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MEDIRAD project "implications of medical low-dose radiation exposure": Enhancing the protection of patients and health professionals from exposure to low-dose medical radiation

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Summary. — The EC-funded project MEDIRAD addresses numerous low-dose exposure situations for patients and workers in the medical context, to further develop risk models and draw operational recommendations for improving radiation protection. The four-year project (2017–2021) relies on a 33-partner consortium from 14 European countries and is coordinated by the European Institute for Biomedical Imaging Research (EIBIR, AT). Prof. Elisabeth Cardis (ISGlobal, ES) and Prof. Guy Frija (Université Paris Descartes, FR) are the scientific coordinator and the clinical coordinator, respectively. The MEDIRAD Project consists of six interdependent and complimentary Work Packages (WPs). WP1: project management and dissemination; WP2: dose evaluation and optimisation in medical imaging; WP3: impact of low-dose radiation exposure from I-131 radioiodine in thyroid cancer treatment; WP4: breast radiotherapy and secondary cardiovascular risks; WP5: possible health impact of paediatric scanning; WP6: bringing together medical and nuclear scientific communities for radiation protection purposes. The Italian National Institute of Health (ISS), thanks to its consolidated experience in the field of quality assurance in radiological sciences, will contribute to the latter issue coordinating a Working Group to develop recommendations on patient radiological protection, directed to the medical communities, considering the scientific outcomes of the MEDIRAD WPs and the stakeholders'comments.

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1. – Introduction

In Europe, ionising radiation exposure in the medical field represents a significant part of the total exposure of the population [1]. Diagnostic and interventional radiology expose the patient's tissues to low-dose levels; most tissues and organs outside the tumour targeted in the oncological radiotherapy (RT) receive similar dose values, or moderately higher. Promoting research in this dose range is therefore of high relevance for the continuous improvement of clinical protocols using ionising radiation. MEDIRAD moves into this direction: it addresses the need to better understand and evaluate the health effects of low-dose ionising radiation exposure from diagnostic and therapeutic imaging and from off-target effects in RT, by advancing, beyond the state-of-the-art, the scientific bases and clinical practice of radiation protection in the medical field [1-8]. MEDIRAD is supported by five European medical associations: European Association of Nuclear Medicine (EANM), European Federation of Organisations for Medical Physics (EFOMP), European Federation of Radiographer Societies (EFRS), European Society of Radiology (ESR) and the European Society for Radiotherapy and Oncology (ESTRO), and builds upon their partnership with the Multidisciplinary European Low Dose Initiative (MELODI) and the European Radiation Dosimetry Group (EURADOS), and on the Strategic Research Agendas of MELODI and the European Alliance for Medical Radiation Protection Research (EURAMED). The four-year MEDIRAD project kicked off in June 2017 and is led by the European Institute for Biomedical Imaging Research (EIBIR). The consortium brings together a wide range of multidisciplinary expertise, with 33 partners from 14 European countries (see table I), and involves research groups that focus on radiology, nuclear medicine, radiotherapy, dosimetry, epidemiology, biology, bioinformatics, modelling, radiation protection, and public health.

Such a large consortium represents a sound starting point toward a significant improvement of the interaction between the radiation protection and medical scientific communities at the European level, leading to cross-interaction of research efforts and the provision of more consolidated and robust science-based policy recommendations to decision-makers in the relevant sectors.

2. – MEDIRAD objectives and preliminary results

The MEDIRAD strategic goal is to promote an active policy to integrate radiation protection research across Europe bringing together national programs and all the relevant disciplinary fields and thus overcoming the complexities of some open scientific questions on radiation protection optimisation. This can be achieved by combining two complementary approaches: a) demonstrating the scientific added value of combining multi-disciplinary and transnational teams from both medical and nuclear (radiation protection) fields; b) demonstrating the potential of stakeholder influence in enhancing the actions aimed at improving radiation protection for patients and also medical professionals, on the basis of new scientific evidence. MEDIRAD aims to enhance the scientific bases and clinical practice of radiation protection (RP) in the medical field and thereby addresses the need to understand and evaluate the health effects of low-dose ionising radiation exposure from diagnostic and therapeutic imaging and from off-target effects in RT. MEDIRAD will pursue 3 major operational objectives through the activities of its Work Packages (WPs): first, it will improve organ dose estimation and registration to inform clinical practice, optimise doses, set recommendations and provide adequate dosimetry for clinical-epidemiological studies of the effects of medical radiation.

