IAEA
International Atomic Energy Agency
Atoms for Peace and Development

Summary of the IAEA Technical Meeting on Radiation Protection in Fluoroscopically Guided Interventional Procedures, 7-9 March 2022

Objectives

The Technical Meeting had the following objectives:

- To review existing guidance, information, and training resources for the optimization of radiation protection of patients and staff and for the prevention and management of unintended medical exposures in fluoroscopically guided interventional (FGI) procedures.
- To identify a need for additional resources for patient and staff safety in response to the new aspects of radiation protection.
- To inform participants of the preparation of the new IAEA-coordinated international study of patient doses and tissue effects from FGI procedures and increase participation.
- To evaluate the status of the reporting and learning systems SAFRAD and ISEMIR-IC and their further development and promotion of their use for benchmarking and learning from best practices around the world and thus improving patient and staff radiation protection.

Attendance

The Technical Meeting was held 7-9 March via the online platform WebEx.

The meeting was attended by 105 participants and experts representing 42 Member States, as well as 18 international organizations and professional bodies presented in Annex 1. Meeting participants represented a wide spectrum of specialties including interventionalists, medical physicists, technologists/ radiographers, fluoroscopic equipment manufacturers, radiation protection specialists, researchers, and regulators.

Agenda and session recordings

The meeting agenda is in the Annex 2, with links to the video recordings of all meeting sessions.

Summary of Session 1: Setting the Scene

The increase of variety, frequency and complexity of fluoroscopically guided interventional (FGI) procedures pose many challenges for radiation protection of patients and medical staff. These include: risks of tissue reactions such as skin injuries for patients and eye lens opacities for staff, as well as elevated stochastic risks for patients and staff. The summary of recent data presented on behalf of the ICRP Committee 1 showed more evidence from the epidemiology on the increase of cancer risk with dose at the dose range specific to FGI procedures. Recent knowledge of radiation cataract justifies the reduction of the dose limit for the lens of eye. Further data is needed to study the dose-effect relationship for skin injuries.

These procedures provide an excellent alternative to many surgical interventions that explains their increasing use worldwide. The increased usage is reflected in the new UNSCEAR 2020-2021 Report Annex A (to be published). While overall national surveys show that levels of of medical exposures have stabilised, there was an increased contribution from FGI procedures to the collective dose to the population.

There is no direct evidence of cancer from FGI procedures. However, recent epidemiological research demonstrated heightened risks at doses comparable to FGI patient and staff irradiation levels. The primary goal of performing FGI procedures and the expected benefit for the patient should be well balanced against risks. Radiation risks for patients should always be considered in the context of the overall risks and the various underlying factors such as patient medical condition and age. Some high exposures might be unavoidable, but they must be well predicted, managed and monitored to provide the best possible care for patients. Most tissue reactions are preventable if the procedure is optimized and performed by skilled personnel.

FGI procedures are increasingly performed by medical professionals outside radiology and cardiology. Training of such staff might not always be sufficient, and so training requirements must be emphasized and enforced. Another challenge is occupational dose monitoring and especially the eye lens dosimetry.

The International Basic Safety Standards, published in the IAEA Safety Standards Series No. GSR Part 3, set the basic principles for ensuring radiation protection of patients and staff in FGI procedures. Guidance for their practical implementation is provided in the IAEA Safety Guide SSG-46. Further resources such as informational material, training material (including e-learning), webinars, posters, etc, are provided by the IAEA through the specialised website on Radiation Protection of Patients. The IAEA established two international online databases relevant to facilities performing FGI procedures: Safety in Radiological Procedures (SAFRAD) for reporting cases of patient exposures exceeding defined trigger levels, and the occupational exposure focused module on interventional cardiology (IC) in the Information System on Occupational Exposure in Medicine, Industry and Research (ISEMIR).

Other international organizations and professional bodies also provide guidance and training resources for radiation protection. Results of various successful projects funded by international, regional, and national organizations have been presented in the meeting.

Fluoroscopic imaging technologies are rapidly developing, these enable dose reduction opportunities. Examples are hybrid imaging for guidance with fluoroscopy using ultrasound and CBCT There is better standardization of patient dose reporting with the DICOM Radiation Dose Structured Report (RDSR), improved assessment of patient skin doses, including software tools for real time or post-procedure skin dose maps, as well as improved developments in staff dosimetry through active and passive dosemeters and software tools. Also, automatic radiation exposure monitoring systems have become available in many clinics around the world, including national automatic dose index registries.

