Lessons learned from accidents in conventional external radiotherapy

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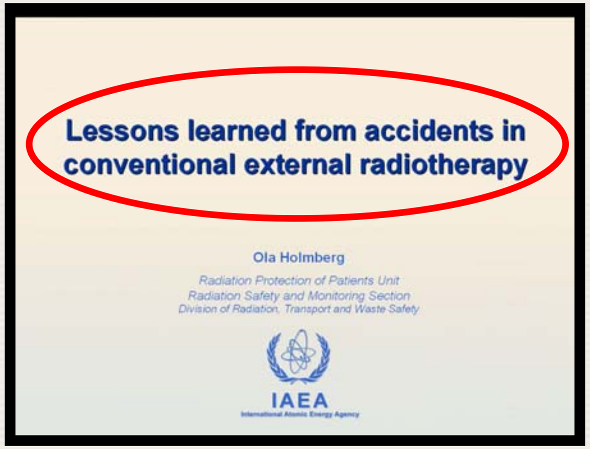
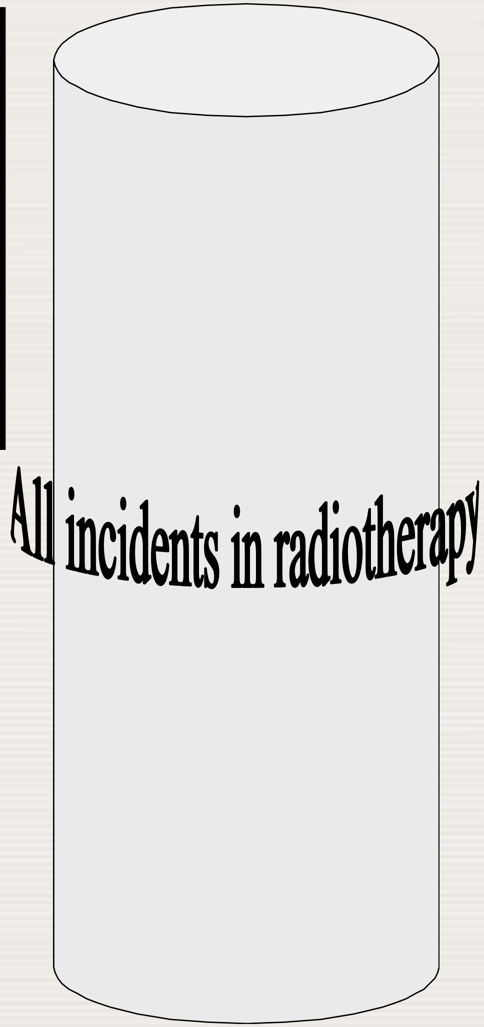
Introduction





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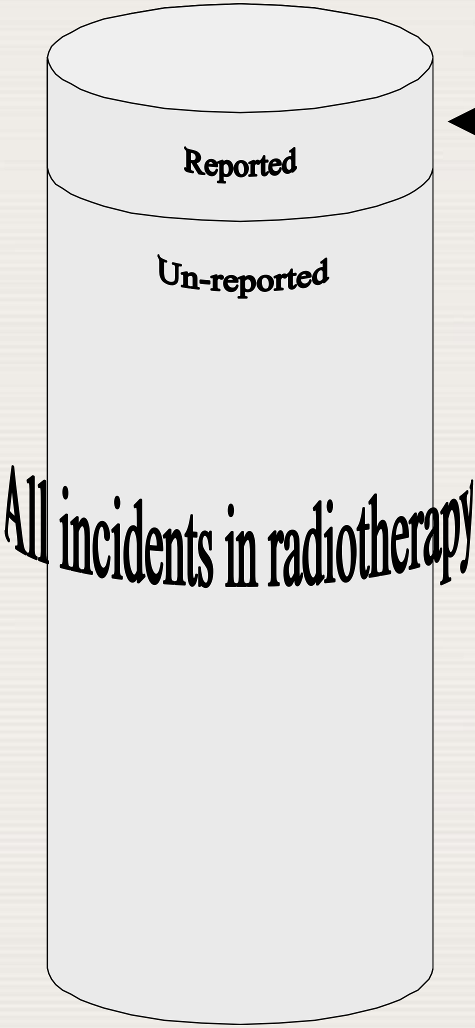

It is only possible to learn lessons from reported incidents

Note: Review by WHO World Alliance for Patient Safety (2008):
'76-'07 – 3125 patients reported affected by RT incidents
'92-'07 – 4616 near misses reported

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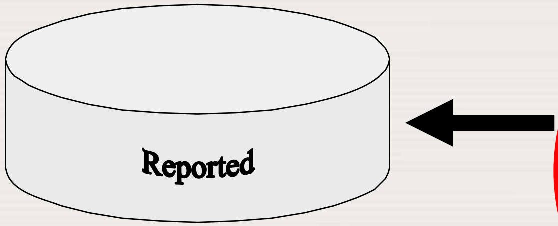

