RC II.

Learning from incidents in radiotherapy: retrospective and prospective risk analysis

Eduard Gershkevitsh
North Estonia Medical Centre

Incidences, mistakes and near misses may happen in every radiotherapy department. The course is aimed to show how to use and minimise those events to improve radiotherapy safety through establishment of incidence learning system. As radiotherapy treatment techniques get more complex, there is a need to prospectively analyse and develop risk management system.

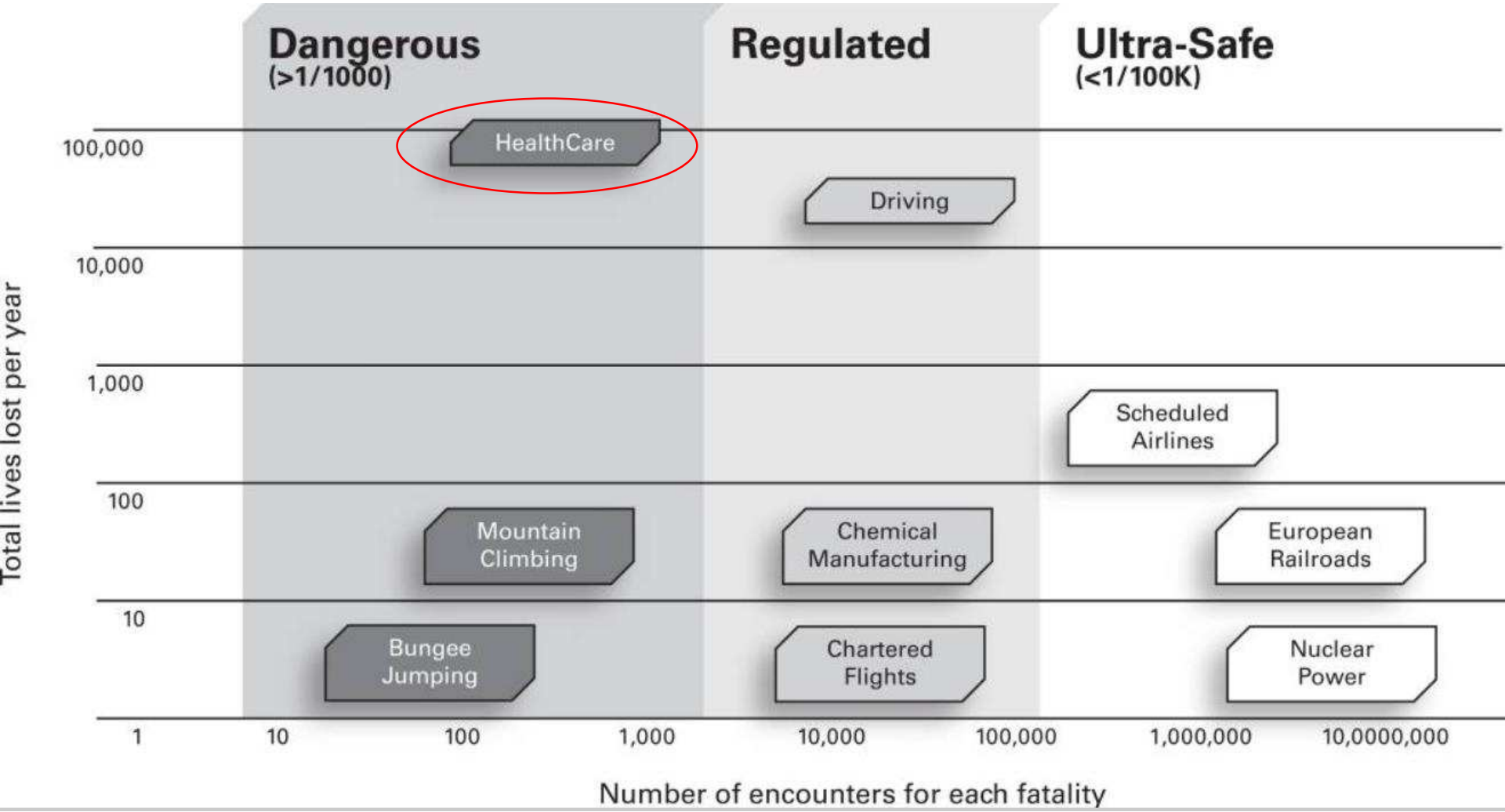
Learning from incidents in radiotherapy: **retrospective and prospective risk analysis**

Eduard Gershkevitsh
North Estonia Medical Centre

Objectives

- To be aware of potential for incidents in radiotherapy
- To define reportable incident/incident/near misses
- To present an overview on incidents learning systems
- To present prospective risk management system

How hazardous is Healthcare?

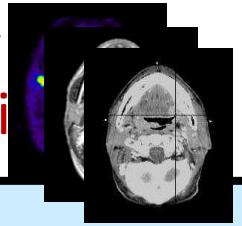


Agency for Healthcare Research and Quality

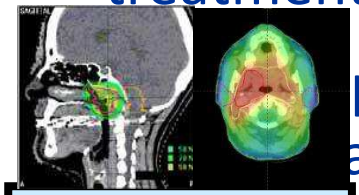
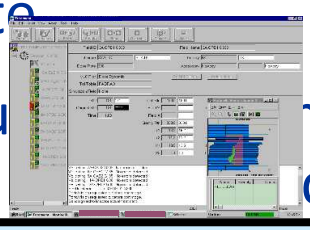
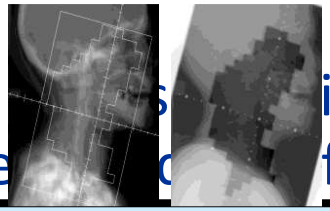
Potential for accidents in radiotherapy

- Ra[illegible]herapy is a[illegible]x proce[illegible]g many be[illegible]n differer[illegible]sionals [illegible]ent equi
- [illegible]or:
  - [illegible]peu[illegible]t [illegible]t
  - A therapeutic treatment was delivered to the wrong treatment site
  - peu[illegible]nent [illegible]ivered a [illegible]ally [illegible]dose [illegible]fraction [illegible]hat [illegible]d b[illegible]l p
- [illegible]nal



Patient referral → Immobilisation device → Image acquisition (CT, MRI, PET) → OAR and target definition


Treatment planning → Export to treatment unit → Position check → Delivery of treatment

Potential for accidents in radiotherapy

- Radiotherapy is a complex process involving many steps between different professionals and different equipment
- Human error:
  - A therapeutic treatment was delivered to the wrong patient
  - A therapeutic treatment was delivered to the wrong treatment site
  - A therapeutic treatment was delivered with a substantially different dose or dose fraction to that prescribed by the medical practitioner
- Equipment malfunction

Investigation of accidental medical exposures (BSS)

Registrants and licensees shall promptly investigate:

- therapeutic treatment to wrong patient, wrong tissue, with wrong pharmaceutical, or with dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects
- diagnostic exposure significantly greater than intended or repeated so as to exceed guidance levels
- equipment failure, accident, error or mishap with potential for causing patient exposure significantly different from that intended

IAEA Safety Standards
for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Jointly sponsored by EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO

General Safety Requirements Part 3
No. GSR Part 3

IAEA International Atomic Energy Agency

Definition

Incident:

Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety. (*Source: IAEA Safety Glossary, 2007*)

Reportable incident:

An incident of which the significance is large enough that it must be reported to the regulatory authority (it may differ from jurisdiction to jurisdiction)

Near misses

Actual incident:

The unforeseen event has affected the treatment of the patient

Potential incident:

“Near miss” - The unforeseen event was discovered and halted before it affected the treatment of the patient

Example: QUATRO checklist

The definitions on the previous slides may be different in different circumstances and countries:

What would be regarded as reportable incident and what not?

