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

Welcome to day 2 of the MARLIN project workshop!

September 6, Brussels

Day 2 programme

09:00–09:10	Welcome to day 2
09:10–11:00	**Session 3: Presentation of the General Guidelines & Recommendations, Including Methodology of Development and Consensus Procedure**
09:10–10:00	➢ Presentation of the General Guidelines and Recommendations, Including Methodology
10:00–10:30	Coffee break
10:30–10:50	➢ Discussion
10:50–11:00	➢ Conclusions & recommendations
11:00–14:30	**Session 4: Presentation of the Practice-Specific Guidelines and Recommendations**
10:50–11:00	➢ Panel presentation of practice-specific guidelines and recommendations
12:00–13:00	Lunch break
13:00–13:20	➢ Statements of European professional societies
13:20–14:20	➢ Discussion
14:20–14:30	➢ Conclusions & recommendations
14:30–15:00	Coffee break

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Day 2 programme

15:00–16:00	Session 5: Summary
	➢ Final discussion on the guidelines and recommendations per project task ➢ Next steps in the project ➢ Closing
16:00	Close

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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

Session 3: Presentation of the General Guidelines and Recommendations

Maeve Kearney

MARLIN Project Workshop
September 5 & 6, Brussels

Content

- **Methodology of development, including consensus procedure**
- **Structure of guidelines**

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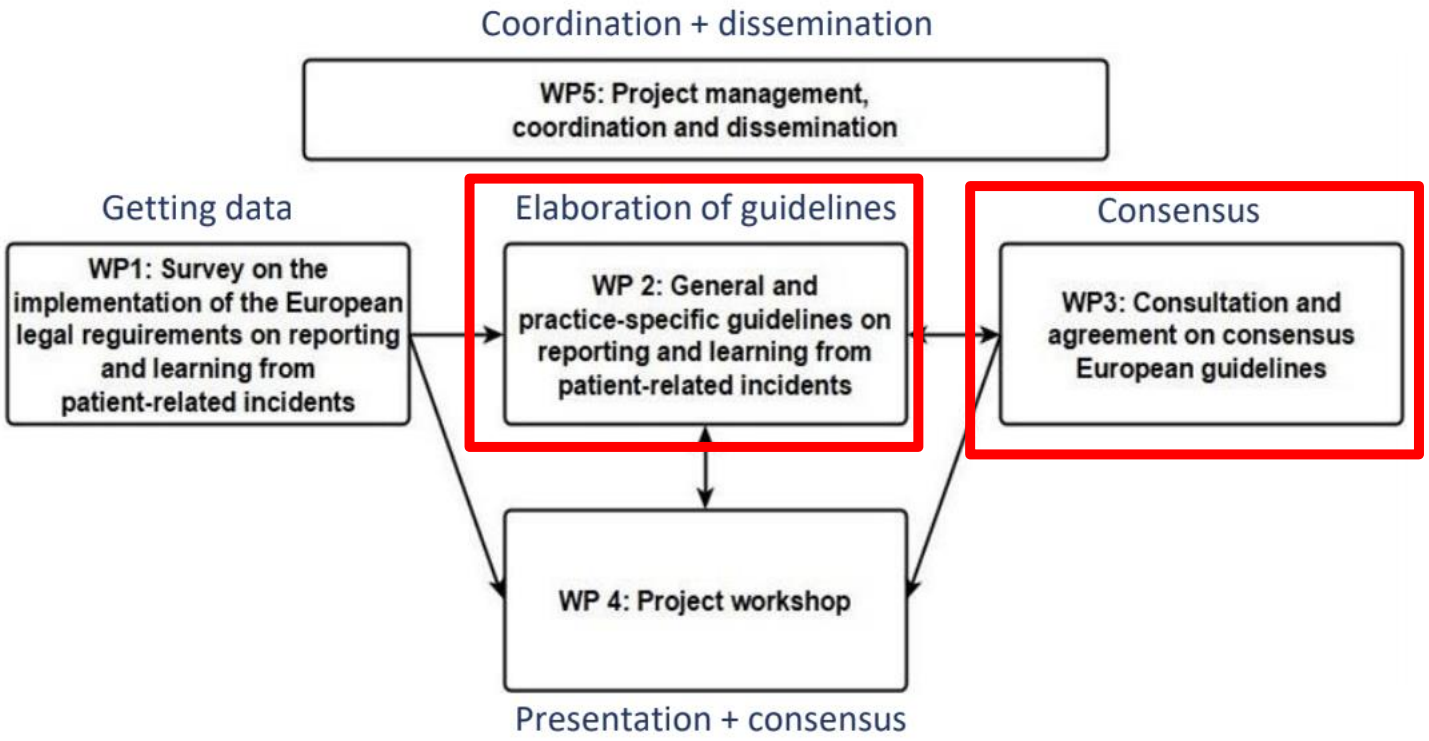
Methodology



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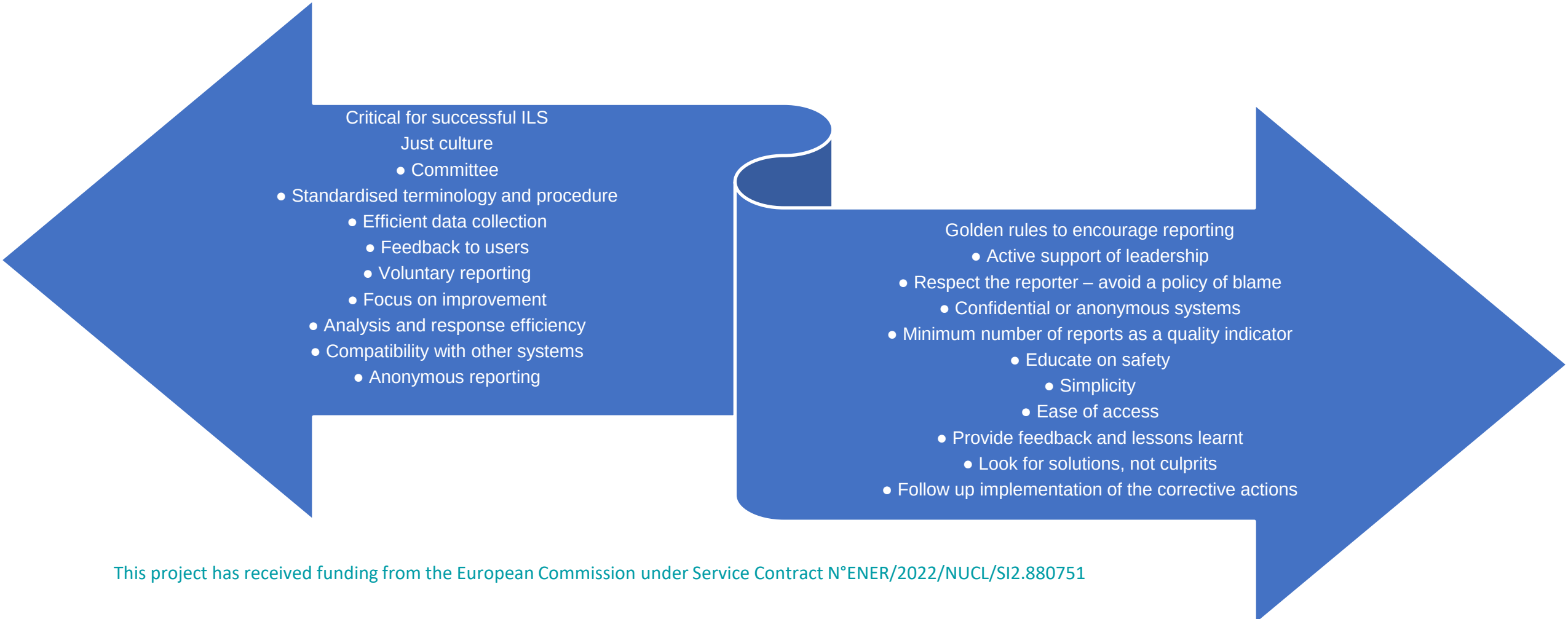
Timelines

Table 1: Gantt chart (duration of work packages and tasks)

Deliverable numbers in bold		2023												2024									
		Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4	
		1 Jan	2 Feb	3 Mar	4 Apr	5 May	6 Jun	7 Jul	8 Aug	9 Sept	10 Oct	11 Nov	12 Dec	13 Jan	14 Feb	15 Mar	16 Apr	17 May	18 Jun	19 Jul	20 Aug	21 Sept	22 Oct	23 Nov	24 Dec
WP1	Survey on the implementation of European legal requirements on reporting and learning from patient-related incidents and near misses																								
T1.1	Update of literature review and analysis carried out as part of the tender application																								
T1.2	Design and implementation of survey	**1.1**				**1.2**																			
T1.3	Design and implementation of expert interviews																								
T1.4	Analysis and preparation of WP1 report, summarising literature review, survey and expert interviews						**1.3**																		
WP2	General and practice-specific guidelines on reporting and learning from patient-related incidents and near misses																								
T2.1	Collection and analysis of findings from WP1; drafting the structure, table of contents and guidelines format						**2.1**																		
T2.2	Drafting of the guidelines													**2.2**											
T2.3	Update and finalise European consensus guidelines, considering stakeholder feedback & workshop discussions																		**2.3**				**2.4**		**2.5**
WP3	Carry out consultations and agree on consensus European guidelines																								
T3.1	Set up stakeholder database for consultation and template document for provision of feedback																								
T3.2	Organisation and implementation of the consultation process for the draft guidelines													**3.1**											
T3.3	Collate, analyse and summarise feedback and suggestions for revisions and achieve consensus																								
T3.4	Implement suggestions received and consensus achieved into draft guidelines for discussion and submission																		**3.2**						
WP4	Project workshop																								
T4.1	Establish the programme structure, identify speakers and panels, handle invitations and dissemination																		**4.1**						
T4.2	Organisational arrangements: meeting room, catering, registration, reimbursements to speakers and panellists																				**4.2**				
T4.3	Preparation of the workshop proceedings, session summaries, main workshop conclusions and recommendations																						**4.3**		
WP5	Project management, coordination and dissemination																								
T5.1	Project governance, management of consortium bodies and related meetings, financial management																								
T5.2	Monitoring of project progress, quality assurance and risk management																								
T5.3	Progress reporting to the EC according to tender specifications	**5.1**	**5.2**				**5.3**								**5.4**					**5.5**				**5.6**		**5.7**
T5.4	Internal and external communication and dissemination																								

