

EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

Session 4: Presentation of the Practice-Specific Guidelines and Recommendations

11:00–15:00



**MARLIN Project Workshop
September 5 & 6, Brussels**

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SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

ILS for Radiotherapy

Maeve Kearney

ESTRO Expert & Asst Prof in Radiation Therapy



**MARLIN Project Workshop
September 5 & 6, Brussels**

Outline

- Radiotherapy in clinical practice
- The need for an agreed taxonomy for event coding
- The ILC in interventional services
- Interventional relevant recommendations

Radiotherapy – medical applications

- Indicated in 50% of patients diagnosed with cancer
- Radiotherapy – EBRT or Brachytherapy
- Over 635 000 radiotherapy courses were delivered in Europe in 2019 (Lievens et al. 2020)
- Despite high therapeutic doses - a relatively safe medical procedure with incident rates of 1.5–8.0 incidents per 100 courses of treatment on average (Smith et al. 2020) - 1 in 30 000 were predicted to result in a significant adverse clinical outcome (Eaton et al. 2018)
- ILS implemented
- Good safety culture
- High doses and very complex patient pathway

Radiotherapy – crucial to review as a separate entity

- High total dose
- Complex patient pathway resulting in a customised treatment plan for each patient

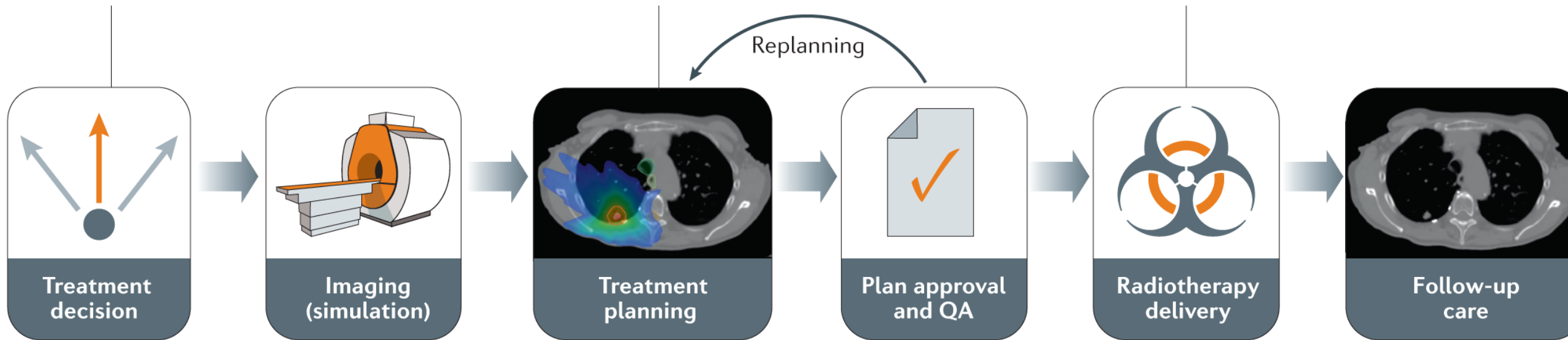


Image from: Huynh, E., Hosny, A., Guthier, C., Bitterman, D. S., Petit, S. F., Haas-Kogan, D. A., ... & Mak, R. H. (2020). Artificial intelligence in radiation oncology. *Nature Reviews Clinical Oncology*, 17(12), 771-781

Taxonomies

- Learning significant part of ILS
- Consistency in taxonomy – homogeneity in data
- Non complex - Ease of use – crucial to increase reporting
- Severity and causal taxonomy models help classify incidents in radiotherapy (Greenham et al. 2018)

Types of ILS

- General hospital or RT specific?
- Survey from WP1 – what is being done clinically?
- National or international?
- Specific examples of ILSs used in RT include PRISMA-RT (PRISMA-RT 2023) used in Netherlands and Belgium, Towards Safer RT (RCR, UK) and RO-ILS (ASTRO and AAPM, US) at a national level; SAFRON (launched in 2012) and ROSEIS (established in 2001) at the international level

Competent Authority - Some Considerations

- Significant events - dose deviation provides a measurable and clear criterion for reporting but
- Under reporting not always considered
- Number of patients affected
- Hypofractionated, e.g., breast cancer 40 Gy in 15 fx – 26 Gy in 5 Fractions now used in clinical practice
- Annex 4: Criteria for reporting significant events to the competent authorities in different countries
- Annex 5: Examples of reported events
- Chapter 3 covered by Carlos – categories of significant events

The Incident Learning Committee [ILC]

- Multidisciplinary composition – RT process complex and level of expertise at each stage unique
- Most incidents reported by MPE or radiation therapist
- Radiation oncologist and hospital management
- Review of 'near misses' – identify possible weaknesses in system

THANK YOU

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Nuclear Medicine: Implementing Incident Learning Systems

Ana Geão

EFRS NM Expert, Radiographer (PT)