Despite the availability of international standards and guidance and the rapid technology development, additional common challenges and new issues have been recognised and solutions proposed. The following sections present the key messages from the technical meeting.

Summary of Session 2: Management of Tissue Reactions for Patients

Management and avoidance of tissue reactions from FGI procedures require robust dose management processes and quality assurance programs. Pre-procedural checklists and ALARA planning that consider patient weight, and ideally the patient thickness, procedure complexity, radiation history, etc., are key for prevention.

Basic information is lacking: There is virtually no evidence available for children. Follow-up programmes are not established in all facilities performing FGI procedures and some important skin injuries might stay unestablished causing serious suffering for the concerned patients. The story presented by a patient who suffered a major tissue reaction showed the importance of raising awareness and the need to ensure support is given to those struggling to develop such procedures. There is insufficient evidence and data for the dose-effect relationship for tissue reactions in FGI

procedures. Coordinated data collection at the global level might improve this knowledge and help define realistic trigger level values for tissue reactions.

There is a need to revisit erythema dose thresholds with more sophisticated dosimetry and radiobiology. Sound trigger levels are needed; 5 Gy for the reference air kerma has been used as reasonable level for triggering follow-up for the past decade. The planned IAEA study will hopefully provide further evidence as to the correct trigger levels. The long-term goal would be to collect good data and develop predictive analytics.

Skin dose mapping (both real-time integrated into the image equipment and as part of third-party software mapping) provide solutions for improving skin dose management. The EU-funded VERIDIC study of available to date skin-dose software showed differences in skin dose maps due to models employed by suppliers (especially in the lateral projections), most within 40%. There are no internationally agreed quality control tests for skin dose mapping software. A key message is the need to know the precise model your skin dose mapping software uses. IEC equipment standards are evolving to support 'in-lab' real time skin dose management. Consensus is still needed on colour/grey levels.

The IAEA SAFRAD system needs updating after the new IAEA study of patient doses and tissue reactions. The results will be used to update trigger levels and recommendations for protection.

Staff training and awareness, concepts of teamwork, as well as the clearly defined roles and responsibilities are integral to the prevention and management of tissue reactions.

Summary of Session 3: Management of Stochastic Risks for Patients

Justification for FGI procedures, is increasingly integrated into clinical appropriate use protocols. The focus of this TM was on optimization to reduce radiation health effects. Both justification and optimization should be investigated further using epidemiological data.

Optimization for patients is still a challenge. This includes the proper use of all optimization tools, such as a robust quality and dose management assurance (QA) process, program in addition to improved dosimetry, and optimization of clinical protocols. The overall accuracy and standardization of dose data, and especially dosemeter calibrations, need improvement. Standardization of procedure naming (the lexicon), dose reporting, transfer of data, including clinical data into registries and reporting technologies are needed.

Cost associated with the newer lower-dose fluoroscopy equipment, dose monitoring and radiation protection tools are high and not always affordable, especially for less developed countries.

One size does not fit all, given the wide variation in patient size and clinical indication, operator experience, and equipment. Diagnostic reference levels (DRLs) for FGI procedures are generally missing, especially for children. Paediatric DRLs for FGI procedures must be established. Pediatric and adult substantial radiation dose levels (SRDL), above which additional monitoring and actions are needed, must be developed.

There is a lack of case reports and dose data for procedures performed outside radiology and cardiology departments. More coordinated dose studies are needed for these procedures.

DRL methodology for FGI procedures requires refinement, development and guidance for the practical implementation, including better accounting for the sample size, patient morphology and clinical indication. There is a need for better accounting for the dependance of dose results on the procedure complexity and operator skills. Collaboration is needed between professional societies and regulatory authority for establishing and utilizing DRLs.

DRLs and achievable doses provide an objective measure of the dose reduction, e.g., DRL decrease with replacement of older equipment and/or improved optimization. Once DRLs are established, they must be used for benchmarking local practices, and for comparison with international or other national DRLs. Operators must be aware of DRL concept and use.

National registries facilitate the process of data collection and DRL establishment. However, solutions are needed for some of the associated challenges, such as:

- Practices performing FGI use many different terms to "name" procedures within internal information systems. Registry-level comparisons require that a common language (lexicon) be used to facilitate data analysis and comparisons. For example, the American College of Radiology (ACR) Fluoroscopy Dose Index Registry (DIR-Fluoro) uses the ACR Common lexicon.
- Access to the information about the complexity of procedure as a factor contributing to variance of doses requires merging of dose data with clinical contextual data. Collaboration with manufacturers is essential for clinical/dose data connectivity and transfer. If data mining is performed, it may be difficult when using billing codes since FGI procedures often have many codes associated with one procedure.
- Privacy concerns (e.g., with the GDPR/'Data Act') may be balanced with radiation dose safety approach analogous to pharmaceutical safety monitoring of untoward events.