Literature review

74 articles identified



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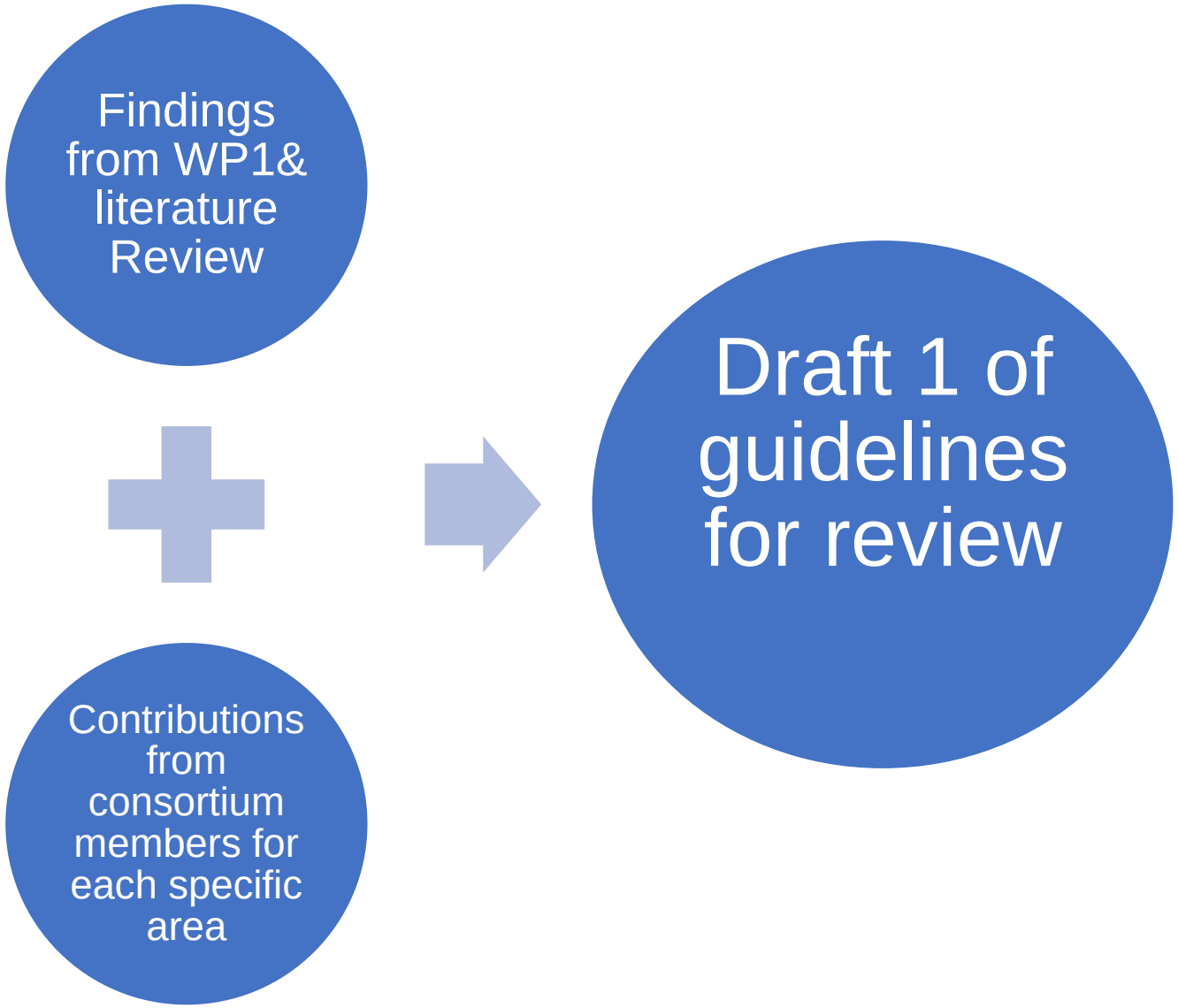
Elaboration of Guidelines



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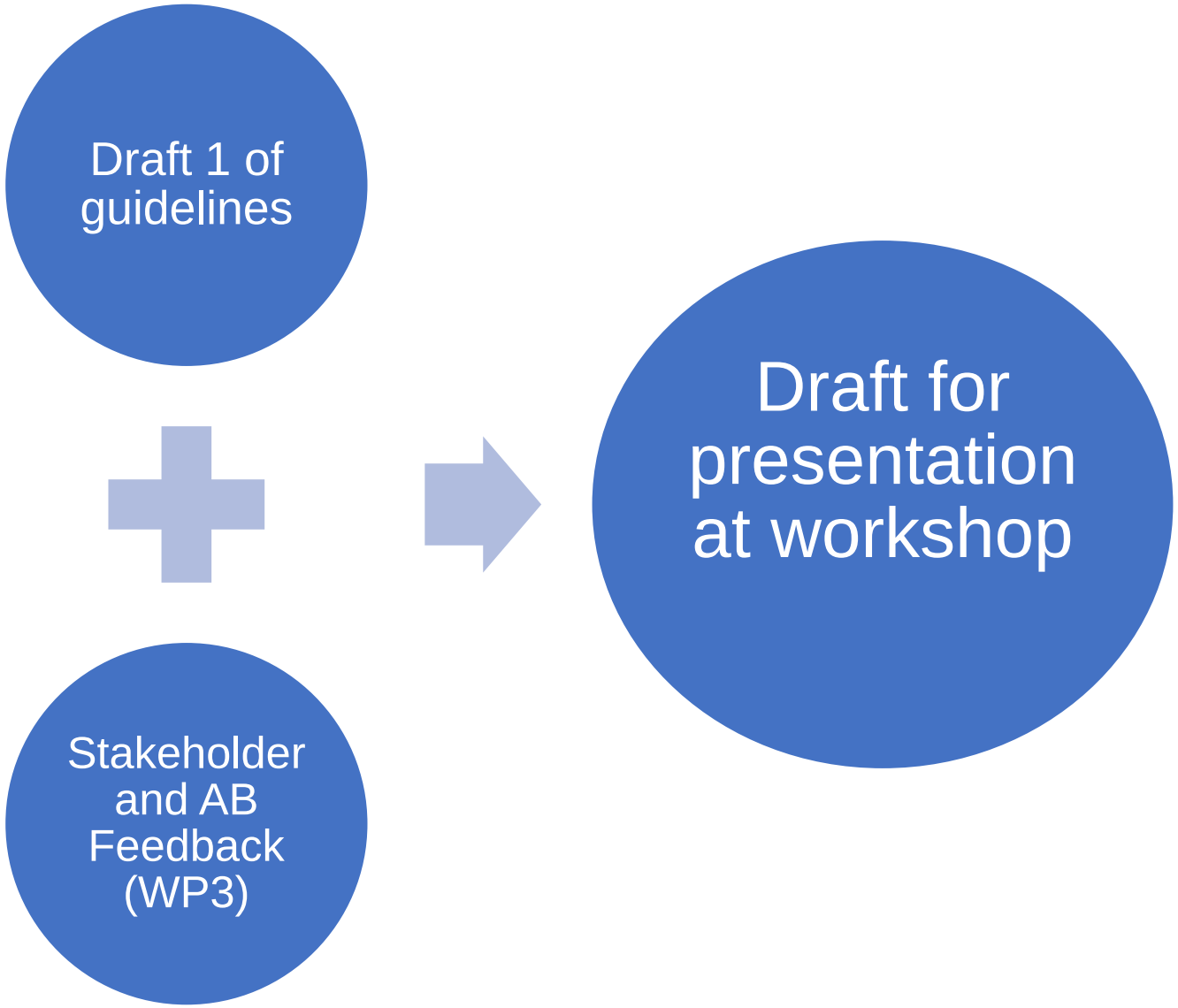
Elaboration of Guidelines



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WP3: Consultations with Stakeholders

Database encompassing national and international stakeholders to be involved in the consultation was devised

→ National competent authorities, professional societies, clinical facilities, international and European organisations

↓

Email sent to stakeholders to protect time to participate in consultation process

↓

Draft guidelines and Jotform template provided for stakeholders to provide feedback

↓

Feedback collated, analysed and implemented into draft guidelines

→ Experts – each specific area
Individual stakeholders contacted where necessary
Guidelines updated

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WP3: Consultations with Stakeholders

- 90 responses
- Geographical spread

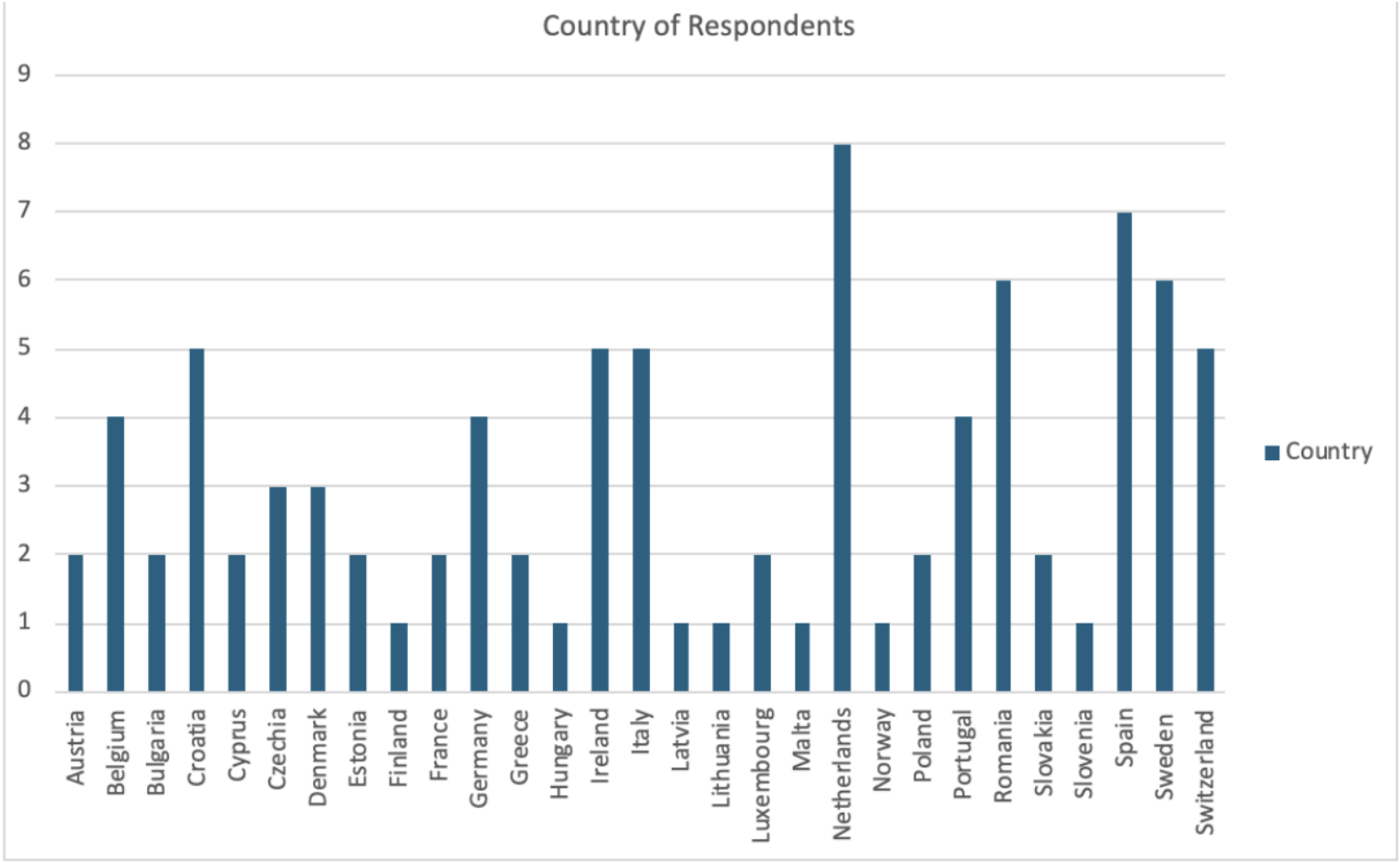

Fig. 1: Graph of the number of respondents per country

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WP3: Consultations with Stakeholders