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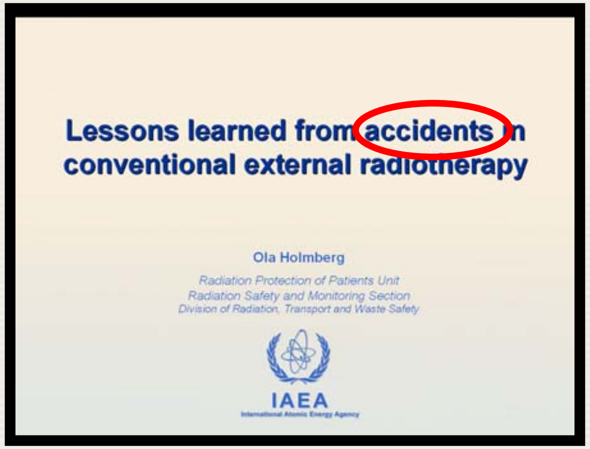
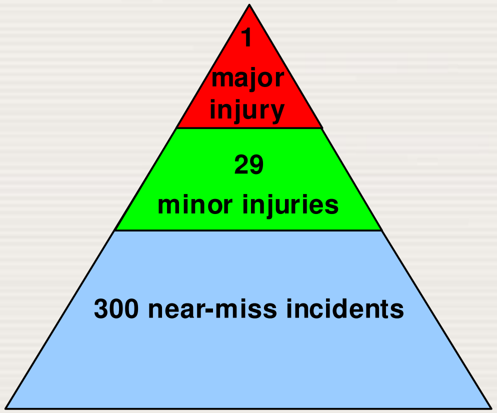


Many reports are on near misses or minor events – Not covered here



H.W. Heinrich (1931)

Note: Near misses often provide excellent learning opportunities and allows proactive approach to prevent actual accidents, e.g. ROSIS

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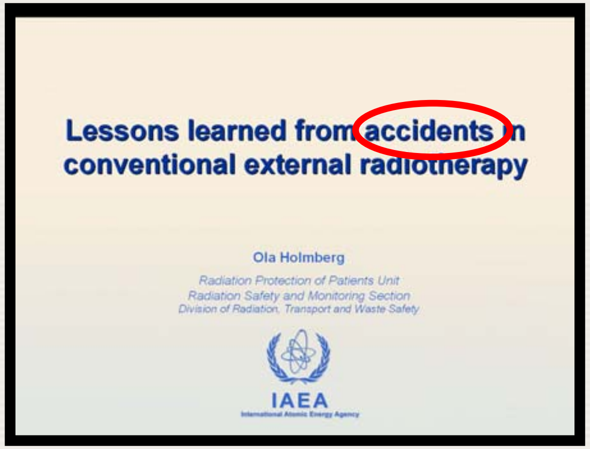

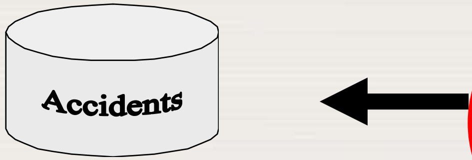

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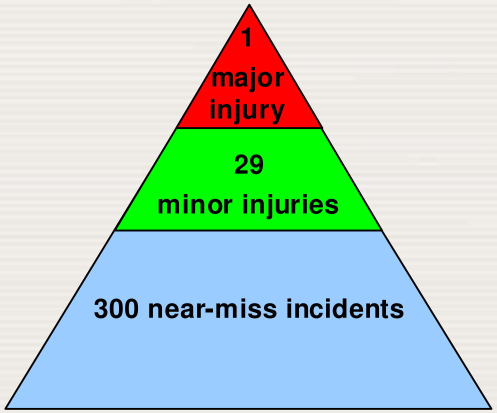

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Note: New RT technology covered in upcoming ICRP Publication 112: Preventing accidental exposures from new external beam radiation therapy technologies

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Conventional RT technology

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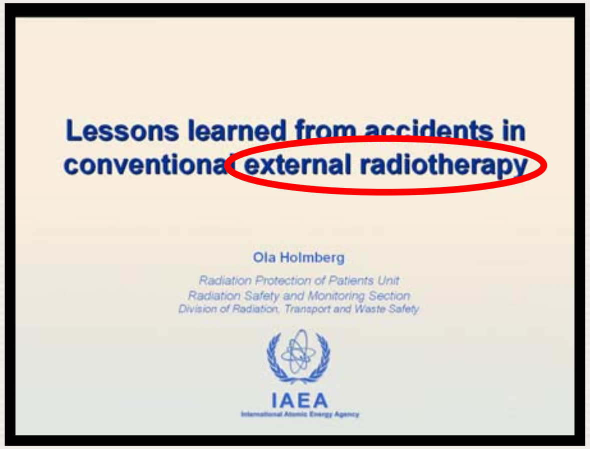

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Note: Covered in ICRP Publication 97 Prevention of high-dose-rate brachytherapy accidents

