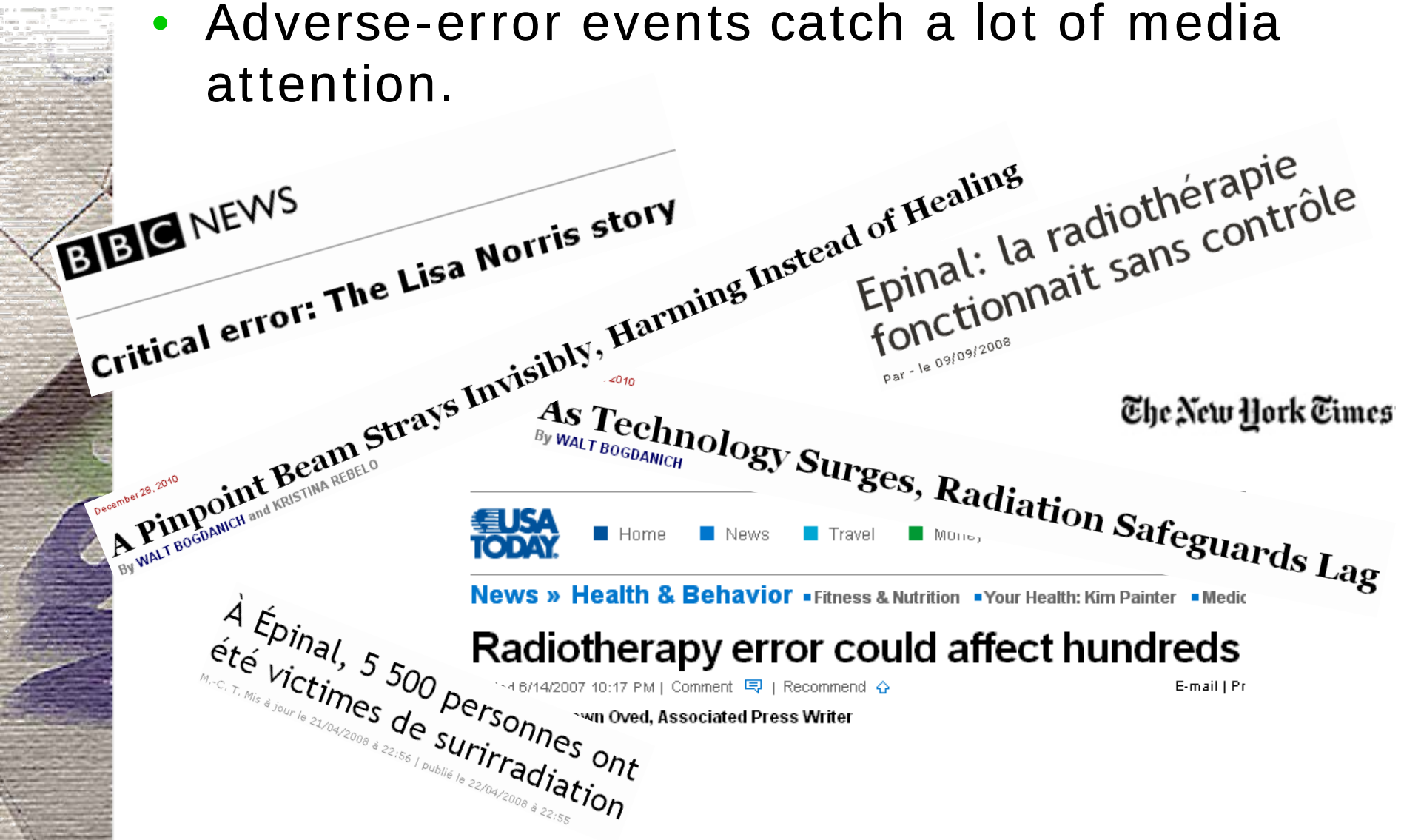
Risk management in Radiation Oncology: Report on ACCIRAD

Arturo Pérez, with slides courtesy of Carlos Prieto (IdISSC)

Adverse-error events

- Adverse-error events catch a lot of media attention.