Fig. 3: Pie chart describing the respondents' area of work

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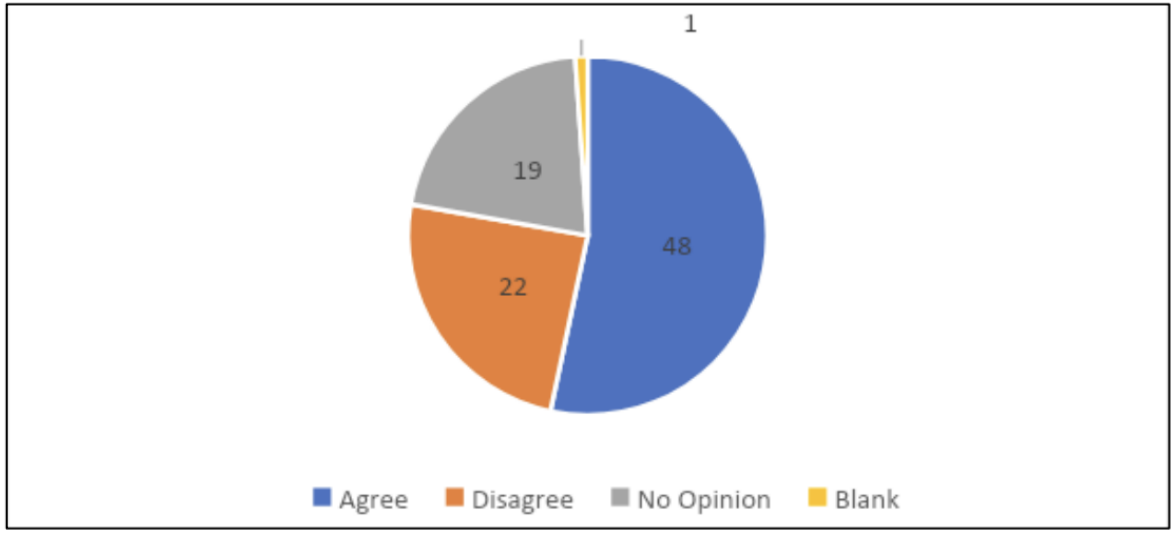
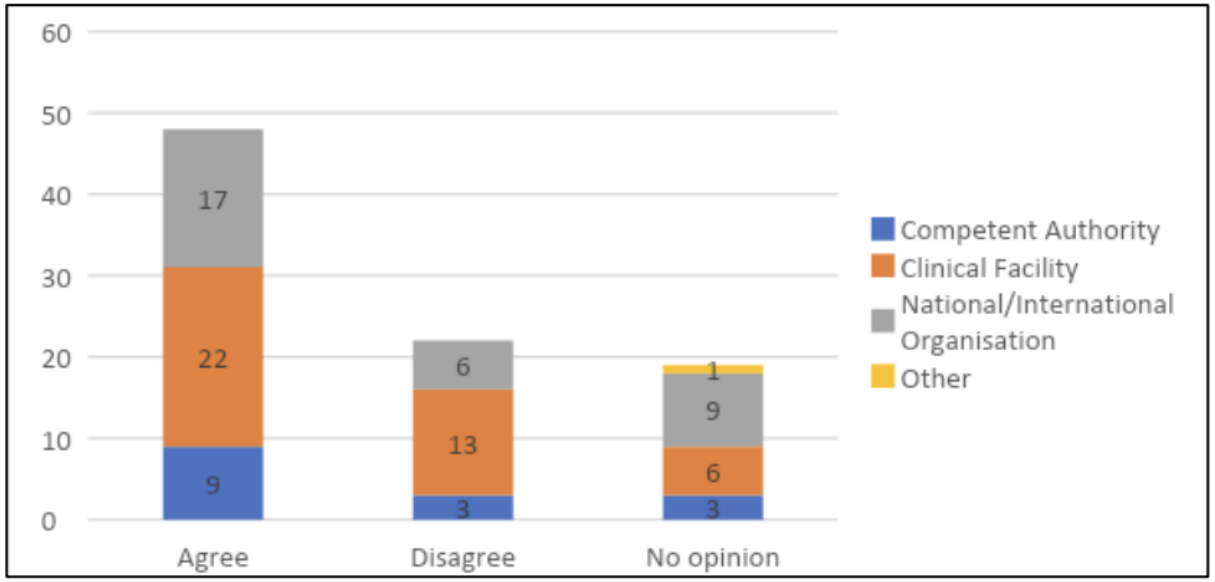
WP3: Consultations with Stakeholders

When asked if the guidelines will encourage reporting of incidents in an area, 48 agreed, 22 disagreed, 19 had no opinion and one did not respond.





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WP3: Consultations with Stakeholders
Other notable changes following consultation

1. Addition of executive summary and a summary of recommendations has been added.
2. The definitions have been revised in detail to comply with the BSSD regarding significant events, harmonise with the rest of the text, and additional definitions e.g. root cause analysis for clarity.
3. The table for the definition of significant events has been updated to reflect more clearly the different clinical areas and define categories 1, 2 and 3 as significant events and category 4 as events that may be reported in cases where they are of particular interest from a patient safety point of view.
4. Dose reference levels as a criterion for triggering the investigation of events have been removed after receiving several comments about their problematic usage.
5. Initial reporting to competent authorities has been made mandatory for all significant events (categories 1, 2 and 3) in line with the BSSD.
6. Because of their many similarities, the particularities of external beam radiotherapy and brachytherapy have been combined in a single section on the particularities of radiotherapy.
7. To clarify the classification of preventive and corrective actions, a new annex on action effectiveness has been added.

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Structure of Guidelines

Table of Contents

Preliminary Sections:
Disclaimer and Abbreviations: Preliminary sections that set the legal context and define abbreviations.

Executive Summary and Main Recommendations: Provide a high-level overview and key recommendations.

Chapter 1: Introduction: Introduces the concept of ILSs, including definitions, background, implementation best practices, and the role of national and international systems. It also covers topics like open disclosure, reporter protection, and management of critical incidents.

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Structure of guidelines

Chapter 2: Clinical Facility Perspective:
Focuses on the governance structure, just culture, and implementation of ILSs at the clinical facility level, including reporting, recording, analysis, learning, and collaboration with authorities. It addresses the management of major incidents and resource allocation.

Chapter 3: Competent Authorities' Systems:
Discusses the role of competent authorities in managing ILSs, including criteria for notification, reporting procedures, follow-up, public dissemination, and coordination with manufacturers and other authorities.

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Structure of guidelines

Chapter 4: Role of Professional Organizations:
Examines whether professional organizations should develop additional ILSs, their collaboration with clinical facilities, competent authorities, and manufacturers, and the structure and resources needed for effective incident learning within these organizations.

Chapter 5: Specific Areas:
Details the specificities of ILSs in different medical areas like radiotherapy, nuclear medicine, interventional procedures, and diagnostic radiology. It discusses local, national, and international systems, professional societies, and incident learning committees. The document is organized to guide different stakeholders—from clinical facilities to national authorities and professional organizations—on how to implement and optimize ILSs to enhance patient safety in radiation practices.

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Thank you

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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

European Consensus Guidelines
Chapters 1 – Introduction

Colin Kelly

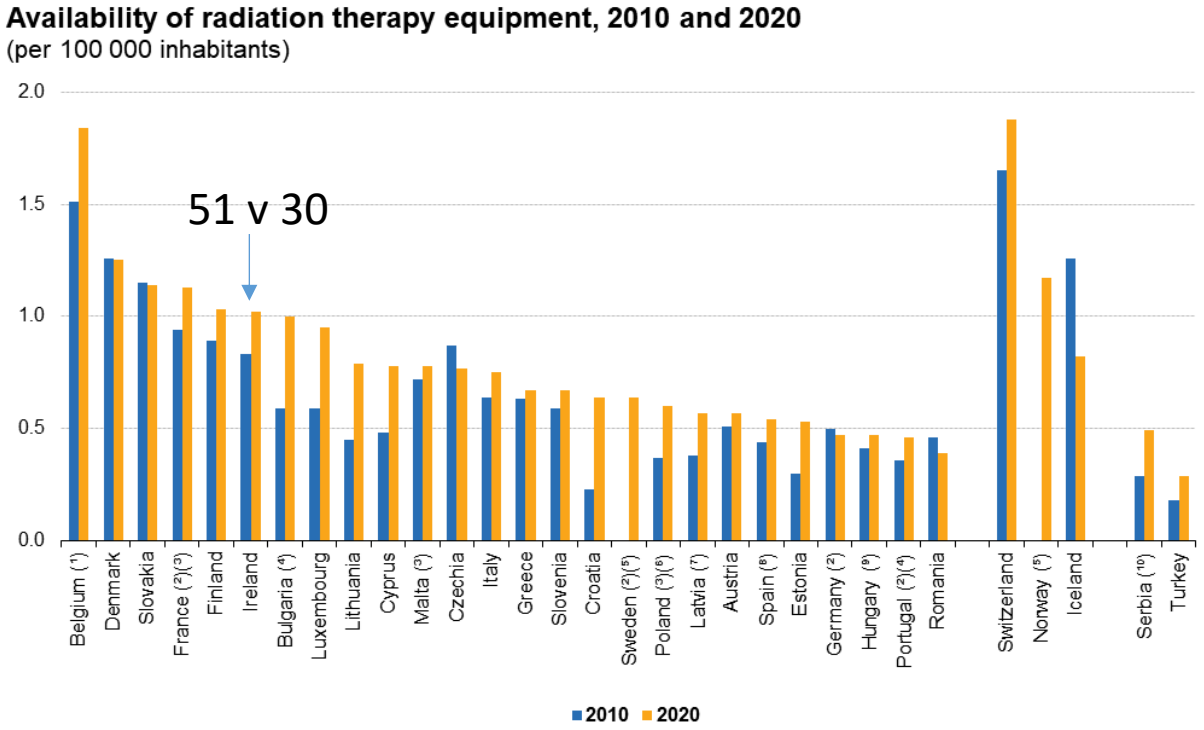
MARLIN Project Workshop
September 5 & 6, Brussels