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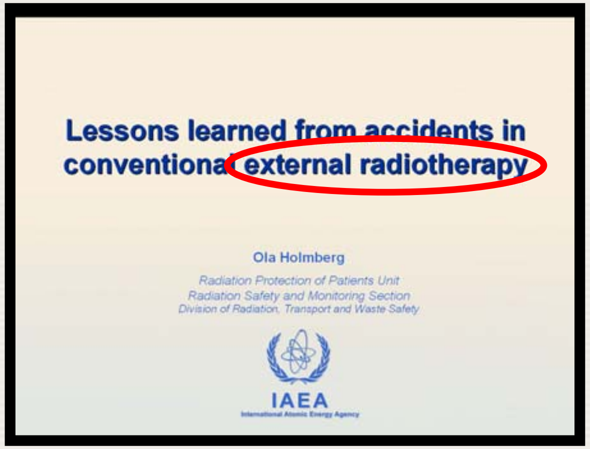

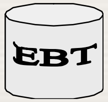

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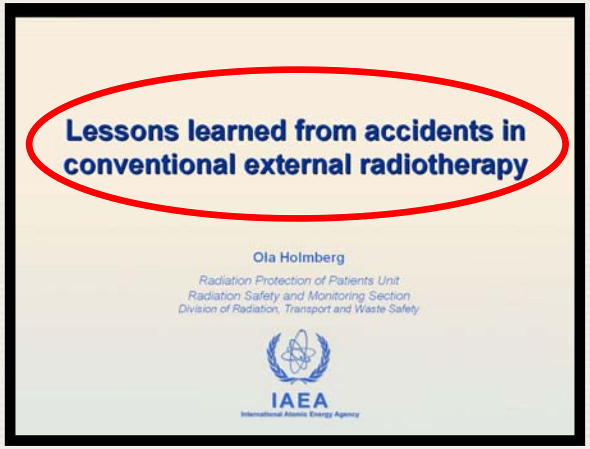
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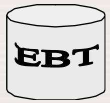

Not a whole lot left?

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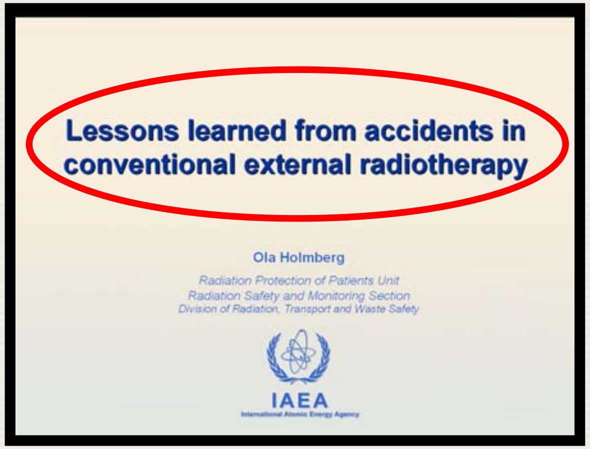
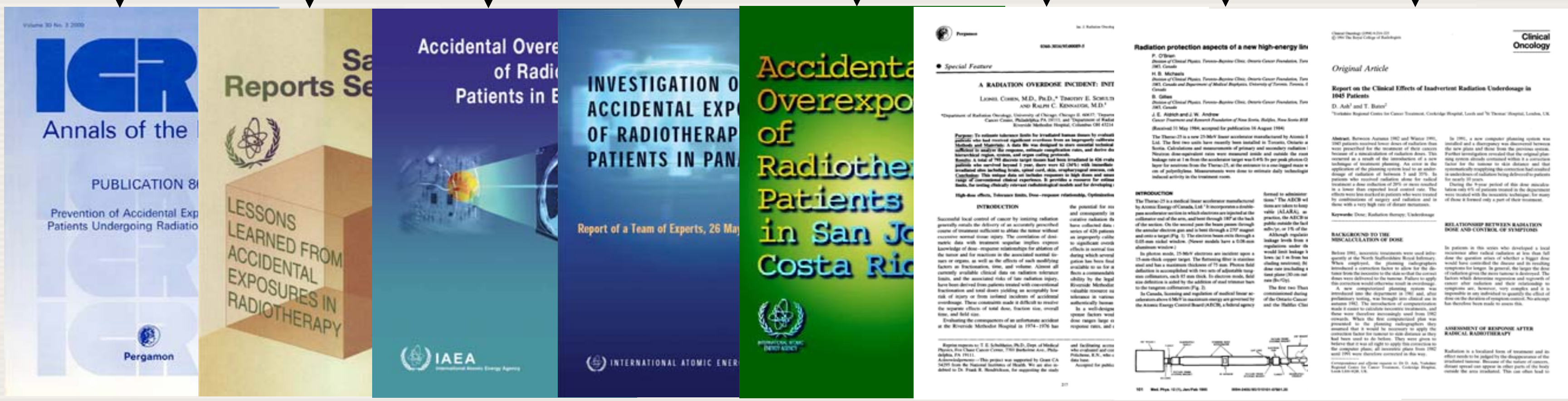


EBT

Not a whole lot left? Fortunately, some of the most well-investigated RT accidents!