ACCIRAD Project

- EC project ENER/D4/160-2011, “Guidelines on a risk analysis of accidental and unintended exposures in radiotherapy (ACCIRAD)”.

- The objective of the project was:

  to perform an EU-wide study on the implementation of the requirements of Article 11 of the Council Directive 97/43/EURATOM (Medical Exposure Directive, MED)

  to develop guidelines for risk analysis of accidental and unintended exposures in external beam radiotherapy.

- Article 11 of MED requires the following: "Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken (...)" and stipulates that "the main emphasis in accident prevention should be on the equipment and procedures in radiotherapy (...)".

ACCIRAD Project

- The new EU BSS lays down the basic requirements for the risk assessment and analysis of events, including timely dissemination of information to the authorities, referrers, practitioners and patients or their representatives.

- Article 63 of the EU BSS entitled “accidental and unintended medical exposures”, introduces new specific requirements for QA and events reporting, stipulating that Member States shall ensure that:

  all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended medical exposures of individuals subject to medical exposure from all medical radiological procedures;

  for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;

  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;

  arrangements are made to inform the referrer and the practitioner**,** and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;

  the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority; 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;

  mechanisms are in place for timely dissemination of information regarding lessons learned from events.

ACCIRAD Project

The guidelines have been prepared by a consortium composed of:

Status	Organization
Lead contractor	The Greater Poland Cancer Centre (GPCC), Poland
Partners	Public Research Centre Henri Tudor, Luxembourg
	Nuclear Safety Authority (ASN), France
	Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC), Consejo de Seguridad Nuclear, Spain.
	Radiation and Nuclear Safety Authority, STUK, Finland
	European Society for Radiotherapy and Oncology (ESTRO)
Panel of Scientific Experts	Prof. Jean Marc Cosset, ICRP Assoc. Prof. Frank Andre Siebert, Germany Dr. Mary Coffey, ESFRS Prof. Pierre Scalliet, ESTRO Assoc. Prof. Tommy Knöös, Sweden Prof. Andrew Nisbet, UK Prof. Will van der Putten, EFOMP Dr. Pedro Ortiz Lopez, ICRP & IAEA Dr. Costas Hourdakis, Greece
Project officers	Remigiusz Baranczyk, Georgi Simeonov

ACCIRAD Guidelines

- The objective of these guidelines is to support EU Member States in implementing the legislative requirement derived from the provision of Article 11 of MED (and the EU BSS).
- The aim of these requirements is to reduce the probability and the magnitude of adverse error-events in radiotherapy. *Patient* safety is the main concern of the risk assessment and analysis of adverse error-events in external beam radiotherapy.
- The document provides *basic information and recommendations* for overall risk management in radiotherapy, with a focus on proactive risk assessment and reactive analysis of events.
- The document also covers systems for reporting of events, with the related terminology and classification systems.

ACCIRAD Guidelines
Basis and contents

- These guidelines are based on :

1. a thorough review of available international and national documents, recommendations, and

2. the results of two detailed questionnaires distributed in EU Member States.

   The first questionnaire: status of the implementation of Article 11 of MED, including the legal and practical arrangements.

