ENGAGE final workshop

11-13 September 2019
Bratislava, Slovak Republic

OVERVIEW OF CONTEXT, WORKING METHODOLOGY, STUDIES, FINDINGS

Medical exposures to ionizing radiation

Marie Claire Cantone, UMIL

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

The context of exposure in the medical field

The exposure of patients has unique aspects:

- the exposure to radiation is related to expectation of direct individual health benefits;
- the dose to patient cannot be reduce indefinitely without compromise the intended result;

*"The exposure of patients is deliberate"; "**The patient, or legal guardian, agrees or consents to a medical procedure using radiation**." ICRP 103*

*"The amount of information provided in order to obtain **informed consent varies based on the exposure level**" ICRP 103*

*"The **final responsibility for the medical exposure of patients** lies with the physician, who therefore should be aware of the risks and benefits (…)" ICRP 103*

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

The context for stakeholder engagement in medical exposure

Attention to medical exposure involves stakeholders in the practice

- **For example**, the use of CBCT spans a wide range of clinical specialties and procedures: radiotherapy; orthopaedics; urology; dental/ maxillofacial; neuro interventions, and vascular and non-vascular interventions
- "*the cone beam nature of the radiation field presents new challenges in dose management to ensure patient safety; guidelines are needed for various stakeholders in this new modality*." (ICRP 129, 2015)
- "*The purpose of this publication is to identify **radiological protection issues for patients and workers** and, in line with other ICRP publications, recommendations are set out for all stakeholders ranging from day-to-day clinical users, auxiliary support workers, buyers, manufacturers, and policy directing committees*" (ICRP 129, 2015)

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Information and campaigns on stakehokolder engagement in medical exposure

The actions of the **Bonn Call-for-Action** (IAEA and WHO, 2012) include:

- Increase awareness about radiation benefits and risks among health professionals, patients and the public.
- Strengthen cooperation and communication between manufacturers and other stakeholders, such as health professionals and professional societies.
- Work towards an active informed decision making process for patients.
- Support improvement of risk communication skills of health care providers and radiation protection professionals.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

ENGAGE, in relation to medical exposure

- *ENGAGE on Medical Field considers:*
  - *how are the RP communities responding to expectations for S.E.;*
  - *how does this show in practice, with consideration of specific cases;*
  - *which real or potential forms of stakeholder engagement can be observed in RP practice.*
- The analysis is based on findings from international prescriptions and national level
  - Analysis of publicly available documents related to legal requirements and recommendations in the RP of medical exposure,
  - Interviews with representatives of international organisations with leading roles in radiological protection and relevant actors in the participating countries.
  - Analysis of stakeholder engagement in practice based on national case studies, through available documents and interviews of directly involved parties.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Stakeholders and ionising radiation in medicine – International documents

- In the medical field the RP focuses on justification and optimization differently from other type of exposures, the medical exposure is not applying dose limits.
- When decisions are taken on justifying a medical procedure, the optimization is requiring the greater specific attention.
- Thus, we can say that stakeholder views and concerns have a highly meaningful role in the medical field.

International prescriptions and recommendations

- ICRP Publication 103, 2007
- ICRP Publication 105, 2006
- ICRP Publication 129, 2015
- Action plan of IAEA, in consultation with PAHO, WHO and UNSCEAR 2002
- Bonn Call for Action, 2012
- HERCA Report CT Manufacturers Stakeholder Involvement, from 2017
- Report of HERCA WG5 , Stakeholder Involvement in Medical Practices, 2008

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Stakeholders and ionising radiation in medicine – International documents

The right of patients to expect the radiation to be used in a safe and effective modality:

- Responsibility for the medical exposure of patients lies with the physician, but the decision-making process may often include the participation of relevant stakeholders, rather than radiological protection specialists alone (ICRP 103, ICRP129, Action plan IAEA, Bonn Call for Action, HERCA)
- The significance of involvement of stakeholders is recognized, having in mind that in the management of patient dose the medical task is not limited to the reduction of dose. (ICRP 105, ICRP 129, Bonn Call for Action, HERCA)
- Direct benefits and risks are expected for the exposed patient; however, other parties may be involved in relation to this exposure. For instance, in some procedures, occupational exposure is related to patient exposure; and - in different form- also members of patient family and friends could be exposed. (ICRP 103, ICRP 105, Bonn Call for Action, HERCA)
- Different approaches are recognized in the informed consent for patients and in the levels of information relevant for family and friends, and the amount of the information provided varies on the basis of the level and the type of exposure. (ICRP 103, ICRP 105, Action plan IAEA, Bonn Call for Action)

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Stakeholders and ionising radiation in medicine – International documents

The continuous development of patient-centred radiation protection together with the benefit for society as a whole:

- Development of high-performance technology, in the field of imaging, is recognized as a benefit for the patients, and at the same time leading to a large increase in exposure for the society. How all the involved stakeholders (manufacturers, prescribers, imaging professionals, physicians, medical physicists, ..) give their contribution to reducing medical exposure has an important role (HERCA, ICRP 129, Action plan IAEA, Bonn Call for Action).
- Commitment of parties includes the development of standardized benchmarks for specific technologies, and an adequate and well disseminated professional education and training, and the awareness of all professional figures of the relevant aspects of radiological protection (HERCA, ICRP 105, Action plan IAEA, Bonn Call for Action).
- Coordinated work to address aspects of RP in medicine can take advantage from a complete integration of RP into the health care system; and from the availability of updated documents on new challenges, and guidelines for various professional stakeholders (Bonn Call for Action, ICRP 129, ICRP 105, HERCA).
- Benefit-risk dialogues in radiology and radiotherapy need to be supported; technical and communication experts in cooperation with patient associations are envisioned to improve risk communication by developing adequate messages and approaches towards patients and the public, and moreover to improve communication skills of medical professionals and RP experts (Bonn Call for Action, ICRP 103, ICRP 105, HERCA).

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Interviews with international actors in the field of medical exposures

- Interviews were conducted with members of key international organizations: WHO, IAEA, HERCA and ICRP.
- Given the international frame in which these organizations work, respondents referred mostly to professional and institutional stakeholders, such as regulatory bodies, professional organizations of medical specialists, technicians or manufacturers, and less to the role of patients and patient organizations as stakeholders.
- These professional and institutional stakeholders are engaged in several ways, ranging from information provision (e.g. trainings), to more active forms of participation such as discussion and joint decision-making when standards and regulations are set.
- Patients are mostly seen as the object to decision making, and to be protection in the exposure, and are not given a direct position at the discussion table.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Interviews with international actors in the field of medical exposures

- Overall, both instrumental (stakeholder engagement as a means in optimization processes) and normative (stakeholder engagement as the right thing to do) rationales for stakeholder engagement were identified in the discussions.
- Main challenges in engaging stakeholders were according to our respondents the search for a common language, or a common ground of understanding which needs to be established when meaningful discussion should take place.
- A lack of equal recognition among different stakeholders was also mentioned, this being due to the position of different stakeholders in the process.
- Time constrains were also seen as a challenge in order to provide for meaningful stakeholder engagement.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Analysis of relevant national documents

As relevant national requirements were identified:

- For **Germany:** ① Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten, by 20th February 2013 (not official translation: "Act to improve rights for patients". ② Gesetz zur Neuordnung des Rechts zum Schutz vor der schädlichen Wirkung ionisiere-nder Strahlung. National legislation, Germany ("New Radiation Protection Act", Germany by 27th June 2017;
- For **Italy**: ① D. Lgs. 187/2000. Legislative Decree 187/2000. Implementation of Directive 97/43 EURATOM on health protection of persons against the dangers of ionising radiation via medical exposures. ② ISISTAN 15/41, 2015 Operative indications for the optimization of radioprotection in interven-tional radiology procedures.
- For **Slovenia**: Ionising radiation protection and nuclear safety act (ZVISJV- 1), Off. Gaz. 76/2017 – Atomic Act.
- For **Spain**: The royal decree project on justification and optimization of the use of ionising radiations for the radiological protection of people on the occasion of medical expositions, 7/02/2018.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Analysis of relevant national documents