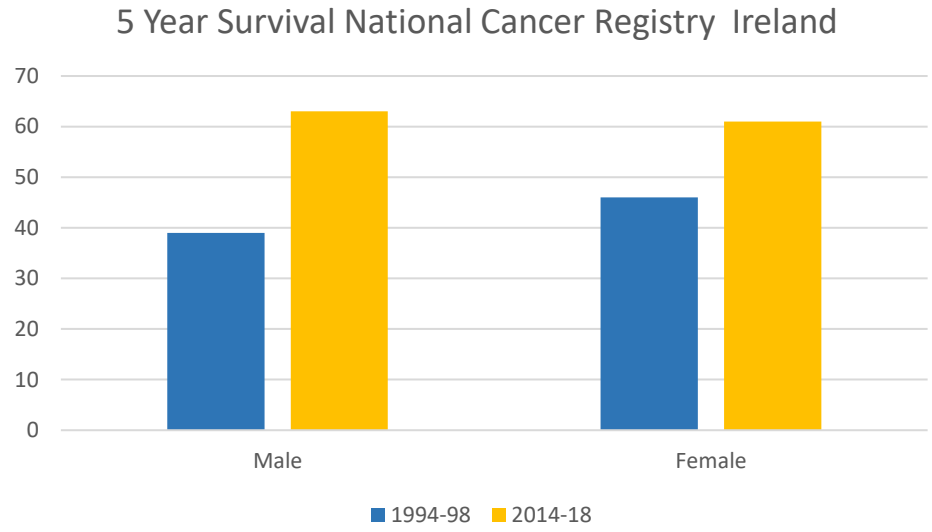
Saint Luke's Radiation Oncology Network

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Dublin Midlands Hospital Group
Academic Partner Trinity College Dublin

Medical Ionising Radiation Cost and Benefit





"..in consenting the patient knowingly acquiesces to a further risk of sub-optimal care due to preventable human errors Introduced into the medical process" – Ford et al 2012

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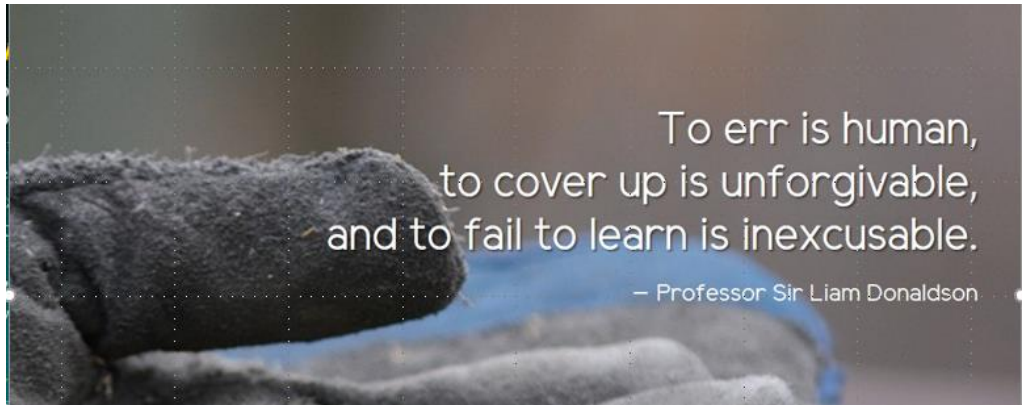

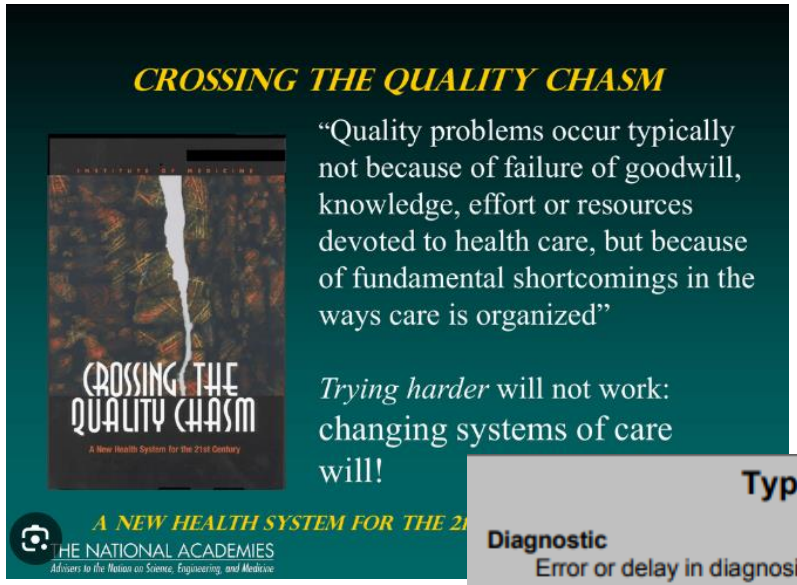

As medical science and technology have advanced at a rapid pace, however, the health care delivery system has floundered in its ability to provide consistently high-quality care to all Americans. Research on the quality of care reveals a health care system that frequently falls short in its ability to translate knowledge into practice, and to apply new technology safely and appropriately. During the last decade alone, more than 70 publications in leading peer-reviewed journals have documented serious quality shortcomings (see Appendix A). The performance of the health care system varies considerably. It may be exemplary, but often is not, and millions of Americans fail to receive effective care. If the health care system cannot consistently deliver today's science and technology, we may conclude that it is even less prepared to respond to the extraordinary scientific advances that will surely emerge during the first half of the 21st century. And finally, more than 40 million Americans remain without health insurance, deprived of critically important access to basic care (U.S. Census Bureau, 2000).

Types of Errors

Diagnostic
- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment
- Error in the performance of an operation, procedure, or test
- Error in administering the treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventive
- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other
- Failure of communication
- Equipment failure
- Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. Qual Rev Bull. 19(5):144–149, 1993.

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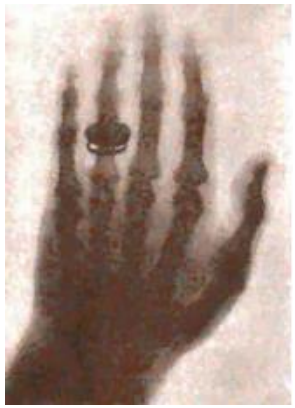

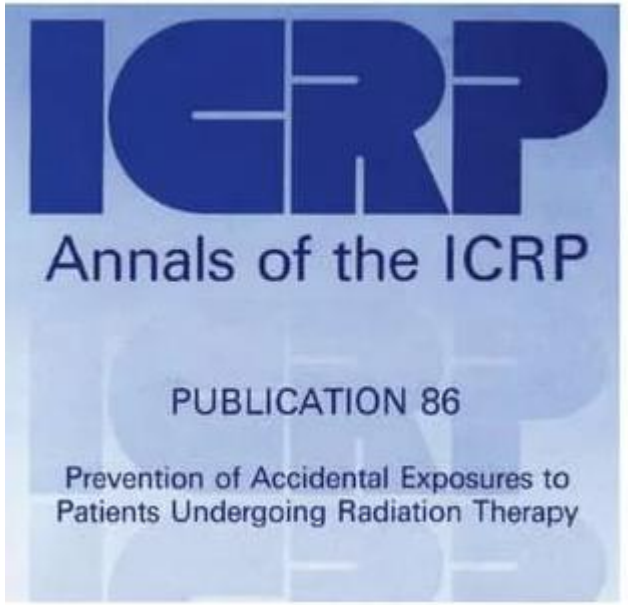

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A French court on Wednesday sentenced two doctors and a radiophysicist to 18 months in prison for their role in radiation overdoses given to nearly 450 cancer patients.

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

Give this article

By Walt Bogdanich
Jan. 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

SOCIÉTÉ

Accidents de radiothérapie à Epinal : les responsables de l'hôpital mis en cause

Selon un rapport de l'inspection générale des affaires sociales publié mardi, de graves défaillances sont à l'origine de la sur-irradiation de 23 patients traités en radiothérapie à l'hôpital d'Epinal. Le ministre de la santé demande des sanctions contre les responsables administratifs et médicaux.

Le Monde avec AFP
Publié le 06 mars 2007 à 09h54, modifié le 12 juin 2007 à 09h10 · Lecture 2 min.

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Preventing treatment errors in radiotherapy by identifying and evaluating near misses and actual incidents

Published online by Cambridge University Press: **20 November 2006**

Ola Holmberg and Brendan McClean

Show author details

› Int J Radiat Oncol Biol Phys. 2008;71(1 Suppl):S200-3. doi: 10.1016/j.ijrobp.2007.06.085.

Taxonometric applications in radiotherapy incident analysis

Peter B Dunscombe [1], Edidiong U Ekaette, Robert C Lee, David L Cooke

Affiliations + expand

PMID: 18406929 DOI: 10.1016/j.ijrobp.2007.06.085

Review › J Med Imaging Radiat Oncol. 2022 Mar;66(2):291-298. doi: 10.1111/1754-9485.13358.

Incident review in radiation oncology

Anthony Arnold [1], Iain Ward [2], Senthilkumar Gandhidasan [1]

Affiliations + expand

PMID: 35243784 DOI: 10.1111/1754-9485.13358

› Radiother Oncol. 2010 Jun;95(3):344-9. doi: 10.1016/j.radonc.2010.03.022. Epub 2010 Apr 17.

The management of radiation treatment error through incident learning

Brenda G Clark [1], Robert J Brown, Jodi L Ploquin, Anneke L Kind, Laval Grimard

Affiliations + expand

PMID: 20400189 DOI: 10.1016/j.radonc.2010.03.022

› Med Phys. 2012 Dec;39(12):7272-90. doi: 10.1118/1.4764914.

Consensus recommendations for incident learning database structures in radiation oncology

E C Ford [1], L Fong de Los Santos, T Pawlicki, S Sutlief, P Dunscombe

Affiliations + expand

PMID: 23231278 DOI: 10.1118/1.4764914

› J Radiol Prot. 2021 Mar 26;41(1). doi: 10.1088/1361-6498/abd913.