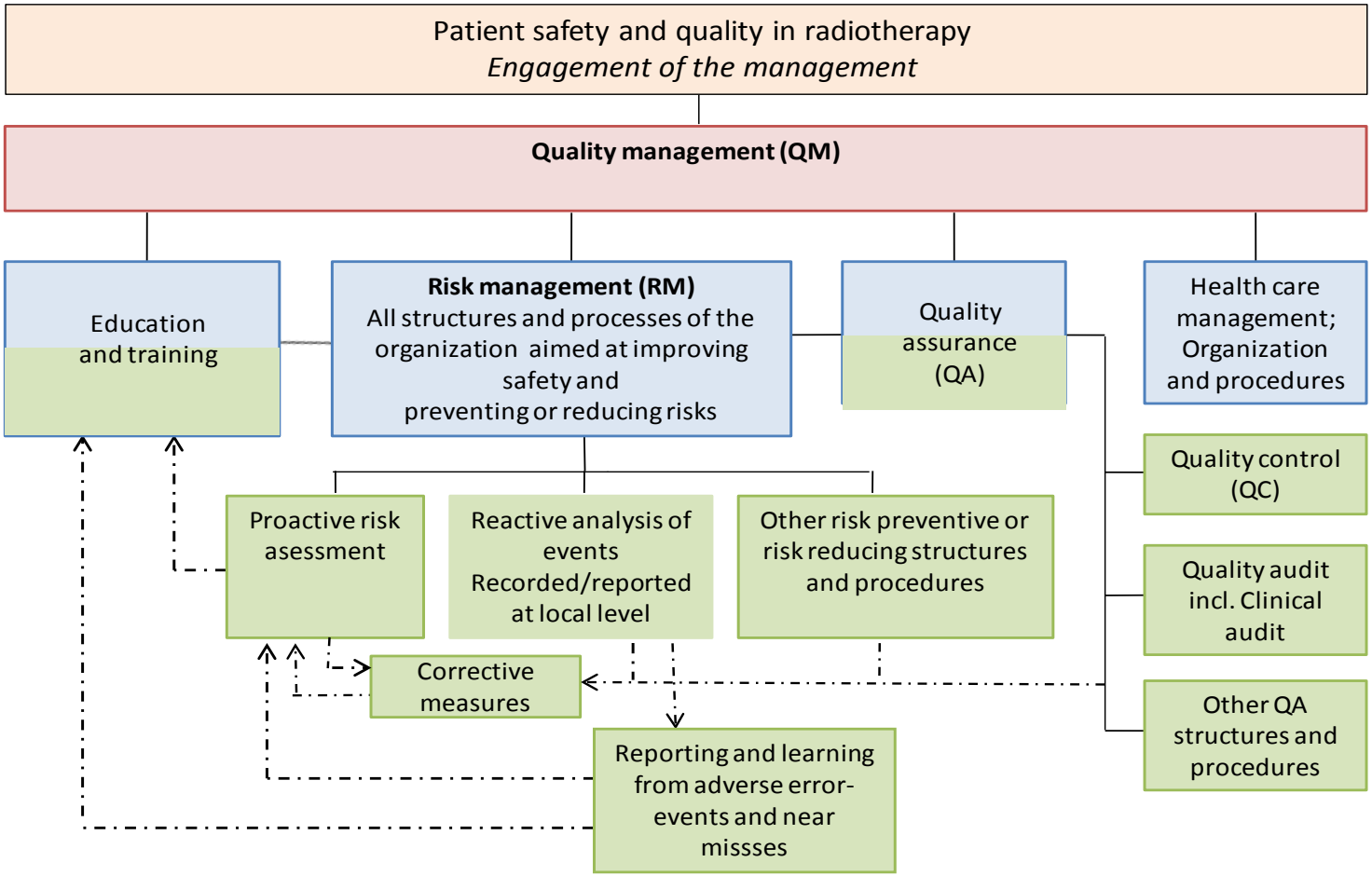
   The second questionnaire: detailed information on the systems and guidelines in place in the countries which had this information available.

- Guidelines: main concepts, general information on risk management and recommendations.

- Technical Supplement: More detailed, technical information on the legislative and normative basis, the various methods of proactive risk assessment and reactive analysis of events, event classification, reporting and learning systems and on other preventive measures or risk reduction interventions, as well as summaries of the results of the two questionnaires.

ACCIRAD Guidelines
Main concepts

Relationships of the main procedural concepts discussed in these Guidelines. Blue boxes represent the main tools for QM, while the green boxes describe the main tools for RM (depicted here as QM "sub-tools").



ACCIRAD Guidelines
Risk Management

Risk management for patient safety in external beam radiotherapy: identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs (National Patient Safety Agency, UK). Only risks related to the use of radiation are considered.

- Risk management: all structures and processes of the organization intended to improve safety and to prevent or reduce risks or to limit the consequences of said risks.