Introduction

1. A look at some accidents in conventional external radiotherapy – brief case histories

2. Patterns in the lessons learned – what were the conditions surrounding these accidents?

3. Drawing simple practical conclusions for safety in radiotherapy from these patterns

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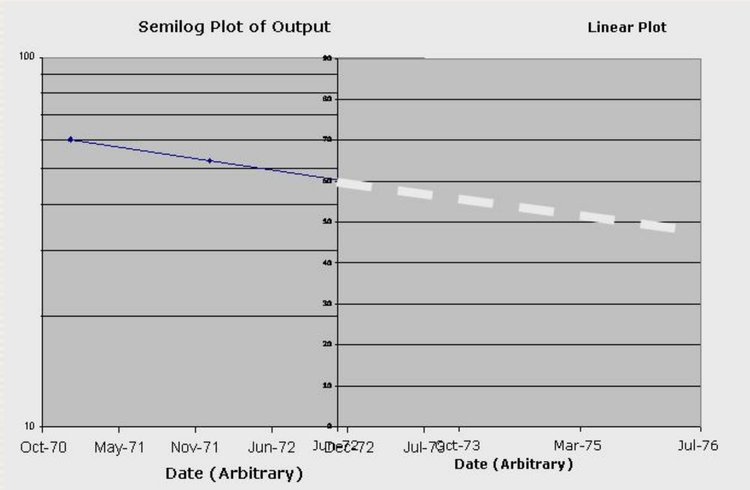
Brief case histories

1. Incorrect decay data (USA, 1974-1976)

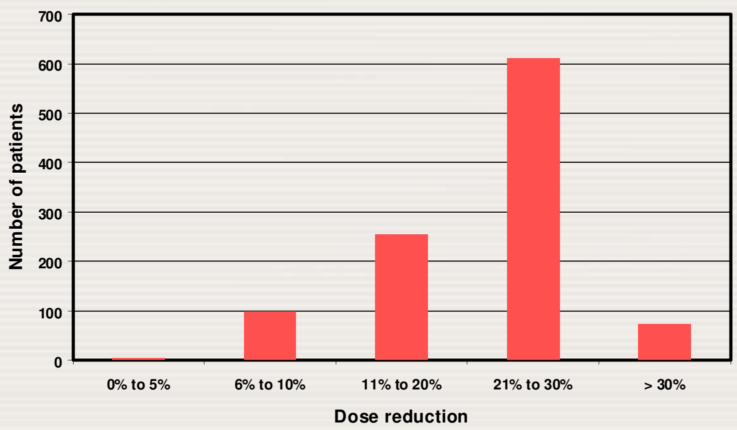
Physicist estimated decay of cobalt source incorrectly, instead of regular measurements, resulting in overdoses (10 to 55%) over 2 years. Also fabricated calibration documents.



Brief case histories

2. Erroneous use of TPS (UK, 1982-1991)

Newly bought TPS correctly applied inverse-square correction for isocentric treatments. Additional distance correction factor was manually applied in error. Underdose resulted for some patient categories for nine years.



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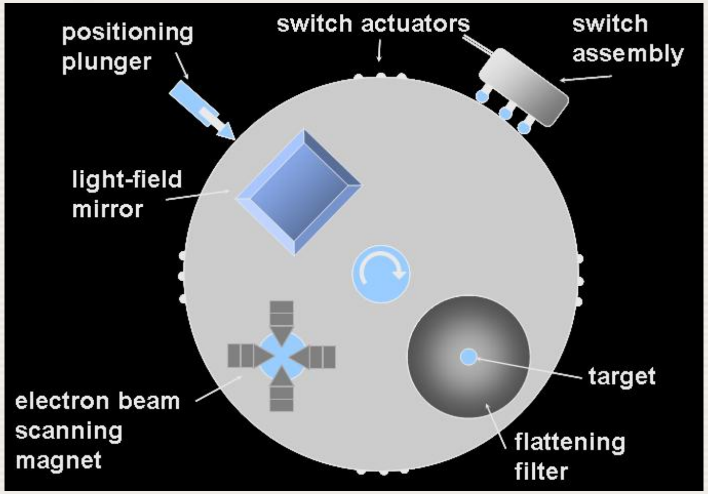
Brief case histories

3. Accelerator software problems (USA and Canada, 1985-1987)

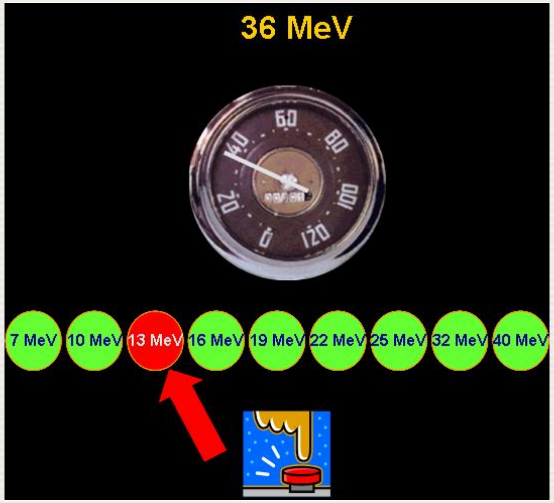
A specific type of accelerator relied on software for safety interlocks. Several accidents occurred involving unintended carousel positioning prior to treatment, resulting in extremely high electron energy fluence directed towards patient.



