given to the patients and others (staff, carers and comforters), whether there are any procedures in place, how the staff at OI are trained and what is

the education related to use of IR. Any other information was collected also by other involved personnel (nurses and technicians) or responsible officers, as well as from patients organisations in Slovenia. The interviews were recorded and analysed to answer the questions for WP2. The results of investigation are compared with legal requirements. Good practice, findings and recommendations are also identified. For the interviews a protocol was established, in which leading questions were assigned to the topics as presented below:

- Socio-demographic
 - What is the role of the organisation in the field?
 - What is the role of the interviewee in the organisation?
- TOPIC 1 (e.g. **Awareness and acceptance** - what did you experience regarding the awareness of and acceptance /resistance to stakeholder engagement by different actors in the field of medical exposures?
- TOPIC 2 (e.g. **other forms of engagement**, for instance non-institutional) What did you experience in other forms of engagement, for initiatives by citizens or civil society groups
- TOPIC 3 (e.g. **Practice of stakeholder engagement**: What are the motivators for stakeholder engagement in practice? What is the role of external prescriptions or recommendations? What constitute a good engagement process?

Questions that can be answered in this case study

For discussion with representatives, the following questions were asked to the SRPA – Slovenian Radiation Administration:

1. How the requirements from legislation about stakeholder engagement in medicine (patients, careers, others) are implemented in practice?
2. Are doctors (practitioners) fulfilling the requirements from legislation on provision of information to patients (information in advance, warnings, written instructions)?
3. How do you know this and how you obtain feedback information?
4. What are current problems in relation to stakeholder engagement and where are the opportunities for improvements?
5. Do you provide any advices, or do you have any practical guidelines?

Regarding the OI- Institute of Oncology Ljubljana, the following questions were asked to Radiation protection officer, Doctors (2x), Other staff (nurses, technician), Patients association.

1. Who is involved into provision of information on IR for individual treatment in practice?
2. How are doctors (practitioners) fulfilling the requirements from legislation on provision of information to patients (information in advance, warnings, written instructions, justification and optimization)?
3. Do they obtain written consent before use of IR from patients? Does the doctors and staff explain the patients about the risks related to IR? How does it look in practice?
4. What material is available to patients about use of IR?
5. How do you involve patients into dialogue? Do you see advantages of such approach?
6. What are current problems in relation to stakeholder engagement and where are the opportunities for improvements?

3.6.2. Analysis and results

In Slovenia the relevant radiation protection authority for medical application is Slovenian Radiation Protection Administration (SRPA) which performs professional, administrative, supervisory and development tasks in the field of the implementation of activities and use of ionizing radiation sources in health and veterinary medicine, protection of human health against the harmful effects of ionizing radiation.

Discussion with representatives

- SRPA - Slovenian Radiation Protection Administration

Following questions were asked:

1. How are the requirements from legislation about stakeholder engagement in medicine (patients, careers, others) implemented in practice?
2. Are doctors (practitioners) fulfilling the requirements from legislation on provision of information to patients (information in advance, warnings, written instructions)?
3. How do you know this and how you obtain feedback information?
4. What are current problems in relation to stakeholder engagement and where are the opportunities for improvements?
5. Do you provide any advice, or do you have any practical guidelines?

Here after the results of the interviews:

Ad 1: All requirements from the legislation must be addressed in the licencing procedure for particular equipment or for practice in advance. The approaches, including the obligations of clinical responsibility and other requirements are described in the application for licence. This would include also the approaches to inform the patients, special groups of patients (breastfeeding or pregnant women, children), for which activities the written instructions should be available, and for education and training of the staff, as well as written procedures for individual practice. Before starting the work in the ionizing radiation environment all staff need to obtain certificate on the prescribed education. There are two providers of education in Slovenia for different staff and SRPA supports the improvement of the quality of lecturing material. SRPA also notices the lack of appropriate implementation within the trainees.

Ad 2: The inspections at different institution (hospitals and other medical centres using radioactive substances or using equipment with ionizing radiation) is performed every 3 years. The institutions have forms which they fill in with information what patients sign. But then in reality, many times after the treatment with RA substances patients do not follow the instructions and in the last years several times they received the call from commune disposal about the alarm of IR (they have new very sensitive alarm doors for ionizing radiation).

Doctors have in their trainings also how to inform patients and responsibilities for justification and optimisation (if relevant). But on the other hand, the SRPA notices that doctors do not want to provide this information to patients as they are afraid to frighten them. With this they do not follow the instructions. There is special protocol for pregnant women and breastfeeding. The education is also organised and required for the equipment owners and users. It could be quite demanding as the equipment is now quite sophisticated.

Ad 3: There are regular inspections performed of all institutions and equipment. In addition, also there are authorised experts, which provide feedback to SRPA on their regular interactions (measurements, educations, assessments, ...). SRPA receives yearly around 10 complains from citizens or from competition, which are then addressed by administration.

Ad 4: The major problem is lack of appropriate personnel at the SRPA – currently there are only two inspectors at the administration. There are also changes within employees and within authorised experts. The increase of knowledge would be important within all stakeholders, in particular within practitioners, staff and experts. Awareness related to IR within patients is rather low, there are some information available, but more could be done. There are written instruction but could be also improved.

Ad 5: SRPA has the plan to develop more related information for stakeholders also in medicine field. Currently, they produced some leaflets. In their development they do not involve any specialist for risk

communication (sociologists or psychologists). Currently they do not have any official guidance for any of requirements.

- OI- Institute of Oncology Ljubljana

The discussion was performed with:

- Radiation protection officer
- Doctors (2x)
- Other staff (nurses, technician)
- Patients association

Following questions were asked:

1. Who is involved into provision of information on IR for individual treatment in practice?
2. How are doctors (practitioners) fulfilling the requirements from legislation on provision of information to patients (information in advance, warnings, written instructions, justification and optimization)?
3. Do they obtain written consent before use of IR from patients? Does the doctors and staff explain the patients about the risks related to IR? How does it look in practice?
4. What material is available to patients about use of IR?
5. How do you involve patients into dialogue? Do you see advantages of such approach?
6. What are current problems in relation to stakeholder engagement and where are the opportunities for improvements?