CHECKLIST 18. DEVIATIONS IN RADIOTHERAPY ADMINISTRATION
(Refer to Section 5.1.2, Checklist 35)

Items to be reviewed by auditors	YES	NO	n.a.
What would be regarded as an incident and what would not be regarded as an incident?			
Is the treating physician immediately notified of an incident?	☐	☐	☐
Is there a systematic reporting of incidents to a hospital committee?	☐	☐	☐
If so, is this verbal or written?	Verbal	Written	
Is a decision taken on the significance of the deviation?	☐	☐	☐
If so, is a significant deviation reported to the regulatory authorities?	☐	☐	☐
Have incidents been reported and, if so, how many?			
What is the RTT procedure for the reporting of error?			
Is there a system to enable anonymous reporting? Is there a 'no-blame' policy? Comment.			
What is the process for reviewing errors and 'near misses'?			
What is the policy on feedback?			
What is the policy on informing patients about incidents?			
What is the mechanism for corrective actions and how are RTTs involved?			
What is the mechanism for the implementation and monitoring of change?			

Why would one like to know about ‘near misses’?

Question:

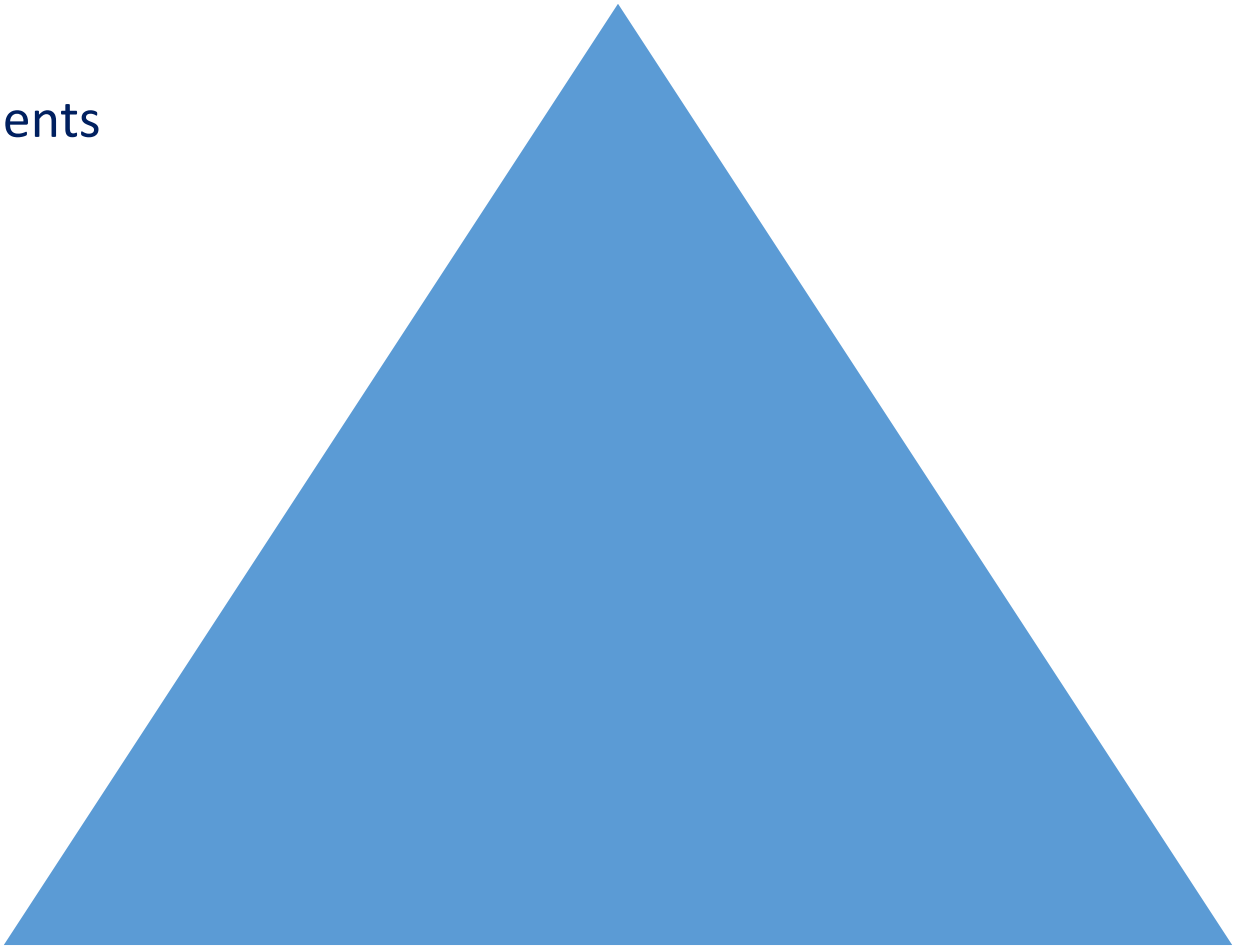
Near misses

- Incidents in radiotherapy are rare - however, near misses often share the same root cause with a real accident

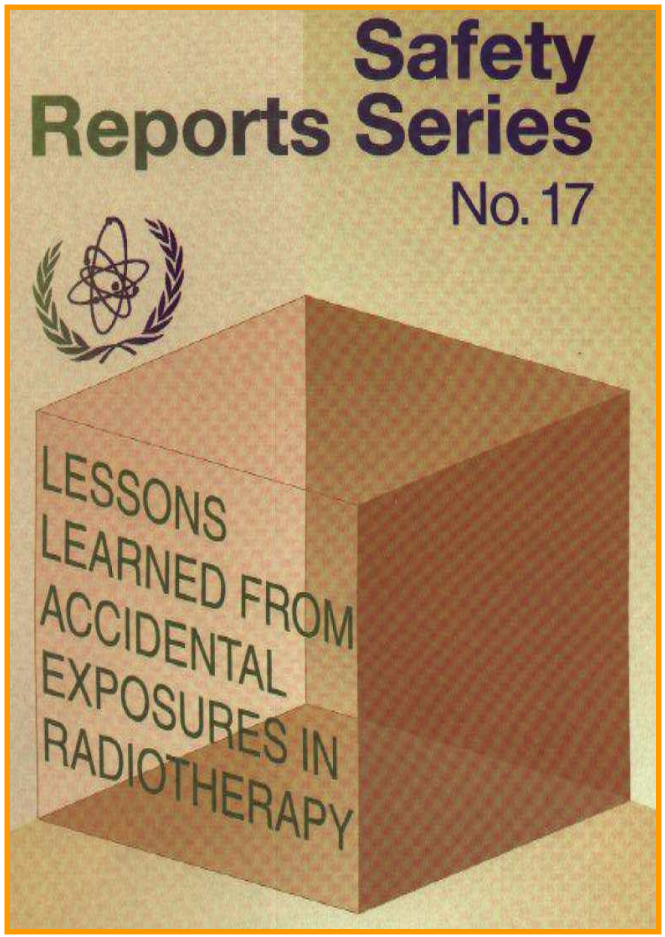
- Therefore, it is possible to learn from ‘near misses’ as well