Brief case histories

4. Incorrect repair of accelerator (Spain, 1990)

A linac broke down, a company technician repaired, and a beam was recovered. A meter display indicated an energy selection problem, but treatments were resumed. Due to a transistor short-circuit, beam-on was only possible when maximum electron energy was used.



Brief case histories

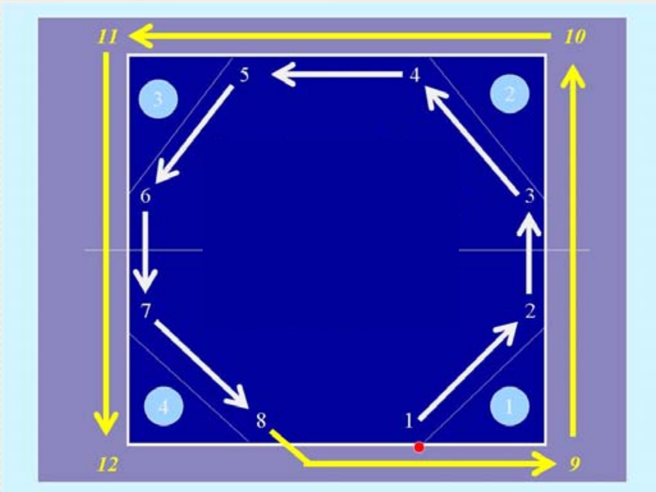
5. Miscalibration of beam (Costa Rica, 1996)

An old Co-source was replaced with a new. A Medical Physicist incorrectly interpreted 0.3 minutes as 30 s (instead of 18 s) during calibration. Consequently, treatment times to be used were overestimated by 66%.

Brief case histories

6. Error in TPS data entry (Panama, 2000-2001)

The TPS used in a clinic had limitations in the calculations and presentation of results. To overcome these limitations, a new way of entering data was devised locally. The TPS accepted this new data entry, but calculated incorrect treatment times, resulting in severe overdoses.



Patterns in the lessons learned

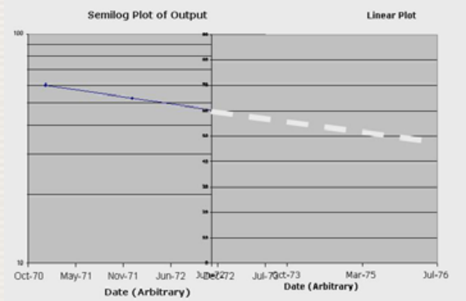
1. Incorrect decay data (USA, 1974-1976)

1. Independent check of a physicist’s work should be performed

2. Formal procedures for calibrating a treatment unit regularly should exist and be followed

3. A department should provide sufficient staff to handle the workload

4. Records must accurately document performance in accepted QC procedures



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Patterns in the lessons learned

1. Incorrect decay data (USA, 1974-1976)

1. Independent check of a physicist's work should be performed
   Procedure insufficient
2. Formal procedures for calibrating a treatment unit regularly should exist and be followed
   Procedure not followed
3. A department should provide sufficient staff to handle the workload
   Staffing insufficient
4. Records must accurately document performance in accepted QC procedures
   Procedure not followed

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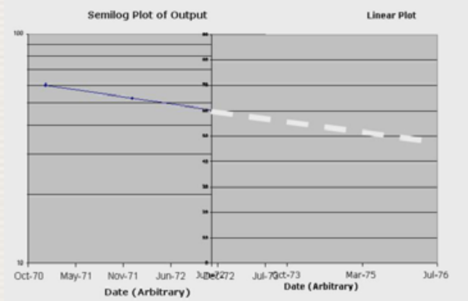


Patterns in the lessons learned

2. Erroneous use of TPS (UK, 1982-1991)

1. Staff should be properly trained in the operation of the equipment and understand the operating procedures

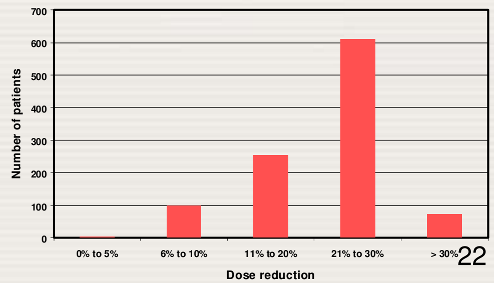
Training and understanding insufficient

2. Procedures should include complete commissioning of TPS before first use

Procedure insufficient

3. QC should include independent checking of TPS calculations

Procedure insufficient



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Patterns in the lessons learned

