Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy

International Commission on Radiological Protection

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- This is a PowerPoint file
- It may be downloaded free of charge
- It is intended for teaching and not for commercial purposes
- This slide set is intended to be used with the complete text provided in ICRP *Publication 86*

**Contents**

- Case histories of major accidental exposure in radiotherapy
- Clinical consequences of accidental exposures
- Recommendations for prevention
Case Histories of Major Accidental Exposures of Patients in Radiotherapy

Case 1: Use of an incorrect decay curve for $^{60}$Co (USA, 1974-76)

Initial calibration of a $^{60}$Co beam was correct, but ..

- A decay curve for $^{60}$Co was drawn: by mistake, the slope was steeper than the real decay and the curve underestimated the dose rate
- Treatment times based on it were longer than appropriate, thus leading to overdoses, which increased with time reaching up to 50% when the error was discovered
- There were no beam measurements in 22 months and a total of 426 patients affected
- Of the 183 patients who survived one year 34% had severe complications
Case 2: Incomplete understanding & testing of a treatment planning system (TPS) (UK, 1982-90)

- In a hospital, most of the treatments were with a SSD of 100 cm
- For treatments with SSD different from standard (100 cm), corrections for distance were usually done by the technologists
- When a TPS was acquired, technologists continued to apply manual distance correction, without realising that the TPS algorithm already accounted for distance

Cont’d: Incomplete understanding and testing of a treatment planning system (UK, 1982-1990)

- As a result, distance correction was applied twice, leading to underdosage (up to 30%)
- The procedure was not written, and therefore, it was not modified when new TPS was used
- Problem remained undiscovered during eight years and affected 1,045 patients
- 492 patients who developed local recurrence probably due to the underexposure
Case 3: Untested change of procedure for data entry into TPS (Panama, 2000)

- A TPS allowed entry of four shielding blocks for isodose calculations, one block at a time
- Need for five shielding blocks led to deviation from standard procedure for block data entry: several blocks were entered in one step
- Instructions for users had some ambiguity with respect to shielding block data entry
- TPS computer calculated treatment time, which was double the normal one (leading to 100% overdose)

Cont’d: Untested change of procedure for data entry into TPS (Panama, 2000)

- There was no written procedure for the use of TPS, and therefore, a change of procedure was neither written nor tested for validity
- Computer output was not checked for treatment time with manual calculations
- The error affected 28 patients
- One year after the event, at least five had died from the overexposure
Case 3: Patient treated with overdose

Colonoscopy of a patient treated with overdoses of 100%
Necrotic tissue
Telangiectasia

Case 4: Accelerator software problems (USA & Canada, 1985-87)

- Software from an older accelerator design was used for a new, substantially different, design
- Software flaws were later identified in the software used to enter treatment parameters, such as type of radiation and energy
- Six accidental exposures occurred in different hospitals and three patients died from overexposure
Case 5: Reuse of outdated computer file for $^{60}$Co treatments (USA, 1987-88)

- After source change, TPS computer files were updated…
- Except a computer file, which was no longer in use (this was intended for brain treatments with trimmer bars)
- The computer file was not removed although no longer in use

Cont’d: Reuse of outdated computer file for $^{60}$Co treatments (USA, 1987-88)

- A new radiation oncologist decided to treat with trimmer bars and took the file corresponding to the prior $^{60}$Co source
- There was no double or manual check for dose calculation
- 33 patients received 75% higher overexposure
Case 6: Incorrect accelerator repair & communication problems (Spain, 1990)

- Accelerator fault followed by an attempt to repair it
- Electron beam was restored but electron energy was misadjusted
- Accelerator delivered 36 MeV electrons, regardless of energy selected
- Treatments resumed without notifying physicists for beam checks

Cont’d: Incorrect accelerator repair & communication problems (Spain, 1990)

- There was a discrepancy between energy displayed and energy selected, which was attributed to a faulty indicator, instead of investigating the reason for the discrepancy
- A total of 27 patients were affected with massive overdoses and by distorted dose distribution due to wrong electron energy
- At least 15 of these patients died from the accidental overexposure and two more died with overexposure as major contributor
**Case 7: Malfunction of HDR brachytherapy equipment (USA, 1992)**

- HDR brachytherapy source detached from the driving mechanism while still inside the patient
- While the console display indicated that the source was in retracted to the shielded position, an external radiation monitor was indicating that there was radiation
- Staff failed to investigate the discrepancy with available portable monitor
- The source remained in the patient for several days and the patient died from overexposure

**Case 8: Beam miscalibration of $^{60}$Co (Costa Rica, 1996)**

- Radioactive source of a teletherapy unit was exchanged
- During beam calibration, reading of the timer was confused, leading to underestimation of the dose rate
- Subsequent treatment times were calculated with the wrong dose rate and were about 60% longer than required
- 115 patients were affected; two years after the event, at least 17 patients had died from the overexposure
Case 8: Beam miscalibration of $^{60}$Co (Costa Rica, 1996)

Failure to perform independent calibration

Failure to notice that treatment times were too long for a new source with higher activity

Child affected by overdoses to brain and spinal cord and lost his ability to speak and walk

Clinical Consequences
**Side effects and complications in radiotherapy**

- Side effects are usually minor and transient
  
  *e.g.* xerostomia and localised subcutaneous fibrosis
  
  Relatively high frequency acceptable to achieve cure

- Complications are more severe and long lasting
  
  *e.g.* radiation myelitis
  
  Expected only at very low frequency

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**Impact of accidental underexposure**

