MEDIRAD

Project title: Implications of Medical Low Dose Radiation Exposure

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Topic: NFRP-9

Deliverable D6.4

Third Stakeholder Board Annual Report

Lead partner:	IRSN
Author(s):	Jacques Repussard, Marc Benderitter
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Abbreviations

SF: MEDIRAD Stakeholder Forum

SHB: MEDIRAD Stakeholder Board

WP: Work Package

1. Introduction

MEDIRAD WP6 aims to transfer the operational results reached by the MEDIRAD project to a wider community (researchers, practitioners, authorities, stakeholders), by seeking consensus on proposed recommendations, lessons learnt and solutions. It relies on the extensive networks of the European medical associations and of the MELODI and EURADOS associations, which are brought together into the so-called MEDIRAD Stakeholder Board (SHB).

According to the MEDIRAD Grant Agreement, the SHB will (i) support the coordination of the MEDIRAD stakeholder related activities, (ii) formulate proposals on the composition of the Stakeholder Forum (SF), (iii) advise on the design and content of the web-based stakeholder consultation, (iv) contribute in an advisory role to the development of the MEDIRAD recommendations, (v) give views and thoughts on the most suitable ways to ensuring appropriate promotion and dissemination of the MEDIRAD outcomes to concerned stakeholders.

The first year of the MEDIRAD project (1 June 2017-31 May 2018) was devoted to the identification of the MEDIRAD SHB members and its chair, to the drafting of its terms of reference and the organisation of its first annual meeting. See MEDIRAD deliverable D6.2 for detailed information.

The second period (June 2018 – March 2019) was devoted to the setting up of the stakeholder consultation infrastructure, to the establishment of the SF membership, and to the development of the first questionnaire to SF members, based on an initial list of themes for future MEDIRAD recommendations, as identified by the MEDIRAD research work packages (WP) 2-5. See MEDIRAD deliverable D6.3 for detailed information.

This report summarises the activities related to MEDIRAD stakeholders for the period April 2019 to November 2020, when SHB held its third annual meeting, which was organised as an online meeting due to current COVID-19 pandemic. The report also presents the next steps of the stakeholder related activity for the last period of the MEDIRAD project.

2. MEDIRAD Stakeholder activities during the period April 2019 to November 2020

2.1. Finalisation of the SF constitution

Deliverable D6.3 (Second Annual Report of the Stakeholder Board) described the state of development of the MEDIRAD SF as almost complete in March 2019, with over 70 positive responses for participation out of 150 organisations which were contacted. This process was consolidated over the next months, and the final list of SF members currently consists of 85 organisations (see Annex 1).

The geographical distribution of the 150 identified candidates resulted from the collection of information from MEDIRAD consortium members, and was not homogeneous, as can be seen in Figure 1 below. However, the responses did not follow the same density pattern, as can also be seen in this figure. Nevertheless, considering the participation of several pan-European organisations, as well as of some non-European organisations, the distribution of SF members is best analysed from the point of view of the profession of its members, as can be seen on the right-hand side of the figure. The preponderance of medical doctors and medical physicists reflects the strong interest of the “user community” of MEDIRAD research for the improvement of radiological protection of patients and medical professionals, and as such makes the SF a most valuable component of the MEDIRAD project.

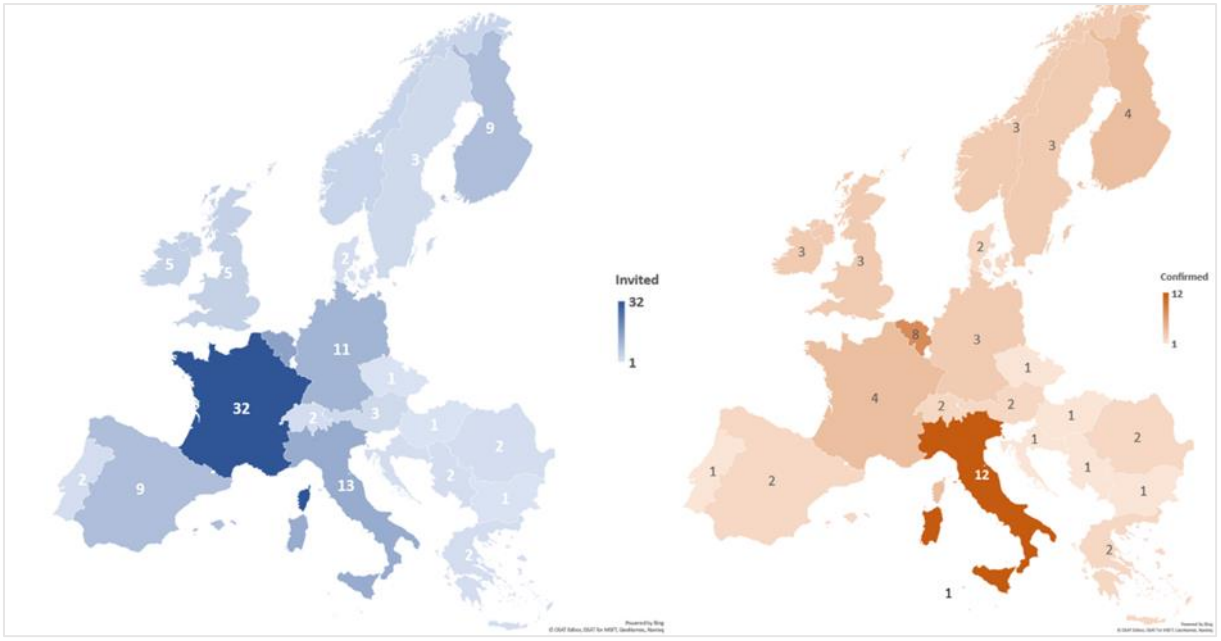

Figure 1: Geographical distribution

Notes: Left: Number of national stakeholders invited and its distribution in Europe (blue).
Right: Number of national stakeholders confirmed and its distribution in Europe (orange).