3. Accelerator software problems (USA and Canada, 1985-1987)

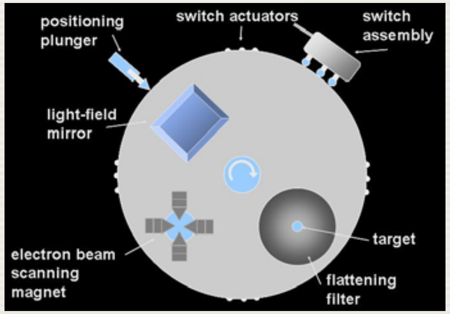
1. Patient reactions should be observed, reported and followed up on
   Procedure insufficient — *Lacking awareness and alertness*

2. Reports of abnormal machine operation should be followed up on
   Procedure insufficient — *Lacking awareness and alertness*

3. The QA Programme should include a review of procedures for reporting unusual events
   Procedure insufficient

4. Only the software for safety can not be relied on
   Procedure insufficient

5. Safety of the patients is ultimately a local responsibility
   Responsibilities not clear



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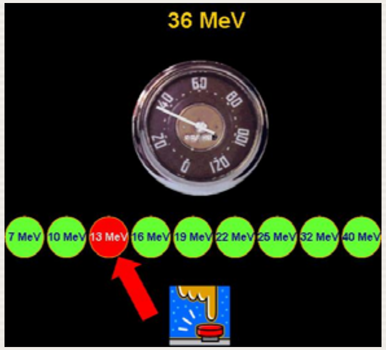
Patterns in the lessons learned

4. Incorrect repair of accelerator (Spain, 1990)

1. QA Programme should include formal procedures for returning medical equipment after maintenance or repair, including making it mandatory to report to the Medical Physicists

Procedure insufficient

Responsibilities not clear



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Patterns in the lessons learned

5. Miscalibration of beam (Costa Rica, 1996)

1. Ensure there is a sufficient level of training and competence in staff

Training and understanding insufficient

2. Ensure there are provisions to work with awareness (e.g. a new source is expected to require shorter treatment times)

Lacking awareness and alertness

3. Ensure there are written procedures for calibration of beams and for independent verification of safety critical tasks before clinical use of equipment

Procedure insufficient

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Patterns in the lessons learned

6. Error in TPS data entry (Panama, 2000-2001)

1. Manufacturers should avoid ambiguity in instructions and perform thorough testing for sw, also for non-intended use

   Procedure insufficient

2. QC should include TPS and a change in procedure should be validated before being put into clinical use

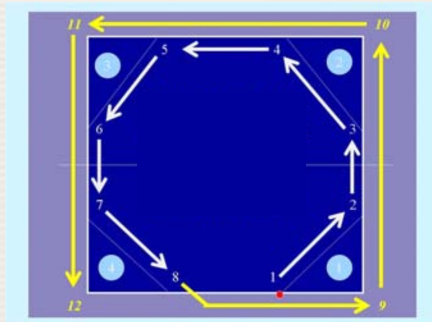
   Procedure insufficient

3. Computer calculations should be verified independently

   Procedure insufficient

4. Awareness of staff for unusual treatment parameters should be stimulated

   Lacking awareness and alertness



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Patterns in the lessons learned

Recent study

100 unintended RT exposures

- Most frequent initiating events and contributing factors
- Five most frequent contributing factors listed below

Contributing factor	Number of incidents, frequency	Normalized frequency (%) of total
5a. A lack of awareness or alertness or inattention to detail	39	14.0
3b. No independent check before treatment of beam calibration, source strength or decay curves	33	11.8
2b. A lack of clear and concise written procedures	19	6.8
1a. Insufficient formal training of the radiotherapy staff	17	6.1
3c. Failure to verify for consistency different sets of data	17	6.1

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Unintended exposure in RT

Unintended exposure in radiotherapy: Identification of prominent causes ☆

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ABSTRACT

Background and purpose: Unintended exposures in radiotherapy are likely to occur when certain conditions that favour such exposures exist. Based on the frequency of occurrence of various causes of 100 events of unintended exposures in radiotherapy as derived from the analysis of published reports, a checklist for assessing the vulnerability of radiotherapy facilities for potential accidents has been prepared. The list presents items to be considered for safety critical assessments of a radiotherapy department for the improvement of patient safety and the entire radiotherapy processes.

Materials and methods: The resources used for this paper consist of 100 unintended radiotherapy exposures and were derived from existing published reports. The analysis was performed by forming two templates: one consisting of 10 initiating events and another of 35 contributing factors.

Results: Four most prominent initiating events were identified and together accounted for about 70% of all the unintended exposure events. Ten most prominent contributing factors were also identified and together accounted for about 70% of all the radiotherapy unintended exposure events covered under this study.

Conclusion: With this knowledge of high frequency of occurrences, the identified four prominent initiating events and the 10 most prominent contributing factors must be checked and dealt with as a matter of priority when assessing the safety of a radiotherapy facility. A simple checklist for checking the quality assurance programmes of a radiotherapy department for every aspect of the design and delivery of radiation have been provided.