Pyramid of events…

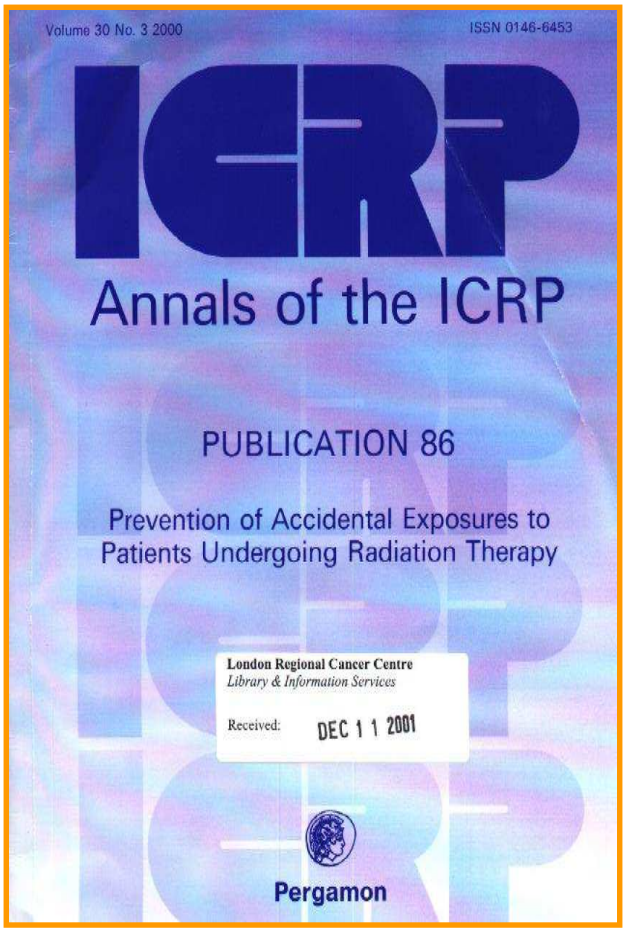
- Reportable incidents
- Minor incidents
- Near misses
- Mistakes



Reports of Radiotherapy Accidents

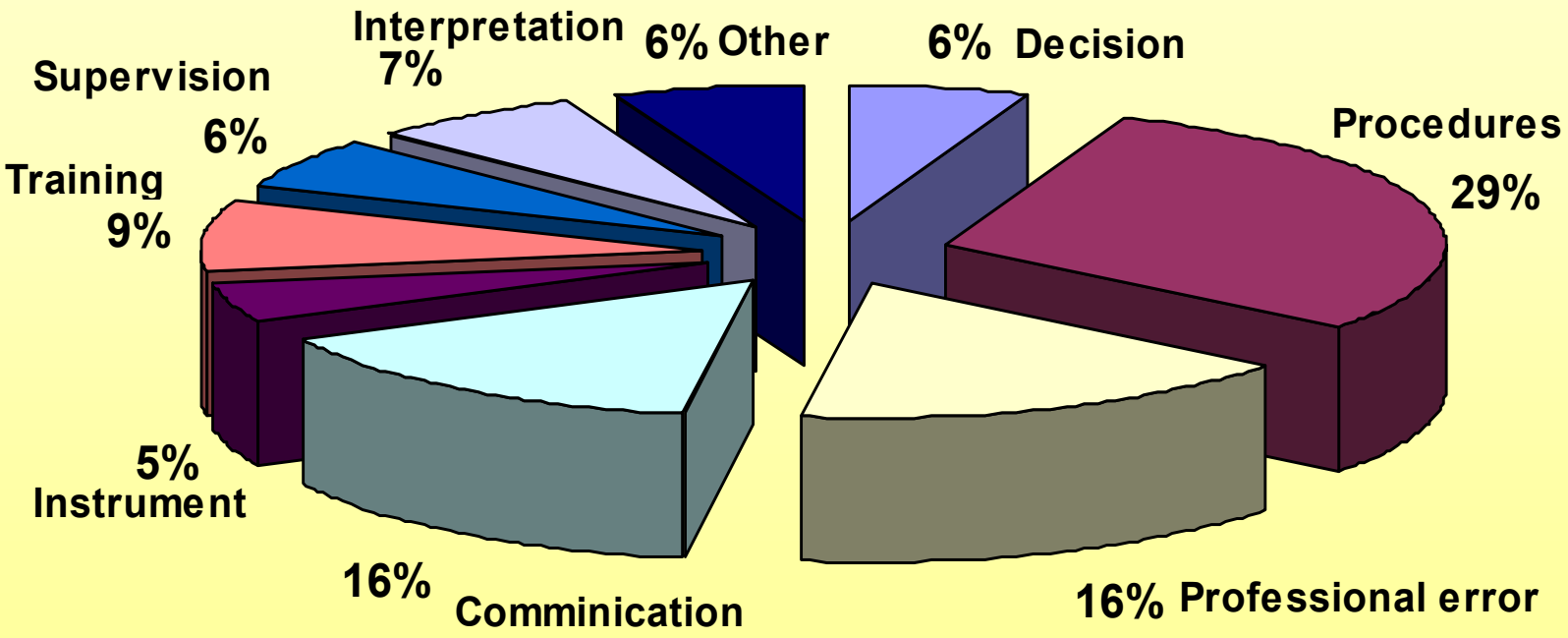


IAEA 2000



ICRP 2000

Errors in RT: contributing factors



~ 90 % human errors

Error in small field calibration

CoxHealth

TOOLS

EMAIL THIS ARTICLE
PRINT THIS ARTICLE
YOUNEWS™
DIGG THIS!
SAVE TO DELICIOUS
POST TO FACEBOOK
SHARE ON TWITTER

CoxHealth Issues Statement on Increased Radiation for Patients

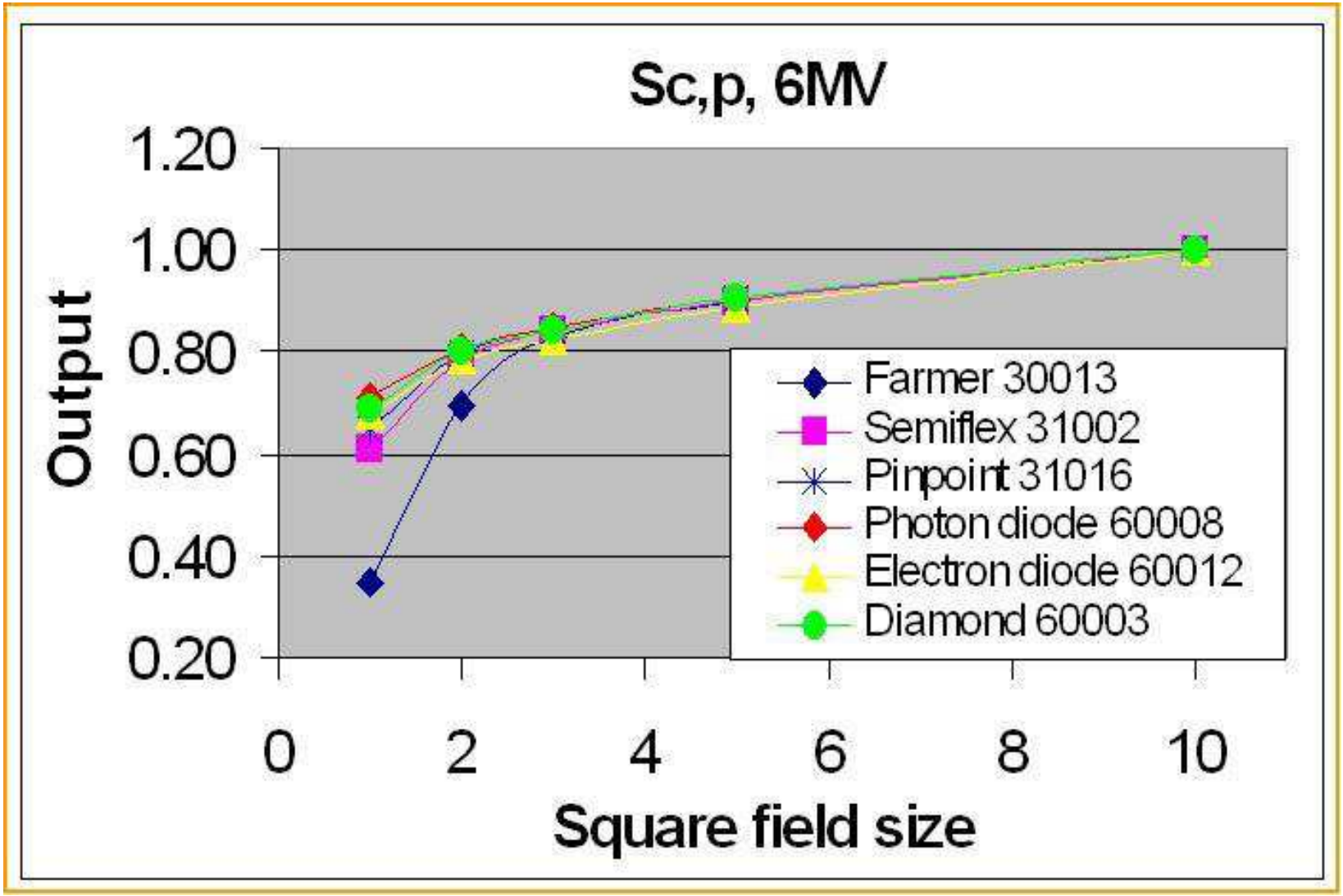
By KSPR News
Story Created: Feb 24, 2010 at 4:29 PM CST
Story Updated: Feb 24, 2010 at 6:47 PM CST