MARLIN Project Workshop
September 5 & 6, Brussels

Outline

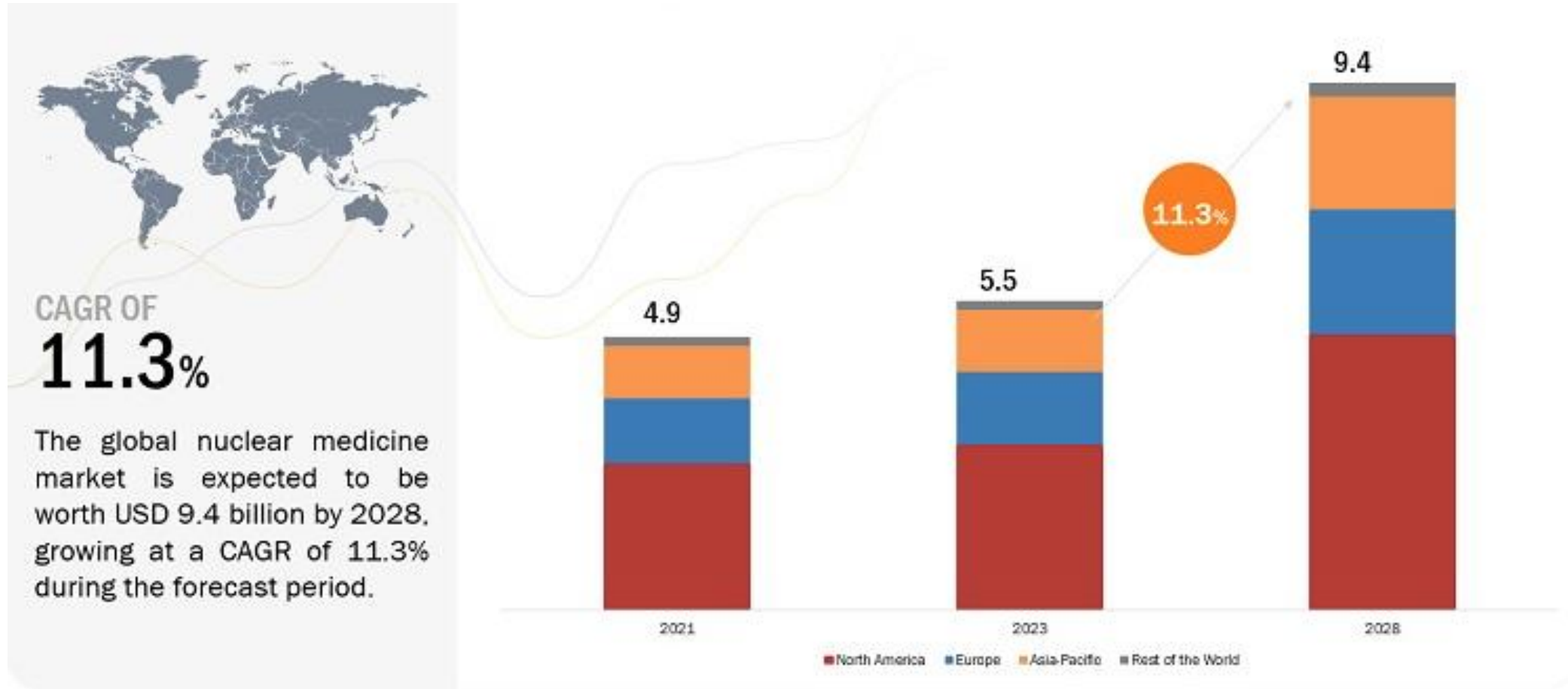
- Nuclear medicine in clinical practice
- Speaking the same language: taxonomy for event coding
- The implementation of incident learning committees

Nuclear Medicine

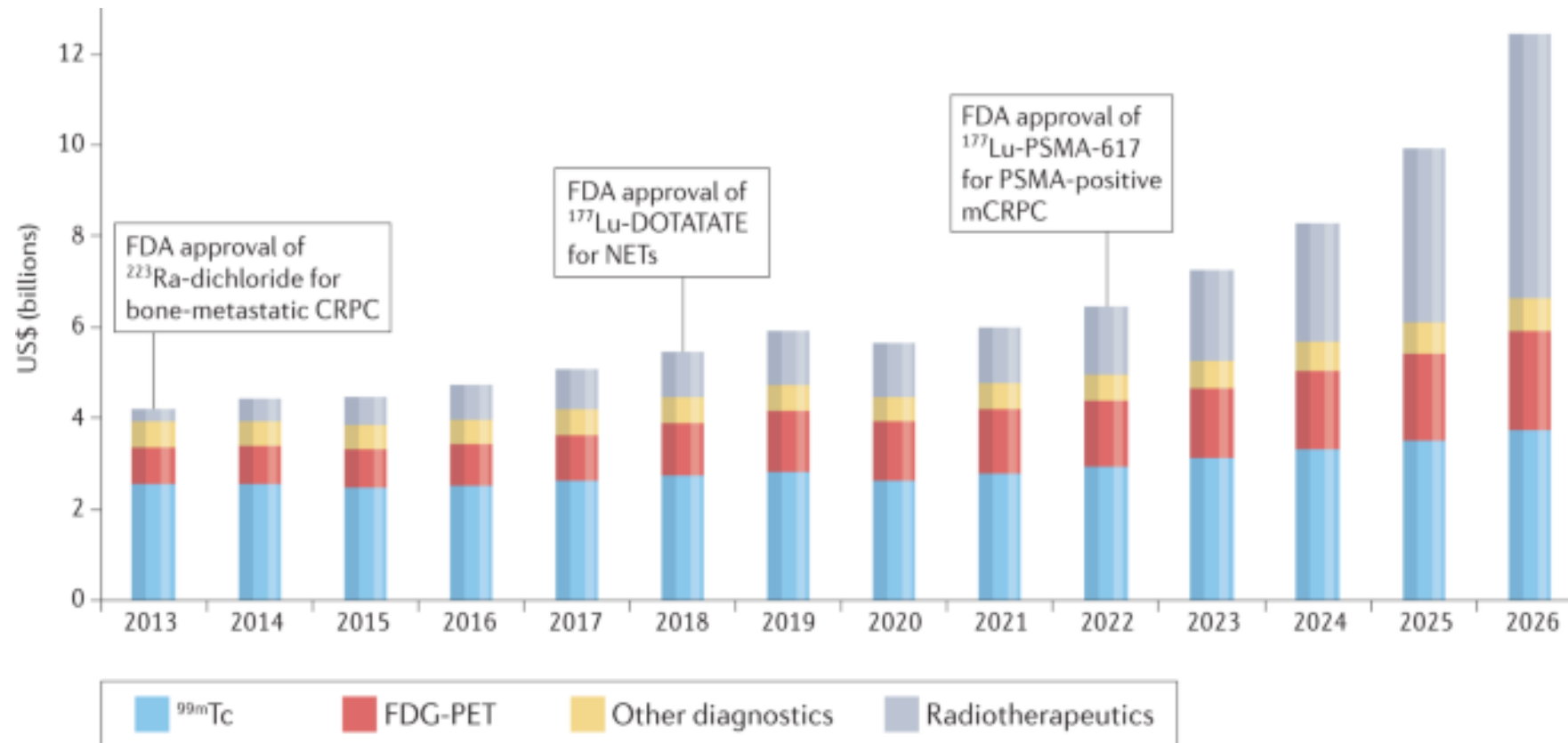
- Nuclear medicine provides a multitude of highly effective pathways for medical diagnosis and treatment
- With more than 100 different procedures approved by regulators every year, more than 10 million patients in Europe benefit from nuclear medicine in diagnosis and treatment