Ad 1: For diagnostic of cancer there is no other alternative than the use of IR. For such diseases the risks of IR are considered to be less important compared to the consequences of cancer. Information on the received dose it therefore considered less important for patients. Patients are not concerned because of IR and also not interested. But sometimes they ask information, which is then given. More attention is given to the results of investigation, they are afraid to learn what is wrong with them and what illness they have. Therefore, some patients do not want to use diagnostic because they are afraid to find out what is wrong. Patients receive special instructions and also sign the informed consent. Special attention is given to pregnant and breastfeeding women, and to children. Also, information when they are dismissed from hospital and go home is provided in written with warnings about IR. Usually a doctor discusses the instructions with patients to make it clearer. In the information provisions also administrative staff, nurses, technicians and others are involved. There is a system to check that a patient understands what is said.

In case there are some specific questions related to IR, the radiation protection officer is involved and can provide more information. Also, there are organized education courses for staff who are not professionals according to the Atomic Act on IR and radiation protection. The frequency depends on the needs (new staff, new topics and events). The professional staff have to renew certificates according to legislation.

Ad 2: Respondents consider that most important for providing appropriate and good treatment is to achieve reliable information about the situation of diseases, the extent, type and so on. Therefore, the doses received are higher, so the images are better. This is a considered a justifiable approach and one needs to balance between the effectiveness and potential harm. All requirements are followed in general. It might happen that there is no sufficient time to go into details, but there is not a lot of interest from patients.

Ad 3: First information about the treatment is sent by mail with description about the procedure, the information about the radioactive substance, why it is used, how the patients will be prepared, how the testing is made, what are the side effects, how to behave after release from diagnostic (in relation to IR) and similar. Description is prepared in a language which is understandable for patients with a general

level of education. There is also a contact number, where people can call and can get more information. On the day of investigation, an additional discussion takes place with the doctor. The patients sign the informed consent for the particular therapy where also warnings for pregnancy and breast feeding are given. Also information for non-professionals is available on intranet: about IR, about the equipment, rooms and limitations. There, staff can see where the radiation is increased. For volunteers there are additional education activities performed by the responsible radiation officer, although they do not have real knowledge and could not answer the related questions.

Ad 4: Several materials are available for patients: on websites in the section with information to the patients, instruction to patients for particular therapy, instruction for release from hospital, informed consent, the detail information for treatment with some warnings.

Ad 5: The information to the patients is given to inform them what the procedure will be and to obtain written consent. The aim is also that patients are not afraid and that they know how the procedure will be executed. This assures that there are no problems during implementation. But sometimes it also happens that the patients are afraid and that they are a bit confused. Staff is there to help them within the available time. Also, volunteers are trying to assist those in need.

Ad 6: Problems due to lack of communication become obvious during the diagnostic, treatment or radiotherapy. For example, people are moving when they would need to be absolutely still, which leads to repetition of procedures and higher doses. Or people do not want to continue with diagnostics even when they already receive the injection with radiative substance in the body. This would mean that they would need to repeat the procedure which again lead to higher doses. In addition, when patients are isolated in room, some have problem as they might be claustrophobic. Breastfeeding women who receive iodine treatment should stop breastfeeding. Better communication with patients on IR and the related consequences would improve implementation. It has to be emphasised also that patients are many times so confused, that even when they receive the information, they do not understand it and they are not aware what to expect. If there are problems with patients and if they are in need, usually the technician should stay in the radiation zone next to them. Consequently, he/she receives high doses (e.g. 45 minutes in 500 micro Sv/h) which can be traced within monthly dose reports. Nurses receive fewer effective doses, but still approximately 4-5 mSv per month.

3.6.3. Main findings

- Transposition of all requirements from BSS directive in Slovenian legislation was done in the law and subordinate rule with provisions regarding engagement of patients and other involved in radiological procedures. Basically, one-way communication with provision of information by the responsible practitioners and others is required. But during this information, dialogue could also be established with all actors involved in the radiological procedures: patients, carers, pregnant women, breastfeeding women, personnel, visitors, all other people who come in contact with potential exposure. There is broad awareness of legal requirements among the practitioners, although there is not enough time for proper implementations, or even there is risk of increase the fear.
- The webpage of Oncological Institute contains information devoted to public and patients with facts about cancer, the approaches to diagnosis & treatment with IR, protection measures, advices for patients and links to other websites and patients' associations with additional explanations and data. It can be seen that all prescribed stakeholders are identified.
- Some information included in publications and leaflets related to IR exists:
 - Information about diagnostics, treatment with ionizing radiation and radiotherapy – with short information how it is done, why and also risks.

- Link to the booklet Radiation as part of the treatment – where also information about risk is presented.
- Communication with patients is perceived by medical staff as beneficial, since effective two-way discussion can improve the medical treatment, reduce the concern of the patients and reduce the doses for patients and other involved. However, there are no formal records about the needs, events or requirements, which could lead to guided improvements.
- The patients' associations distribute booklets and other material, but they are oriented to the support of patient and do not really have knowledge on IR.
- There is no information on the webpage about justification and optimisation of ionizing radiation use by practitioners for individual medical exposures.
- Education and training for staff and for patients (and others) involved in use or applications of IR – organised trainings for staff, also patients' associations and volunteers are available, and continuously performed.
- The practitioners communicate about the use of ionizing radiation with the patients, but the extent of their explanation is limited as they do not want to frighten people, or they do not have time to devote to more demanding patients.

3.6.4 Conclusions

- There should be more visibility about legal prescriptions related to information for public and patients in use of IR.
- Publications for patients on IR are relatively old and not comprehensive, therefore new should be developed with more attention to IR, and to the related risks and benefits.
- Radiation protection unit is established at the Institute of Oncology and provides support to all involved and also provides education and training for non-professionals: a description should be added on the website of the Institute of Oncology – what is the role, how it is done, who is involved.
- For improvement of visibility one website section would need to be prepared with focus on IR: what is required, how it is done, further information, links to more information.
- E&T for practitioners and other staff should be organized on how to communicate the medical exposure with patients and others.
- A system should be established in which the collection of the needs or requirements related to IR would be recorded, which could lead to guided improvements.