Stochastic risk assessment associated with recurrent FGI and other imaging procedures needs attention. A study from the MGH estimated additional cancer risk of 1 in 200 to 1 in 20 for cumulative doses above 100 mSv. This needs further investigation including policy guidance, and patient disclosure. Consideration of stochastic risk for FGI should include patient benefits along with lifespan reductions and other risks of their underlying medical conditions.

Summary of Session 4: Management of occupational risks for interventionalists and improving their radiation protection competence

Lack of radiation protection culture among specialists outside of radiology and cardiology is common for many countries. Initial education and training should be improved especially for specialists outside radiology, e.g., surgeons, gastroenterologists, urologists that increasingly rely on FGI procedures. Successful approaches such as peer training sessions dedicated to radiation protection during professional medical congresses must be further expanded to cover different professional groups.

Formal radiation protection training requirements if they exist at the national level are helpful but may not be effective if not adjusted to local resources and practical needs. Additional informal training by a clinical medical physicist and practical in-room training by radiographers/technologists and IR specialists have proven to be effective.

Compliance with wearing personal dosimetry is still poor. This might be overcome with (a) education about radiation health effects specific to the operator — the 'why' for wearing dosimeters, (b) occupational optimization educational videos such as those now available at RPOP and (c) the implementation of passive systems such as video systems for automatic detection and dose calculation for persons in the catheterisation rooms or use of active electronic dosimeters.

Interventional professionals are not always aware of their individual doses. Improved information feedback to the exposed professionals is needed, would improve awareness and compliance with wearing personal dosimetry; further, this might be facilitated through an online access to the occupational doses from computers or mobile devices.

Passive dosimeters provide delayed retrospective information about occupational doses. This can be improved with the use of active personal dosimeters with real time dose displays provided directly in the interventional room. However, in addition to their higher cost, active personal dosimeters have limitations with high dose rates and angular dependence. These devices should be carefully selected.

Low dose values measured by personal dosimeters are not always a guarantee of adequate occupational protection. In such cases, the regular use of personal dosimeters and the workload might need to be audited.

Scatter radiation is inhomogeneously distributed, and the use of a single point dosimeter might provide unrealistic estimate of dose. For some procedures, there is a need to estimate doses in different parts of the body (e.g., lens of the eyes and hands). Use of several dosimeters might be needed in these cases, with specific training and personalised advice from medical physicists.

Several presentations brought forward areas where education, training, and/or audit could be strengthened. For example: There is still lack of proper use of radiation protection tools (especially ceiling suspended protective screens). Audit of occupational doses compared to patient dose values, and personal dosimetry results compared to a reference ambient dosimeter at the C-arm might help indicate the problem.

Some patient dose reduction imaging modes may not be equally effective to reduce occupational doses (e.g., high X-ray beam filtration decreases patient dose but might increase staff dose per unit kerma-area product). The topic needs further research. Such consideration should be included in training sessions with interventionists.

Knowledge is lacking on the impact of geometrical parameters and image acquisition modes on occupational doses. Practice-oriented training using videos (such as the IAEA practical tutorials) have proven to be effective and should be promoted. Although still costly, virtual simulators offer realistic and safe radiation safety training and help increase awareness.

Procedure success and radiation protection results depends on the knowledge of the specific options of the fluoroscope model. Standardized training on the use of the specific equipment (buttonology) is needed; collaboration with industry would facilitate this effort.

Wearing heavy protective aprons can have a long-term ergonomic impact. Ergonomic and radiation protective aspects need to be balanced. Light weight aprons and non-PPE designs that provide equivalent shielding can be effective. potential solutions, however, they can be expensive. The effectiveness of lead caps, drapes and gloves strongly depend on design, exposure conditions and staff position. and are generally found to be less effective than other measures.

Design of lead glasses is critical for their dose reduction effectiveness; most available glasses provide less than 30% protection. A simulation study showed that increasing lens length by 1 to 2 cm and decreasing thickness from 0.7 to 0.1 mm reduces weight and seems to have greater protection than conventional lead glasses.

Efforts are needed to extend radiation protection culture beyond the traditional hospital setting to venues such as out-patient surgical centers and individual physician's offices.