- The transposition of the revised EURATOM BSS Directive is active in Germany and Slovenia, while in Italy and Spain it is under development.
- A specific definition of stakeholder and stakeholder engagement was not found in the context of medical exposure, although adequate information and dialogue is mentioned for patients in general, and different groups in medical exposures, as children, pregnant women, breastfeeding women; and people who might come in contact with, such as caregivers and visitors.
- No focus on participation of patients as a way to evaluate and deliberate specific diagnoses or treatments emerged in the analysis.
- A common focus on the knowledge of and cooperation among relevant experts, 'professionals', mandatories and contracting parties was evidenced in particular in Slovenia, Italy and Spain, as a form of responsibility towards the patients (protection, safety, justification, optimization, dose limitation).
- Responsibility, understood as the responsibility of practitioners, involved either in prescription of ionising radiation for medical purposes or administrating it during procedures, is mostly seen as providing (one-way) information to patients, 'as appropriate'.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Analysis of relevant national documents

- There is also, as emerged in Slovenia, a clear emphasis on the importance of 'dialogue' (two way communication), but without specification of formal methods of a more 'participatory character'. In Germany, for example, a specific authority is assigned to an ethics committee to judge accuracy of information towards the patient, as the only 'stakeholder' to be engaged.
- Patients as stakeholders are still seen as a subject of concern needing protection and having the right to information as a basis for informed consent, and thus the engagement of patients is mostly 'restricted' to having the autonomy of giving informed consent (or not).
- No specifications of formal procedures in this sense, except for Spain, mentioning 'the signing of informed consent by himself or by his legal representative', this basic procedure being known and applied also in other countries.
- With regards to stakeholder participation in deliberation and decision making in the context of radiological protection policies, it is mentioned the need to involve professionals, including experts, technical staff and ethics committees, **but** not systematically of the need to include patients as co-decision makers.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Main conclusions on the analysis on national documents

- The patient as stakeholder is still seen as a subject of concern needing protection and having the right to information as a basis for informed consent;
- Engagement of the patient is mostly 'restricted' to having the autonomy of giving informed consent (or not). No specifications of formal procedures in this sense, except for Spain, mentioning 'the signing of informed consent by himself or by his legal representative';
- With regard to stakeholder participation in deliberation and decision making in the context of specific individual cases or in the more general context of radiological protection policies, mentioning is made of the need to involve professionals (including experts, technical staff and ethics committees), **but not** systematically of the need to include **patients as co-decision makers**.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies at national level -Stakeholder engagement in the practice

- Stakeholder participation in the medical field (Belgium)
- Stakeholders' view and approaches- education and training related to medical exposure to ionising (Germany)
- Stakeholders' role in the performance of medical exposures of pregnant women (Greece)
- Stakeholders' role in medical interventional procedures (Italy)
- Stakeholders' role in radiation protection in radiation therapy (Romania)
- Stakeholder engagement in justification, optimisation, education and training, Institute of Oncology Ljubljana (OI) (Slovenia)
- Stakeholder engagement in Medical Justification, Optimization of IR use in Paediatric CT-Scanning (Spain)
- Stakeholder in X-rays use in dental clinics (Spain)
- Self-engagement of stakeholders (general public) via internet Forums in Belarus, Russia and Ukraine (Spain)

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies at national level -Stakeholder engagement in the practice

Analysis of national documents and interview with the main professionals experts involved in the case studies. The following basis was considered for individual interviews:

- TOPIC 1 - **Awareness** - Regarding general indications and recommendations, what levels of awareness can be evaluated in stakeholder engagement in interventional radiology?
- TOPIC 2 - **Acceptance** - How is stakeholder engagement interpreted and practiced, at an individual and institutional level?
- TOPIC 3 – **Motivation** - What were the motivations initially for Stakeholder involvement? Did an implementation and evaluation follow on the objectives, and on the forms of acceptance-resistance-refusal?
- TOPIC 4 - **Challenges** - Which challenges, opportunities and advantages for stakeholder engagement can be encountered in the specific case of Interventional Radiology?
- TOPIC 5 - **Lesson learned** - What are the lessons learned and suggestions for establishing efficient processes of stakeholder engagement?