CoxHealth Issued this news release:

Springfield, MO - CoxHealth today announced that it has discovered that 76 patients who had received a very specific type of treatment for brain

The average variation of all the treatments of the 76 patients exceeded the prescribed dose by approximately 50 percent.

Output factors for small fields



Lessons to learn

Ensure that staff

- Understand the properties and limitations of the equipment they are using

Include in the Quality Assurance Program

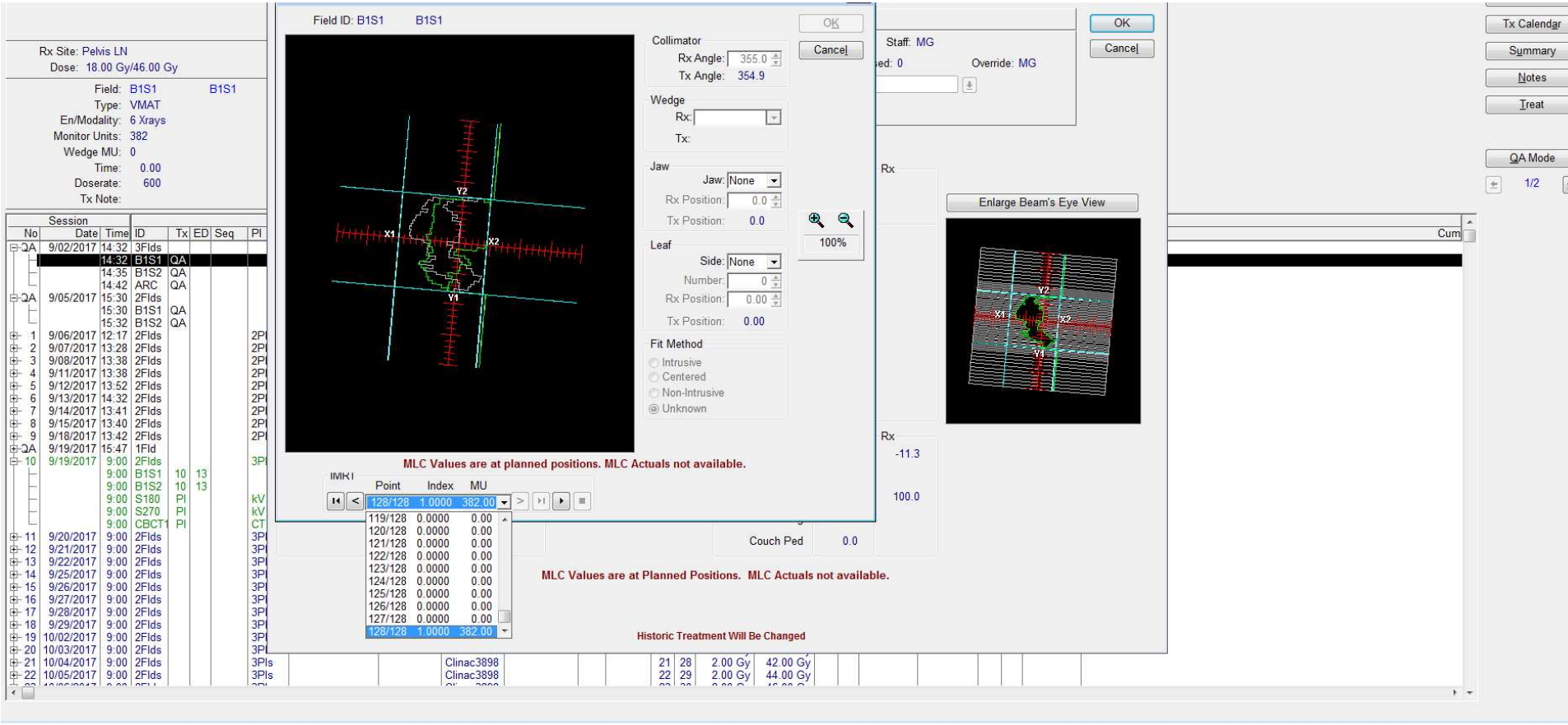
- Intercomparison with other hospitals, i.e. independent check of new equipment by independent group (using independent equipment) before equipment is clinically used

Incidence can only happen somewhere, right?

Own experience

- Pelvic lymph nodes treatment plan made using two VMAT arcs
- The plan is exported to R&V system
- During export the dose distribution on TPS becomes invalidated and plan is shown with the “frozen dose” sign
- Successful import into R&V (128 control points, 2 arcs, correct MU number, MLC is present)
- Plan is transferred to the linac and prepared for patient specific QA, no errors
- The arc is moving, the MLC shape is changing, but no MUs is delivered until the arc reaches the final position where all MUs are delivered at once

Own experience



Lessons to learn

- Patient specific QA
- Stay alert if you see unexpected behaviour
- Independent recalculation would only worked if the plan would be transferred from R&V system, not TPS

Generalizing the lessons learned

Working with Awareness and Alertness

Accidental exposures have occurred owing to inattention to details, lack of alertness and lack of awareness. This could also be made worse if personnel have to work in conditions prone to distractions

Procedures

Accidental exposures have occurred when there is a lack of procedures and checks, or when they are not comprehensive, documented or fully implemented.