3.6.5 References:

1. ZVISJV-1, Ionising Radiation Protection And Nuclear Safety Act, Off. Gaz. 76/2017
2. Rules on the criteria of using ionising radiation sources for medical purposes and practices involving non-medical imaging exposure, SV3, 201
3. OI webpage
4. SRPA webpage
5. SNSA webpage

3.7. Spain

Spain presented three case studies, that are reported here below.

3.7.1.1 Description of case study 1

Topic

Stakeholder engagement in practice in Medical field: Justification, Optimization of IR use and Stakeholders' role in radiation protection: Paediatric CT-Scanning

Context

Although CT scans provide the benefits in medical field, potential cancer risks exist from associated ionising radiation, in particular for children since they are more radiosensitive compared to adults¹.

Objectives

This study is aimed to check 1) how is the EUROATOM/2013 Directive implemented in practice and 2) how stakeholders (professionals and general public or patients) are involved and participate in issues of justification and optimisation of CT-scan uses, especially in case of children (vulnerable group). The results of the case study will provide insights in the benefits of stakeholder engagement processes, what the lessons learned are and provide recommendations for the radiation protection community.

Methodology

During this study the following methodologies were used:

- 1) *Web content search and analysis*: general info on tendencies of CT-scan use and RP information given to patients, patient's IC (informed consent); FAQ and worries of patients, and best practices that could be applied to CT-scan patients (children and adolescents).
- 2) *4 interviews* with professionals of different levels (1 pediatrician + radiologist (Sweden/Spain); 1 main radiologist of the hospital, 1 responsible person for RP in hospital, and 1 researcher in the area of CT-scan including in children and adults < 21 years old).

Questions that can be answered in this case study

To examine this case study these questions were addressed during the information search:

1. What levels of awareness about external prescriptions of stakeholder engagement in RP do researchers and practitioners reveal?
2. How do researchers and practitioners understand and practice stakeholder engagement (at individual and institutional level)?
3. What were the rationales for stakeholder engagement, the final objectives? Has there been a critical evaluation of the attainment of objectives and of the impact of stakeholder engagement? Have there been any guided improvement activities?
4. What forms of acceptance, resistance, denial, or alteration of engagement do you observe or encounter? And how do these forms change over time?
5. What are RP actors and communities doing that may *de facto* count as stakeholder engagement (but are not necessarily labelled that way)?
6. Are there any alignments/misalignments between case practice, on the one hand, and external conceptions and prescriptions, on the other, and if so why? Which challenges and opportunities do you encounter for stakeholder engagement in your specific case?
7. What else have you found or should we be asking?

3.7.1.2 Analysis and results of case study 1

The peer-review literature showed:

- 4.5% per year increase of CT-scan uses in children and Young adults (<21 years old) in Catalonia (1991-2013) ²
- IC is one of the obligatory ways of informing patients on risks of medical intervention; but in case of emergency (where to save life is a priority) it can be skipped in order not to lose a valuable time. In ED (emergency departments) the awareness about benefits & risks concerned CT-scans is low: 7% of patients in ED reported that they were informed about them and 22% professionals reported that they provided it.
- IC can be improved with help of view of stakeholders' opinion on it: for example, parents of children with leukaemia, asked for "to giving parents more time to make their decision, the amount and type of information provided, organization of the consent conference, communication style, and providing additional materials" ³.
- Also alternative methods in medical diagnostics methods are suggested to be applied in order to reduce exposure from X-rays or other tests in mild brain injuries, for example⁴.

The interviews performed with professional stakeholders reveal:

- That awareness of implementation of a new Directive EUROATOM/2013 exists among professionals of state hospitals; and also some steps on its implementation are done in Spain.
- The existence of ideas and plans that go even further than "information on doses of patients" (as prescribed by the Directive): creating a kind of unified "passportization" of patients with reference of collecting the information on doses they received from different medical centers (mainly of state and other clinics but not including for the moment dentists) that will allow to any professional to see information for each patient as a whole and to be oriented for a better decision-making processes. However, such ideas are limited by missing recourses or lack of findings and support from local government to realise it.
- Professionals on their initial stage of work need to have more assistance by more experienced professionals nearby in order to avoid possible errors (examples: performing CT or X-ray to left leg instead of right). Also, it is important that all such possible errors are to be reported (and not hid) to have information on all real exposures to a patient.
- General lack of time and resources (personnel in a hospital) leads to less attention (and time of this attention) to patients in reality.

3.7.1.3 Main findings of case study 1

- The patients are informed about risks arisen from radiation exposure in medical procedures, mainly by the leading doctor. However, some patients expressed non-trust or wished to reconfirm the information provided with the hospital professionals on radiation protection.
- There are singular cases when parents also do not believe to the results of diagnostics and repeated the CT scan to their kids in another center in the same day (double exposure).
- Professional stakeholders (the interviewed) agree and suggest that improvement of basic knowledge on ionising radiation and possible risks and benefits in medical field would be a plus. It can be achieved by creating special cartoons with easy demonstration or explications to be displayed for children and adolescents in waiting halls, as well as distribution of leaflets with infographics. The patients and

professional associations could help by posting the professional information on their web pages or blogs with open access and which can easily be found in internet.

- Stakeholder engagement via effective relationship between professionals and patients could provide more efficiency in issues of optimization and justification of IR use in medicine and also make patients (their parents and caregivers) perceive more security and satisfaction via a patient-centred approach and giving them an opportunity to participate more actively in decision-making processes with reference to their treatment and diagnostic procedures choices.

3.7.1.4 Conclusions

Stakeholder engagement via effective relationship between professionals and patients could provide more efficiency in issues of optimization and justification of IR use in medicine and also make patients (their parents and caregivers) feel more security and satisfaction via patient-centred approaches and giving them an opportunity to participate more actively in the decision-making processes with reference to their treatment and diagnostic procedures choices.