https://eanm.org/wp-content/uploads/2024/05/EANM-overarching-narrative_0707.pdf

Nuclear Medicine: Forecast



Nuclear Medicine: Forecast

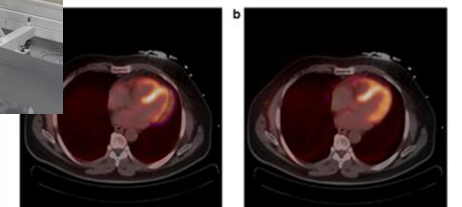
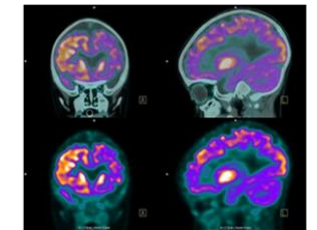
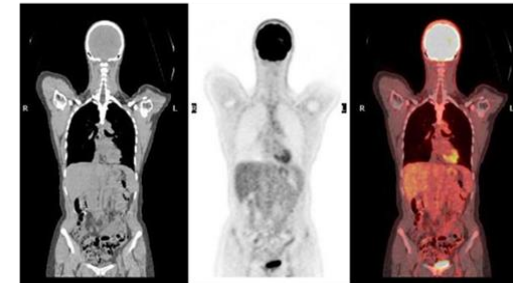


Herrmann, K., Schwaiger, M., Lewis, J. S., Solomon, S. B., McNeil, B. J., Baumann, M., Gambhir, S. S., Hricak, H., & Weissleder, R. (2020). Radiotheranostics: a roadmap for future development. *The Lancet. Oncology*, 21(3), e146–e156. [https://doi.org/10.1016/S1470-2045\(19\)30821-6](https://doi.org/10.1016/S1470-2045(19)30821-6)

Nuclear Medicine: Main Activities



Nuclear Medicine: Main Activities



Implementing ILSs in Nuclear Medicine

- Diagnostic procedures: ensuring accurate and safe imaging practices (PET, SPECT)
- Therapeutic procedures: focus on the safe administration of therapeutic radionuclides
- Specific coding: adaptation of coding systems to reflect the specifics of nuclear medicine

Specific Guidelines for ILSs in Nuclear Medicine

The guidelines focus on enhancing safety in nuclear medicine by:

- Ensuring accurate reporting of incidents specific to radionuclide diagnostic procedures and therapy
- Developing a comprehensive taxonomy that includes all relevant incidents, including dosimetric and procedural errors

Speaking the Same Language: Taxonomy

- Taxonomy plays a critical role in incident learning systems (ILS) by providing a structured and standardized way of organizing information about incidents, enabling consistent communication, analysis, and improvement of safety practices
- Vital in ILSs for fostering clear communication, promoting systematic analysis, ensuring compliance, and enabling the continuous improvement of safety practices. It forms the foundation for an effective learning system that can prevent future incidents by understanding and addressing past ones

Incident Learning Committee (ILC)

- Role of the ILC: Reviewing and analyzing incidents
- Multidisciplinary team, including:
 - Nuclear medicine experts
 - Nuclear medicine physician
 - Medical physicists
 - Radiographers
 - Other professionals involved in the incident and/or nuclear medicine

Analysis and Classification

Incidents are to be analysed by a multidisciplinary ILC

Classification of incidents should consider severity, potential for harm, and frequency of occurrence

Root cause analysis should be applied to understand underlying factors and prevent recurrence

Collaboration:

Competent authorities and national societies

- Nuclear medicine facilities need to collaborate closely with national and international authorities as well as national societies
- Sharing lessons learned from incidents to prevent future occurrences is a key responsibility

Challenges and Opportunities

- Challenges: Barriers to effective ILS implementation, such as underreporting, procedural complexity, taxonomy, “blaming culture”
- Opportunities: Continuous patient safety improvement

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ILS for Interventional Radiology & Cardiology

Andy Rogers
EFOMP Expert & UK MPE

MARLIN Project Workshop
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Outline

- Why are interventional procedures 'different'
- The need for an agreed taxonomy for event coding
- The ILC in interventional services
- Interventional relevant recommendations