Generalizing the lessons learned

Training and Understanding

Accidental exposures have occurred when there is a lack of qualified and well-trained staff, with necessary educational background and specialized training

Responsibilities

Accidental exposures have occurred when there are gaps and ambiguities in functions of personnel and lines of authority and responsibility. Safety critical tasks can be insufficiently covered

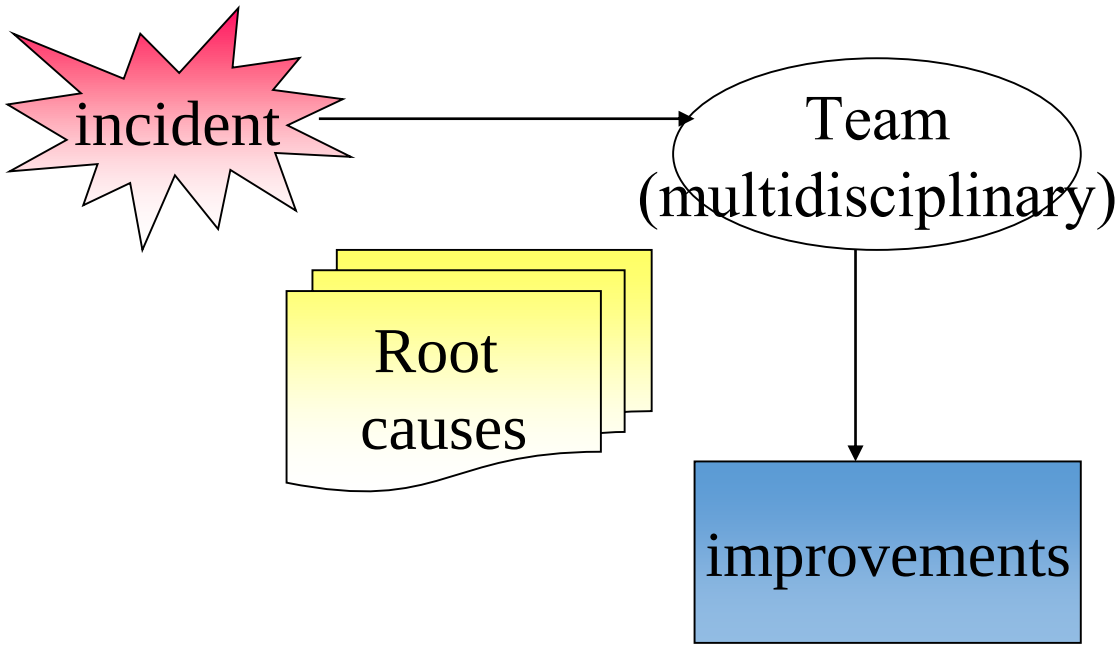
Workload

High workload and insufficient number of staff have contributed to accidental exposures

How to minimize incidents and accidents?

- Set up incidents learning system
- No blame policy
- Regular feedback to the staff
- Encourage questions

Incident learning system is used retroactively to analyze incidents that have occurred



Incident learning systems

Different types of incident learning systems:

Internal reporting systems:

Reporting inside organization (*e.g.* local incident reports)

External reporting systems:

Reporting outside organization (*e.g.* web-based systems)

Internal reporting systems

Reporting of incidents within organization

Specific in relation to intra-organization …

- … procedures
- … equipment
- … characteristics

- "Lessons to learn" become more direct and explicit

- Follows up management of actual patients affected by the incidents

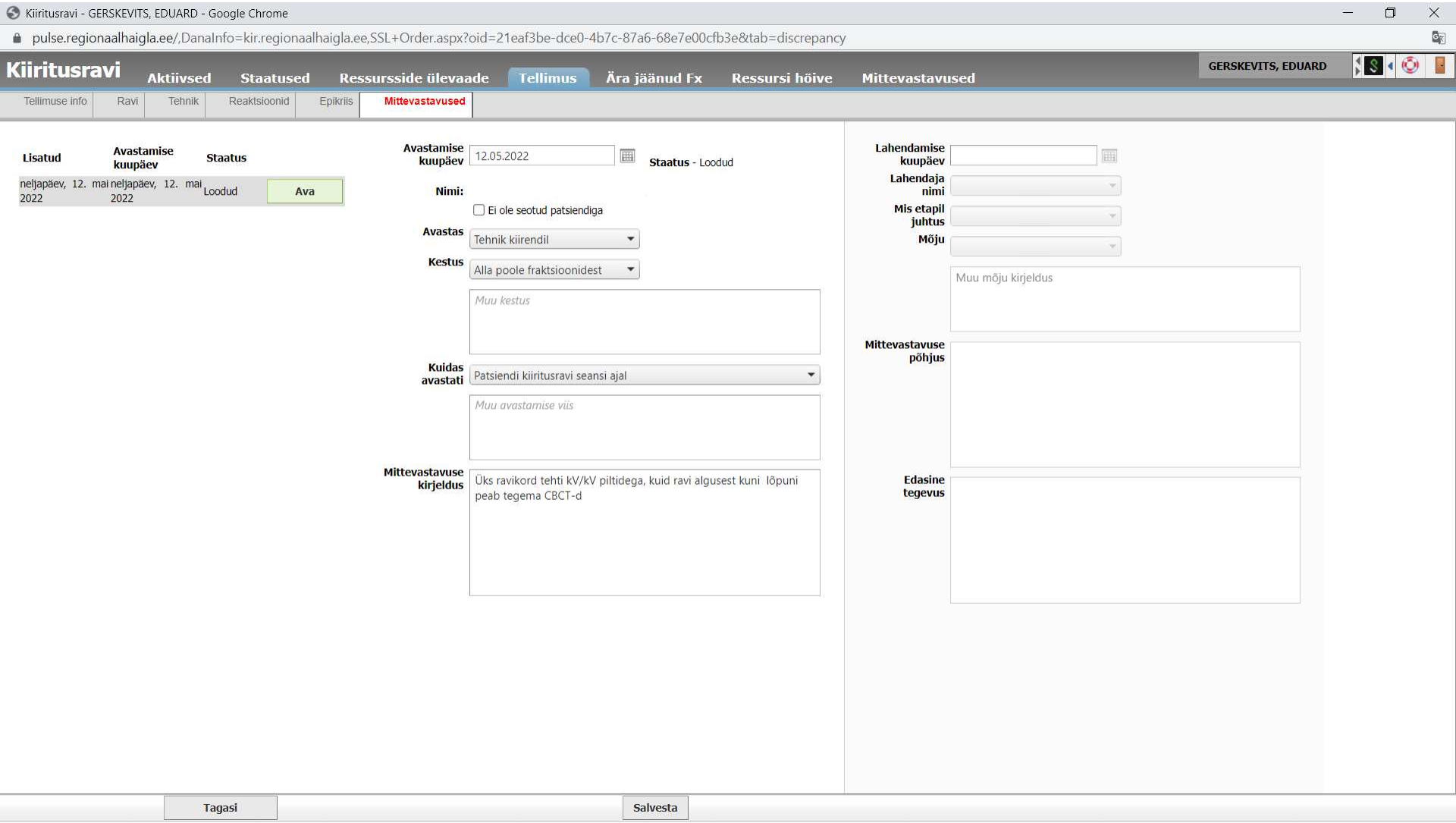
- Should evolve locally, but could be aided from the outside