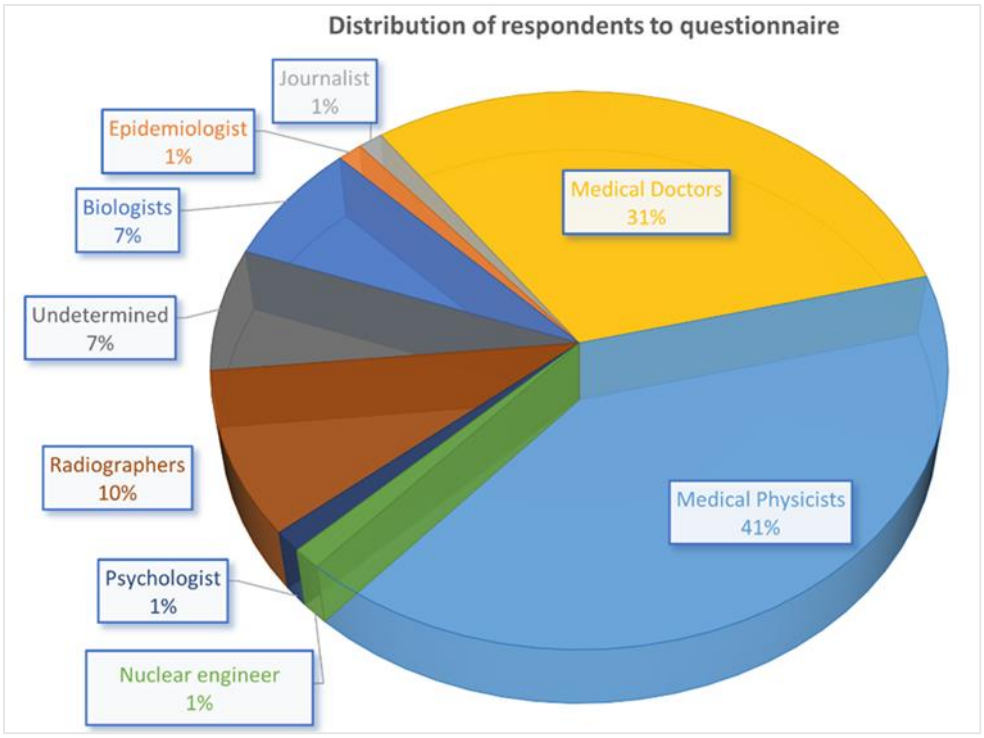

Figure 2: Professions of respondents

Note: Distribution of respondents to the questionnaire according to their professions, based on public information available on the internet.

It is also worth noting that SF members, in their majority, agreed to have their names and that of their organisation quoted in reference to the development process of the MEDIRAD recommendations. This will add to the influence of these recommendations, once published, among the concerned professional communities across Europe and beyond.

2.2. First and second questionnaire for SF consultation

The two questionnaires were developed consecutively, the second one complementing the first one on themes related to radiation oncology, which were not fully investigated through the first questionnaire. They were drafted by the SHB Chair, WP6 Leader and Task 6.3 Working Group Chair based on proposals for potential topics for MEDIRAD foreseen recommendations made by MEDIRAD WPs 2- 5. The draft questionnaires were then submitted for consultation to the SHB members, and finally for approval to the MEDIRAD Coordinators and MEDIRAD Executive Board.

The questionnaires were provided to the SF via the IT infrastructure operated by consortium member SCK•CEN. All 85 SF members responded to the questionnaires, after several reminders sent out by EIBIR to collect missing answers.

2.3. Analysis of SF consultation results

Many SF members took advantage of the possibility to include full text comments to each question. The consultation was therefore particularly rich, beyond the simple hierarchisation of the proposed topics. An in-depth analysis was therefore performed for each question by statistical analysis experts at IRSN, and then the results were merged into a single analysis report. This merger was justified in the sense that some of the questions from the second questionnaire were overlapping or going into more detail compared to some of the questions raised in the first questionnaire. This analysis report was approved by the WP6 Lead in November 2020 and is provided in Annex 5 of this report.

The combination of a quantitative and qualitative analysis resulted in the clear identification of 11 priorities expressed by SF members, as shown in Figure 3 below. These 11 selected priorities regroup topics, which attracted consistent opinions in their ranking through the questionnaires, as shown in the graph below (green and blue lines).