Why is interventional different

- Much wider causes of error, e.g. device malfunction, that are non-radiation
- Broader medication errors, e.g. anti-coagulant misuse
- Patient dose outliers NOT necessarily 'events' or 'errors' (but there may be learning points)
- Fewer numbers of events
- Dose outliers often detected via dose monitoring rather than ILS reporting
- ILS often used both for 'incident learning' and 'optimisation'

Taxonomies

- If we have a generic CF-wide reporting database must have interventional relevant coding
- E.g., tissue reaction, high dose follow-up procedure initiated
- Must include other non-radiation issues, e.g., medication
- **Discussion** – should we include non-incident outliers in reporting system? [my centre doesn't add them to ILS database but does investigate outside of that system]
- UKHSA national taxonomy is a start but hasn't been extensively tested yet for interventional procedures

The Incident Learning Committee [ILC]

- Does it need to be separate?
- Incidents often discussed at M&M meetings
- Need a rigorous approach - ?RCA
- Must be multi-disciplinary (Practitioner, radiographer, nurse, MPE + any other expertise required, e.g. quality/risk manager)
- **How many interventional services would have easy access to MPE?**
- If separate, ILC may require links to other groups such as Optimisation Teams, Governance Committee – depends upon local service setting

Relevant interventional recommendations

- 'High-dose' triggers should be employed in addition to standard 'error' reporting to identify all potential events
- The use of PDMS in coordination with ILS is strongly encouraged (see recent EuroSafe paper) – **How do we encourage PDMS in interventional?**
- Specific interventional aspects of coding should be included

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ILSs for Diagnostic Radiology

Deniz Akata



**MARLIN Project Workshop
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Radiation Doses in Diagnostic Radiology

- Usually low, far from the minimum thresholds for deterministic effects
- Exposures imply low risks of stochastic effects, but often many patients are involved

<https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging>

higher radiation–dose tests, such as CT and nuclear imaging.

Over 80 million CT scans are performed in the United States each year, compared with just three million in 1980. There are good reasons for this trend. CT scanning and nuclear imaging have revolutionized diagnosis and treatment, almost eliminating the need for once-common exploratory surgeries and many other invasive and potentially risky procedures. The benefits of these tests, when they're appropriate, far outweigh any radiation-associated cancer risks, and the risk from a single CT scan or nuclear imaging test is quite small. But are we courting future public health problems?

Exposure to ionizing radiation on the rise

Not so appropriate causes of increased CT utilisation

- Areas of high medicolegal risk (emergency departments)
- Patient desire for certainty
- Physician desire for certainty
- Obesity (CT>>>US)
- Not reading the medical records or checking prior images
- Ordering more exams (increasing the area of coverage)
 - Bundling CTs: ordering more than one CT exam (e.g., brain and cervical spine) without a good reason



Defensive
medicine

Doses can be high in CT procedures due to different protocols for the same study

JAMA Internal Medicine | [Original Investigation](#) | LESS IS MORE

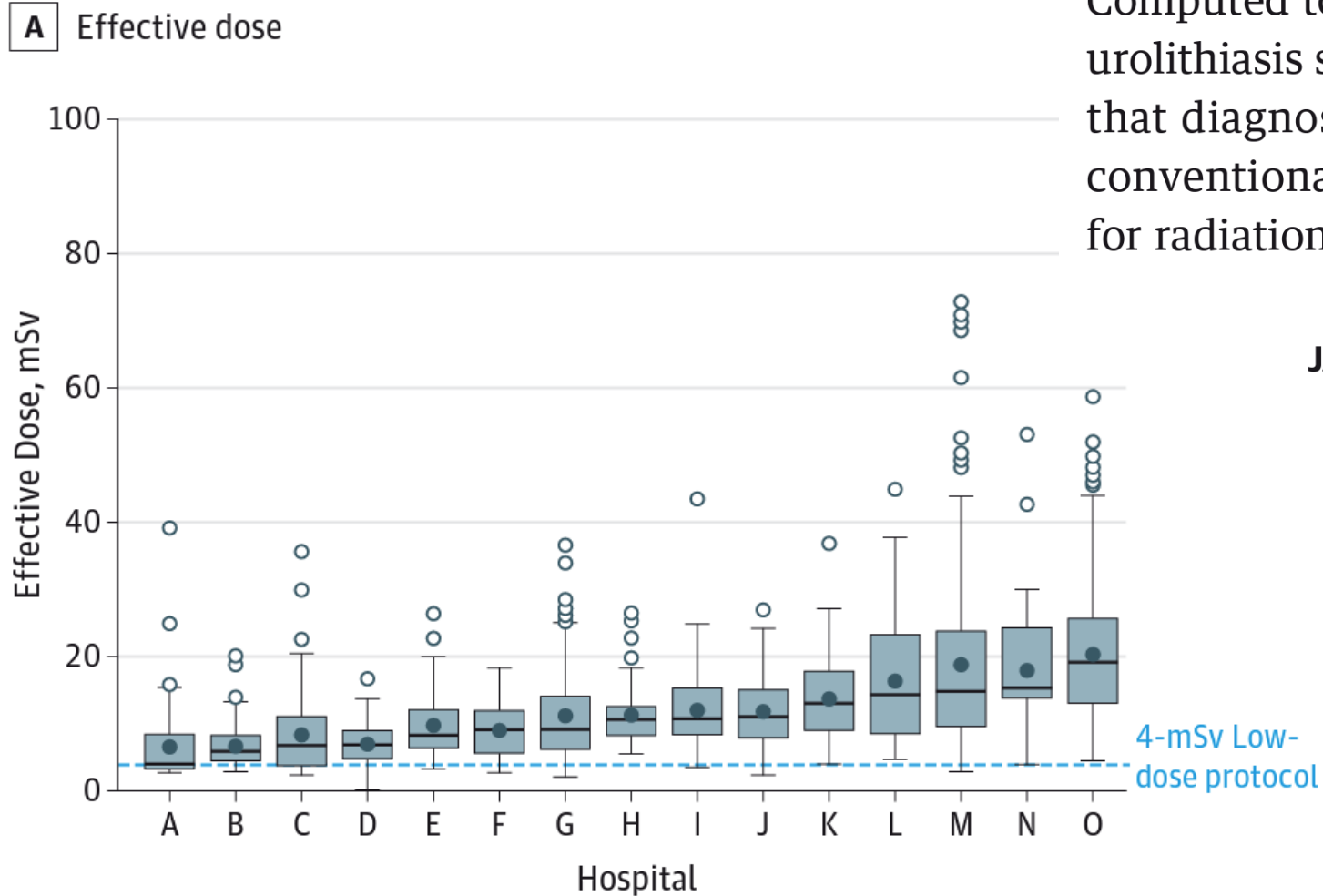
Comparison of the Harms, Advantages, and Costs Associated With Alternative Guidelines for the Evaluation of Hematuria