The numbers of patients with cancer and of deaths resulting from cancer are increasing. Radiation therapy is an effective way to treat many kinds of cancers in almost any part of the body. Currently, about half of all cancer patients receive radiotherapy either as part of their primary treatment or in connection with recurrences or palliation. It has been estimated that a little less than half of all cancer patients are cured of their disease. Of 100 cancer patients, it has been indicated that approximately 22 will be cured by surgery, 18 by radiotherapy – alone or combined with other modalities but with radiotherapy as the prominent agent – and 5 by chemotherapy – alone or, more often, combined with other modalities [5]. Radiotherapy is anticipated to play an increasing role in cancer treatment due firstly to improvements in detection and early diagnosis which implies that increasing number of patients will have cancers which are curable by loco-regional means with radiotherapy featuring prominently. Furthermore, there are improvements in radiotherapy treatment modalities, substantial improvement in radiotherapy results over the years as well as an increasing use of adjuvant radiotherapy treatments as a move away from radical surgery towards less drastic organ conserving surgery combined with radiation.

It is desirable not only that cancers be cured, but also that the therapies cause minimal damage to the patient's organs and physical form in consideration of the patient's rehabilitation. The success of radiotherapy in terms of the probability of tumour control depends on accurate delivery of radiation dose to the intended target volume. Accuracy and reliability in dose delivery is achieved, through the establishment of quality assurance (QA) programmes for every aspect of the design and delivery of radiation. The International Commission on Radiation Units and Measurements realizing this has recommended that the dose delivered to cancer patients is within 5% of the prescribed dose [2]. To achieve the ICRU recommendation each of the many steps involved in delivering dose to a target volume in a patient, must be performed with accuracy much better than 5%. To meet the ICRU standards requires the availability of the necessary facilities and equipment including treatment and imaging units, radiation measuring devices, computer treatment planning systems and the appropriate staffing levels of radiotherapy professionals. ISO 9000 defines QA generally as all those planned and systematic actions necessary to provide adequate confidence that a product or service will sat-

☆ The views expressed in this paper are those of authors', rather than that of the organizations they belong to.

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3c. Failure to verify for consistency different sets of data	17	6.1

Lacking awareness and alertness
Procedure insufficient
Procedure insufficient
Training and understanding insufficient
Procedure insufficient

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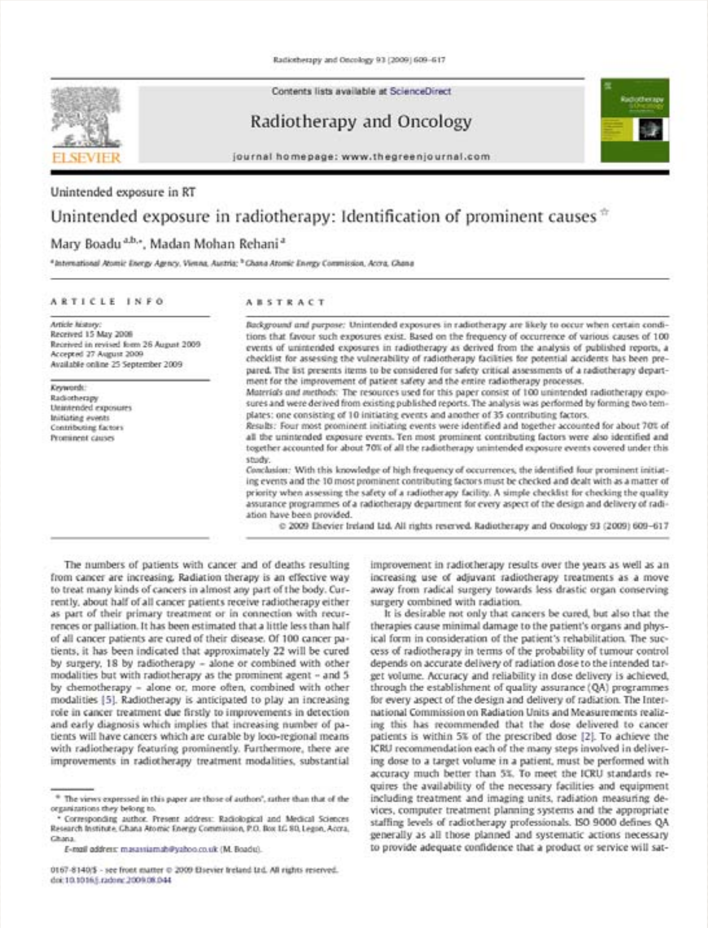

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Patterns in the lessons learned

1. Working with awareness and alertness

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

2. Procedures

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

Patterns in the lessons learned

3. Training and understanding

Accidental exposures have occurred when there is a lack of qualified and well-trained staff (or lack of staff overall), with necessary educational background and specialised training.