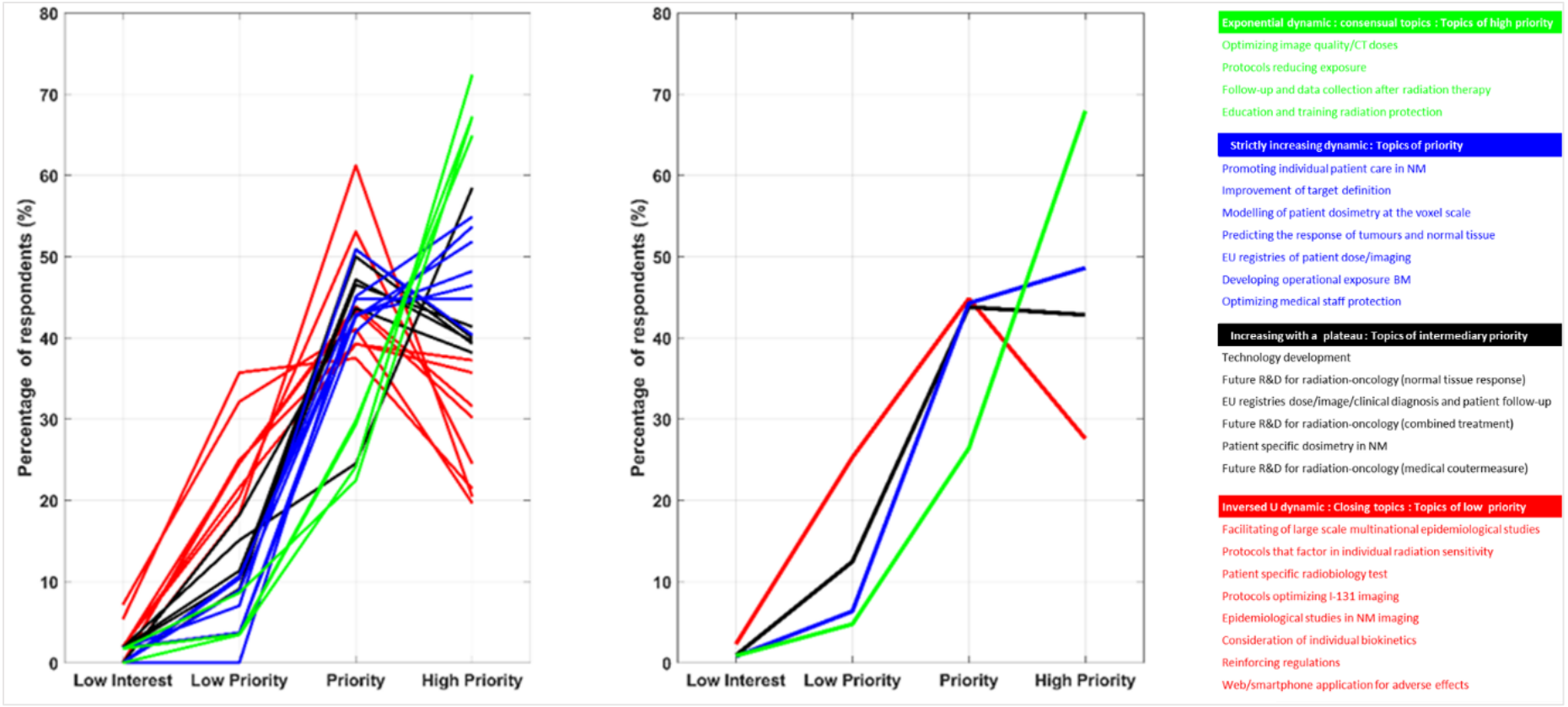

Figure 3: Item profiles grouped according to the clustering based on the global priority scoring

Notes: *Left: The graph clustering with all the variables (items) and their different patterns.*
Middle: Cluster centroids (central tendency within each cluster).
Right: the variables analysed and classified by priority (names were shortened).

The eleven priority topics are as follows:

1) Optimising image quality / dose during CT scans, including multimodality imaging procedures (e.g. SPECT-CT and PET-CT-scans)
2) Improved protocols aimed at reducing exposure whilst preserving or improving diagnostic quality/therapeutic benefits (e.g. better accounting of potential secondary or late effects of healthy tissue exposure
3) Optimising patient follow-up care after radiation therapy and collecting valuable epidemiological data through a better linkage of medical professionals from relevant disciplines
4) Increasing education and training of medical professionals on radiation protection optimisation
5) Promoting individualised patient care in nuclear medicine. Procedure for evaluating patient-specific doses delivered to volumes and organs through activity uptake
6) Improvement of target definition (of radiotherapy irradiation protocols) by better delineation of the target volume, better margins definition and better definition of the heterogeneity and of the biological volumes of the tumours at the voxel scale.
7) Modelling of patient dosimetry at the voxel scale (radiotherapy)
8) Predicting quickly and accurately the response of tumours and normal tissue to ionizing radiation using new multimodal and functional imaging and/or new biological and molecular surrogates.
9) Development of EU registries of patient dose/imaging, with recommended appropriate quantities for radiological examinations.
10) Development and validation of operational biomarkers.
11) Optimising medical staff protection

These expressed priorities were presented to the SHB members at their third meeting and will be integrated with the proposals resulting from MEDIRAD research, through the consortium's work packages 2-5, in order to draft the 4 recommendation documents, which are expected as deliverables D6.5-D6.8.

The analysis report has also been sent to the SF members, as feedback following the consultation.

2.4. SHB members interface with MEDIRAD research activities

SHB members were invited to attend the online full meeting of the MEDIRAD consortium which was organised in September 2020 following the cancellation of the event initially planned to take place in Lisbon in spring 2020. This meeting provided the SHB members with detailed information about the progress of MEDIRAD research. At the SHB meeting in November 2020, each WP leader also presented a summary of their research undertakings and answered questions from SHB members. Finally, the SHB members will also be invited to attend the next full meeting of the MEDIRAD consortium organised in 2021.

2.5. Third SHB meeting, 19 November 2020

This meeting was held online, due to public health constraints applicable across Europe at the time related to the COVID-19 pandemic. It was attended by ten SHB members, by the MEDIRAD coordination team, representatives of every WP of the MEDIRAD consortium and members of the working group of task 6.3 (see Annex 4) responsible for the drafting of the MEDIRAD recommendations.

The agenda and draft meeting minutes are available in Annexes 2 and 3.

The participants were as follows:

Stakeholder Board members: K. Dieckmann, P. Gilligan, G. Glatting, C. Hoeschen, Z. Knezevic, R. Loose, M. Perez, J. Repussard, S. Salomaa, A. Widmark

MEDIRAD consortium: M. Benderitter, E. Cardis, R. Coppes, J. Damilakis, C. De Angelis, S. Della Monaca, V. Dini, G. Flux, S. Foley, G. Frija, S. Grande, M. Lassmann, U. Mayerhofer-Sebera, J. McNulty, A. Palma, G. Paulo, A. Rosi, I. Thierry-Chef, F. Vanhavere

It can be noted that ESTRO designated a new representative to SHB, Dr. Karin Dieckmann, in replacement of Dr. Wolfgang Doerr, and that there were for the second time no representative of patients' associations, although numerous attempts were made by EIBIR (WP1), in coordination with the SHB Chair, to draw the attention of the European Patients Association (EPF) which had initially accepted to be represented in SHB about the importance of their contribution to this project.

The meeting validated the analysis of the responses to the SF questionnaires, in terms of priorities from the concerned medical communities. It took note of the list of topics that MEDIRAD WP's have proposed to be addressed in the recommendations, in the light of expected research results. Three members of the task 6.3 working group responsible for the initial drafting of recommendations presented the work done so far to prepare elements of recommendations for three of these topics: 1) characterisation of non-conventional medical staff radiation shielding equipment; 2) issues related to the impact on research of implementation of GDPR European legislation; and 3) development of patients' dose repositories. Following these presentations, the SHB recommended that the recommendations be drafted in such a way as to address identified end user priority expectations, with "actionable" and concrete suggestions.

The meeting also approved the revised timeline for the development of the MEDIRAD recommendations, including the further stakeholder consultation steps, as indicated below:

Action	Responsibilities	Timeline
Drafting of technical components of recommendations (based on Excel Table)	WG 6.3	Until March 2021
Validation of technical components contents	WP6, Coordination team	End March 2021
Assembly into 4 draft recommendations with common format	WG 6.3	April 2021
Consultation of MEDIRAD & stakeholders	WP6 & 1, SHB, SF	May/June 2021
Revision of draft recommendations on basis of consultation results	WP6	July-Sept 2021
Validation and diffusion of drafts to participants of seminars	WP6 & 1, Coordination team	Oct 2021
MEDIRAD Seminars	WP6 & 1	Nov 2021
Finalisation of recommendations & approval as MEDIRAD deliverables	WP6, Coordination team	Jan 2022

Table 1: MEDIRAD recommendations timeline

Finally, the SHB members agreed to meet again in September 2021, through an online session, in order to review the texts of recommendations that will be proposed for the two MEDIRAD seminars that will be organised in October/November 2021.