Mihaela V. Georgieva, PhD; Stephanie B. Wheeler, PhD, MPH; Daniel Erim, MD, PhD, MSc; Rebecca Smith-Bindman, MD, MPH; Ronald Loo, MD; Casey Ng, MD; Tullika Garg, MD, MPH; Mathew Raynor, MD; Matthew E. Nielsen, MD, MS

- Annually 2 million patients with hematuria referred to urologists in US
- CT volumes tripled in the last 2 decades in US
- **Median radiation dose per examination and the facility-level variation is 13 fold**
- UT cancer has low pretest probability

JAMA Intern Med. 2019;179(10):1352-1362

Figure. Distribution of Radiation Doses by Hospital



Computed Tomography Radiation Dose in Patients With Suspected Urolithiasis

Computed tomography (CT) for the evaluation of suspected urolithiasis should use low-dose techniques (<4 mSv)¹ given that diagnostic accuracy is equal to or better than that of conventional CT² and that this technique reduces the risk for radiation-related carcinogenesis. Despite its widespread

JAMA Internal Medicine August 2015 Volume 175, Number 8

Radiation dose:

- differs 200× among patients
- 5× among hospitals



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

European Journal of Radiology

journal homepage: www.elsevier.com/locate/ejrad



CT protocols and radiation doses for hematuria and urinary stones: Comparing practices in 20 countries

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Dario Faj^d, Emil Georgiev^e, Olga Girjoaba^f, Birute Griciene^g, Edward Gruppetta^h,
Darka Hadnadjev Šimonjiⁱ, Sjarhei Kharuzhyk^j, Andrej Klepanec^k, Desislava Kostova-L
Anna Kulikova^m, Ivan Lasicⁿ, Aleksandra Milatovic^o, Graciano Paulo^p, Jenia Vassileva
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- 20 countries 51 HC centers
- CTU
 - 80% 3–6 phase, ED (26,5–54,3 mSv)
 - 20% 2-phase, ED (11,1 mSv)
- Abdominal-pelvis CT
 - 52% 3–5 phase, ED (23,61 – 44,2 mSv)
 - 37% single phase (10,1 mSv)

Significance of Radiation Doses in Diagnostic Radiology

- Recurrent imaging with CT, fluoroscopically-guided interventions and hybrid imaging modalities such as PET-CT and SPECT-CT is more prevalent and more accessible
- Monitoring of expensive therapies
- Patients with diseases but longer life expectancies are being exposed to high doses of radiation, enabling radiation effects to manifest over a longer time period
- Guidelines have been proposed on investigation and prevention of unintended and accidental medical radiation exposures in RY (Martin 2005; Martin et al. 2017; The Royal College of Radiologists 2020), and some publications show the specific characteristics and results of the use of ILS in this area

Golnari et al. 2016; Itri and Krishnaraj 2012; Mansouri et al. 2016; Martin 2005; Sarvananthan et al. 2021; Siegal et al. 2017; Snyder et al. 2018; Tarkiainen et al. 2020

Criteria for Notification (Chapter 3):

- The definition of significant events should not be a decision of the facility but a decision of the CA
- Significant events require a declaration to the CA
- Not only serious events should be reported, as small anomalies or deviations may be of a repetitive nature that could be the sign of a deeper problem

Criteria for Reporting Significant Events to the Competent Authorities in Different Countries (Annex:4)

- The following criteria are extracted from the responses to the CAs' questionnaires in the survey made as part of the MARLIN project
- The criteria vary significantly from country to country
- The criteria have been grouped by risk area (EBRT, brachytherapy, therapeutic & diagnostic nuclear medicine, interventional & diagnostic radiology procedures)
- The criteria have also been grouped by:
 - clinical consequence criteria
 - deviation of dose or activity administered
 - number of patients affected
 - wrong patient, tissue or area
 - fetal exposure or exposure of breastfeeding children
 - equipment failure