- Is part of the overall quality management, requires appropriate education and training to be properly implemented, and is closely linked to important tools of quality assurance such as quality control and quality audits.

- Risk management involves two primary activities ("tools"): proactive *risk assessment* (*study of risk)* and reactive *analysis of events*. The reporting and analysis of adverse error-events and near misses, whose main purpose is to learn from such incidents in order to improve safety and avoid recurrence, are also a part of risk management.

ACCIRAD Guidelines
Proactive Risk Assessment

Risk assessment (Study of risk)*:* Proactive (prospective, a priori) assessment of risk is a process that helps organizations to understand the range of risks (both internal and external) that they face, their capacity to control those risks, the likelihood (probability) of the risk occurring and the potential impact thereof. This involves quantifying risks and using judgment, assessing and balancing risks and benefits and weighing these against cost.

- The aim of proactive risk assessment is to identify potential hazards and to identify measures that can be implemented to avoid, prevent, detect, or control the potential occurrence of adverse error-events and to mitigate the consequences of such errors when they do occur.

- Also, to define how to decide (method, criteria) which risk reduction actions should be implemented and to use feedback from reporting and analysis of events as appropriate.

- A more comprehensive discussion of available methods of risk assessment is presented in the Technical Supplement. For proactive risk assessment, two radiotherapy-specific methods are available: dedicated Failure Mode, Effect and Criticality Analysis (FMECA) and dedicated risk matrix.

ACCIRAD Guidelines
Reactive Risk Management

***Analysis of events**:* Reactive (retrospective, a posteriori) analysis (or assessment) of adverse error-events and near misses to determine causes and to prevent their recurrence.

- The reactive analysis of events is directly related to the recording and reporting of events.

- When something goes wrong and results in an adverse error-event or a near miss, the event is recorded and reported within the radiotherapy department with a preliminary analysis of the causes and consequences of the event, and “immediate” corrective actions.

- This initial analysis might not provide a full understanding of the event and its causes, and a more detailed analysis is often required.

- The final reporting of the event takes place through the local and/or external reporting systems (e.g., international systems such as Safety in Radiation Oncology, SAFRON, and Radiation Oncology Safety Information System, ROSIS), with the primarily purpose of more widely disseminating the lessons learned to other professionals.

ACCIRAD Guidelines
Reporting Systems

- The purpose of event *reporting systems* is to learn from experience, that is, from past errors. For this reason, such systems should more accurately be called *reporting and learning systems*.
- How an organization learns from its own and from other's experience is a critical safety feature and an expression of its safety culture.
- A successful reporting system should be non-punitive, confidential, and its main aim should be to promote learning through information sharing and feedback.

- The purpose of *classification systems* for event reporting is to organize such reports, to facilitate the analysis of events, and finally, to improve safety through this analysis.
- These objectives may best be achieved by using existing general classification systems that have been modified to include radiotherapy-specific details.
- Classification of events based on how the event affects the patient (i.e., consequences) is a common approach, although other factors, such as causes and contributing factors or the stage in the process, have also been used in classification.

ACCIRAD Guidelines Recommendations

- The guidelines present *recommendations* on the risk management (risk assessment and analysis and reporting of events) for external radiotherapy in two levels:
  1. Recommendations to institutions that provide radiotherapy services, whose primary responsibility is patient safety,
  2. Recommendations to national authorities, which focus on the need for strong support at the national or regional level to promote a culture that values risk management and safety.
- In addition, a few recommendations on reporting and learning systems are given separately.

- The recommendations on *risk management at the institutional level* emphasize the fundamental importance of having a dedicated quality management system. Likewise, the importance of reporting events is also stressed.

- The recommendations on *risk management at the national level* call for the development— or updating of—a national strategy on quality and risk management to promote a safety culture in radiotherapy.

- The recommendations on *classification and reporting* systems highlight the need for harmonized terminology, a few desirable characteristics of the systems and systematic and timely dissemination of information. A collection of recommended terms is presented.

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ACCIRAD report

LIST OF CONTENTS