TABLE I. – *List of partners of the MEDIRAD consortium.*

Grant Agreement No. 755523 *Acronym* MEDIRAD

#	Participant legal Name	Country
1	Eibir Gemeinnuetzige GmbH Zur Foerderung Der Erforschung Der Biomedizinischen Bildgebung	Austria
2	Fundación Privada Instituto de Salud Global Barcelona	Spain
3	Université Paris Descartes	France
4	Panepistimio Kritis	Greece
5	The Royal Marsden National Health Service Trust	United Kingdom
6	University Medical Center Groningen	Netherlands
7	Institut De Radioprotection et de Sûreté Nucléaire	France
8	Otto-Von-Guericke-Universitaet Magdeburg	Germany
9	Instituto Politécnico de Coimbra	Portugal
10	Vastra Gotalands Lans Landsting	Sweden
11	Universitat Politécnica de Catalunya	Spain
12	Instytut Medycyny Pracy Imienia Prof. Dra Med. Jerzego Nofera W Lodzi	Poland
13	B-Com	France
14	Universitaetsmedizin der Johannes Gutenberg-Universitaet Mainz	Germany
15	Université de Genève	Switzerland
16	Helmholtz Zentrum Muenchen Deutsches Forschungszentrum Fuer Gesundheit und Umwelt GmbH	Germany
17	Studiecentrum Voor Kernenergie/Centre d'Etude de l'Energie Nucléaire	Belgium
18	Universiteit Gent	Belgium
19	Universitaetsklinikum Wuerzburg - Klinikum der Bayerischen Julius-Maximiliansuniversitat	Germany
20	Philipps Universitaet Marburg	Germany
21	Institut National de la Santé et de la Recherche Médicale	France
22	Associação para Investigação e Desenvolvimento da Faculdade De Medicina	Portugal
23	Klinikum Rechts der Isar der Technischen Universitat Munchen	Germany
24	Universita degli Studi di Roma La Sapienza	Italy
25	Imperial College London	United Kingdom
26	Vereniging Voor Christelijk Hoger Onderwijs Wetenschappelijk Onderzoek en Patientenzorg	Netherlands
27	University of Newcastle upon Tyne	United Kingdom
28	Stichting Het Nederlands Kanker Instituut-Antoni Van Leeuwenhoek Ziekenhuis	Nertherlands
29	Universitat Autònoma de Barcelona	Spain
30	Istituto Superiore di Sanità	Italy
31	University College Dublin, National University Of Ireland, Dublin	Ireland
32	Institut Claudius Regaud	France
33	Institut Català d'Oncologia	Spain

Second, it aims at evaluating and understanding the effects of medical exposures, focusing on the two major endpoints of public health relevance: cardiovascular effects of low-to-moderate doses of radiation from RT in breast cancer treatment including the understanding of mechanisms; and long-term effects on cancer risk of low doses from Computed Tomography (CT) in children. Third, it will develop science-based consensus policy recommendations for the effective protection of patients, workers and the public. The task 6.3 is responsible for the latter objective. Specifically, it will develop recommendations on the following topics:

1) standardised procedures for patient data repositories (subtask 6.3.1);

2) radiological protection of patients, aiming at the medical communities (subtask 6.3.2);

3) radiological protection of patients and worker, aiming at policy makers and competent authorities (subtask 6.3.3);

4) future radiological protection research, aiming at the research community (subtask 6.3.4).

It is worth pointing out that in this scenario of a close European synergy among the platforms MELODI, EURADOS and EURAMED, ISS has an institutional commitment to the topics of protection of health from natural and anthropogenic radiation sources of the public, the patients and the workers [9-13]. ISS has been part of the Italian Working Group (WG) for the discussion of the Proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and in other topics related to radiation protection (Directive 2013/59/EURATOM) and it is currently part of the WG for the transposition of this Directive. As a further example, since 1995, ISS has been coordinating, with a multidisciplinary approach, a quality assurance activity in radiological sciences (RT, nuclear medicine, diagnostic and interventional radiology).