IV.6.2 Dose deviation

Table IV.12: EU Member State criteria for dose deviation

Country	Deviation in the Dose	Comment
Croatia	25%	Administering a dose to the patient d procedure that deviates by more than 25 dose
Czechia		The categorisation of events based on e and the number of repetitions of events from the Czech legislation from 1 Janua following categories will no longer be ap Category A: CVOL >10 Gy Category B: CVOL >3 Gy (if an eye is beam) CVOL >0.5 Gy (if an eye is not in the pri 23 (Czechia 2016))
Finland	+10 mSv	The additional effective dose caused to wrong patient by the examination or p 10 mSv (STUK 2018)
France	4 times DRLs (2 times for paediatric procedures or CT scans)	Criterion 2.2 (Exposure of patients for di Inappropriate practice or malfunctio radioactive sources or diagnostic X ray (or likely to result in exposures significat the DRLs ³ (*) It may be considered to be significat <ul style="list-style-type: none"> • For conventional radiography in- adults: 4 times the reference levels • In conventional paediatric radiography: 2 times the reference levels • In adult CT scans: 2 times the reference levels defined by this decree
Germany		<ul style="list-style-type: none"> • Group of persons: each time a mean value is exceed by more than 100% of the respective DRL over the last 20 consecutive examinations of the same type, as soon as the DRL of an individual examination was exceeded by 200% • Individual persons: <ul style="list-style-type: none"> a) each time the volume-related CT dose index of a computed tomographic use to the brain of 120 mGy and another computed tomographic use to the body of 80 mGy is exceeded, and each time the total dose area product of an X ray fluoroscopy of 20 000 cGy·cm² is exceeded. The value first exceeded by CT or fluoroscopy shall apply to uses with digital volume tomography equipment, b) Each time a use is repeated, in particular due to a misidentified body part, a setting error or a previous fault in the device, if the criterion in accordance with (a) is satisfied for the resulting total additional exposure c) Each misidentified person, if the criterion in accordance with (a) has been met for the resulting total additional exposure. (Annex 14 (Germany 2018a))
Greece	V	<ul style="list-style-type: none"> • CT when the patient dose is 2 times greater from the expected typical dose (dosimetric quantities CTDIvol and DLP). • Mammography when the patient dose (AGD) is 5 times greater than the expected typical doses. The same as mammography applies to simple radiographic examinations in ESAK/KAP. • Dental CBCT when the patient dose (ESAK/KAP) is 2 times higher than the typically expected dose.
		<ul style="list-style-type: none"> • 4 times (CT and dental CBCT) • 5 times (Mammo and conventional)

Ireland	+10 mSv or +20 times (child: +3 mSv or +15 times)	<ul style="list-style-type: none"> • Diagnostic overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 mSv or 20 times the dose intended (criterion 3) • Diagnostic overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 mSv or 15 times the dose intended (criterion 4) • Dose given to comforters and carers greater than 3 mSv for adults under 60 years of age and 15 mSv for those over 60 years of age (criterion 5)(HIQA 2019)
Lithuania	+20 times if <0.5 mSv +10 times if >0.5 mSv but <5 mSv +5 mSv	<p>The patient has been exposed to radiation in excess of the medical X ray diagnostic procedure the typical effective dose:</p> <ul style="list-style-type: none"> • 20 times, if the typical effective dose of the medical X ray diagnostic procedure does not exceed 0.5 mSv; • 10 times the typical effective dose of a medical X ray diagnostic procedure exceeds 0.5 mSv but does not exceed 5 mSv; • If the typical effective dose of a medical X ray diagnostic procedure exceeds 5 mSv;
Malta	+20 times	Multiplying factor applied to intended dose=20
Norway	Not specified	Incidents that cause or could have caused unintentional exposure of workers, patients or other persons significantly beyond normal levels
Switzerland	+100 mSv	Unanticipated exposures in which the patient received an effective dose in excess of 100 mSv (Swiss Federal Council 2017)

Table 3.1: Proposed criteria for investigation and reporting of significant events to the CA. Each CA decides which category of events are considered significant and therefore need to be reported

Significant Events (Covered by Article 63.e.i of the BSSD) should always be reportable			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	Category 2	Category 3 Reportable as best practice	Category 4 Not reportable exhaustively, only those interesting from the PS perspective
Clinical consequences			
CTCAE v5.0 Grade 3 to 5	CTCAE v5.0 Grade 2	CTCAE v5.0 Grade 1	No consequences
Investigation dosimetric triggers			
Medical Imaging Procedures			
X_9	Unintended dose deviation >200 times ¹⁰ or >100 mSv	Unintended dose deviation >20 times, >10 mSv or area error ⁷ Category 3 in ≥10 patients becomes category 2	Unintended dose deviation >2 times or >1 mSv <1 mSv in ≥10 patients Category 4 in ≥10 patients becomes category 3
Fetal Exposure			
Unintended deviation >100 mSv	Unintended deviation >30 mSv	Unintended deviation >1-30 mSv	Unintended deviation <1 mSv

- If an event affects several patients, it is a sign of a system failure
- Random errors usually affect individual patients, whereas systematic errors usually have the potential to affect many patients
 - a collimation error
 - systematic image cropping, especially of pediatric patients
- The level for categorising significant events is lowered when more than 10 patients in a diagnostic procedure

Recommendations for Specificities in Diagnostic Radiology

5.6.2 Local (departmental or hospital level) systems

The risks in medical imaging go beyond the use of radiation

- Incorrect diagnosis through misinterpretation
- Misdiagnosis (e.g., a primary or critical finding not observed)
- The use of contrast
- Patient falls
- Delays in performing the procedure that affect the course of the disease
- Misreferral or lack of justification