Development of a model for registration and notification of accidents and incidents in nuclear medicine

Marlon Da Silva Brandão Rodrigues [1], Susie Medeiros Oliveira [2], Lidia Vasconcellos de Sá [1]

Affiliations + expand

PMID: 33406513 DOI: 10.1088/1361-6498/abd913

Incident Learning Systems

- Almost directly as a consequence of catastrophic incidents ILSs began to be implemented in RT centres
- Inspiration from the aviation and nuclear power industries
- Currently well established in radiotherapy with many clinics publishing mature data
- Considered a key element in safety management
- The experience of RO indicates that the use of incident learning reduces the severity of incidents over time, promotes a safety culture and strongly encourages the reporting of incidents
- Underpinned now by EU and national legislation

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Definitons I

- " Defining a common terminology for incident learning is important to ensure consistency and minimise ambiguity in communication" ……Radicchi et al. 2020
- WHO, AAPM, IAEA, SAFRON, ROSEIS

RP 181 (EU 2015)

- Event involving accidental or unintended medical exposure
- Adverse Event
- Minor or no-harm event
- Significant event
- Near miss

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Definitons II

- Critical event
- Clinically significant event
- Incident learning system
- Root cause
- Latent cause/contributory factor
- Clinical facility
- Competent authority
- Second/Third victim

- Non-compliance
- Concessions

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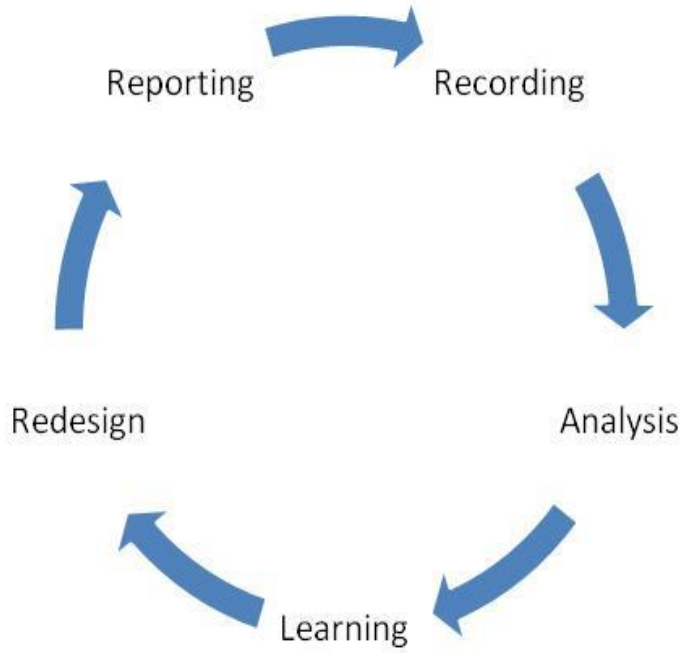
Concept



- Cycle of learning where practices are continually and iteratively strengthened
- Inclusion of near misses and potential errors
- Purpose to continually identify weaknesses
- Reduce actual errors reaching the patient

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National ILSs

- Mandatory reporting of significant events a requirement
- National ILSs maintained by the CA with database of events
- Greater numbers – better data
- Can ensure standardisation of approach – taxonomy, etc.
  - dissemination and sharing of data
  - new equipment, new technique
- Particularly beneficial for small centres
- Helps establish and optimise a uniform safety culture at national level
-

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International ILSs

- International systems potentially generate data on an even greater scale
- Access to such databases can be enormously beneficial to new centres and countries with less well-developed medical infrastructure
- ESTRO's ROSEIS or the IAEA's SAFRON have both been in operation for >10 years
- The ROSEIS and SAFRON taxonomies are broadly compatible which facilitates data sharing and comparative analysis
- Can be used to set standards for national and local ILSs
- International ILSs are particularly useful when centres are introducing new equipment or technologies as rapid access to incidents experienced worldwide can be used to design interventions and workflows that reduce risk and enhance patient safety

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Reporter Protection

- ILSs rely fundamentally on open reporting
- In some countries this can be affected by the fear of litigation
- This can be addressed by confidentiality and anonymity within the ILS
- However judicial authority can compel full disclosure
- Legislation in the USA protects healthcare professional
- Strong need for European legislation
- Best Practice – Irish Protected Disclosures Act (2014)

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European Consensus Guidelines
Chapter 2 – Incident Learning in the Clinic: Clinical Facility Perspective

EU Council Directive 2013/59/Euratom

- BSS for protection against ionising radiation
- Promotes safe use of radiation in medicine
- Outlines roles and responsibilities of the undertaking, the practitioner, the referrer and the MPE
- Introduces and defines responsibility of the Competent Authority (CA) at national and/or federal level
- “Provides an opportunity to establish a comprehensive system for developing a safety culture”

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Responsibilities of the Clinical Facility and the Authority under the BSSD

- ….all reasonable measures are taken to minimise the probability and magnitude of accidental exposures of individuals
- ….an appropriate system is implemented for the record keeping and analysis of events
- ….arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant events and the results of the analysis
- ….the CA is notified, promptly of any significant event
- ….the results of the investigation into any significant event and the corrective measures are reported to the CA within the time period specified…
- ….the CA shall ensure timely dissemination of information regarding lessons learned from significant events

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Ethical and Operational Obligations of the CF

- Establishment and continual maintenance of a safety culture where all staff feel enabled to report incidents
- Prompt identification of significant events and their reporting to the CA and the analysis and recording of all incidents
- Identification of learning outcomes from singular events or incident clusters
- Redesign or alteration of clinical procedures or policies as a result of incident-based learning
- Communication of learning outcomes to all relevant staff
- Clinical audit to assess the efficacy of the actions recommended for ILSs

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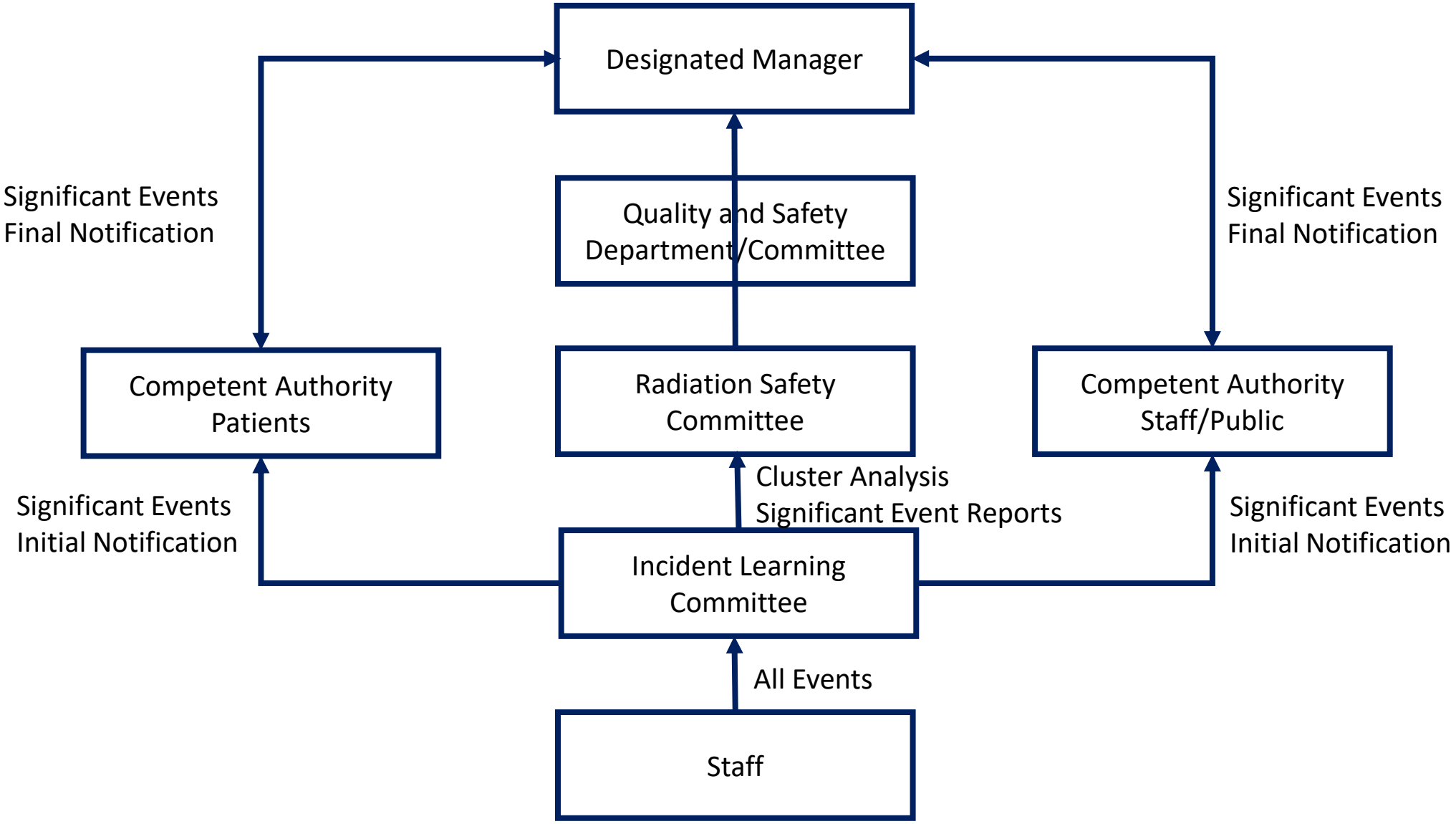
Governance



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Just Culture

- Staff confident to report openly and honestly
- No fear of repercussion
- Concentrate on organisational or systems failures
- Continual organisational learning
- Atmosphere of trust and shared accountability
- Staff not responsible for systems failings for which they have no control
- Comfortable to work within the limits of their competency
- Accountable for their practice
- Act at all times in accordance with established professionalism and ethical standards