Recommendations for the IAEA Project on Strengthening Radiation Safety in FGI procedures

The first project phase: Study of patient doses and tissue reactions has been announced and to date over 70 facilities expressed an interest in participating and will shortly be notified about the next steps. The Meeting advised on the need to continue promotion through various channels and involve national and regional registries, in addition to individual facilities. The discussion revealed a need for a more detailed study protocol. The time required for the ethical approvals may determine the start date of the study. The study needs broad participation to minimize 'selection' bias. The deadline for expression of interest to participate in the study will be extended and promotion will continue. The targeted start of data collection is June, although some facilities might need longer

time for ethical approval. The IAEA will offer webinar(s) to explain the methodology and provide guidelines. The study success depends heavily on the participation of more interventional facilities.

Planning of the Phase 2 can start later this year. Possible topics to be considered include:

- International data collection to establish reference levels for some FGI procedures
- Cumulative doses of the cohort of patients undergoing recurrent imaging
- Study to establish correlation between patient and staff doses, and on evaluation of worker risks by job, and perhaps by their age, sex, and pregnancy status

The meeting participants advised on the need to further promote means to reduce patient and worker risk and requested the IAEA and other relevant organizations to continue to promote training and awareness raising, resources, and development of new resources.

The IAEA databases SAFRAD and ISEMIR-IC provide a unique opportunity to collect data at international level but they need updates to make the best use of the newest technologies and to provide analytical and learning opportunities for participating facilities.

ANNEX 1. Represented international organizations and professional bodies (in alphabetical order)

American College of Radiology (ACR)
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA)
European Commission (EC)
European Federation of Organisations for Medical Physics (EFOMP)
European Radiation Dosimetry Group
European Society of Cardiology (ESC)
European Society of Radiology (ESR)
Heads of the European Radiological Protection Competent Authorities (HERCA)
International Commission on Radiological Protection (ICRP)
Image Gently Alliance
International Organization for Medical Physics (IOMP)
International Society of Radiographers and Radiological Technologists (ISRRT)
Latin American Society of Interventional Cardiology (SOLACI)
Society of Interventional Radiology (SIR)
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)
U.S. Food and Drug Administration (FDA)
World Health Organization (WHO)

ANNEX 2. AGENDA of the IAEA Technical Meeting on Radiation Protection in Fluoroscopically Guided Interventional Procedures

Monday, 7 March 2022

Video recording: https://iaea.mediasite.com/Mediasite/Play/ef5ac2621370468898fe8804e16952b31d

13:00 – 13:15	Opening and welcome	IAEA
Session 1. Setting the scene ***Objective:*** *Identifying the current state and challenges for the radiation protection in FGI procedures* Session rapporteur: Roberto Sanchez (Spain)		
13:15 – 13:30	Motivation, scope and objectives of the TM	Jenia Vassileva, Scientific secretary
13:30 – 13:45	Overview of the topic	Stephen Balter (USA) Meeting chair
13:45 – 14:00	Latest data on interventional procedures from the UNSCEAR global survey	Ferid Shannoun (UNSCEAR)
14:00 – 14:15	Update from radiobiology and epidemiology on radiation effects	Dominique Laurier (ICRP Committee 1)
14:15 – 14:30	ICRP recommendations related to FGI procedures and ongoing work	Kimberly Applegate (ICRP Committee 3)
14:30 – 14:40	Enhancing radiation protection in image-guided interventions: WHO's views and actions	Maria Perez (WHO)
14:40 – 14:55	Break	
14:55 – 15:05	Dosimetry considerations relevant to FGI procedures	Olivera Ciraj-Bjelac (IAEA, NAHU)
15:05 – 16:00	Status of radiation protection in FGI procedures, problems, challenges, and ongoing efforts: Perspectives of represented organizations	Georgi Simeonov (EC) Donald Miller (FDA) Katrien Van Slambrouck (HERCA) Philip Malca (DITTA) Madan Rehani (IOMP) Stewart Whitley (ISRRT) Werner Jaschke (ESR, CIRSE) Jeremy Collins (SIR) Amalia Descalzo (SOLACI) Samuel Brandy (Image Gently) Mahadevappa Mahesh (ACR) Paddy Gilligan (EFOMP) Vijay Kunadian (ESC)

Tuesday, 8 March 2022

Video recording: https://iaea.mediasite.com/Mediasite/Play/4c83d7790d4b4800a810490cf9005c4e1d