4. Responsibilities

Accidental exposures have occurred when there are gaps and ambiguities in the functions of personnel along the lines of authority and responsibility. In these cases, safety critical tasks have been insufficiently covered

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Practical conclusions

1. Working with awareness and alertness

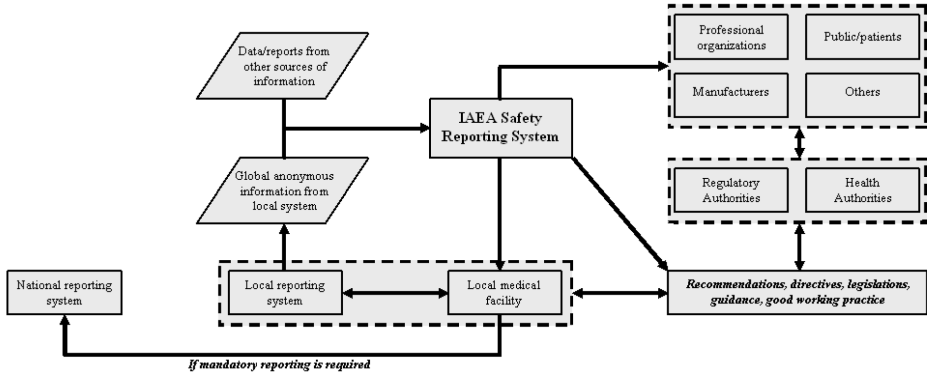
Foster and maintain safety culture among radiotherapy professionals.

How?

Basic steps:

- *Regular feedback on safety to staff*
- *Management giving priority to safety*
- *Prioritize incident reporting, investigating and learning*

SAFRON (Safety in Radiation Oncology)



Practical conclusions

2. Procedures

Ensure there are written, comprehensive procedures (QA programme) that are known and followed, relating to all steps in the radiotherapy process.

How?

Basic steps:

- *Use programmes from international and professional organizations and adapt these locally – motivating modifications*
- *Ensure there are independent checks at safety-critical steps*

Practical conclusions

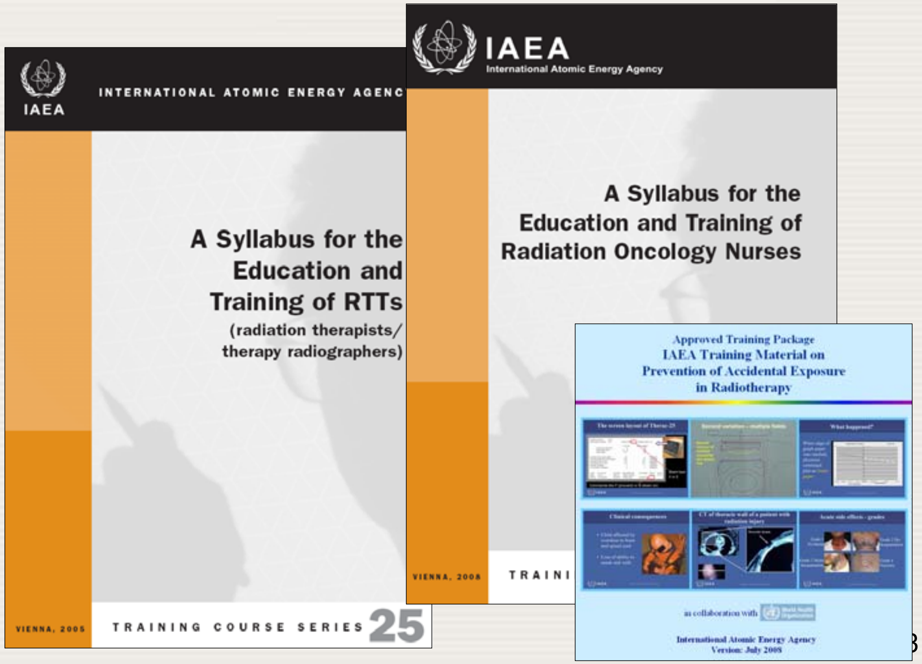
3. Training and understanding

Ensure appropriate education and training of professionals, and adequate level of staffing.

How?

Basic steps:

- *Promote the use of syllabi for education and training from international and professional organizations*
- *Ensure staff is trained in thinking about safety in radiotherapy*



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Practical conclusions

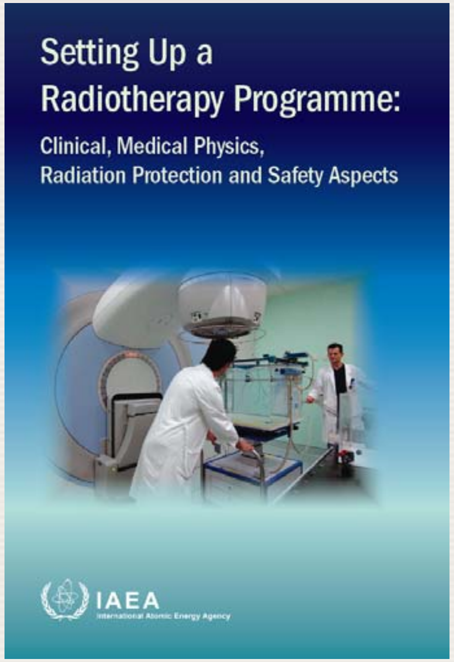
4. Responsibilities

Ensure there are clear and unambiguous definitions of responsibilities in all aspects of the process and that these are understood by staff.

How?

Basic steps:

- *Set up local organization with clear responsibilities*
- *Ensure there are clear and comprehensive job descriptions for all staff, and that these are communicated and understood*



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