3. Deviations from the revised MEDIRAD workplan

The tables below show revised workplan (deliverables & milestones) of WP6 adopted in 2019 as a result from the 9-month prolongation of the MEDIRAD Grant Agreement. The COVID-19 pandemic has impacted research in several areas of the MEDIRAD project, and has forced to rely only on online meetings to coordinate ongoing work. Therefore, it was agreed to delay the deliverables D6.4-D6.8 by one month. It is not anticipated to propose further deviations to this workplan. In fact, it is foreseen to prepare the draft versions of D6.4-D6.8 earlier (see Table 1) in order to be able to incorporate the results of the two seminars into the final versions of the four recommendation documents, which will be submitted to the European Commission for approval in project month 56.

No	Title	Lead	Due date
D6.1	First Stakeholder Board annual report	IRSN	M12
D6.2	Report on the Stakeholder Forum: composition, content of the web-consultation, guidelines for the use of the stakeholder infrastructure	SCK•CEN	M12
D6.3	Second Stakeholder Board annual report	IRSN	M24
D6.4	Third Stakeholder Board annual report	IRSN	M43
D6.5	MEDIRAD First Recommendations	UCD	M55 > M56
D6.6	MEDIRAD Second Recommendations	ISS	M55 > M56
D6.7	MEDIRAD Third Recommendations	SCK•CEN	M55 > M56
D6.8	MEDIRAD Fourth Recommendations	IRSN	M55 > M56
D6.9	Report on the organization and findings of the two seminars organized within Task 6.4	IRSN	M57

Table 2: WP6 deliverables

No	Milestone	Lead	Due date	Means of verification
MS9	Stakeholder Board established	EIBIR	M6	Publicly available member list and TORs
MS11	Development of stakeholder survey	SCK•CEN	M8	Content of the survey finalized
MS31	Recommendation Working Groups	SCK•CEN	M24	Working Groups operational
MS21	Stakeholder Forum	SCK•CEN	M28	Online forum operational with publicly available participant list

MS51	Dissemination seminars	IRSN	M56	Detailed agendas of seminars available and list of participants decided

Table 3: WP6 milestones

Although the formal workplan does not foresee more than 3 annual meetings of SHB, it has been agreed that one or possibly two further online meetings should be organised to supervise the recommendations' elaboration process. These additional meetings, which would be organised respectively before and after the two MEDIRAD seminars, will not incur any significant costs to MEDIRAD budget.

As for the seminars, it is envisaged that, subject to public health rules at the time, they will be organised with a combination of a physically present attendance, respectively in Brussels or Luxembourg and in Barcelona, and of an additional online audience, thus maximising the impact of these events. It now appears possible and preferable to organise them in October/November 2021, rather than January 2022, to make some time and resources available to finalise the recommendations, taking into account the remarks and suggestions made at the seminars.

4. Next steps

4.1 Development of MEDIRAD Recommendations

As shown in the figure below, the recommendations will combine information from three complementary sources. Materials for sources 1 & 3 are available. For source 2, what is currently available, is a detailed list of 14 topics proposed by the WP leaders. These topics have been validated by WP6 and SHB as relevant with respect to stakeholder priorities. A responsible WP6 expert has been nominated for each topic, and a "corresponding expert" in the research WPs 2-5 of MEDIRAD will be appointed.

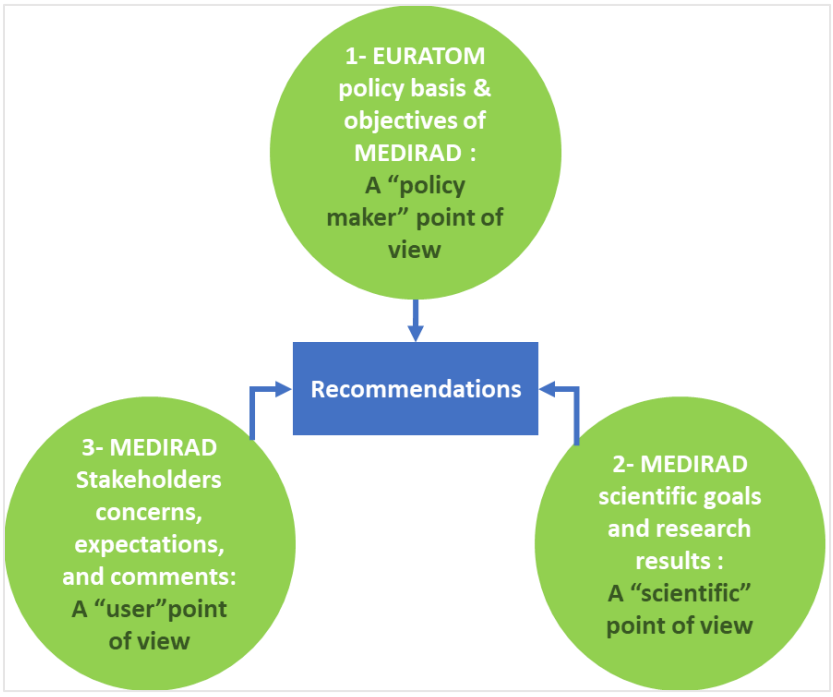

Figure 4: Sources of information

The general format of the recommendations has also been approved in principle by SHB and by WP6 members.

On this basis, the drafting of recommendations will take place in three consecutive steps:

1) Each of the 14 topics (some may be merged along the process) will be further developed as a component of the future recommendation documents. The main task will be to elaborate short draft "actionable messages" addressing one or more of the 4 target groups of the recommendations, and to identify more precisely which MEDIRAD research results (and if useful concurrent results from other sources) can be used to justify the proposed messages. This first step should be finalised by the end March 2021. The list of "actionable messages" will then be reviewed by the members of WP6, the SHB and the MEDIRAD Executive Board, and adjusted where needed by the task 6.3 working group.
2) Once this first step is completed, the assembly of messages into the four draft recommendations, according to the approved format, will start within the task 6.3 working group. Once mature, the drafts will be submitted to MEDIRAD stakeholders (SHB & SF members), and to the project consortium. The comments received will lead to an adjustment of the draft recommendations, which will then be released as working documents for the two MEDIRAD seminars.
3) Finally, WP6 will review comments received at the seminars, and prepare a final version of the recommendations for approval by the MEDIRAD Executive Board and submission to the European Commission as formal deliverables. After approval by the European Commission, these recommendation documents will be released publicly and promoted towards the key target groups of MEDIRAD.