Session 2: Management of tissue reactions for patients ***Objective:*** *Identifying areas of work to improve management of skin injuries* Session rapporteur: Andy Rogers (UK)		
13:00 – 13:20	Tissue reactions: factors, classification, patient follow-up and dose management	Stephen Balter (USA)

13:20 – 13:25	Skin injury: patient's perspective	Hal Workman (USA)
13:25 – 13:35	Skin dose mapping: IEC standard	Andrew Kuhls-Gilcrist (IEC WG37)
13:35 – 13:50	Skin dose mapping in interventional radiology: results from the VERIDIC project	Jérémie Dabin (EURADOS)
13:50 – 14:00	SAFRAD: status and development. New IAEA study on patient doses and tissue reactions – objective and organization	Jenia Vassileva (IAEA)
14:00 – 14:10	IAEA study: Q&A on the methodology	J. Vassileva (moderator) Panel: S. Balter, D. Miller, E. Vano, R. Sánchez, W. Jaschke, S. Srimahachota, K. Jones, V. Tsapaki
14:10 – 14:25	Break	
Session 3: Management of stochastic risks for patients ***Objective:*** *Identifying areas of work to reduce stochastic risks for patients* Session rapporteur: Kimberly Applegate (USA)		
14:25 – 14:35	Managing risks for children	Eric Monroe (Image Gently)
14:35 – 15:35	Optimization and DRLs: experiences from countries and regions (10 min per talk)	Roberto Sánchez (Spain, EFOMP) Madan Rehani (US, MGH) Suphot Srimahachota (Thailand) Andy Rogers (UK) OPRIPALC project: Carlos Ubeda (Chile) EUCLID project: Werner Jaschke (ESR)
15:35 – 15:50	Individual patient doses from recurrent FGI procedures: is cumulative dose of concern?	Madan Rehani (USA)
15:50 – 16:05	Patient-specific dosimetry: methods and tools	Annalisa Trianni (Italy, EFOMP)
16:05 – 15:20	Challenges in establishing dose registries	Kyle Jones (USA)
16:20 – 16:30	Patient privacy rights in relation to radiation safety improvements: implication of privacy legislation for dose tracking"	Sjirk Boon (DITTA)

Wednesday, 9 March 2022

Video recording: https://iaea.mediasite.com/Mediasite/Play/a0a0c00a6bed4921a84f0ef3b5cbeaa61d

Session 4: Management of occupational risks for interventionalists and improving their radiation protection competence ***Objective:*** *Identifying areas of work to reduce occupational risks and improve radiation protection competence* Session rapporteur: M. Mahesh (USA)		
13:00 – 13:20	Status of occupational risk management in FGI procedures and problems to be addressed.	Eliseo Vano (Spain), Donald Miller (USA)
13:20 – 13:40	Staff dosimetry: use of APD's in interventional radiology, new computational developments: PODIUM project	Filip Vanhavere (Belgium, EURADOS)

13:40 – 13:50	Design of protective eyeglasses	Edilaine Honorio da Silva (France)
13:50 – 14:05	MEDIRAD project: novel methodologies to reduce patient and staff radiation dose in FGI procedures	Merce Ginjaume (Spain, EURADOS)
14:05 – 14:15	Use of simulators to support training and dose management	Gabriel Bartal (Israel)
14:15 – 14:25	IAEA resources for RP in interventional procedures	Jenia Vassileva (IAEA)
14:25 – 14:45	Radiation protection training of interventionalists: What works and what not?	Moderator: Eliseo Vano (Spain) Panel: S. Balter (USA), D. Miller (USA), W. Jaschke (Austria), A. Tchekmedyian (Uruguay), I. Kralik (Croatia), K. Akyea-Larbi (Ghana)
14:45 – 14:55	Break	
Session 5: Summary and closing ***Objective:*** *Summarize and prioritize meeting recommendations (to the Members States, IAEA and partnering organizations)*		
14:55 – 15:30	How the discussions in this meeting would impact my clinical work and patient management? Perspective of interventionalists (panel) Comments from Member States & Organizations	Moderator: S. Balter (USA) Panel: A. Duran (Uruguay), S. Srimahachota (Thailand), S. De Silva (Sri Lanka), A. Nagy (Hungary) General discussion
15:30 - 15:55	Reports from the sessions Meeting summary IAEA study logistics and timeline, request for feedback (IAEA online form)	Session rapporteurs: R. Sanchez, A. Rogers, K. Applegate, M. Mahesh Stephen Balter (Meeting chair) Jenia Vassileva (Scientific secretary)
15:55 - 16:00	Closing	IAEA