3.7.1.5 References:

1. Pearce, M. S., Salotti, J. A., Little, M. P., McHugh, K., Lee, C., Kim, K. P., ... & Parker, L. (2012). Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *The Lancet*, 380(9840), 499-505. Available at: <https://www.sciencedirect.com/science/article/pii/S0140673612608150>
2. Bosch de Basea i Gómez, M., Salotti, J. A., Pearce, M. S., Muchart, J., Riera, L., Barber, I., ... & Cardis, E. (2016). Trends and patterns in the use of computed tomography in children and young adults in Catalonia- results from the EPI-CT study. Available at: <https://repositori.upf.edu/bitstream/handle/10230/25952/bosch-pra-tren.pdf?sequence=1&isAllowed=y> <https://www.ajronline.org/doi/full/10.2214/AJR.12.8581>
3. <https://pediatrics.aappublications.org/content/119/4/e849.short>
4. Muñoz-Santanach, D., de la Maza, V. T. S., Gallego, S. M., González, A. C., & Cubells, C. L. (2017). Clinical observation: A safe alternative to radiology in infants with mild traumatic brain injury. *Anales de Pediatría (English Edition)*, 87(3), 164-169.

3.7.2.1 Description of case study 2

Topic

Justification and optimisation of the use of X-rays in dental clinics.

Dental clinics in Spain are of private type. Dentists use also X-ray in their practice for diagnostics and treatment of patients as well as for esthetical treatments related to the patient's and client's teeth. Stakeholder engagement (both of professionals and patients or clients of clinics) in radiation protection issues is important in terms of justification and optimisation of use of IR in dental practice.

Context

During the previous interviews with professionals working at state hospitals in Spain they reoffered that "passportization" (the project on collecting centralised information on individual doses received by each patient) is considered both by state and private hospitals, but at this point dental clinics were not incorporated in the plan yet.

The analysis of peer-reviewed publications showed that IC in dental clinics was important. But, in reality the exposure in dental clinics is considered of lower attention from RP point of view, and the related IC is not taken at the same level as in other medical practices.

For these reasons, the observational study was performed to see how questions on IR procedures (mainly X-rays here) were addressed by professionals of dental clinics and how patients were informed on doses they obtained during diagnostics or treatment or esthetical procedures follow-up.

Objectives

The objective of this study was to observe where theoretical prescription (as per EUROATOM Directive/2013) on information, optimization and justification of IR in medical field comply with practice.

The ways of possible stakeholder engagement is analysed as well.

The results of the case study will provide insights in the benefits of stakeholder engagement processes, show lessons learned and provide recommendations for the radiation protection community

Methodology

The main method applied was an observation in practice (patients' visits to a dental clinic) and interviews with professionals of this clinic.

Questions that can be answered in this case study

To examine these issues, in the ISGlobal (Spain) case study, the following questions were addressed during the information search:

1. Are there any alignments/misalignments between case practice, on the one hand, and external conceptions and prescriptions, on the other, and if so why? Which challenges and opportunities do you encounter for stakeholder engagement in your specific case?
2. What is knowledge professionals of dental clinics have on IR exposure and risks in their practices?
3. The role of professional stakeholders (workers of dental clinics) in RP, optimization and justification issues. Does IC (informed consent) exist in a dental practice?
4. Do professionals of dental clinics provide information on IR exposure, doses, risks, RP, etc.?

3.7.2.2 Analysis and results case study 2

Analysis of one of the professional's blog (posted by a dentist and owner of this clinic) showed confusing or erroneous information on radiation (including some basic knowledge as units of measurements and general statistics on sources of radiation in Spain).

No any Informed Consent form was presented at any case of X-rays applied to patients, not even any information given on it. After the question on doses arose a patient received "a panoramic picture", the answer was that dentists see essentially the numbers on the screen, but often without real knowledge of the meaning in terms of dose. In conclusion, no any stakeholder participation on justification and optimisation of doses was applied in the dental private clinic. Moreover, the knowledge of professionals was scarce and very confused, and for this reason they could not event provide a correct information to their patients.

3.7.2.3 Main findings

Both professional stakeholders (dentists) and patients need to obtain more information to increase their awareness and knowledge on IR use in dental practice, about risks and benefits and the most efficient way of mutual collaboration on IR use, justification and optimisation.

Professionals in dental clinics have to receive additional information to up-date their knowledge on IR, RP and new changes in law and its application in practice.

3.7.2.4 Conclusions

- There is no stakeholder participation in justification and optimisation of doses applied in a dental private clinic.
- Both professional stakeholders (dentists) and patients need to obtain more information to increase their awareness on IR use in dental practice, about risks and benefits and the most efficient way of mutual collaboration on IR use, justification and optimisation.
- Professionals of dental clinics have to receive additional education to update their knowledge on IR, RP and new changes in law and its application in a practice.

4. Conclusions

The case studies focused on various aspects of stakeholder engagement in the use of ionising radiation in medicine. The results illustrate the experiences collected from the analysis of documents and interviews, related to different practices of medical exposures, in the different countries involved in the projects. Most probably these results do not give a complete view; nevertheless, a number of findings from the case studies, conducted with attention to stakeholder engagement, in justification and optimization practice, informed consent, communication in radiation protection and education and training, have common bases, even in the cases considering different situations of exposures, such as: pregnant women, paediatric CT, dental imaging, interventional procedures and radiotherapy.

a) Stakeholder involvement/ engagement

The current continuous increase of medical exposure, a matter of concern from a radiological protection point of view, is often accompanied by lack of awareness, about risk, from the members of the public, and in some cases also from the medical professionals. Cooperation among the relevant stakeholders is recognised to help keeping attention to the justification process, and to engage the patients in the process of defining the prescriptions of radiological imaging by the family doctors. The awareness for the implementation of stakeholder engagement, in the view of some professional figures is still poor, and it emerged the need to go through an obligation. Benefits of the engagement of stakeholders are recognized in medical exposures, such as the prevention of unjustified medical exposures, the optimization of the doses received by patients, careers, family members, unborn child in case of pregnant women, and in the case of interventional procedures also by the members of the medical staff. The more complex the procedure of medical exposure, the more important involvement and consultation of stakeholders, enabling to address appropriate approaches and informed decision making process, both in radiotherapy as in radiology.