ISS, as co-founding member of MELODI and partner of other European projects such as DoReMi, OPERRA and EJP CONCERT, is confident of the relevance of European research integration. It is willing to support any effort in the specific field related to the research of health effects of low dose of ionising radiation. On the basis of its recognised expertise, ISS has been invited to lead the subtask 6.3.2: *Development of a recommendation on patient radiation protection towards the medical communities.* ISS's activities will mainly deal with: i) setting-up of a multidisciplinary WG with member representatives of European clinician and medical physicist communities; ii) identifying the main criticalities/gaps in the different fields of radiological sciences, *e.g.*, radiotherapy, nuclear medicine and diagnostic and interventional radiology on the basis of the MEDIRAD WP2-3-4-5 outcomes; iii) gathering stakeholder comments by a web-based consultation; iv) developing recommendations on patient radiation protection aiming at medical professionals; and v) disseminating the recommendations to medical communities and concerned stakeholders. As several of the mentioned activities are in common with the other 6.3 subtasks, efforts have been preliminarily focused on outlining jointly a common strategy and coordinating the actions to be done. The working methodology provides for the set-up of WGs of experts from the medical and research communities. These WGs will be responsible for the development of the recommendations. Specifically, their role will be to: outline the architecture of the four recommendations by developing

a template structure; contribute to the draft short questionnaire to gather the stakeholder community expectations (expected within the end of 2018); analyse deeply the outcomes of each scientific WPs, to be translated into the recommendations (end 2019); draft the first version of the recommendations taking into account the collected information (survey results and WPs outcomes) (first half of 2020); formulate the final version of each recommendation taking into account feedback from stakeholders, gathered through a web-consultation (end 2020).

At present, the subtask 6.3.2 has identified people from all the WPs to provide scientific relevant outcomes for discussion within the WG as main topics of recommendations. Currently, the subtasks 6.3.1–4 are outlining the architecture of the recommendations by developing a structure template. The text of the recommendation will be adapted to a common pattern for all MEDIRAD recommendations. It will provide synthetic information about the EURATOM research and development program, about MEDIRAD, and about the recommendation development process, including the stakeholder consultation. The scope of the recommendations and the problems addressed have to be clearly indicated. This text will list all considerations and it will represent a synthesis built upon three sources of information: i) the policy makers' point of view (based on EURATOM policy and MEDIRAD objectives); ii) the users' point of view (based on stakeholder concerns, expectations and comments); and iii) a scientific point of view (based on scientific goals and research results). Where appropriate, the recommendation documents will also refer explicitly to relevant and important background documents, such as EURATOM directives, IAEA standards or ICRP recommendations. The text will report the recommendations based on the outcomes of the four-year MEDIRAD project and on the WPs 2–5 outcomes together with the stakeholder comments gathered by the e-survey. One paragraph for each item of recommendation will be presented, making the scope of each item as explicit as possible, including limits or precautions if justified, and the recommendation contents as practical as possible, taking care of analysing any possible regulatory or EURATOM policy impact.

In December 2019 the first draft of the task 6.3 recommendations will be available for download from the MEDIRAD project web share point for stakeholder consultation. The text has to highlight outcomes of the stakeholder consultation process to demonstrate how the conclusions reached by the MEDIRAD consortium were discussed and enriched through a consultative process that gives additional weight to the recommendation contents.

3. – Work in progress

The WG led by ISS will contribute to drafting a short questionnaire to gather the stakeholder communities' expectations. This activity will be discussed during the "3rd European Radiological Protection Research Week" in Rovinj, Croatia, in October 2018 and should be finalised by the end of 2018. In-depth analysis of the outcomes of each scientific WP, to be translated into recommendations, will be performed by the end of 2019. Then, the draft first version of the recommendations that takes into account the collected information (survey results and WPs outcomes) will be due within the first half of 2020. The WG will formulate the final version of recommendations taking into account feedback from concerned stakeholders, gathered through a web-consultation (end 2020). Finally, recommendations will be openly disseminated to the scientific community and will be publicly available.

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