External reporting systems

Reporting of incidents outside organization

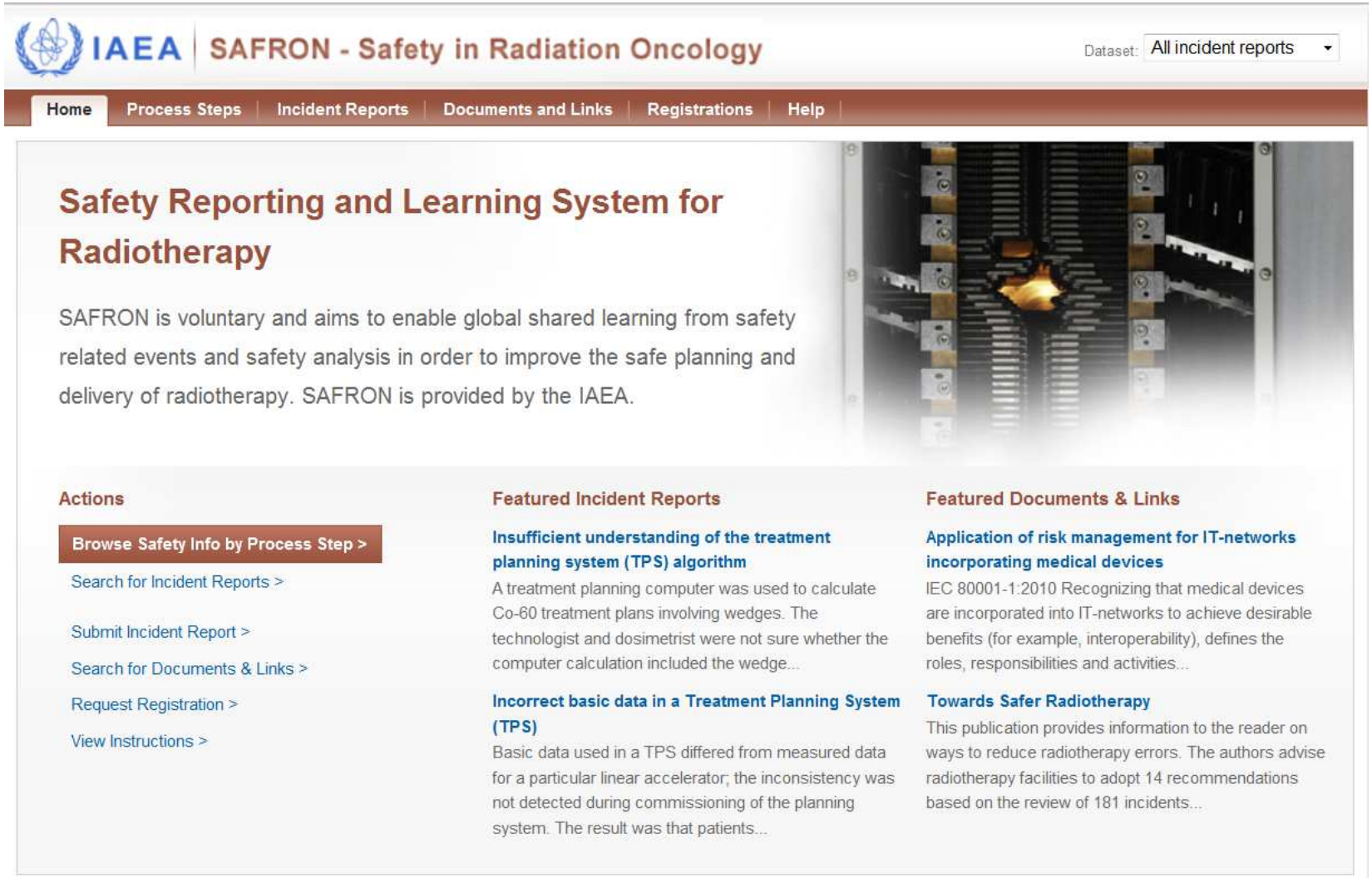
- "Lessons to learn" will come from a bigger pool of events
- An incident in another hospital can lead to identification of the hazard before a similar incident is realised locally
- With a more extensive pool of events, safety-critical steps in the radiotherapy process can be identified
- A general culture of safety-awareness can be created by making this information available

Example: Internal reporting system

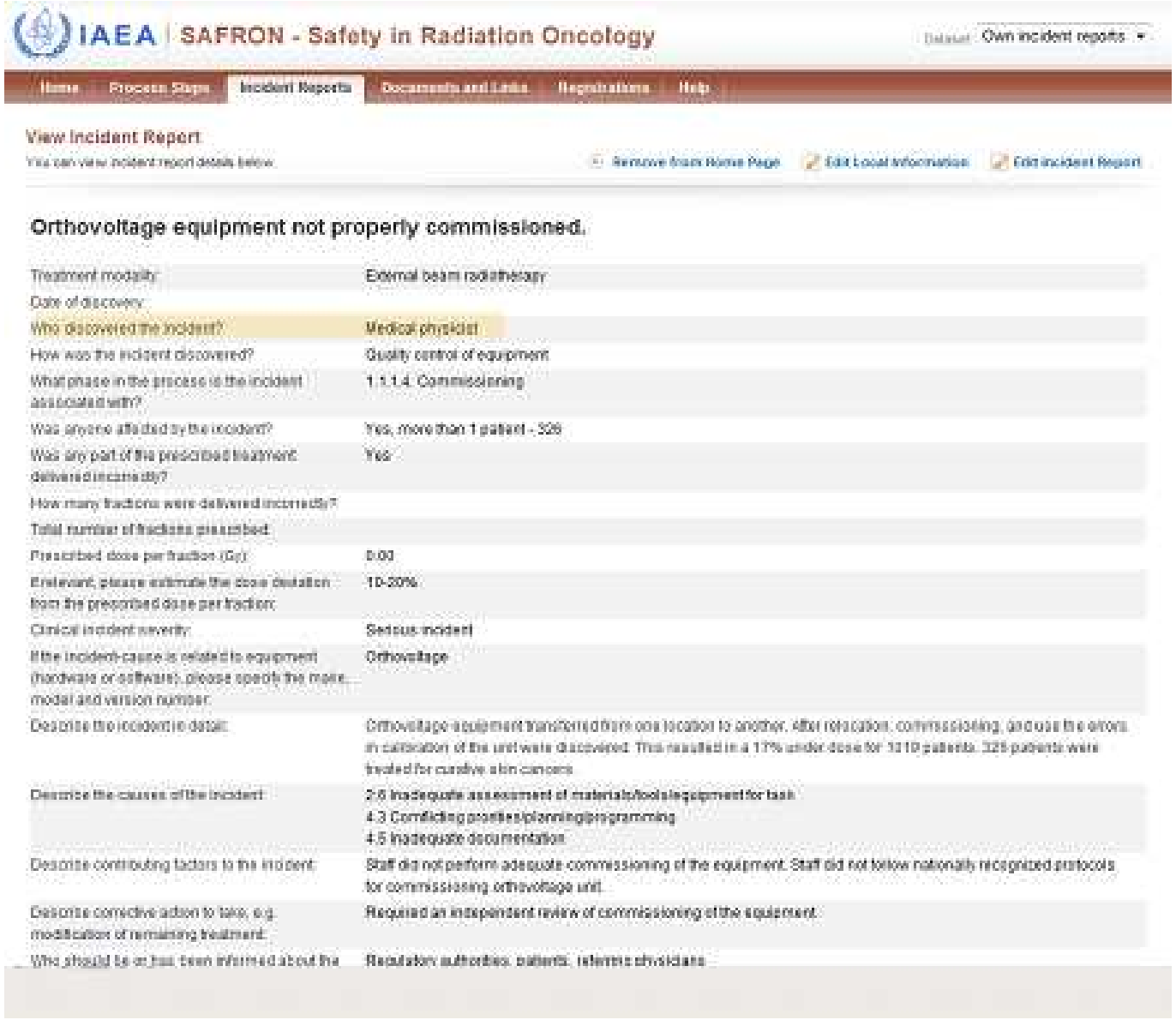


SAFRON

https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm



SAFRON



IAEA | SAFRON - Safety in Radiation Oncology

Dataset: Own incident reports

Home | Process Steps | Incident Reports | Documents and Links | Registrations | Help

View Incident Report

You can view incident report details below

Remove from Home Page | Edit Local Information | Edit Incident Report

Orthovoltage equipment not properly commissioned.

