Lessons Learned from Misadministrations and Accidents in Radiation Therapy: Teletherapy
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Overview
- Introduction
- Summary of accidents and misadministrations
- Resources and guidance
- Lessons learned
- Conclusions

Purpose/Objectives
- To learn from previous accidents and misadministrations
- To understand the types of things that can occur
- Not to point fingers or criticize other institutions
- Not to beat on the vendors
- Some of these incidents could have happened to any one of us

What are the sources of errors?

WHO Radiotherapy Risk Profile 2008
SUMMARY OF ACCIDENTS

Incorrect decay data and lax dosimetric QA
- Location: USA
- Year: 1974 - 1976
- Issue: Incorrect decay data for cobalt unit
- Consequences: 10 – 45% overdosage for 426 patients leading to severe skin reactions, bone necrosis and myelopathy
- Lesson: Get an independent check and calibrate unit on a regular basis

Inverse square error
- Location: United Kingdom
- Year: 1982 - 1990
- Issue: New TPS put into clinical use, but inverse-square corrections were still applied manually
- Consequences: 1045 patients received up to 30% underdose, 492 developed local recurrence
- Lesson: Commissioning/Independent Check

Malfunction 54
- Location: USA and Canada
- Year: 1982 - 1990
- Issue: Linac operated in photon mode without x-ray target in place
- Consequences: 3 patients died, 4 others with severe/debilitating injuries
- Lesson: Vendors should act more quickly and be more responsive to customer issues and software should not be solely responsible for safety

Malfunction 54
- Male patient being treated for surgically removed sarcoma on upper back
- Treatment #8 with 22 MeV electrons
- Prone setup with electron trimmers in place
- Mode: Fixed
- Beam Type: X
- Default energy: 25 MV
- Edited to correct Beam Type

Setup VERIFIED
- Beam Ready
- Beam ON
- Malfunction 54, 6 MUs delivered
- P key
- Malfunction 54, 6 MUs delivered
Malfunction 54 Re-enactment
- Therapist recalls setting Beam Type as X with default to 25 MV
- Used up arrow key to change Beam Type to E and energy to 10 MeV
- Used enter key to go to the bottom of the screen
- Beam Ready
- Beam On
- Malfunction 54

Malfunction 54 Visualized
- 25 MeV Electrons, 16,000 rads in 100 msec

Malfunction 54 Timeline

Incorrect Linac Repair
- Location: Spain
- Year: 1990
- Issue: Linac repair led to 36 MeV electron beams, regardless of console input
- Consequences: 15 patients died from overdose
- Lesson: Notify physicist any time linac repairs are performed and do not ignore console warnings

Decay rate error
- Location: Costa Rica
- Year: 1996
- Issue: 60Co dose rate calculation error; 0.3 min mistakenly believed to be 30 s, not 18 s
- Consequences: Patients overdosed by ~73%; Side effects include ulceration, bleeding and anemia
- Lesson: Periodic calibration checks of machines, clinical awareness

Investigation of an accidental exposure of radiotherapy patients in Panama
- Location: Panama
- Year: 2000
- Issue: TPS block entry had limitations in way blocks were entered, a new way of entering data was tried and seemed to work
- Consequences: Treatment times were calculated incorrectly, 5 patients died from overexposure
- Lesson: Validate procedure changes/second check of calculations, clinical awareness
Accidental Overexposure of Radiotherapy Patients in Blatyck
- Location: Poland
- Year: 2001
- Issue: Power outage; on startup, machine indicates low dose rate; dose rate had actually increased and five patients were overdosed.
- Lesson: Check linac output after repairs before it goes back into service/investigate unusual displays.

Procedure change
- Location: France
- Year: 2004
- Issue: Clinic moved from physical wedges to dynamic wedges for prostate treatment, but MU continued to be calculated for physical wedges.
- Consequences: Overdoses of 20 – 30%; 1 patient died, others with severe complications.
- Lesson: Validate procedure changes, independent calculation.