b) Complexity of communicating risks-benefit

In view of stakeholder participation, even if communication with patients is perceived by medical staff as beneficial, considering a two-way discussion, very often communication is mainly considered as a one-way approach. In general, health professionals, while introducing the use of IR to patients in relation to justification, tend to limit the extent of their explanation, and this on the basis of different views: they do not want to scare patients; they do not have time to dedicate; and in addition they would have to face with the complexity in deciding what to and how to communicate risk-benefits. The attention to communication is very rarely present as part of education and training courses, for health professionals

and practitioners, while communication would help in the practice to introduce to patients both the expected benefits and potential risks of medical exposure.

The intrinsic complexity of the nature of radiation risk estimate, as based on population risk and on levels of uncertainties, and the differences between how the professionals evaluate and the patient perceives the related risk and benefits of the medical exposure, requires clearly a significant role in communication. With an improved risk benefit dialogue with patient, the level of information on radiation risk-benefits would be tailored to the different medical exposures and to the attention and respect of patient.

c) Informed consent

Informed consent is a process, starting with communication, providing adequate information and answers to patient on the risks-benefits and options about the diagnostic, or therapeutic, or interventional procedures, and defining if there is an agreement by the patient about the proposed procedure.

Depending on the medical situation and the preferences of patients, there is an increasing expectation by the patient to be involved in the decision process or, on the opposite, there are patients in situation where they are considering radiation as their last problem needing attention. In reality, in many instances, the informed consent is currently a formality, as patient has to sign a formal document, without high priority for the medical practitioners. The use of an adequate informed consent, with a procedure including a higher consideration for patient dignity in decision-making, is still considered a challenge.

5. Annex Additional information for case studies

5.1 German case study

5.1.1 Details on IAEA approaches on education and training

The following IAEA documents were reflected with respect to the role of communication in education and training.:

- Building competence in radiation protection and the safe use of radiation sources. Safety Guide No. RS-G-1.4

- IAEA SSG 44. "Establishing the Infrastructure for Radiation Safety"

- IAEA SSG 46 "Radiation Protection and Safety in Medical Uses of Ionizing Radiation"

- IAEA GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

- Building competence in radiation protection and the safe use of radiation sources. Safety Guide No. RS-G-1.4

The new IAEA Standard Syllabus Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources mentions in paragraph 3. Education, training and work experience, part 3.3. mentions communicative skills: "3.3 *"In addition to the minimum qualifications, various personal attributes should be considered in the selection of candidates for particular functions or responsibilities. Personnel working with ionizing radiation should demonstrate reliability, selfcontrol, responsibility and the ability to work in a team. Some positions may also necessitate certain standards of health and fitness. Additionally, personnel should have particular personal attributes as relevant, such as communication skills (for example for discussing safety issues with workers and managers and drafting procedures)"*.

Additionally, the part dealing with qualified experts, says:

3.25. *Qualified experts may be required to have highly developed personal attributes, including communication skills, leadership skills and analytical skills, since they give advice to a wide range of personnel, such as workers, managers, health professionals and staff of government authorities, and provide training.*

IAEA SSG 44. "Establishing the Infrastructure for Radiation Safety".

Within the part "Regulatory framework", two actions deal with "Communication and consultation". Action 27 is dedicated to "The regulatory body should develop and implement a strategy for effective communication and consultation with interested parties and the public." Action 28. "The regulatory body should take steps to implement the requirements on collecting feedback from operating experience and regulatory experience, on the analysis of lessons learned and on the dissemination of such lessons learned." deals therefore with reflection processes, feedback processing and progress through evaluation. However, this is very general and no specific link is drawn to medical area. Of course this reflects the main responsibility levels of IAEA.

IAEA SSG 46 "Radiation Protection and Safety in Medical Uses of Ionizing Radiation", 2018:

In the section Roles and responsibilities one paragraph is dedicated to "Patients":

2.117. *Patients are increasingly being involved in the decision making processes concerning their own health care, and this includes medical uses of ionizing radiation. Paragraph 3.151(d) of GSR Part 3 [3] requires that the registrant or licensee for the medical radiation facility ensure that the patient be informed, as appropriate, of both the potential benefit of the radiological procedure and the radiation risks. Information should be provided in an understandable format (e.g. verbally, leaflets, posters and web sites) and in a timely manner. The level of information should be commensurate with the complexity, dose and associated risks; and for some radiological procedures, informed consent may be required, either*

written or verbal. Female patients of reproductive capacity should be informed about the risk to the embryo or fetus from radiological procedures for either diagnosis or therapy.

2.118. 'Self-presenting' patients are individuals demanding a particular radiological procedure on the basis that they believe that this procedure is needed, for example, to detect cancer or heart disease in its early stages before symptoms become manifest. These individuals should be handled in the same way as any other patient, namely through an appropriate referral and the ensuing justification.

Another paragraph describes the following:

3.160. Cooperation of the patient should be ensured to achieve an image of diagnostic quality. This is particularly relevant when imaging children. Good communication helps to achieve this. Verbal interaction between the medical radiological technologist or the medical radiological practitioner and the patient should take place before, during and after the procedure.

IAEA GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Requirement 36: Responsibilities of registrants and licensees specific to medical exposure Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.

More specifically: 3.151. Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

(a) – (c)...

(d) *The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.*

In May 2019, the new IAEA Standard Syllabus Postgraduate Educational Course in Radiation Protection and the Safety of Radiation Sources was launched. Nuclear or radiological emergency, emergency preparedness and response: communication with the public is part of the standard syllabus. But not for the case of medical exposure. There is no word about informed consent, informed decision making, support of participative decision making etc.