4.2 Planning for the MEDIRAD Seminars

It is foreseen to organise one of the seminars in Brussels or Luxembourg, targeted to competent authorities in particular, and the other one in Barcelona, targeted to the research community. End users (medical communities, radiation protection specialists, patient associations) will have an interest in both events. Attendance will be either through physical presence (subject to public health rules at the time, last quarter 2021), or online.

Correspondence with SHB and SF members will be initiated in due course to promote the events and ensure that concerned stakeholders will have the opportunity to attend at least one of the seminars.

A first meeting dedicated to the organisation of the seminars will be organised in January 2021 to agree on dates and locations for both events, and to draw up an action list for preparatory tasks.

4.3 Supplementary SHB Meeting(s)

It is envisaged to organise a supplementary SHB meeting shortly before the seminars, to review the draft texts of recommendations, as well as the detailed organisation of the seminars, to optimise stakeholder contributions.

It could be further envisaged to hold a last meeting, after the seminars, to review the elaboration of the final texts of recommendations, and to discuss avenues towards their dissemination towards key target groups.

As such meetings are not currently foreseen in the MEDIRAD workplan, their organisation (probably as online meetings) however depends on the availability of resources at WP6 level, and on the availability of SHB members.

Finally, as mentioned above, SHB members should be also invited to attend the general meeting(s) of the MEDIRAD consortium in 2021.

5. Conclusion

MEDIRAD research is attracting considerable interest from key stakeholder groups, in particular among medical professionals. This is demonstrated by the successful implementation of the MEDIRAD Stakeholder Forum, its broad membership representing a large array of professional organisations across Europe and worldwide. This signals the importance of the central goal of the MEDIRAD project, to bring together the medical and radiation protection research communities towards further optimisation of radiation protection in the medical environment.

The responses to the two questionnaires about stakeholder priorities for new actions to reinforce radiation protection in the medical field allowed to clearly identify 11 priorities among those proposed in the questionnaires.

On this basis, the drafting of the first elements of the technical topics identified by MEDIRAD research, which will be included in the recommendation documents, has started. MEDIRAD WP6 will dedicate the first half of 2021 to the elaboration of the draft 4 recommendations that will be presented to MEDIRAD stakeholders at 2 seminars, to be held in the last quarter of 2021.

Annexes

Annex 1: SF membership list

MEDIRAD Stakeholder	Representative
Associazione Italiana di Fisica Medica (AIFM)	Annalisa Trianni
Associazione Italiana di Medicina Nucleare (AIMN)	Massimo Salvatori
Associazione Italiana di Radioprotezione Medica (AIRM)	Giulia Castellani
Associazione Italiana di Radioterapia ed Oncologia Clinica (AIRO)	Stefano Pergolizzi
Associazione Italiana di Radioprotezione (AIRP)	Paolo Ferrari
Azienda Sanitaria Local des Provincia di Barletta (ASL BT)	Samantha Cornacchia
Associacao Portuguesa dos Tecnicos de Radiologia (ATARP)	Ana Geão
Bundesamt fur Strahlenschutz (BfS)	Griebel, Juergen
Biobank of Eastern Finland	Jaana Hartikainen
Bulgarian Society for Biomedical Physics and Engineering (BSBPE)	Desislava Kostova-Lefterova
Commissariat à l'énergie atomique et aux énergies alternatives (CEA)	Sylvie Chevillard
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)	Werner Jaschke
Croatian Society of Radiology	Jelena Popic
Czech Association of Medical Physicists	Lucie Sukupova
Danish Health Authority	Anders Ravnsborg Beierholm
Deutsche Gesellschaft für Biologische Strahlenforschung e. V. (DeGBS)	Udo Gaipl
European Federation of Radiographer Societies (EFRS) International Society of Radiographers and Radiological Technologists (ISRRT)	Haakon Hjemly
European Nuclear Education Network (ENEN) Hungarian Society of Medical Physics (HSMP)	Csilla Pesznyak
European Organisation for Research and Treatment of Cancer (EORTC)	Luc Bidaut
European Society of Radiology - Patient Advisory Group (ESR PAG)	Birgit Bauer
European Society of Radiology (ESR)	Franz Kainberger
European Nuclear Education Network (ENEN)	Gabriel Pavel
EuroSafe Imaging	Claudio Granata
European Society of Medical Imaging Informatics (Eusomii)	Federica Zanca
Federal Agency for Nuclear Control (FANC)	Sylviane Carbonnelle
Tecnici sanitari di radiologia medica, delle professioni sanitarie tecniche, della riabilitazione e della prevenzione (TSRM PSTRP)	Chiara Martini
Finnish advisory committee for clinical audit	Tanja Skyttä
Institut National du Cancer (INCA)	Laetitia Gambotti
GISE Italian Society of Interventional Cardiology	Emanuela Piccaluga
Greek Atomic Energy Commission	Christos Pafilis
Head of the European Radiological ¨Protection Competent Authorities (HERCA)	Alexandra Karoussou-Schreiner
Hôpital Lariboisière-Assistance Publique – Hôpitaux de Paris (APHP)	Lama Hadid
International Atomic Energy Agency (IAEA)	Jenia Vassileva
International Atomic Energy Agency (IAEA)	Ola Holmberg
International Agency for Research on Cancer (IARC)	Joachim Schüz