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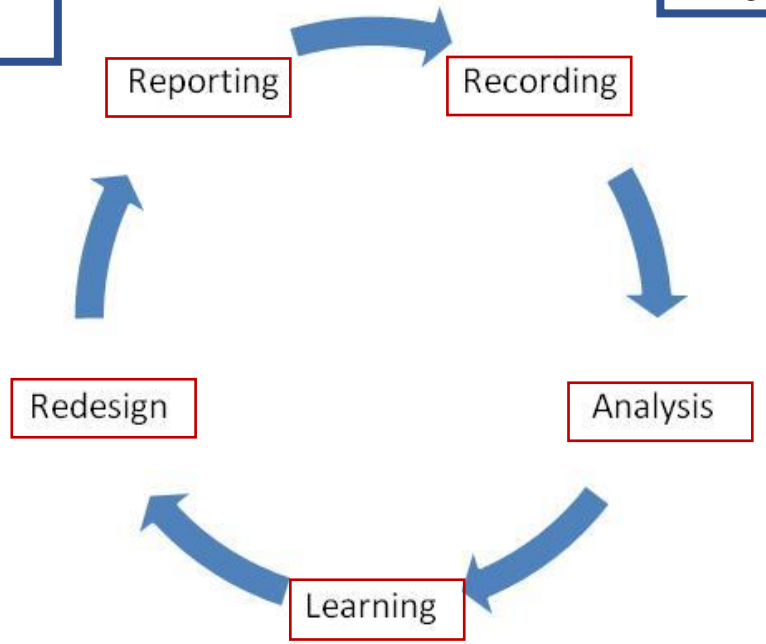
Clinical Facilities - ILS

- Open reporting
  - Adverse events
  - Near misses
  - Non conformances
  - Concessions
- Just Culture

- Easily accessible
- Simple to use
- EPR
- Staff categorisation and classification



- Incident Learning Committee
- Regular review
- Categorisation & classification
- Cluster analysis
- Systems /Ishikawa analysis

- Investigation of clusters or singular events
- Root cause
- Latent causes

- Alteration of clinical protocols or procedures
- Training and Education
- Success measured by elimination or reduction of similar incidents

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Collaboration with the CAs

Collaboration is a partnership; a union; the act of producing or making something together

- Significant events reported by the CF to the CA
- Criteria for significant events defined, in general, nationally
- Time frame for preliminary notification through a secure portal
- Within a subsequent timeframe - comprehensive system analysis review comprising of (i) chronology of events (ii) dosimetric and clinical impact (iii) root cause and contributory factors (iv) recommendations to reduce probability of recurrence
- CA can seek clarification where necessary and use the report recommendations for subsequent inspection of the CF
- CA maintains a database of significant events
- CFs would encourage a national database of *all events*

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Open Disclosure and Patient Engagement

- Open disclosure is an essential element of ILSs in the clinic
- Required by BSSD to inform patients of clinically significant events
- Responsibility of the ILC and the referring practitioner
- Patient should be provided with (i) a dosimetric analysis (ii) a review of potential clinical consequences (iii) potential salvage options
- Communication with patient in a sensitive and supportive manner
- Language understandable and use of patient advocates highly desirable
- Patient kept up to date on progress of the analysis and given opportunity to participate and contribute

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Second and Third Victims

- Second victims can be identified as those health professionals who experience psychological trauma as a result of their involvement in safety events
- Responsibility of the CF and ILS to ensure rights of second victims are considered and respects
- Second victim protocol a vital component of a successful ILS
- Third victims are often identified as healthcare organisations
- Organisational, economic, legal and reputational impact
- Successful ILS can mitigate affect on CFs
- Appropriateness of terms second/third victim currently being questioned in light of the impact on first victims

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Critical Incident Management

- Development of special escalation pathway required in all CFs
- Time is critical - immediate cessation of radiation exposure
- Report through the ILS
- Emergency preliminary review by ILC
- Communication to CF management and medical team
- Open disclosure to patient and family
- Formation of temporary CMIC chaired by the designated manager
- Decide on immediate actions and devise communication strategy
- Inform the CA within legislative time frame
- Conduct systems analysis and immediately implement actions

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Resources

- Considerable dedication of time across the MDT
- Regular training by line managers to new and existing staff
- Updates and team meetings on results of incident learning
- Continual training to all staff in use of the system
- Dedicated time for staff to report events and reacquaint with changes in work practices arising from incident learning
- ILC – meet regularly, write reports, systems analyses, disseminate results
- Liaise with CA, CF management and professional societies
- ILS must lie at the heart of the CF and the clinical process
- Support the development of technological tools to ease workflow

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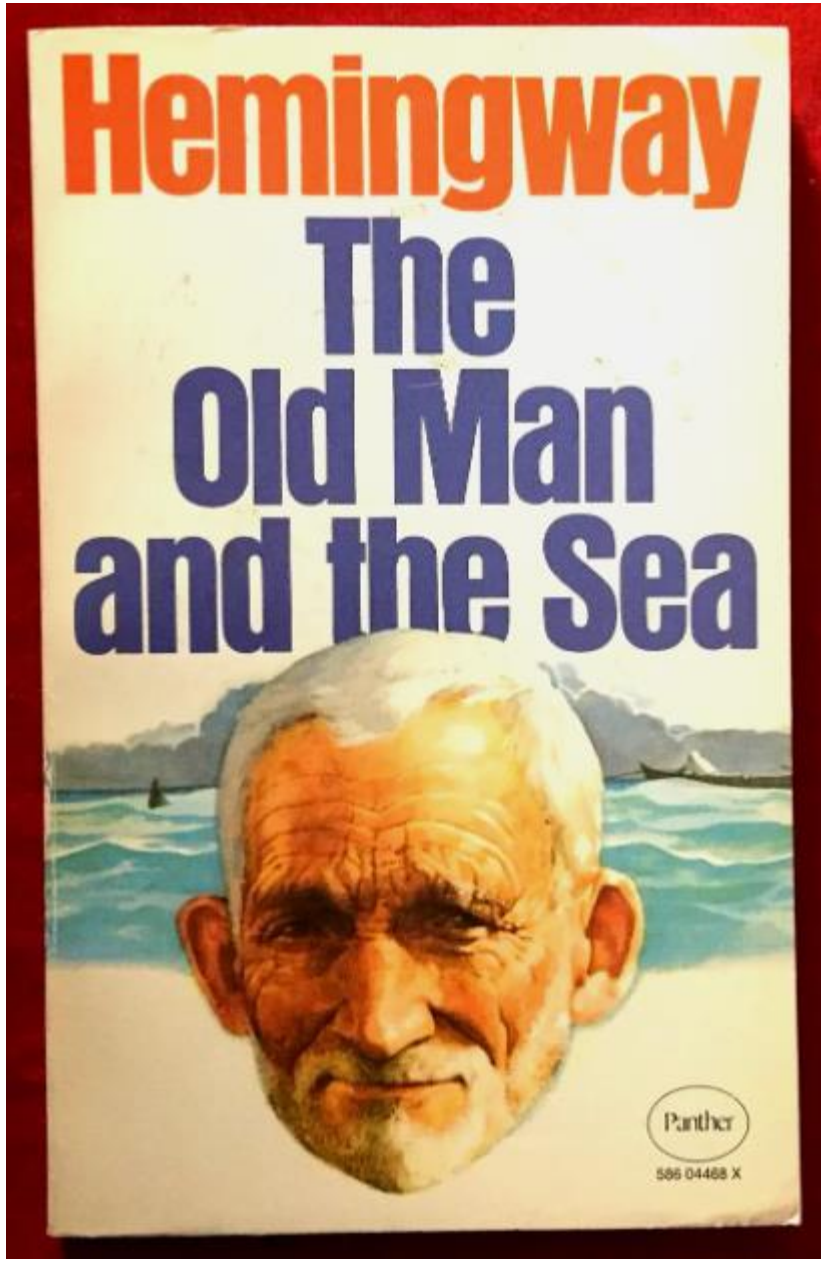
Hemingway
The Old Man and the Sea
Panther
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SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

European Consensus Guidelines Chapter 3 – ILSs of the Competent Authorities

Carlos Prieto Martín

MARLIN Project Workshop
September 5 & 6, Brussels

Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

ICRP 97 (ICRP 2005): "… prescriptive regulations can never work in the long run. The operator, not the regulator, must take the primary responsibility for safety, and the job of the regulator is to ensure that the operator is capable of taking that responsibility, not to handle the actual safety cases"

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Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

BSSD 2013/59/Euratom

63.e (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority; (ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State

63.f mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events

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Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Criteria of notification (significant events)

- Main criterion: clinical consequences (physician)
- Investigation dosimetric triggers (MPE): only reportable if the deviation is not justified. Different for radiotherapy, therapeutic nuclear medicine and medical imaging procedures
- Number of patients affected by the error taken into account
- Categories of significant events: Classification, give a clear idea of the severity, prioritization

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Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Criteria of notification

Significant Events (Covered by Article 63.e.i of the BSSD)			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	**Category 2**	**Category 3**	**Category 4**
Clinical consequences			
CTCAE v5.0 Grade 3 to 5	CTCAE v5.0 Grade 2	CTCAE v5.0 Grade 1	No consequences
Investigation dosimetric triggers			
Radiotherapy			
Treatment dose deviation >25% or total volume miss	Treatment dose deviation >10% or 2.5 times margins Category 2 in ≥2 patients becomes category 1	Treatment dose deviation >5% or 1 time margins Category 3 in ≥2 patients becomes category 2	Treatment dose deviation <5% or <1 time margins 0% but potentially serious in ≥2 patients Category 4 in ≥2 patients becomes category 3
Therapeutic Nuclear Medicine			
Deviation >50% of administered activity	Deviation >30% of administered activity Category 2 in ≥2 patients becomes category 1	Deviation >15% of administered activity Category 3 in ≥2 patients becomes category 2	<15% of administered activity 0% but potentially serious in ≥2 patients Category 4 in ≥2 patients becomes category 3
Medical Imaging Procedures			
X	Unintended dose deviation >200 times or >100 mSv	Unintended dose deviation >20 times, or >10 mSv or area error 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
Other Criteria (For Events with No Consequences and Minor Deviations)			
X	X	X	• Malfunction of equipment or in nuclear medicine the incorrect radiation source or incorrect route of administration • Multiple non-notifiable events with the potential to produce clinically significant events. • Those considered significant by the operator or the CA

CATEGORIES OF SIGNIFICANT EVENTS (Art. 63.e.i):

- Category 1 (critical event)
- Category 2

} should always be reportable

- Category 3

} Reportable as best practice

NON-SIGNIFICANT EVENTS (Art. 63.c):

- Category 4

} Not reportable exhaustively, only those interesting from the PS perspective

63.e.i: The undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority.

63.c for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice.

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Example

Radiotherapy: HDR treatment (^{192}I 15 GBq source) of a gynaecological cancer with 24 Gy in 4 sessions. The length of the catheter was incorrectly entered during planning, resulting in the dose being delivered 15 cm proximal to the correct position. The error was discovered during a review of the plan, as a bright CTCAE Grade 2 erythema appeared on the patient's legs

- Radiotherapy
- Complete miss of the target

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Example

Radiotherapy:

HDR 6 Gy x 4.
15 cm error in the whole treatment.
CTCAE Grade 2 erythema

Volume not treated (underdose)

No, erythema is not the worst consequence.