5.1.2 Details on risk communication in the medical field at national level in Germany

Medical expert associations and internet pages were analysed for Germany. Search was carried out by key terms "risk communication", "informed consent" and "patient information". Results:

- German Association for Medical Education (GMA):
 - Committee for communicative and social competences
 - Diverse workshops in the past years on communication and social skills, not specifically for use of ionising radiation in medicine.
- German Society for Radiation Oncology (DEGRO): working group life quality and ethics in radio oncology. Work priorities:
 - Training for colleagues
 - Recording of life quality of patients in routine and in studies
 - Recording of influencing factors on life quality
 - Potential starting points for improving or maintaining life quality
 - Organisation of communication seminars (patients, relatives, employees, cross-professional communication).
 - Studies related to abovementioned topics as well as subjective job stress in radio-oncology
 - Academy: specialist radiation therapy, no content regarding patients' education

- German Radiological Society:
 - <http://www.mezizin-mit-durchblick.de/> : interactive brochure with terms related to radiation protection
 - <https://www.bavarian-health.com/de/patientenaufklaerung/medbogen/#c274> (digital patient education): ca 24 information sheets for single applications and procedures with a certain structure: operating principle, examination procedure, alternative procedures (if appropriate), prospects of success (if appropriate), planning (for therapy), procedure, information sheet, videos, digital education.
 - Professional association of radiation therapists (registered society).
 - Information for patients on the webpage
 - German Association of Nuclear Medicine
 - Differentiated Information for patients on the webpage
 - German Public Health Association
 - No matches
 - German Association for medical Psychology
 - No matches
 - German Association for interventional Radiology and minimally-invasive Therapy
 - "European Curriculum and Syllabus for Interventional Radiology": Communication is a small part
 - Association for paediatric Radiology
 - No matches
 - German Association for Neuroradiology
 - No matches
 - Radiology net („Radiologienetz“):
 - Extensive information for patients, well-structured and provided in form of modules
- Additionally, a quick glance was taken at approaches to informed consent from radiological associations and projects on the **European level**:
- European society for Health and Medical Sociology
 - No matches
 - European Public health association
 - International association for communication in healthcare / Improving the quality of communication in healthcare
 - A couple of course offers for professional communication for doctors exist.

5.2 Slovenian case study

5.2.1. Legal framework

Ionising Radiation Protection and Nuclear Safety Act (last modified in 2017 and amended in 2019) transposed also latest requirements from BSS Directive in Slovenian legal system and is the central law in the area in Slovenia. The Act regulates ionising radiation protection for the purposes of reducing, to the maximum possible level, damage to human health due to ionising radiation exposure and radiation contamination of the living environment and at the same time allow the development, production and use of radiation sources and the performance of activities involving radiation. It also regulates the execution of nuclear and radiation safety measures for radiation sources intended for production of nuclear energy and execution of special protective measures in cases where nuclear materials are used.

Details of the use of IR in medicine are defined in Rules on the criteria of using ionising radiation sources for medical purposes and practices involving non-medical imaging exposure, SV3, 2018.

Definitions from Atomic Act and from Rule

Clinical responsibility for radiological procedure is responsibility of a practitioner in relation to the justification and optimisation of ionising radiation exposure levels for patients undergoing a radiological procedure. In relation to this, a practitioner shall be responsible for: the clinical assessment of the outcome of the procedure; cooperation with other specialists or health personnel with regard to appropriate radiological practices; obtaining information on previous procedures; the conveying of existing information or documentation on radiological procedures to the referrer or other practitioners; suitable informing of patients and other affected individuals about the risks of procedure or ionising radiation.

Clinical assessment is the systematic review of performance and results of the radiological procedures with the aim of raising the quality and results of patient care. It is based on a comparison of the procedures and results of interventions with the agreed standards of a good radiological practice and leads to changes in procedures or harmonization with modern standards, where necessary and appropriate.

Medical exposure is the exposure incurred by patients or asymptomatic individuals as part of their own diagnosis or treatment, intended to benefit their health, as well as exposure incurred by carers and volunteers in medical or biomedical research.

Practitioner responsible for radiology procedure is a medical practitioner or a dental health professional, who is entitled to take clinical responsibility for an individual medical exposure.

Referrer is a medical doctor or dentist, who is entitled to refer individuals for medical radiological procedures.

The **referred person** is a patient, or other individual sent for a radiological procedure.

Carers are individuals, knowingly and willingly incurring exposure to ionising radiation by helping, other than as part of their occupation, to care and comfort of patients and other individuals undergoing medical exposure.

Justification of a radiation practice (Atomic Act)

The person carrying out a radiation practice must:

- justify every new radiation practice and prove that the benefits due to the new radiation practice outweighs the health detriment to people;
- re-justify carrying out a radiation practice for which a licence has already been given, if there is new important evidence and knowledge on its effectiveness or consequences to health of people;
- ensure that doses for exposed workers, apprentice, students and members of the public do not exceed the prescribed dose limits because of the radiation practice;
- optimise the ionising radiation protection of people and the environment in such a way that exposure is at such low levels as reasonably achievable while considering the economic and societal factors;
- apply dose constraints in the optimisation of radiation protection.

A decision on introducing a radiation practice is justified when the benefit for an individual or the society due to such radiation practice is greater than the detriment to health resulting from it. The decision to introduce or alter an exposure pathway for existing and emergency exposure situations is justified when it leads to more benefit than harm (**the principle of justification**).

Optimisation (Atomic Act)

Radiation protection of individuals in public or occupational exposure shall be optimised with the aim of keeping as low as is reasonably achievable the magnitude of individual doses, the probability of exposure and the number of individuals exposed, considering the current state of technical knowledge and economic and societal factors. The protection of individuals from medical exposure shall be optimised by the magnitude of individual doses where the optimisation must be consistent with the medical purpose of the exposure. This principle shall apply not only to effective doses but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties to health detriment below the limit above which effects on tissue are known (**the principle of optimisation of radiation safety**). The principle of optimisation of radiation safety also applies to the design of protective measures by comparing the exposure at the implementation of the protection measure with the benefits of this measure, namely by reducing the damage caused by an emergency.