Commission on Radiological Protection (ICRP)	Kimberly Applegate
Irish Institute of Radiography and Radiation Therapy (IIRRT)	Elizabeth Forde
Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro (INAIL)	Francesco Campanella
International Society of Radiology (ISR)	Luis Donoso
International Organisation for Medical Physics (IOMP)	Madan M Rehani
Iridium	Paul Meijnders
Iridium Network	Dirk Verellen
Irish Institute of Radiography and Radiation Therapy	Dean Harper
International Radiation Protection Association (IRPA)	Marie Claire Cantone
King's College London	Professor Bijan Modarai
Konstantopouleio	Konstantina Paraskeva
Kuopio University Hospital, Finland	Jan Seppälä
National Cancer Institute (NCI)	Jonas Venius
Medical University Graz	Erich Sorantin
Nordic Association for Clinical Physics (NACP)	Anders Tingberg
World Health Organization – Non Governmental Organization (WHO NGO) network of patients for patient safety	Mohammed M. Albaadani
Norwegian Radiation and Nuclear Safety Authority	Turi Danielsen
Patient for Patients Safety Australia	Stephanie Newell
Patient for Patients Safety Malaysia	Manvir Victor
Patient Safety Foundation and World Patients Alliance	Jolanta Ewa Bilinska
Plataforma Nacional de I+D en Protección Radiológica (PEPRI)	Alegria Montoro Pastor
Radiation Protection Officers working group on the West Coast of Norway	Evabeth Roseth Bruvoll
RadioTransNet	Bayart Emilie
Romanian College of Medical Physicists (CFMR)	Marin Bodale
Romanian Society of Nuclear Medicine and Molecular Imaging	Cirpiana Stefanescu
Sociedad Espanola de Oncologia Radioterapica (SEOR)	Paula Peleteiro
Italian Society of Medical and Interventional Radiology (SIRM)	Antonio Orlacchio
Société Française de radiologie (SFR)	Jean-Francois Chateil
Society for Medical Physics	Heidi S. Rønde
German Commission on Radiation Protection	Anna Friedl
St James Hospital	Michael Rowan
Superior Health Council	Marie-Thérèse Hoornaert
Svenska Sjukhusfysikerförbundet	Ulrika Svanholm
Swedish Radiation Safety Authority	Anja Almén
Swiss Society of Radiobiology and Medical Physics	Marta Sans Merce
Swiss Society of Radiobiology and Medical Physics	Michael Fix
The Society & College of Radiographers	Maria Murray
U.S. Food and Drug Administration (FDA)	Donald Miller
Undetermined	Hilde Bosmans
University of Arkansas for Medical Sciences	Rupak Pathak
University of California, Irvine	Charles Limoli
University of Eastern Finland	Jaana Hartikainen
University of Gent	Stefaan Vandenberghe
University Hospital of Gent	Geert Pittomvils

University Hospital of Saint Luc	F Vanneste
University of Malta	Francis Zarb
University of Padova	Biagio Castaldi
University of Salford	Andrew England
University of Umea	Katarina Westberg
Institute of Nuclear Sciences	Olivera Ciraj Bjelac

Annex 2: Agenda of the third MEDIRAD SHB meeting

MEDIRAD Stakeholder Board online meeting

19 November 2020, 9:00-13:00 CET

Agenda

9:00-9:10: Opening of the meeting, introduction of SHB members, and adoption of the agenda (J. Repussard)
9:10-9:15: Approval of minutes from previous meeting in Vienna (March 2019) (J. Repussard)
9:15-9:45: Brief update on MEDIRAD project progress (5min each) • Short project introduction (M. Benderitter) • WP2 (J. Damilakis) • WP3 (G. Flux) • WP4 (R. Coppes) • WP5 (I. Thierry-Chef)
9:45-10:30: Presentation of the Stakeholder Forum consultations results (J. Repussard, M. Benderitter) • Presentation of SF membership • Presentation of the 2 questionnaires • Results of consultations and top priorities topics for recommendations
10:30-10:45: Coffee break
10:45-12:45: Elaboration of MEDIRAD Recommendations (J. Repussard, F. Vanhavere) • Development timeline • Proposals of MEDIRAD WP's for recommendation contents • Update on ongoing Task 6.3 • Proposed structure for MEDIRAD recommendations • Presentation of three draft recommendations • Planning for SHB & SF consultation on draft recommendations • Discussion
12:45-13:00: AOB, next meeting, closure of the meeting (J. Repussard, M. Benderitter)

Annex 3: Draft minutes of the third MEDIRAD SHB meeting

MEDIRAD Stakeholder Board online meeting

19 November 2020, 9:00-11:45 CET

Participants:

Stakeholder Board members: K. Dieckmann, P. Gilligan, G. Glatting, C. Hoeschen, Z. Knezevic, R. Loose, M. Perez, J. Repussard, S. Salomaa, A. Widmark

MEDIRAD consortium: M. Benderitter, E. Cardis, R. Coppes, J. Damilakis, C. De Angelis, S. Della Monaca, V. Dini, G. Flux, S. Foley, G. Frija, S. Grande, M. Lassmann, U. Mayerhofer-Sebera, J. McNulty, A. Palma, G. Paulo, A. Rosi, I. Thierry-Chef, F. Vanhavere

Summary

1. Opening of the meeting, introduction of SHB members, and adoption of the agenda (J. Repussard)

J. Repussard welcomes all meeting attendees, who agree on the agenda as presented to them.

He summarises that this is the 3rd meeting of the Stakeholder Board (SHB). It was initially scheduled in Lisbon in May, but due to the COVID-19 pandemic it was postponed and finally organised as an online meeting. The 1st SHB meeting was held in Rome in April 2018, and the 2nd one in Vienna in March 2019. He indicates that according to the project proposal three meetings of the SHB should be organised. However, J. Repussard proposes organising 1-2 additional online meetings before the end of the project to conclude the SHB's work. This is agreed by E. Cardis and G. Frija.

2. Approval of minutes from previous meeting in Vienna (March 2019) (J. Repussard)

The present SHB members approve the minutes unanimously.

3. Brief update on MEDIRAD project progress (5min each)

3.1 Short project introduction (M. Benderitter)

M. Benderitter provides a short overview of the MEDIRAD project and indicates that the recommendation documents will be among the main deliverables. The MEDIRAD research results and expectations and priorities of the SHB and the Stakeholder Forum (SF) will be reflected in the envisaged four recommendation documents.

3.2 WP2 (J. Damilakis)

J. Damilakis summarises the progress of work from WP2 tasks.

1. Development of a novel tool for the optimisation of chest CT examinations: recent activities include image data uploading for subjective image quality assessment; objective image quality assessment activities are also ongoing. At the University of Crete, CT exams were collected, and patient models created. A method was developed for organ dose estimations for CT examinations. The software tools on radiation dose and on image quality are currently finalised.