Recommendations for Specificities in Diagnostic Radiology

5.6.2 Local (departmental or hospital level) systems

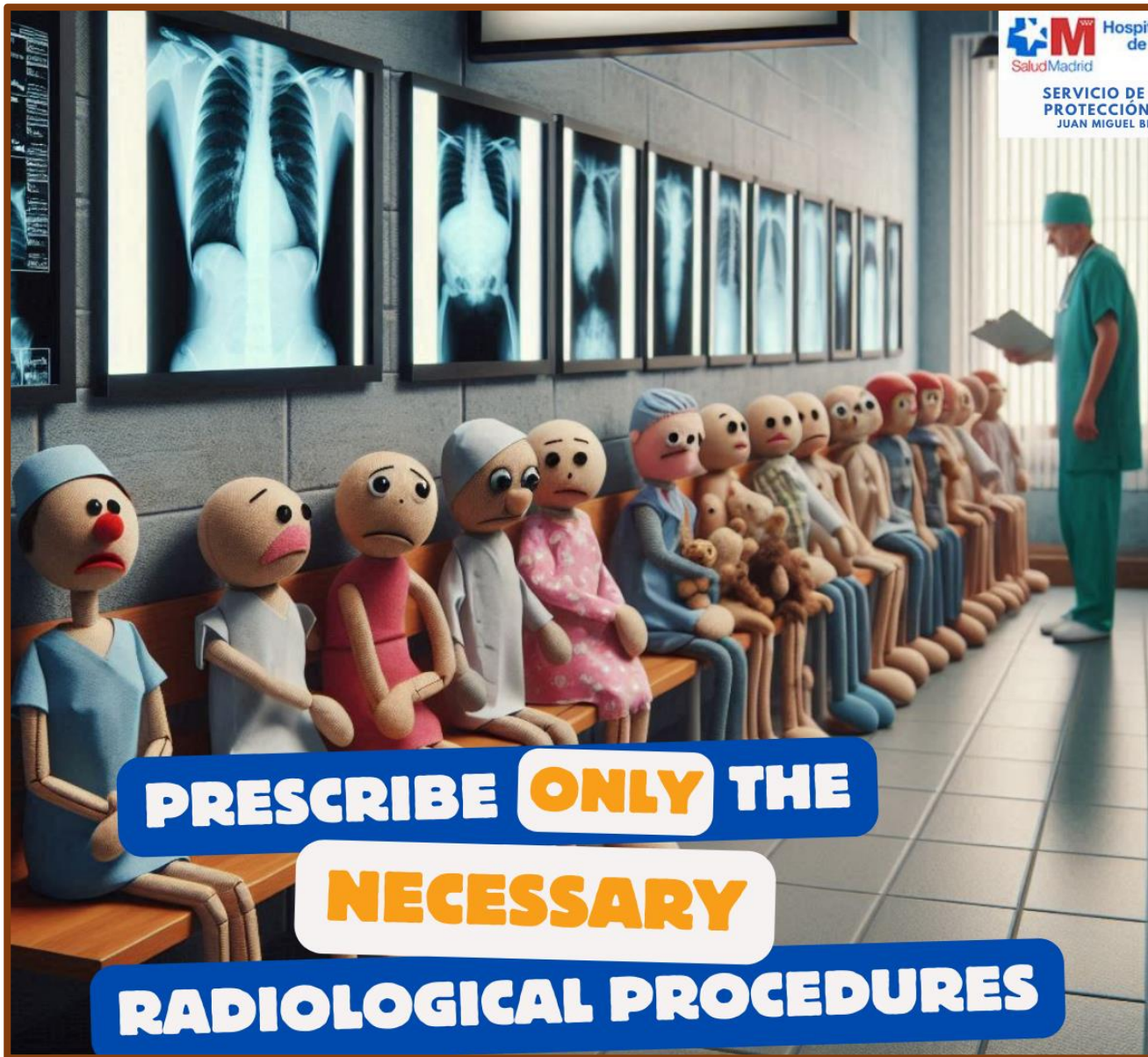
- For diagnostic radiology, a specific ILS for a department is usually not needed
 - The general incident learning system of a clinical facility should provide the possibility of filtering by service, so that events from diagnostic radiology can be extracted
- Patient-dose management systems
- Quality, optimisation and timing of an exam is important
- Justification process can be managed by implementing clinical decision support systems

Role of Professional Societies

Professional societies could collaborate with clinical facilities and their departments in the following

- *design of the incident learning system*
- *development of guidelines and recommendations*
- *training and develop a safety culture*
- *analysis of significant events*

Agreements between societies, e.g., radiographer, physician and medical-physics societies, can be beneficial in sharing experiences on patient safety, organising dissemination activities and establishing safety recommendations and policies in the area



REDUCE:



IATROGENESIS



UNNECESSARY DELAYS



RADIATION DOSE



WAITING LIST



COST



ANXIETY

Courtesy of Prof. Carlos Prieto Martín

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Lunch break

12:00–13:00

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Statement of EANM

Michel Koole

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Statement of EANM

- EANM interested in further necessary research in nuclear medicine, considering multiple departments in handling of radioactive material
- Increasingly important as activities become higher and half-lives longer
- Role of radiation protection officers is important
- Support for proper reporting, integration of lessons learned and continuous training

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Statement of EFOMP

Andy Rogers



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What is EFOMP?

National Member Organisations (NMOs)