Improper Jaw Size During SRS
- Location: France
- Year: 2004
- Issue: Physicist told therapist to set a “40x40” for cone SRS treatment; therapist set 40x40 cm².
- Consequences: Some normal tissue received more dose than the target; developed “fibrosis and oesotracheal fistula” requiring surgery; patient died from “brutal haemorrhage” a few days after surgery.
- Lesson: Have clear procedures/checklists in place.

Miscalibration
- Location: Florida
- Year: 2004-2005
- Issue: Miscalibration of linac.
- Consequences: 77 patients received a 50% overdose.
- Lesson: Get independent/second check of the output (RPC).

Procedure change
- Location: Glasgow, Scotland
- Year: 2005
- Issue: Treatment parameters manually transferred incorrectly after R&V upgrade.
- Consequences: One patient received ~60% overdose to the whole brain and died.
- Lesson: Independent check of calculations/understand procedure changes.
**Publicity**

Radiation Errors Reported in Missouri

By MARK STOVER and JEFFREY S. MILLER

**Who’s responsible?**

This happened in France in 2007!

**Improper Jaw Size During SRS**

- **Location**: United States
- **Year**: 2009
- **Issue**: Collimator jaws for SRS treatment using cones were left open during treatment
- **Consequences**: Patient “is in a nursing home, nearly comatose…”
- **Lesson**: Interlocks needed, better communication, standardized procedures

**Miscalibration**

- **Location**: Trinidad and Tobago
- **Year**: 2009 - 2010
- **Issue**: Linac miscalibrated, skipped annual QA
- **Consequences**: 223 patients received overdoses ranging from 4 – 20% (13.9%)
- **Lesson**: IAEA report pending

**Wrong Interlock Board Installed**

- **Location**: United States
- **Year**: 1991a
- **Issue**: An interlock board intended for a Varian Clinac 2100C was placed in a Clinac 1800
- **Consequences**: Output of the Clinac 1800 increased over 100%, but was caught during a routine constancy check
- **Lesson**: QA procedures work!

*a Berkley LW and Purdy JA. The need for better communication between accelerator manufacturers and in-house service engineers. MEDICAL PHYSICS 18(3), May/June 1991, p. 608.*
Wrong Software Installed

Location: United States
Year: 2008
Issue: A buggy version of treatment planning software was installed during upgrade.
Consequences: MU calculated for IMRT led to 15% underdose, but was caught during commissioning measurements.
Lesson: QA procedures do work!

But they must be in place!
They must be followed!
“...routine quality assurance procedures would have stopped most of the horrific events that have happened in radiation therapy.”*
Where can we find guidance and recommendations for implementing well-thought-out and comprehensive QA procedures and policies?

* Eric Klein, Point/Counterpoint, Med Phys (38)11.

Sources of Guidance
- AAPM
- ACR
- ASTRO

AAPM Task Groups
- TG25 and TG70 – electrons
- TG42 - SRS
- TG53 – QA for TPS
- TG40, TG45, TG142 – linacs
- TG101 – SBRT
- TG103 – physicist peer review
- TG106 – linac commissioning
- TG114 – MU verification for non-IMRT
- TG119 – IMRT commissioning

Task Group 40 Outline*
- Comprehensive QA Program
- QA of EBRT Equipment
- Treatment Planning Computer System
- External Beam Treatment Planning
- Brachytherapy
- QA of Clinical Aspects

Role of Radiation Oncologists
- Patient consultations
- Prescribe dose
- On treatment supervision
- Treatment summary
- Follow-up evaluations
- Experienced radiation oncologists can detect overdoses of 10% during OTV

*TG142 has updated the TG40 recommendations
Role of Medical Physicists
- Calibration of therapy equipment
- Specifications of therapy equipment
- Acceptance testing, commissioning, and QA
- Treatment planning
- Weekly chart checks
- Outline written QA procedures

Role of Dosimetrists
- Accurate patient data acquisition
- Treatment planning
- Documentation of treatment plan