The definitions used in Atomic Act and in Rules SV3 correspond to the one used in BSS directive related to the medicine treatments. They define the medical exposure as exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research. As part of clinical responsibility is also responsibility of practitioner for individual medical exposures, in particular, justification; optimisation and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.

The Atomic Act transposed all related requirements from BSS directive in Slovenian legal system which relates to information provisions to different groups for medical treatments:

- For any radiological procedures the information must also include information on the dose received by the patient.
- In the case of radiological intervention, it must be ensured that information on the patient's exposure due to radiological intervention is an integral part of the survey report.
- The minister responsible for health determines in detail the conditions for special radiological interventions for children, pregnant women and nursing women, and voluntary care and care services for patients. In the separate rule also written instructions for patients are prescribed after they leave the hospital.
- The minister responsible for health determines in detail the conditions for education and compulsory training and qualification requirements for doctors responsible for radiological intervention and radiological intervention providers.
- The holder of an authorization to carry out a radiation practice must inform the medical doctor, the doctor responsible for the radiological intervention, and the patient or his legal representative of clinically relevant unintentional exposures and findings of the analysis of these events.
- Every patient or his legal representative shall have the right in the manner prescribed by the law governing the patient's rights for acquaintance with the medical documentation, to obtain data from the doctor responsible for the radiological procedure on the doses received during the conduct of radiological procedures.

In separate "Rules on conditions on use of Ionizing sources in medicine and for exposure situations in non-medicine treatments" more detailed information and instructions on how to implement requirements are set. The following is defined:

- For any radiological procedure, the referrer and the practitioner must provide the patient, its legal guardian or carer with adequate information relating to the benefits and risks associated with the medical exposure before the procedure.

- The written instructions following dismissal from the health-care institution after the therapeutic use, when radionuclides are input into the body of the patient or for procedures in nuclear medicine shall be given to inform the patient or his legal guardian on the risks of radiation and appropriate instructions to minimise, as far as reasonably achievable, the irradiation of people, who come in contact with the patient.
- In the case of pregnant or breastfeeding female special attention shall be given to the justification, particularly the urgency, and the expected exposure of the woman. The licence holder must have established written procedures for the procedures. Where appropriate and possible (e.g. in waiting rooms outside the facilities in which radiological procedures are taking place), the licence holder must alert women to inform the practitioner of the possibility of being pregnant, or they are breastfeeding.
- The practitioner, responsible for radiological procedure, must establish and implement the dose constraints for carers and must inform the carers about the risk associated with the radiological procedure and, if necessary, issue appropriate written instructions.
- When entering the facilities where brachytherapy irradiation takes place, personnel and visitors must comply with written procedures approved by an authorised medical physics expert.
- The patient with the applied radionuclide must receive written instructions and warnings about radiation hazards and procedures for radiation protection before dismissal from the hospital, which the patient must consider reducing the risk of unnecessary external irradiation or contamination of other persons.
- Autopsy and cremation of deceased persons who have received radionuclides for therapeutic purposes should be carried out in accordance with the instructions for radiation protection that the operator must have in written form.

5.2.2. Information at responsible institutions

In Slovenia there are two responsible authorities: **Slovenian Nuclear Safety Administration (SNSA)** which is authority competent for nuclear safety and performs specialised technical and development administrative tasks and activities of inspection control in the areas of radiation and nuclear safety, activities involving ionising radiation and use of radiation sources, with exception to use in medicine and veterinary medicine, environment protection against ionising radiation, physical protection of nuclear materials and facilities, non proliferation of nuclear weapons and safeguards, monitoring radioactivity in the environment and responsibilities for nuclear damage. At the webpage <http://www.ursjv.gov.si/si/> there is a complete overview of legislation, also framework related to medical field.

The relevant radiation protection authority for medical application is **Slovenian Radiation Protection Administration (SRPA)** which performs professional, administrative, supervisory and development tasks in the field of the implementation of activities and use of ionizing radiation sources in health and veterinary medicine, protection of human health against the harmful effects of ionizing radiation, systematic inspection of the working and living environment due to human exposure to natural resources ionizing radiation, monitoring the radioactive contamination of food and drinking water, limiting, reducing and preventing the harmful effects of non-ionizing radiation, assessing the appropriateness and empowerment of radiation protection experts. The relevant data are available at the webpage <http://www.uvps.gov.si/si/>, covering mainly legal framework, work responsibilities, annual reports and main findings from inspections.

Institute of Oncology Ljubljana - OI has variety of information and data available on the internet webpage <https://www.onko-i.si/>. Content is divided in three sections: information about Institute of Oncology with

data about institute, the organisation with departments and sectors, composition of employees (1111 together) and other, information about the activities, including description of sector for radiotherapy with department for teletherapy, brachytherapy, unit for radio-physics and clinical department, and information devoted to public and patients with facts about cancer, the approaches to treatment, protection measures, advices for patients and links to other websites and patients associations with additional explanations and data. In relation to our investigations the results are following:

- Justification and optimisation of Ionizing Radiation (IR) use by practitioners for individual medical exposures: no information on webpage.
- Information on the risk of ionising radiation to patients and other individuals involved (technical staff, nurses, carers and comforters): there are information available about the use of IR in diagnostics, in radiotherapy and other treatments. The attention is given to the patient and documents provide information about the procedures and consequences for the patient. An example is booklet on radiation as part of medical treatment and provides a comprehensive description of examinations and consequences according to different cancer types: https://www.onko-i.si/fileadmin/onko/datoteke/dokumenti/Obsevanje_kot_de_zdravljenja.pdf. There are no available instructions for other staff (non-professionals) on the webpage.
- Education and training for staff and for patients (and others) involved in use or applications of IR: on webpage there are information about continuous education for staff (doctors and nurses) on different topics including the communication with the patients and relatives. There is internal newspaper "Onkoskop" <https://www.onko-i.si/onkoloski-institut/onkoskop-interni-casopis/> which also inform about the education and trainings at the OI.