2. Optimisation of fluoroscopically-guided procedures: Monte Carlo calculations for cardiac ablation procedures were finished on six mathematical chest phantoms. As regards real-time dose monitoring in fluoroscopically-guided procedures, it was verified that the MC-GPU code provides good estimates of the dose when compared to the Penelope Monte Carlo programme. Complex procedures should be simulated with several projections too.

3. Hybrid imaging: DRLs for specific applications for CT in hybrid imaging were established. There is an issue with the estimation of organ doses from two PET and SPECT tracers, as it was not possible to recruit any patients yet for various reasons. However, alternatives have just been discussed with the European Commission and the Scientific Advisory Board, and the relevant steps will be taken.

4. Dose biobank: Bugs are being corrected, and collaboration with WP3 is ongoing.

3.3 WP3 (G. Flux)

G. Flux provides a summary of the five tasks.

1. A clinical study to assess radiation doses delivered to patients undergoing radioiodine treatment for low or intermediate risks for thyroid cancer is ongoing in four centres. However, activities are currently a bit delayed due to the COVID-19 pandemic, but still 88 (out of 100) patients were recruited so far. It is planned to complete recruitment by the end of the year.

2. Dosimetry work is nicely underway, and the database is up and running for a few weeks. Different techniques for dosimetry are being compared in Toulouse now.

3. The biokinetic modelling is largely in place. The model is applied to other data already.

4. The biomarkers work in Würzburg is on target, and nice results coming out there.

5. Recommendations for conducting a large-scale epidemiology study in Europe will be prepared in Newcastle.

3.4 WP4 (R. Coppes)

R. Coppes summarises the WP4 activities.

1. Cardiovascular side effects of breast radiation therapy: 2 clinical trials are performed: 1. The prospective EARLY-HEART study looks at the dose to delivered to the heart. All patients were included, and the analysis is ongoing. Blood samples are sent to WP2 for analysis too. 2. The retrospective BRACE study is dedicated to patients treated for breast cancer. Thousands of patients were included; it is the largest study so far in this area. A predictive model was developed from the data based on some specific parameters, e.g. dose to left ventricle. The work was presented at the recent ASTRO meeting. However, as the first model was only based on data from Groningen, it is now validated with data from other institutes.

2. Biology and irradiation of animals: A lot of parameters were measured, and biomarkers related to cardiotoxicity were determined. They are not very predictive on their own, but a multi-biomarkers approach could be helpful for this. This will be verified in another animal model too.

3. Modelling: Models were already developed and published. Now, input from biology and biomarkers is gathered and put in this model to try to make a final predictive model for cardiotoxicity.

3.5 WP5 (I. Thierry-Chef)

I. Thierry-Chef introduces that the WP5 is divided into two main activities.

The follow-up of paediatric CT cohorts in France, the Netherlands, Spain, and the UK. The follow-up is completed in France and in the Netherlands. Unfortunately, the last signature in the UK is still missing, and they are in very close contact with hospitals in Spain to get information from them. In addition, Sweden was included, but they are currently waiting for the legal documents to be signed. Some work on dosimetry is performed too. In this regard, a literature review on CT technology advances in last 8-10 years is conducted. The material can be used for contributing to the recommendations on optimisation.

The case-control-study faces major difficulties in contacting cases and controls due to the COVID-19 pandemic because health offices are overwhelmed with work related to the pandemic. The work progressed a bit in Sweden, as they got information on the medical files directly. The analysis is currently under way. Activities on biomarkers are pending, as they are waiting for samples, but preparatory work has already been done, e.g. to optimise the analysis framework. This can also contribute to a recommendation on biomarkers of radiosensitivity.

4. Presentation of the Stakeholder Forum consultations results (J. Repussard, M. Benderitter)

J. Repussard reminds that the SHB supported the establishment and organisation of the SF, which is an extended list of partners, to be consulted in the process of the development of the recommendation documents. Over 150 organisations were contacted in Europe and worldwide, and over 80 positive replies were received. Based on the input from the WPs, a 1st questionnaire was developed to gather the SF's interests and expectations on the proposed topics for the recommendations. A 2nd questionnaire was prepared later, as the 1st one was lacking specific radiation oncology topics. Both questionnaires were successful and had high response rates.

M. Benderitter introduces that 85 of 86 SF members responded to the questionnaires and that the respondents showed a good coverage in terms of disciplines and targeted competences. More specifically, the respondents were medical doctors (31%), medical physicists (41%) and others from different fields, like radiographers, biologists, epidemiologists, nuclear engineer, etc. 59% of the SF participants confirmed their willingness to be referenced in the final recommendation reports.

The questionnaire was split into 2 main parts: 1. Priorities toward optimizing patient care and medical professional's protection in the context of radiological diagnostics and radiation-based therapies; 2. Priorities of potential topics for MEDIRAD recommendations. The 2nd part was more technical and included 20 topics covering 4 different fields (radiology & medical imaging; nuclear medicine; radiation oncology; radiology & epidemiology).

M. Benderitter provides an overview of the main results. He explains that the questions were analysed for their priorities. Four main categories turned out: green = high priority; blue = medium priority; black = low priority; red = very low priority. In total, 11 topics with high and medium priority were identified. They were related to the relevant topics for recommendations.

Each question received around 5-10 comments from the respondents. Therefore, a qualitative analysis of the open comments was performed too for the 11 top priority topics.

Currently, work is ongoing to finalise the report, as the results from the 2nd questionnaire still must be included. The final report will be shared with the SHB as soon as available.

J. Repussard points out that the responses were very rich and therefore the full analysis of the text provides a lot of input for the recommendations. He adds that the SF is extremely representative, as most European and national organisations of interest to the radiation protection community are represented. This will also guarantee a lot of attention for the final recommendations.

C. Hoeschen agrees that we should take advantage of the number of open answers. However, we should be careful in the evaluation, as not everybody filled a lot of text, and therefore the open answers might distort the results. He points out that we should not exclude topics because they were not mentioned in the comments. M. Benderitter explains that they tried to take best advantage to use all available data. However, this information will be implemented in the reflections and considered as complementary information.