Significant Events (Covered by Article 63.e.i of the BSSD)			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	**Category 2**	**Category 3**	**Category 4**
Clinical consequences			
CTCAE v5.0 Grade 3 to 5	CTCAE v5.0 Grade 2	CTCAE v5.0 Grade 1	No consequences
Investigation dosimetric triggers			
Radiotherapy			
Treatment dose deviation >25% or total volume miss	Treatment dose deviation >10% or 2.5 times margins Category 2 in ≥2 patients becomes category 1	Treatment dose deviation >5% or 1 time margins Category 3 in ≥2 patients becomes category 2	Treatment dose deviation <5% or <1 time margins 0% but potentially serious in ≥2 patients Category 4 in ≥2 patients becomes category 3

Total volumen miss

Category 1

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Example

Nuclear medicine: A patient was to be assessed for hyperthyroidism with the administration of 10 MBq ^{123}I. The patient was given 100 MBq of ^{131}I for a whole-body scan. The estimated dose to the patient's thyroid gland was approximately 33 Gy and the effective dose was 200 mSv

- NM imaging procedure
- Wrong radiohpharmaceutical
- Wrong activity administered

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Example

Nuclear medicine:

Instead of 10 MBq ^{123}I, 100 MBq ^{131}I.
Thyroid gland approximately 33 Gy, E≈200 mSv

Significant Events (Covered by Article 63.e.i of the BSSD)			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	**Category 2**	**Category 3**	**Category 4**
Clinical consequences			
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X	Unintended dose deviation >200 times or >100 mSv	Unintended dose deviation >20 times, or >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
Other Criteria (For Events with No Consequences and Minor Deviations)			
X	X	X	• Malfunction of equipment or in nuclear medicine the incorrect radiation source or incorrect route of administration • Multiple non-notifiable events with the potential to produce clinically significant events. • Those considered significant by the operator or the CA

No, but significant increase of stochastic risk

No, it is a medical imaging procedure

Category 2

No, it is not a minor deviation

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Example

Interventional radiology: Interventional radiology embolization of an arteriovenous malformation in a patient using a bi-plane flat panel angiography device. Due to an equipment malfunction, the patient had unexpectedly large areas of alopecia, which were graded as 2 on CTCAE

- Imaging procedure
- Clinical consequences

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Example

Interventional radiology:

Alopecia grade 2 due to equipment malfunction

Significant Events (Covered by Article 63.e.i of the BSSD)			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	**Category 2**	**Category 3**	**Category 4**
Clinical consequences			
CTCAE v5.0 Grade 3 to 5	CTCAE v5.0 Grade 2	CTCAE v5.0 Grade 1	No consequences
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Other Criteria (For Events with No Consequences and Minor Deviations)			
X	X	X	• Malfunction of equipment or in nuclear medicine the incorrect radiation source or incorrect route of administration • Multiple non-notifiable events with the potential to produce clinically significant events. • Those considered significant by the operator or the CA

Category 2

No, there were clinical consequences

No, it has consequences

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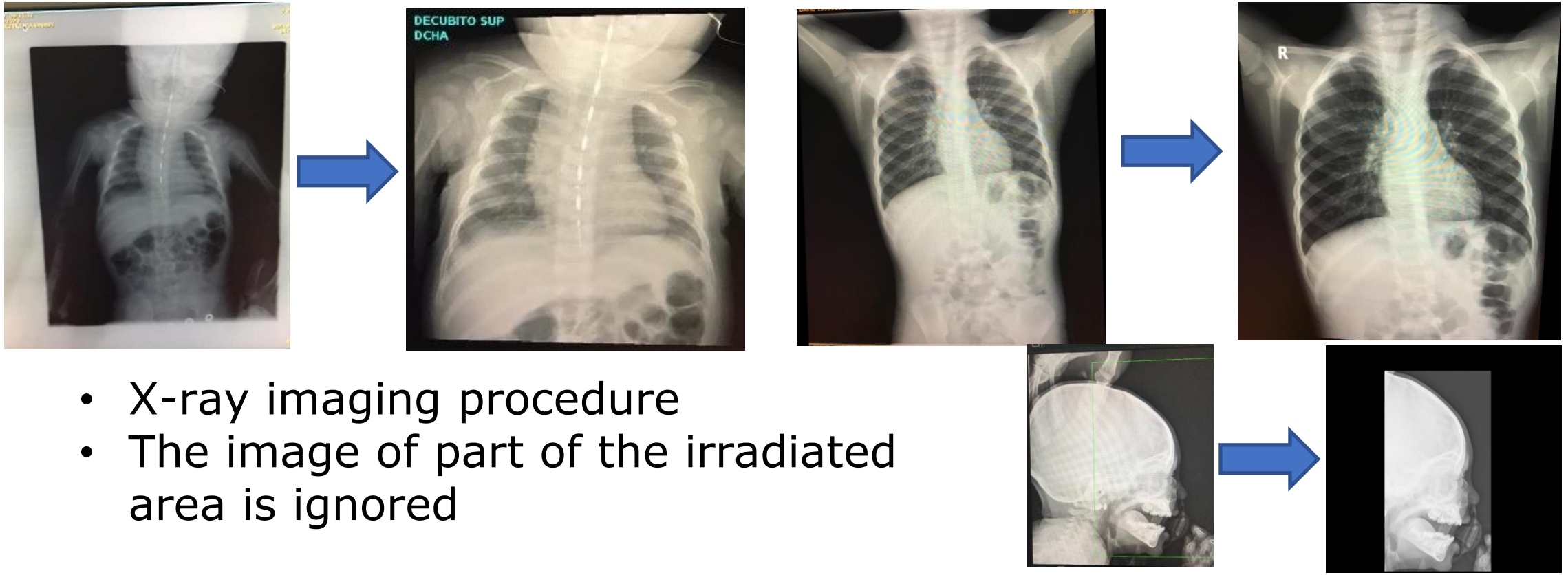
Example

Radiology: A radiographer does not properly collimate and systematically crop images of paediatric patients before sending them to the MIMPS (medical image management and processing system)



- X-ray imaging procedure
- The image of part of the irradiated area is ignored

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Example

Radiology:

Systematic Image cropping:

- Many patients affected
- Wrong collimation (dose excess)
- Detrimental effect on image quality (more scatter)
- Possible miss of incidental findings

Significant Events (Covered by Article 63.e.i of the BSSD)			Non-Significant Events (Events Covered by Article 63.c of the BSSD)
Category 1 (Critical Event)	**Category 2**	**Category 3**	**Category 4**
Clinical consequences			
CTCAE v5.0 Grade 3 to 5	CTCAE v5.0 Grade 2	CTCAE v5.0 Grade 1	No consequences
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Other Criteria (For Events with No Consequences and Minor Deviations)			
X	X	X	• Malfunction of equipment or in nuclear medicine the incorrect radiation source or incorrect route of administration • Multiple non-notifiable events with the potential to produce clinically significant events. • Those considered significant by the operator or the CA

No, but increase of stochastic risk

Category 3

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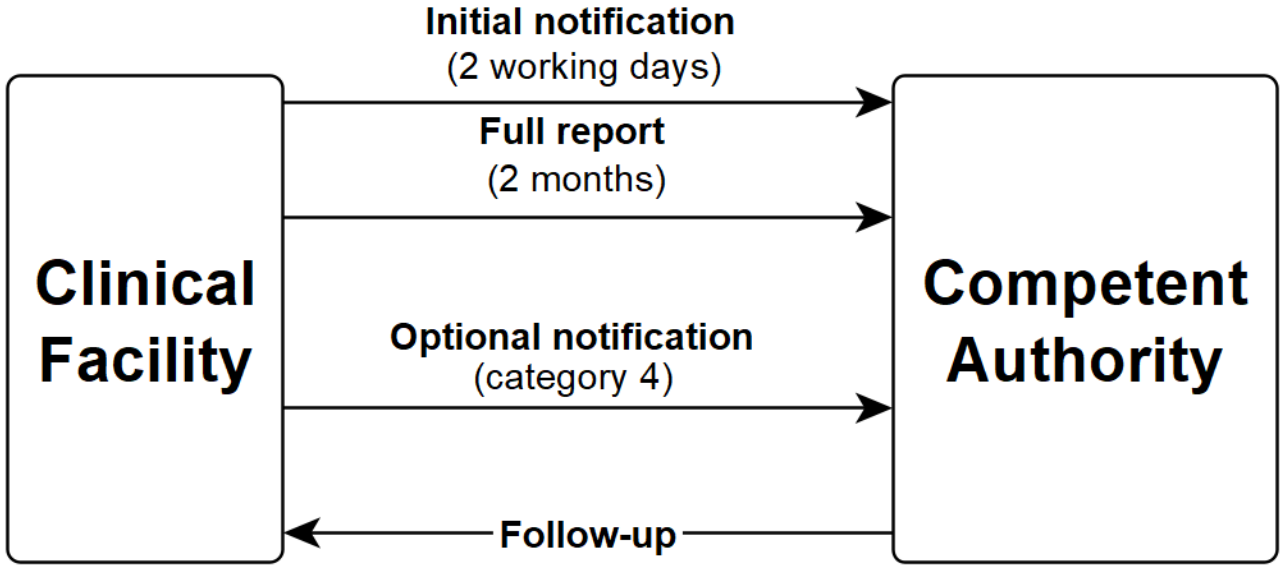
Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Time for notification



Follow-up:

- There is a plan to properly manage the risk.
- It is properly implemented

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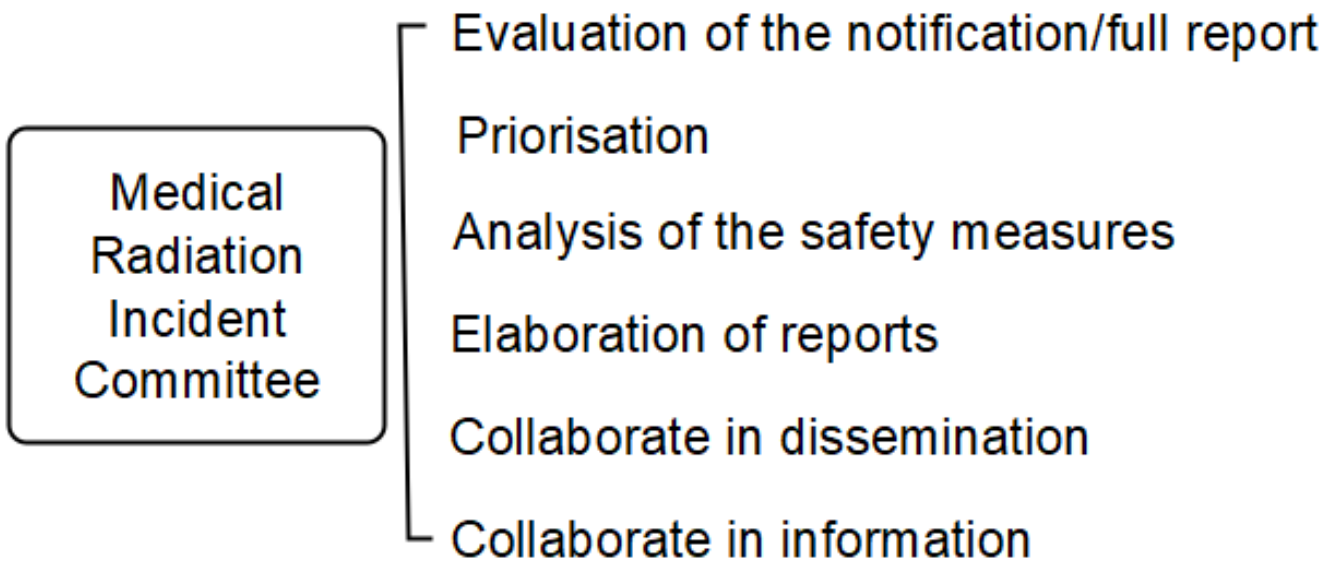
Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Medical radiation incident committee



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Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Dissemination

- It is a duty for the CA
- To professionals
- Periodic publications, courses, workshops, etc
- Collaboration with PS
- CA may require organisations to adopt safety measures

63.f mechanisms are in place for the timely **dissemination** of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Information to the public

- Provide contrasted information
- Transparency
- Information on individual events with important clinical consequences for one or more patients
- Anonymised statistical information on the number, type and category of significant events reported

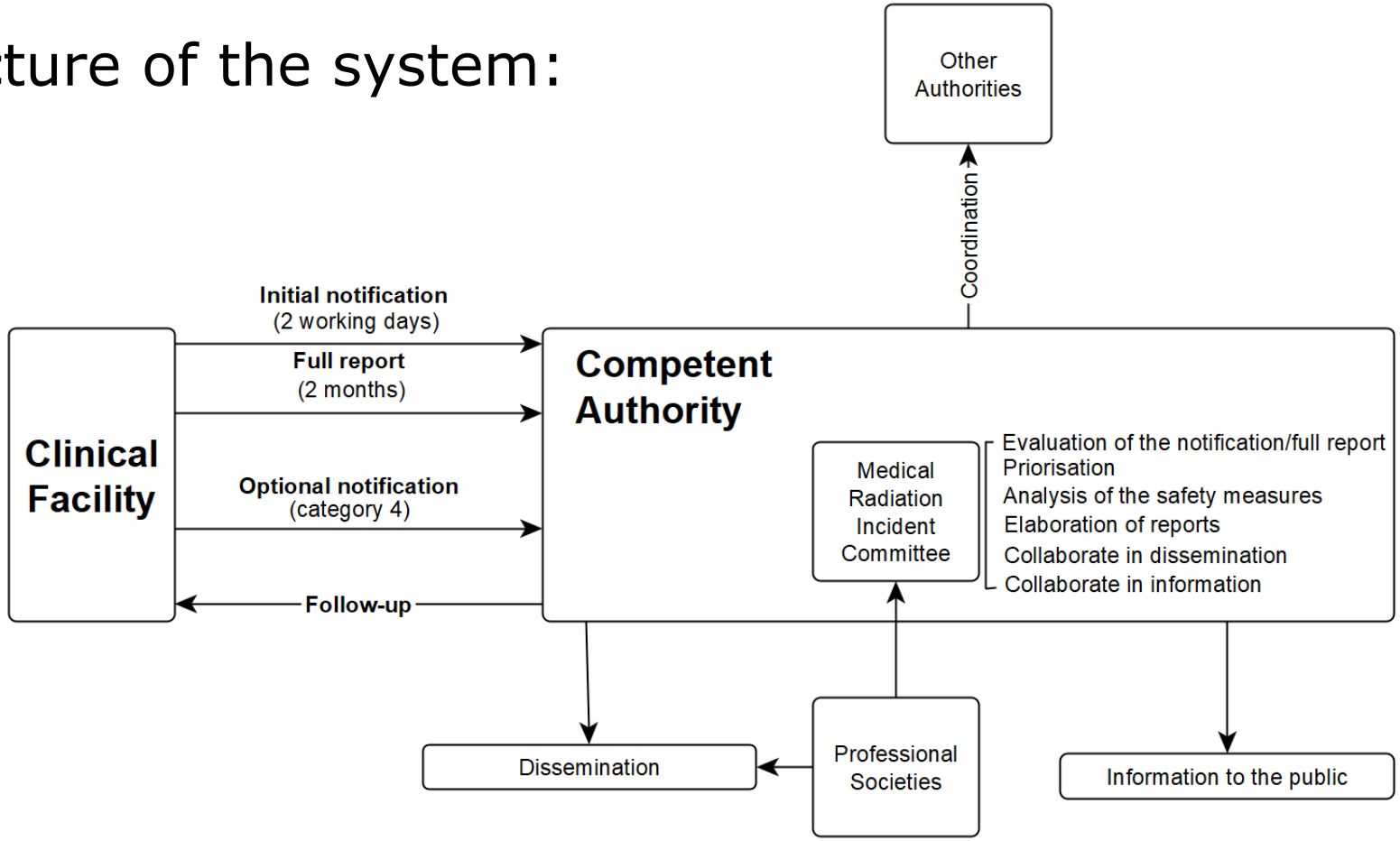
Coordination between CAs

- Several CAs: Significant events related with the use of ionising radiation/Medical devices/Workers or public affected
- Overlaps and interfaces inevitable. Ex: Equipment error due to a component or system failure / improper use of the equipment / poor calibration or commissioning / design error / cybersecurity issue

Presentation of the General Guidelines and Recommendations

INCIDENT LEARNING SYSTEMS OF THE CA

Structure of the system:



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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

European Consensus Guidelines Chapter 4 – Role of Professional Organisations

Presentation of the General Guidelines and Recommendations

THE ROLE OF PROFESSIONAL ORGANISATIONS

Safety committee of professional societies

- Improve professional practice
- Development and improvement of ILSs
- Dissemination and training
- Standardisation, guidelines
- Dialogue and collaboration with members, CA, other PSs and manufacturers
- Information

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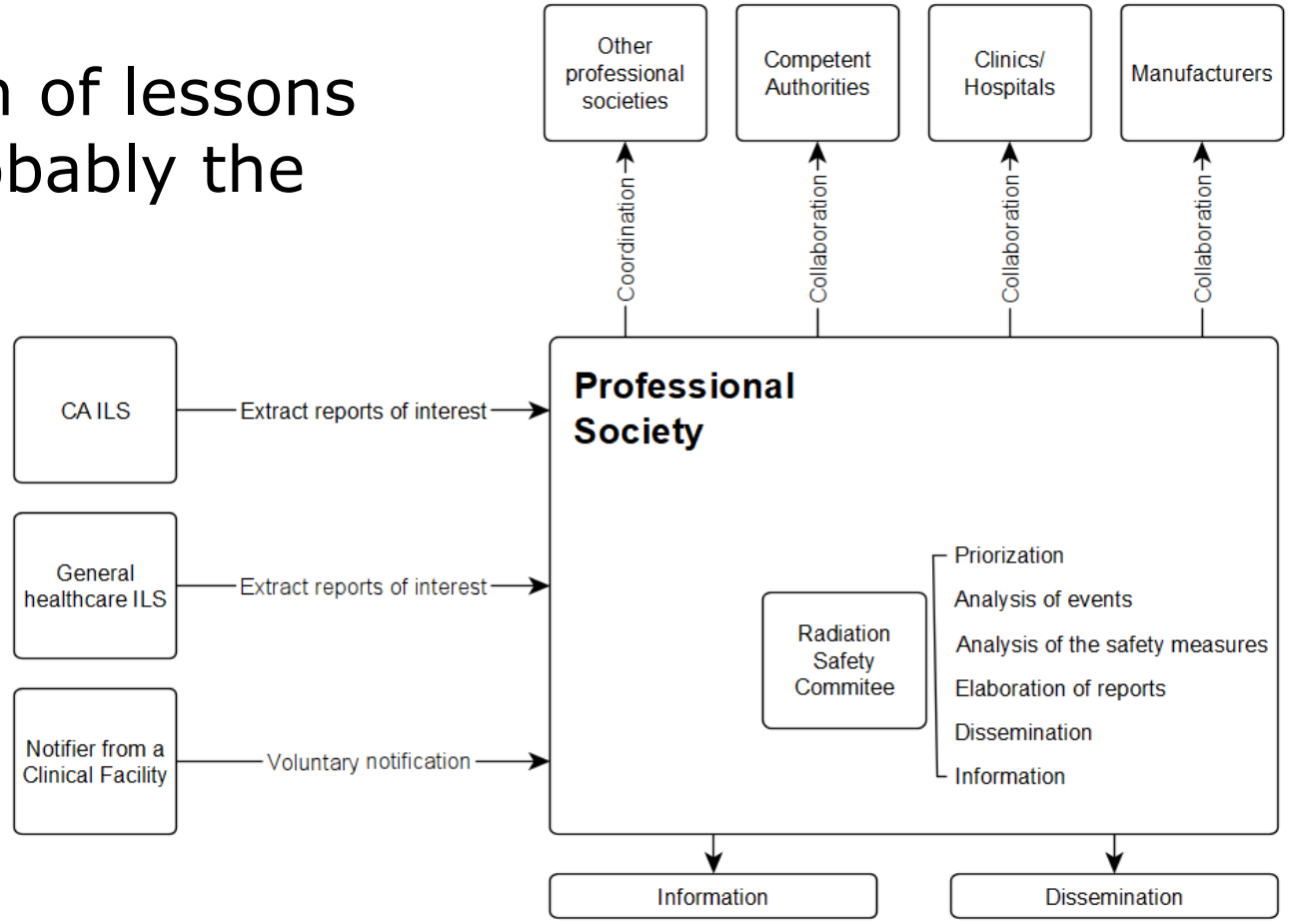
Presentation of the General Guidelines and Recommendations

THE ROLE OF PROFESSIONAL ORGANISATIONS

- Dissemination of lessons learned is probably the main role



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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

Coffee break

10:00–10:30

MARLIN Project Workshop
September 5 & 6, Brussels

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

Discussion

10:30–10:50

MARLIN Project Workshop
September 5 & 6, Brussels

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

Conclusions & Recommendations

D. Akata

MARLIN Project Workshop
September 5 & 6, Brussels