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Belgium

- The awareness of prescriptions for stakeholder engagement is limited. One-way communication on safety measures is common practice, while stakeholder participation, including patients is non-existing according to the medical practitioners.
- Stakeholder participation and communication are often used interchangeably. Understanding of what stakeholder participation is, is therefore skewed towards communication.
- Rationales for stakeholder participation are scares. 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.
- 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
- Stakeholder participation expresses itself most explicitly in the informed consent, other expressions include mainly communication activities.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Germany

- Risk communication is no, or only seldom a really small, part in courses for RP.
- Social scientists deal with risk communication in the medical area.
- 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 skill are trained.
- Patient involvement and participatory decision making are only side issues, in literature more than in education. Those topics are partly dealt within the medical community.
- The RP community does not deal with requirements of good risk communication or questions of participatory decision making in the medical field.
- The gap between RP activities on academic level and requirements from vocational level does not support S.E. activities and a penetration of the RP community with the consciousness of the importance of communicative skills in other areas than emergency management.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Greece

- 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 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.
- In some cases 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.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Italy

- Awareness about the stakeholder involvement is very poor, the attention is for some professional figures, manufacturers.
- It is recognised a lack of collaboration between the professional figures, even considering the figures of the same structure.
- The attention is in general not given to patient's involvement in a decision process, the patient is seen as care receiver and the attention is dedicated to technical aspects of RP for patient care.
- The state of art of patient and staff protection in interventional procedures is in continuous evolution and changes have to be introduced, TG are active on interventional radiology with attention to optimization of patients and operators.
- There is the vision that patient has low knowledge in RP, the attention to patient information may be seen of poor interest.
- The Postgraduate Schools in Diagnostic Radiology provides accurate training in the field of RP, it is not possible to say the same for other schools whose specialists are involved in complementary interventional activities.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Slovenia

- At the webpage of OI 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 are available. 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** as effective two-way discussion can improved 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.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Slovenia

- The **patients' associations** distribute the 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 webpage about **justification and optimisation** of Ionizing Radiation (IR) 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 are **presenting the IR use to 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.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies - Findings – Spain

- The patients are informed about risks arisen form radiation exposure in medical procedures, mainly by leading doctor. However, some patients expressed non-trust or wished to reconfirm the information
- There are singular cases when parents do not believe to the results of diagnostics and repeated the CT scan to their kids in another center in the same day
- General lack of time and resources (personnel in a hospital) leads to less attention (and time of this attention) to patients in reality.
- No any stakeholder participation on justification and optimisation of doses applied in a dental private clinic. Moreover the knowledge of professionals was scarce and very confused, and for this reason they cannot event provide a correct information to their patients.
- 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.
- It is recognised the need and expected positive outcome in rising awareness and at least of some knowledge on IR, and IR protection in general public, e.g. Stakeholders' self-organization for open discussion questions on IR exposure justification & optimisation.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Case studies related to the development of RP culture for medical professionals

- France: Elaboration of a RP training course to be included in the 3rd year of studies of a nurse school
- Greece: Specific actions undertaken to build and enhance RP culture among hospital staff involved in fluoroscopy guided medical procedures
- Italy: Actions undertaken to mitigate the risk of accidental exposures in the field of radiotherapy

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Target Stakeholders – Aim of RP Culture (1/2)

- Target stakeholders are **medical professionals directly** or **indirectly** involved in medical procedures using ionising radiations. According to their specialty, they have **different role to play** regarding the radiological protection of patients and staff.