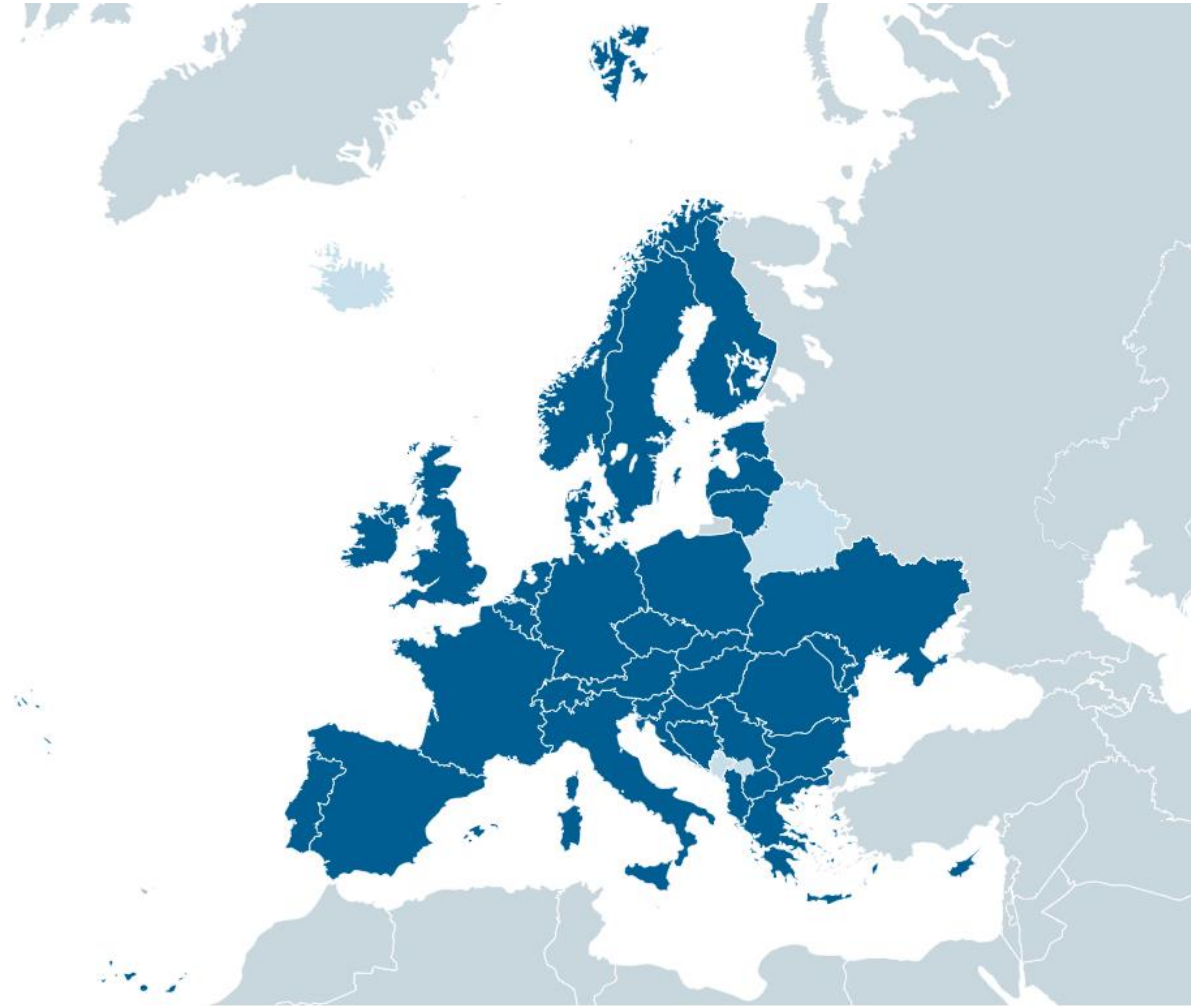
- **37 NMOs with more than 9000 medical physicists and clinical engineers working in the field of medical physics**
- **voting members in Council**

Individual Associate Members

- **Individuals with an interest in medical physics. Around 1000/year**
- **non voting members**

Company Members

- **39 manufacturers & suppliers of equipment**
- **non voting members**



What does EFOMP actually do?



- Mission
 - **Harmonise & advance** MP both in professional clinical & scientific expression
 - **Strengthen & make activities of NMOs more effective** by exchange of professional & scientific info by formulating common policies & promoting education & training



Position statement on MARLIN Guidelines

- EFOMP strongly supports:
 - The publication of guidance for ILS aimed at improving healthcare for patients
 - The flexible nature of structures to deliver ILS to match local circumstances
 - The emphasis on a multi-disciplinary approach to learning from, and management of, incidents
- EFOMP understands the additional human resource required to fully implement these guidelines
- EFOMP undertakes to:
 - Work collaboratively with relevant stakeholders to ensure appropriate MPE resources are in place to deliver the ‘MARLIN Vision’

[see *Physica Medica* **117** (2024) 103197

<https://doi.org/10.1016/f.ejmp.2023.103197>]

**THANK
YOU**

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Statement of EFRS

Andrew England

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Statement of EFRS

- EFRS strongly support incident reporting and MARLIN recommendations
- Radiographers have a role in communicating with patients and other professionals that could be expanded
- Implementation should focus on simplicity
- Patients should see benefits from incident reporting and learning
- EFRS can integrate incident training in professional training programme and safety culture
- The role of AI should be explored

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Statement of ESR

Boris Brkljačić



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ESRIF
**EUROPEAN SOCIETY
OF RADIOLOGY**

Statement of ESR

- ESR fully endorses MARLIN guidelines and recommendations for improvement of quality and safety
- Collaboration of stakeholders is welcome
- ESR promotes recommendations by Quality and Safety Committee and in conference activities
- Specifics for diagnostic and interventional radiology are welcome
- Publication RP205, results of EU-JUST-CT project, emphasises need to implement MARLIN guidelines

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Statement of ESTRO

Uulke van der Heide

MARLIN Project Workshop
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ESTRO



Statement of ESTRO

- ESTRO is committed to patient safety and welcomes MARLIN guidelines and recommendations
- ESTRO ROSQC has a role in implementation
- ROSEIS is being upgraded; ILSs should include brachytherapy
- Will collaborate with national societies to support radiotherapy recommendations
- Education and training programme should integrate incident learning

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Discussion

13:20–14:20



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Conclusions & Recommendations

C. Kelly



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On to the final session!

Coffee break

14:30–15:00

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