Treatment modality:	External beam radiotherapy
Date of discovery:	
Who discovered the incident?	Medical physicist
How was the incident discovered?	Quality control of equipment
What phase in the process is the incident associated with?	1.1.1.4: Commissioning
Was anyone affected by the incident?	Yes, more than 1 patient - 326
Was any part of the prescribed treatment delivered incorrectly?	Yes
How many fractions were delivered incorrectly?	
Total number of fractions prescribed:	
Prescribed dose per fraction (Gy):	0.00
If relevant, please estimate the dose deviation from the prescribed dose per fraction:	10-20%
Clinical incident severity:	Serious incident
If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:	Orthovoltage
Describe the incident in detail:	Orthovoltage equipment transferred from one location to another. After relocation, commissioning, and use the errors in calibration of the unit were discovered. This resulted in a 17% under dose for 1010 patients. 326 patients were treated for curative skin cancers.
Describe the causes of the incident:	2.6 Inadequate assessment of materials/tools/equipment for task 4.3 Conflicting priorities/planning/programming 4.5 Inadequate documentation
Describe contributing factors to the incident:	Staff did not perform adequate commissioning of the equipment. Staff did not follow nationally recognized protocols for commissioning orthovoltage unit.
Describe corrective action to take, e.g. modification of remaining treatment:	Required an independent review of commissioning of the equipment.
Who should be or has been informed about the	Regulatory authorities, patients, referring physicians

SAFRON database

Can be searched by incident occurrence:

- Where in the process
- Who discovered
- How discovered

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐
Time out	☐	☐	☐
Use of record and verifying system	☐	☐	☐
Verification of treatment accessories	☐	☐	☐
Image based position verification	☐	☐	☐
In vivo dosimetry	☐	☐	☐
Intra-treatment monitoring	☐	☐	☐
Regular independent chart checks	☐	☐	☐
Regular clinic patient assessment	☐	☐	☐
Post treatment evaluations (evaluation of clinical and process)	☐	☐	☐
Independent review of commissioning	☐	☐	☐
Regular internal audit	☐	☐	☐
Regular external audit	☐	☐	☐
Regular equipment performance verification	☐	☐	☐
Other, please specify	☐	☐	☐

Multilayer prevention

RO-ILS

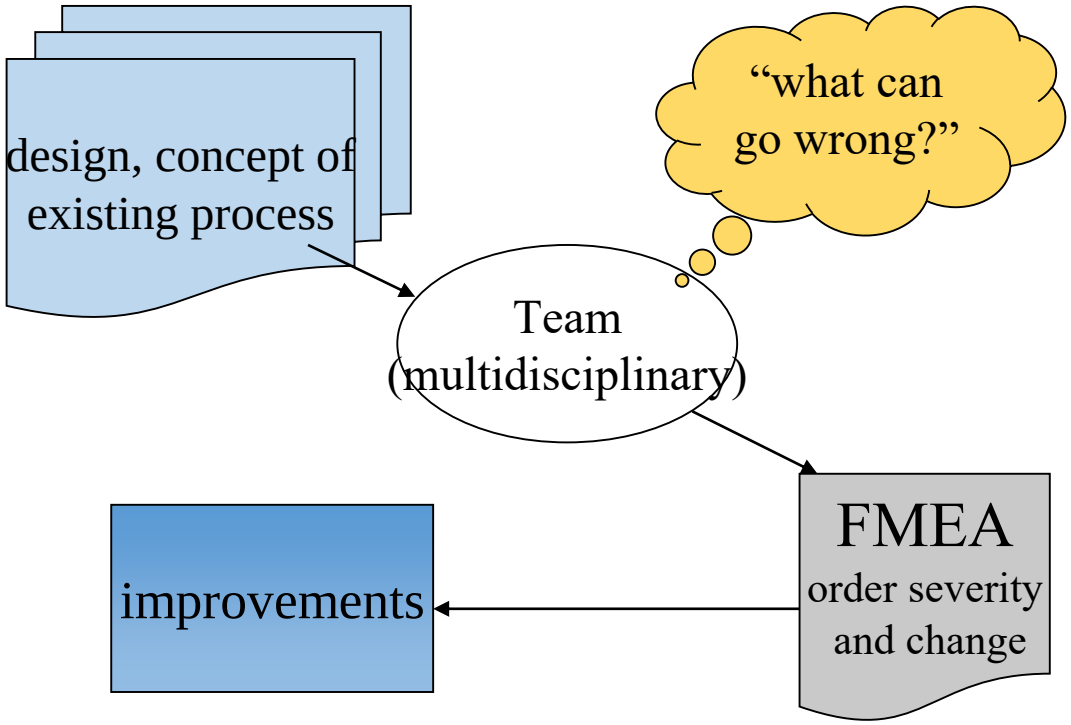
RO-ILS facilitates patient safety reporting and serves as a national incident learning system to build awareness about radiation oncology practice risks

With RO-ILS, participants can:

- Track and analyze internal incidents while contributing to a national database.
- Receive institution-specific summary reports, including aggregate data on events entered throughout the country.
- Receive newsletters and other publications designed to educate the radiation oncology community on how to prevent errors.

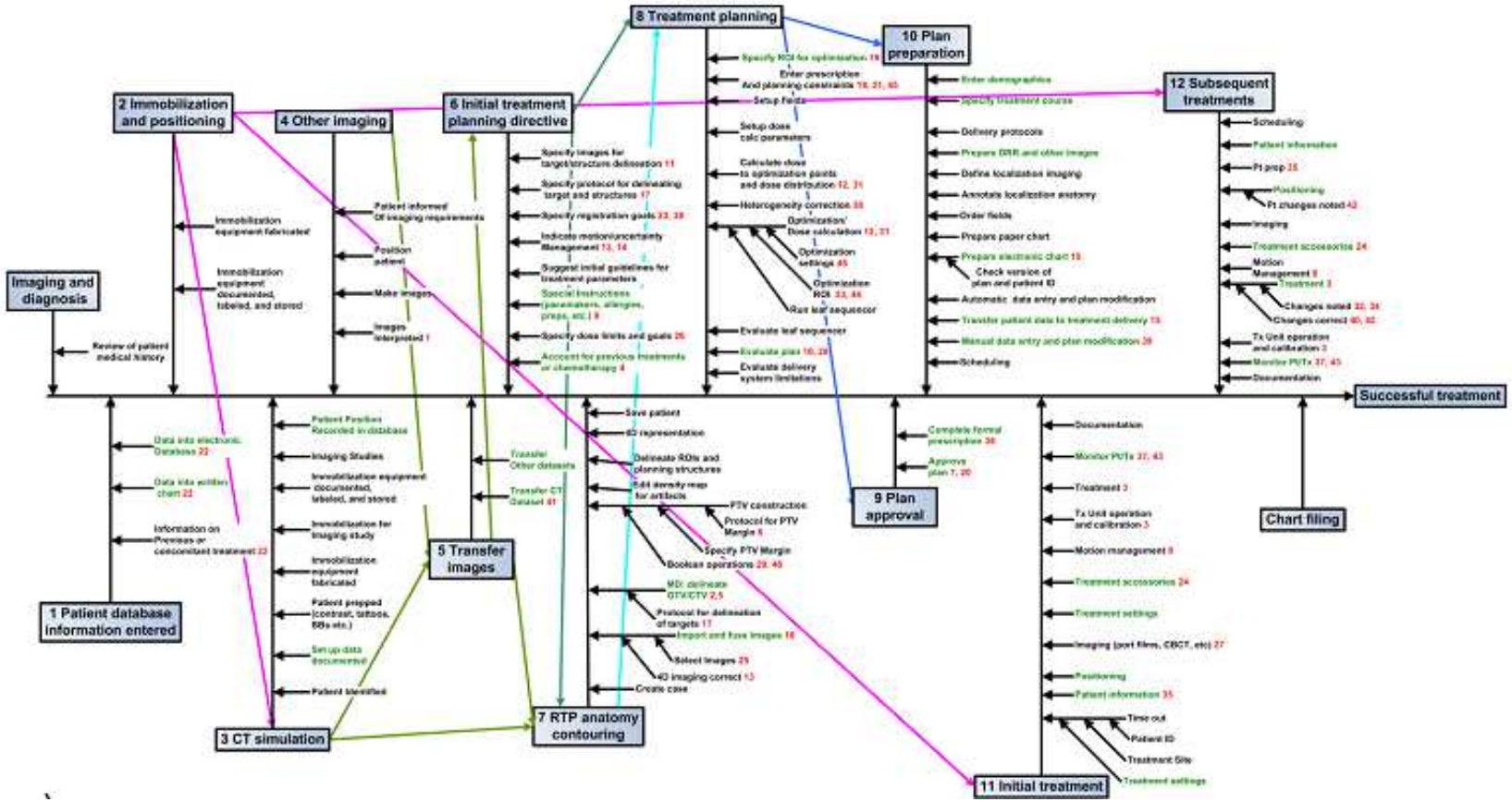
RO•ILS
RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