- Accidental underdosage may jeopardise tumour control probability

- They are difficult to discover, may only be detected after relatively long time and, therefore, may involve a large number of patients
Impact of overdoses on early (or acute) complications

- Usually observed in tissues with rapid cell turnover (skin, mucosa, bone marrow …)
- Overexposure may increase the frequency and severity (up to necrosis)

Early (acute) complications

- Determinant factors for acute complications are:
  1) total delivered dose
  2) total duration (protraction)
  3) size and location of irradiated volume
- Little correlation of early complications with fraction size and dose rate (except if the latter is very high)
Late complications

- Mainly observed in tissues with slowly proliferating cells (arteriolar narrowing which occurs with a time delay)
- Can also become manifest in rapidly proliferating cells (in addition to and after acute effects)
- Manifest more than six months after irradiation and even much later
- Usually irreversible and often slowly progressive

Example of late complications due to an accidental overexposure...

Extensive fibrosis of the left groin with limitation of hip motion as a result of accidental overexposure
Impact of overexposure on late complications (cont’d)

- Determinant factors:
  1) total delivered dose
  2) fraction size and dose rate

- In the case of accidental exposure, increased fraction size may amplify the effects (as occurred in some accidents)

Late complications (cont’d)

- In serial organs (spinal cord, intestine, large arteries), a lesion of small volume irradiated above threshold may cause major incapacity, for example paralysis

- In organs arranged in parallel (e.g. lung and liver), severity is related to the tissue volume irradiated above threshold
Example of late complication on organ with serial arrangement (spinal cord)

Young woman who became quadriplegic as a result of accidental over-exposure to the spinal cord

Clinical detection of accidental medical exposure

- Careful clinical follow-up may lead to detect accidental overdose through early enhanced reactions
- Experienced radiation oncologists can detect overdoses of 10% during regular weekly consultations
- Some overdoses may cause late severe effects without abnormal early effects
In the case of unusual reactions in a single patient, other patients treated in the same period may need to be recalled.
List of Recommendations for prevention

Overall preventive measure: a Quality Assurance Programme, involving
- Organisation
- Education and training
- Acceptance testing and commissioning
- Follow-up of equipment faults
- Communication
- Patient identification and patient charts
- Specific recommendations for teletherapy
- Specific recommendations for brachytherapy

Quality Assurance Programme for Radiation Therapy (QART)

- Quality assurance programmes have evolved from equipment verifications to include the entire process, from the prescription to delivery and post treatment follow-up
- Major accidental exposures occurred in the absence of written procedures and checks (QART); either because a QART did not exist or it was not fully implemented (checks omitted)
Organisation

- Comprehensive QA is crucial in prevention and involve clinical, physical and safety components:
  - Its implementation requires
    - complex multi-professional team work
    - clear allocation of functions and responsibilities
    - functions and responsibilities understood
    - number of qualified staff, commensurate to workload

Education and training

- The most important component of QA is qualified personnel, including radiation oncologists, medical physicists, technologists and maintenance engineers
  - Comprehensive education together with specific training on
    - procedures and responsibilities
    - everyone’s role in the QART programme
    - lessons from typical accidents with a description of methods for prevention
    - additional training when new equipment and techniques are being introduced
Acceptance testing & commissioning

- Errors in these phases may affect many patients

- Acceptance testing:
  Should include test of safety interlocks, verification of equipment specifications, as well as understanding and testing TPS

- Commissioning:
  Should include measuring and entering all basic data for future treatments into computer

- Systematic acceptance and commissioning, including a cross check and independent verification, form a major part of accident prevention

Follow-up on equipment faults

- Experience has shown that some equipment faults are difficult to isolate and to correct

- If an equipment fault or malfunction has not been fully understood and corrected, there is a need for
  - communication and follow-up with manufacturer
  - dissemination of information and experience to other maintenance engineers
Communication and repairs

- Need for a written communication policy, including:
  - Reporting of unusual equipment behaviour
  - Notification to the physicist and clearance by before resuming treatments (because of possible need for control checks after repairs)
  - Reporting of unusual patient reactions

Patient identification and patient chart

- Effective patient identification procedures and treatment charts (consideration of photographs for identification …)
- Double check of chart data at the beginning of treatment, before changes in the course of treatment (for example, a new field) and once a week at least
Specific items for external beam therapy

- Calibration
  - Provisions for initial beam calibration and follow-up calibrations
  - Independent verification of the calibration
  - Following an accepted protocol
  - Participation in dose quality audits

- Treatment planning
  - Include TPS in the programme of acceptance testing commissioning and quality assurance
  - Cross-checks and manual verification

- Adequate in-vivo dosimetry would prevent most accidental exposures

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Specific items for brachytherapy

- Provisions for checking source activity and source identification before use

- Dose calculation and treatment planning
  Provisions for dose calculation and cross-checks

- Source positioning and source removal
  Provisions to verify source position
  Provisions to ensure that sources do not remain in the patient (including monitoring patients and clothes)
Summary

- Radiotherapy has unique features from the point of view of the potential for accidental exposure
- Consequences of accidental exposure can be very severe and affect many patients
- Careful clinical follow up may detect overdoses from about 10%
- A quality assurance programme is the key element in prevention of accidental exposure

Web sites for additional information on radiation sources and effects

European Commission (radiological protection pages):
  europa.eu.int/comm/environment/radprot

International Atomic Energy Agency:
  www.iaea.org

International Commission on Radiological Protection:
  www.icrp.org

United Nations Scientific Committee on the Effects of Atomic Radiation:
  www.unscear.org

World Health Organization:
  www.who.int