Student nurses (& indirectly school pedagogic staff)

- Aim of RP culture: **to raise awareness on RP exposure situations they may encounter** on their workplace in order **to implement self-protection actions**, to **understand and apply the relevant radiological protection protocols** for the patients, as well as **disseminate RP culture elements** to their colleagues.
- As these professionals are in direct contact with the patients, the aim is also **to give them elements to be able to provide advices and explanations to the patients** who might have concerns regarding radiological protection issues.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Target Stakeholders – Aim of RP Culture (2/2)

Medical professionals participating in fluoroscopy guided medical procedures

- Aim of RP Culture for these professionals:
  - **to improve their practice by integrating the radiological risk as an additional criterion in their decision-making process** as well as to understand and implement processes to **optimise the radiological protection** of the patients and the whole staff.
  - to **improve their communication and work with the Qualified Expert** on RP issues related to interventional procedures.

Medical professionals involved in radiotherapy (RT) procedures

- Target stakeholders include: medical physicists, radiotherapist, and other staff that may be involved on RT procedures.
- Aim of RP Culture: to **raise their awareness on the potentiality of incidents/accidents** that can give rise to very high exposure of the patients, and thus **to develop a structured approach in the different steps of the RT process** to identify and analyse adverse events, occurrence rating and potential severity to prevent critical situations.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Tools, methods and process to build RP culture (1/2)

Initial training of nurses

- A **process initiated by local actors** (municipality, university, nurse school, local hospital)
- A **work with the pedagogic staff** of the school to **identify the needs** and elaborate a programme based on initial personnel work by the student, complemented with a 2 hours lecture given by a QE of the hospital

Medical professionals participating in fluoroscopy guided medical procedures

- **Actions initiated by the authority:**
  - **Continuous education and training** : participation to seminars, elaboration of training material, approval of RP training programmes
  - **Use of inspections**: Elaboration of indexes for the evaluation of the RP culture, monitoring and evaluation in a systematic way of the RP culture among interventionists
- **Actions from professional associations:** specific seminars, guidelines,…
- **Work organisation** to integrate RP issues on a day-to day basis in the medical procedures
  - Internal evaluation of RP practices by the Qualified Expert.
  - Implementation of QA programmes

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Tools, methods and process to build RP culture (2/2)

Medical professionals involved in radiotherapy (RT) procedures

- **Actions initiated by the Italian Association of Medical Physics** with a multidisciplinary working group
  - Highlighting the issue of potential events of accidental high exposures through the elaboration of a **report explaining the events and causes of such events** and its presentation of the report in various places at national/regional levels
  - Proposal for **specific organisations** integrating a pro-active approach in the elaboration of RT procedures.

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

Lessons learned – Key issues in developing RP culture for medical professionals

- Importance to **identify the role of medical professionals in the radiation protection actions** associated to medical procedures giving rise to patient and/or staff exposures **to adapt the elements of RP culture needed** and the **dissemination processes**
- **Initial training is a first step** to raise awareness, but has **to be completed by continuous education**, integrating both theoretical and practical aspects.
- Stakeholders to be involved in the dissemination of RP Culture in medical field:
  - **Professional associations of the different medical specialities**: **need to engage them in E&T processes** (various ways of continuous education through symposia, or training programs) and **elaboration of guidelines** to integrate RP in their day-to-day work
  - **Authorities** acting to support the elaboration of training programmes or guidelines, as well as promoting RP through inspections.
  - **Local actors** (municipalities, universities, medical professional schools, local hospitals,..) can also play an role in initiating local actions of education an training to be disseminated at a national level

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

EUROPEAN JOINT PROGRAMME FOR THE INTEGRATION OF RADIATION PROTECTION RESEARCH

CONCERT

ENhancinG stAkeholder participation ENGAGE in the GovernancE of radiological risks

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.