Failure Modes and Effects Analyses and Fault Tree Analyses are used prospectively to analyze systems for weaknesses.



Failure modes and effects analysis (FMEA)

Failure modes and effects analysis helps us, through a structured and logical analysis of a clinical process, to identify the steps in the process which are associated with the highest risk and hence to prioritize interventions and actions which will enhance the safety and quality of the care that radiotherapy patients receive.



AAPM TG 100

Failure modes and effects analysis (FMEA)

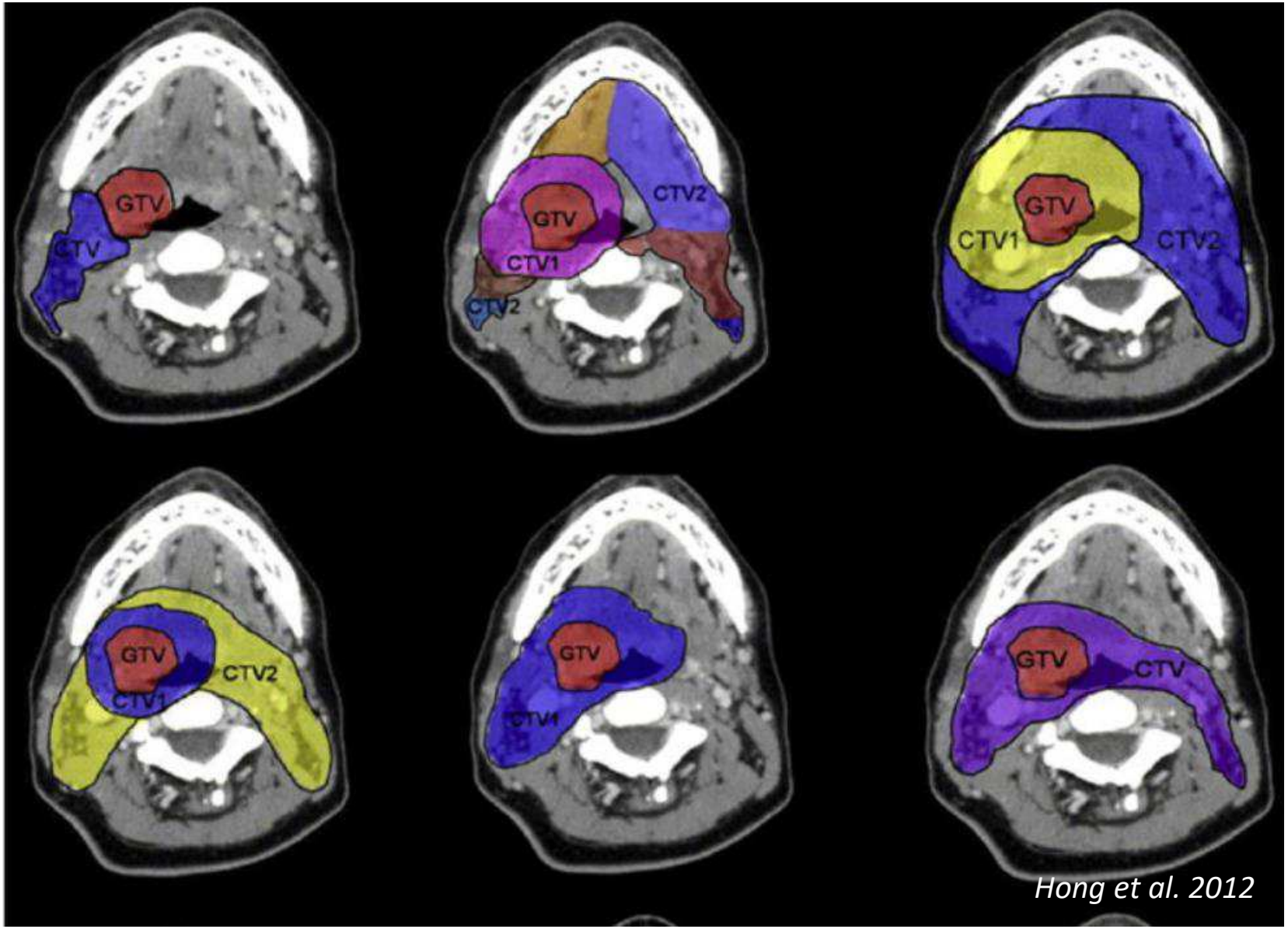
Occurrence, severity, detectability

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

Failure modes and effects analysis (FMEA)

Step	Potential failure	Severity, S	Failure pathways	Occurrence, O	Detectability, D	Risk Priority Number =SxOxD
Target contouring						

CTV contouring by different radiation oncologists



Hong et al. 2012

Failure modes and effects analysis (FMEA)

Step	Potential failure	Severity, S	Failure pathways	Occurrence, O	Detectability, D	RPN=SxOxD
Target contouring	Incorrect outlining	9	CTV underdose or OAR overdose	4	5	180

Lack of contouring guidelines
Lack of training
Lack of peer-review

Failure modes and effects analysis (FMEA)

In general, if a failure pathway is associated with a high **occurrence (O) value** we would look to refining the process to make it intrinsically safer. A high **(un)detectability (D) value** would guide us towards improving our quality control and checking procedures.

Risk priority numbers (RPN) guide us in assigning priorities for quality and safety interventions, failure modes with a **high severity (S) value** may warrant significant attention irrespective their risk priority numbers.

Summary

- We all are human
- Incidents can happen
- Good quality assurance and independent checks can minimise:
  - The probability of an incident
  - The severity of an incident
- Incident reporting is an essential part of safety culture and affords an opportunity to learn
- As radiotherapy techniques get more complex – prospective risk management system is needed

References

- Lessons learned from accidental exposures in Radiotherapy IAEA SRS 17 (2000)
- Radiotherapy Risk Profile WHO (2010)
- Prevention of accidental exposures to patients undergoing radiation therapy ICRP 86 (2000)
- The Consensus recommendations for incident learning database structures in radiation oncology. *Ford et al. 2012*
- AAPM TG 100 „Application of risk analysis methods to radiation therapy quality management“ 2016
- http://rpop.iaea.org/