Role of Therapists
- Accurate delivery of planned course of radiation therapy
- Recognize any change in patient’s condition
- Detect any equipment malfunctions
- Understand safe operating limits of equipment
- Understand treatment planning methods

TG 142 Recommendations
- A comprehensive QA program
- QA team to draft policies and procedures
- Establish baseline reference values for QA measurements
- Qualified Medical Physicist should lead the QA team
- End to end system check recommended any time a new or revised procedure is introduced

QA Program
- Should be written
- Detail all tests and procedures, their frequency, action criteria, and records required
- Personnel to perform the tests

QA Committee
- At least one physician, one therapist, one physicist and one dosimetrist
- Oversees the QA program
- Set action levels and define actions to correct problems
- Review instances where action levels are exceeded or errors are made
- Led by QMP
Comprehensive QA Team/Safety Culture

- Consists of every member of the department
- Every employee should be able to question and express concerns

Quality Audit

- Performed at the frequency stated in the policies and procedures manual
- JCAHO requires at least an annual reappraisal of the radiation oncology QA program as part of hospital’s QA program annual review
- Performed by an outside group whenever possible

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QA of external beam radiation therapy equipment

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Are these procedures outdated?

Big mistakes today usually result from:
1. Mistakes made during commissioning: Wrong dosimeter to calibrate a stereotactic radiosurgery (SRS) beam; corrupted computer file or software bug; not understanding a "hidden equation" underlying an Excel spread sheet, or the data format required for a computer program.
2. Being rushed or complacent and not following existing procedures.

Amols HI and Klein EE. QA procedures in radiation therapy are outdated and negatively impact the reduction of errors. Med Phys 38(11), 5835 – 5837, 2011.
ACR Practice Guidelines

- 3D conformal radiotherapy
- IMRT
- IGRT
- SRS
- SBRT
- TBI
- Practice Accreditation

ASTRO

- ASTRO’s Six Point Action Plan
- Target Safely – IMRT Safety White Paper
- Target Safely – SBRT/SRS Safety White Paper
- ASTRO – Safety is no accident – A framework for quality radiation oncology and care

ASTRO’s Six Point Action Plan


IMRT White Paper


IMRT White Paper

- Recommendations for IMRT QA

SRS/SBRT White Paper

- Solberg et al. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy. PRO 2012.
SRS/SBRT White Paper

■ Focus on personnel and technology requirements
■ Commissioning/credentialing

Appendix provides excellent examples of checklists for SRS, SBRT, simulation and treatment planning.
Are we learning anything?

- Same types of accidents keep happening
- There are multiple sources for guidance
- However, we have no effective way to report accidents and inform the greater community!

There were strong similarities between what happened in Missouri and what happened in Toulouse,” said Dr. Ola Holmberg, who heads the radiation protection unit for patients at the International Atomic Energy Agency.

But without a requirement that accidents and near-misses be reported, other hospitals cannot learn from these mistakes, Dr. Holmberg said.

A Pinpoint Beam Strays Invisibly, Harm Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO

Specific Lessons Learned from Accidents and Overexposures

- Get an independent check of machine calibration and commissioning
- Perform end to end commissioning tests, including the R&V system
- Use an independent method to check MU/time calculations
- Evaluate changes in TPS, R&V and other software thoroughly before implementation
- Check machines after repair
- Don’t take the vendor’s word for it
- What do you take for granted?

Some items to consider…

- What do you take for granted and why?
- A certain error is “impossible”?
- That someone else will interpret your instructions the way you intended?
- That a system works the way you think it "should"?

Conclusions

- Mistakes will happen, we’re human
- Ignoring policies or a dangerous situation is inexcusable
- Major accidental overexposures occur in the absence of written QA procedures or when checks are omitted
- QA procedures and policies are necessary and must be followed in order to catch mistakes
- When errors are discovered, it is often the fault of the process or program, not individuals
- Use the resources at your disposal to implement a comprehensive QA program