C. Hoeschen asks if the surveys were also analysed separately for the different professions, as they might have different priorities. M. Benderitter points out that mainly MDs and MPs replied to the questionnaires and therefore the priorities mainly reflect their views. M. Benderitter shows an analysis of the different professions, which indeed indicates slight differences in the ranking of the priorities. J. Repussard adds that the SF as a whole is quite representative, but the interests are certainly different, and the views are not homogenous. The results show what is expected by the overall community, and as the recommendations should be useful in the real world, we should pay attention to expressed priority needs and expectations.

C. Hoeschen notes as regards the 4th recommendations' document dedicated to research, that all priorities should be mentioned here, as they all need research. M. Benderitter points out that the research priorities presented here are the expectation of the SF and will be the object of a cross analysis with the proposal of the 34 partners of the MEDIRAD project that should finally give a representative view of the research priorities in medical RP, at least for the clinical field covered by the project.

R. Loose notes he is happy with the four high-priority topics, from the radiation protection perspective, CT is the highest source of radiation (66%, compared to interventional radiology with 20%).

J. Repussard concludes this presentation by informing the participants that a MEDIRAD report regrouping the analysis of answers to both questionnaires is being finalised, and that a scientific publication dedicated to the analysis of the questionnaires is planned.

5. Elaboration of MEDIRAD Recommendations (J. Repussard, F. Vanhavere)

R. Repussard provides an overview of the timeline until the project's end (see presentation slides). It becomes clear that the drafting by WG6.3 of the technical elements for the recommendations should be finished in March 2021, to allow for sufficient time for putting together the contents of the 4 recommendations, for their review and consultation by stakeholders as well as internally to MEDIRAD. He asks the SHB to make a note to their calendars already now that they will receive the draft recommendations around April/May 2021 for review.

F. Vanhavere informs that a meeting of the task 6.3 working group in charge of drafting the recommendations was held the day before. He reminds that originally four WGs were planned, but then it was decided to set up only one WG to facilitate the process. In addition, contact points from the different WPs were nominated to gather input from the WPs.

He reminds that technical topics for the recommendation documents were collected previously, and are listed in the Excel table (see Excel file attached). Each of the four recommendations will address several technical topics, and the priorities identified in the questionnaires were assigned to these topics. F. Vanhavere informs that the first topics have been drafted. They were thoroughly discussed yesterday and will be updated in the coming weeks.

As an example, F. Vanhavere shows the draft technical element for a recommendation, dedicated to staff shielding. He notes that the work should be finalised in November, and therefore the final version of that element of recommendation should be soon available. He indicates that five protective tools were selected during the project, and other tools, e.g. lead glasses, were not studied. It was discussed in yesterday's meeting whether information on other tools should also be included and how far the recommendations should rely on literature data. For example, lead glasses were not included, as many studies are already available, however readers might miss this information. Therefore, other tools might still be mentioned with very general information and references. F. Vanhavere points out that it is not possible to do another complete literature review for other tools.

M. Perez notes that it is up to MEDIRAD members to decide on this issue. It is reasonable that the recommendations mainly address the findings from the project, but it cannot be ignored that there are also other elements, which should be considered. She proposes including a clear statement at the beginning of the documents that the recommendations are based on project results and experiences, but also on other existing and relevant evidence and knowledge when available. To make clear where the information comes from, she suggests using tables or different colours. F. Vanhavere agrees on this proposal.

F. Vanhavere also points out that one topic is not always related to a single recommendation, as the topic may be of interest for different audiences, possibly from different angles. Therefore, it may also be necessary to split the topics again, so as to regroup the topics in a 2nd phase. He indicates that clinical repositories are missing in the list of topics, and the GDPR recommendation also needs more discussion.

F. Vanhavere points out that the time is already tight, and therefore a least preliminary results from the WPs are needed to start drafting other topics as well. He asks R. Coppes also to appoint someone who can help with the topics of 2C and 2D.

P. Gilligan asks if they looked at effectiveness for shielding during pregnancy for interventional workers. F. Vanhavere explains that this was not covered but would be an important topic. A reference could be provided in the recommendation too.

J. Damilakis notes that it is important to differentiate recommendations from MEDIRAD research from general recommendations not related to the project.

J. Repussard points out that we cannot ignore the very broad scientific knowledge from a lot of studies that already exists. However, the added value of these recommendations is certainly MEDIRAD-centred, although the context is much broader than the project itself. He adds that we have different "publics", and the information has to be prepared accordingly. Time will be needed to package information accordingly.

J. Damilakis also indicates the terminology (problematic vs. background). F. Vanhavere agrees that an editorial revision will certainly be done.

M. Perez points out that the scientific findings from MEDIRAD should be communicated via actionable recommendations. Moreover, gaps in knowledge should be identified and translated into research needs. Existing knowledge should be acknowledged somehow.

J. Repussard welcomes the term “actionable”, as we have to make sure the recommendations are useful to the users.

6. AOB, next meeting, closure of the meeting (J. Repussard, M. Benderitter)

U. Mayerhofer informs that a date for the next full consortium meeting has not yet been set. Probably, an online meeting will be arranged before summer to discuss the remaining tasks and organise for the last project months. The SHB members will be invited to attend the meeting.

As indicated in the beginning of the meeting, J. Repussard proposes another online SHB meeting in September 2021. The SHB should be consulted on the draft recommendations before this. Another final SHB meeting might also be organised after the seminars to recap comments from the seminars and to close the SHB’s work.

J. Repussard thanks everyone for contributing to the project and closes the meeting.

Annex 4: Task 6.3 working group membership list

As a result of the above mentioned proposed corrective actions, MEDIRAD task 6.3 partners proposed to set up a dedicated working group in charge of the recommendations' development. This working group will comprise the following members:

- EFOMP: Anja Almén
- EFRS: Graciano Paulo
- ESTRO: Rob Coppes
- EANM: Michael Lassmann
- ESR: Guy Frija
- MELODI: Elisabeth Cardis
- EURADOS: Mercè Ginjaume
- ISS: Antonella Rossi
- UCD: Jonathan McNulty
- IRSN: Marc Benderitter
- SCK•CEN: Filip Vanhavere

The WP6 leader (Marc Benderitter) and SHB chair (Jacques Repussard), as well as the MEDIRAD coordinator (EIBIR) will also follow this work and participate in relevant meetings.

Annex 5: Stakeholder Forum Exploratory Questionnaires in-depth analysis

The in-depth analysis of the exploratory questionnaires completed by the members of the SF is available here:

http://medirad-project.eu/storage/app/media/publications/medirad-sf-questionnaires-analysis.pdf