5.2.3. Relevant extracts from the BSS directive

Preamble

*(7) The provisions of this Directive should follow the situation-based approach introduced by ICRP Publication 103 and distinguish between **existing, planned and emergency exposure situations**. Taking into account this new framework, this Directive should cover all exposure situations and all categories of exposure, namely **occupational, public and medical exposures**.*

Article 1 Subject matter

*This Directive establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical and **public exposures against the dangers arising from ionising radiation**.*

Article 2 Scope

*1. This Directive applies to any **planned, existing or emergency exposure situation** which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.*

Article 4 Definitions

- *"**clinical responsibility**" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as*

required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

- **"carers and comforters"** means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;
- **"members of the public"** means individuals who may be subject to public exposure;
- **"public exposure"** means exposure of individuals, **excluding any occupational or medical exposure**;
- **"medical exposure"** means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;
- **"representative person"** means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;
- **"emergency exposure situation"** means a situation of exposure due to an emergency;
- **"existing exposure situation"** means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;
- **"planned exposure situation"** means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures;
- **"practitioner"** means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;

Article 55 Justification

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

Article 56 Optimisation

1. Member States shall ensure that all doses due to medical exposure for radio diagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radio diagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

3. Member States shall ensure that for each medical or biomedical research project involving medical exposure:

- (a) the individuals concerned participate voluntarily;*
- (b) these individuals are informed about the risks of exposure;*
- (c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;*
- (d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.*

4. Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

5. Member States shall ensure that:

- (a) dose constraints are established for the exposure of carers and comforters, where appropriate;*
- (b) appropriate guidance is established for the exposure of carers and comforters.*

6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Article 66 Estimation of doses to the members of the public

1. Member States shall ensure that arrangements are made for the **estimation of doses to members of the public from authorised practices**. The extent of such arrangements shall be proportionate to the exposure risk involved.

2. Member States shall ensure the identification of practices for which an **assessment of doses to members of the public** shall be carried out. Member States shall specify those practices for which this assessment needs to be carried out in a realistic way and those for which a screening assessment is sufficient.

3. For the realistic assessment of doses to the members of the public, the competent authority shall:

- d) require records to be kept and be made **available on request to all stakeholders** relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.*

5.2.4. Related extracts from ZVISJV 1

Article 76: conditions for carrying out a radiological intervention

- (1) A single radiological procedure may be carried out only if it is prescribed by a medical doctor and approved by the doctor responsible for the radiological procedure and bears clinical responsibility for it. The holder of an authorization for the use of a radiation source shall provide the referral physicians with criteria for referrals with radiological procedures, which must also include **information on the dose received by the patient**.*

(4) In the case of radiological intervention, it must be ensured that:

- **information on the patient's exposure due to radiological intervention is an integral part of the survey report;***

*(8) The minister responsible for health determines in **detail the conditions for the implementation** of screening, biomedical and medical research, **special radiological interventions for children,***

pregnant women and nursing women, and voluntary care and care services for patients; education and compulsory training and qualification requirements for doctors responsible for radiological intervention and radiological intervention providers; criteria for the acceptability of radiological equipment; special procedures for radiotherapy, diagnostic and interventional radiology and nuclear medicine; special conditions regarding the involvement of accredited experts in medical physics; quality assurance programs and form of professional supervision.

Article 81: unintentional exposure

(3) The holder of an authorization to carry out a radiation practice **must inform** the medical doctor, the doctor responsible for the radiological intervention, and **the patient** or his legal representative of **clinically relevant unintentional exposures** and findings of the analysis of these events.

Article 83: database of doses due to radiological procedures

(4) The **central register of performed radiological procedures** shall contain the following information: name of the radiological intervention provider, **year of birth and gender of the patient**, year of intervention, type of intervention, data on the implementation of the procedure, which are the basis for the calculation of the dose received.

(6) **Every patient or his legal representative shall have the right in the manner prescribed by the law governing the patient's rights for acquaintance with the medical documentation, to obtain data from the doctor responsible for the radiological procedure on the doses received during the conduct of radiological procedures.**

(7) The body responsible for radiation protection shall exchange aggregated data on performed radiological interventions with international institutions, professional associations and competent authorities of other countries in the field of patient care in radiological procedures.

5.3 Romanian case study

QUESTIONNAIRE REGARDING INFORMED CONSENT FOR CANCER PATIENTS UNDERGOING RADIOTHERAPY

Thank you in advance for filling in this questionnaire which has the task to improve the dialogue between patients and medical staff

1. What information concerning radiotherapy do you consider important?

Information about....	Important	Unimportant
... the risks of procedure application		
... the benefits of procedure		
...possible alternatives, if there are		
...general information about procedure		
... technical details about procedure, for instance the absorbed dose		
Other information (please specify)		

2. To what extent did the information received correspond to your needs?

Information/explanations about...	To a very great extent	To a great extent	Neither great, not small extent	To a small extent	To a very small extent	I did not receive this information
.. the risks of procedure application						
... the benefit of procedure						
... possible alternatives, if there are						
... general information about procedure						
... technical details about procedure, for instance the absorbed dose						
Other information (please specify)						

3. In your opinion the information that you received about ionizing radiation was: (circle the selected answer)

- i. very difficult to understand
- ii. rather difficult to understand
- iii. rather easy to understand
- iv. very easy to understand
- v. I did not receive explanations about ionizing radiation

4. What do you consider as the best moment to receive information about ionizing radiation? (circle the selected answer)

- i. several days before the procedure
- ii. immediately before the procedure
- iii. immediately after the procedure
- iv. another moment (specify).....
- v. I do not wish to receive information about ionizing radiation

5. How do you prefer to receive the information? (circle the selected answer)

- i. written
- ii. verbal
- iii. both (written and verbal)

7. Do you have suggestions for improving the dialogue between medical staff and patients?

.....

- 8. Sex: F M
- 9. Age: Less than 20 years 20-30 years 31-40 years 41-50 years 51-60 years
61-70 years More than 71 years