Lessons Learned from Accidents in Radiation Therapy: How to Prevent Them?

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Do Accidents Happen?
In Radiotherapy?

- Here are a few to discuss:
  - Calibration problem in US (1974-6)
  - Calibration problem in UK (1988)
  - TPS problem in UK (1982-91)
  - Linac problem in Northern America (1985-7)

Information presented are from public available sources, IAEA, mailing lists, and some personal touch.
During the period 1974-1976 the physicist failed to perform regular measurements (calibrations and QA)
- The physicist relied on estimations of the decay of the source to predict dose rate and calculate treatment time

Rather than calculated the decay, the physicist plotted dose rate on graph paper and extrapolated
- Using semi-log paper but replaced it with lin-lin paper when reaching the end
- Linear Y-axis did not correspond to log Y-axis, so straight line extrapolation resulted in ever-more incorrect output values
- Linear X-axis did not correspond to calendar axis, so extrapolation led to incorrect date values

426 patients received significant overdoses
- 11 were untraced - 415 followed up - 795 sites at risk identified
- 57% (243) died within the first year
- In 87 patients there was local control with no documented recurrence
- Survivors beyond the second year had an increased frequency of complications
Exeter, UK, 1988

- Installation of a new cobalt source
- A physicist calibrated the new source
2/2/88

O/P calibration of new source

Scaler: Farmer 2570 with probe, in water tank at depth 5.0m
Water tank outside dimensions (purpose): 32 x 32 x 21 cm 5 water up
T = 293 K, P = 760.3 mm, SSD = 800 mm, 100 x 100 mm FIELD

Farming left on for 45 min before any measurement
Water tank filled and left to come to room temp overnight.

Farming real ize (0.8 min): 90 x 95, 90 92, 90 90, 90 90, 90 90, 90 90

(0.4 min) 46.47, 46.40, 46.40, 46.42, 46.42, 46.42

Steady state 0.4 min reading 44.48

Steady state dose rate

At 800 mm, 100 x 100 = 2 x 293.3 x 760 x 0.947 x 100 x 44.48

= 106.7 cGy/min

"Dose effective TIME = 90.905 - 2 x 44.48
error"

= 0.0218 min

1/0.4 = 2.5 not 2 !!!
Should have been 133.4 rtg/min
Outcome

- 205 patients were significantly overdosed (25%) with increased morbidity and possible deaths considered as a consequence.
- The error was not then recognised, possibly because the physicist was working on his own and his figures may not have been checked.
- The error was detected during a national external audit.
North Staffordshire Royal Infirmary, 1982-1991

- Until 1982, a hospital relied on manual calculations for the correct dose to be delivered to the tumour
  - Treatments were generally performed at standard SSD (100 cm) (very few SAD)
- A computerized treatment planning system was acquired in 1981- clinical use in autumn of 1982
  - Partly because TPS simplified the calculation procedures, the hospital began treating with isocentric techniques more frequently
  - It was assumed that correction factors for non-standard SSD should be applied
- In 1991 a new computer planning system was installed and a discrepancy was discovered between the new plans and those from the previous system
  - Further investigation revealed that the original TPS already contained within it the correction for calculations at non-standard SSD. The INVERSE SQUARE LAW
- During the 9-year period, 6% of patients treated in the department were treated with isocentric technique; for many of these patients it formed only part of their treatment
  - 1045 patients whose calculations were affected by the incorrect procedures, 492 developed local recurrences that could be attributed to the error
  - Under dosage varied between 5 and 35%
Lessons

- Ensure that staff are properly trained in the operation of the equipment
- Ensure that staff understand the operating procedures
- Include in the Quality Assurance Programme:
  - Procedures to perform complete commissioning of treatment planning equipment before first use
  - Procedures for independent checking of patient treatment time calculations

Commissioning is also a learning period!
**Therac 25 US/Canada**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Mode</td>
<td>Fix</td>
</tr>
</tbody>
</table>

**Beam Type:** X  
**Energy (MeV):** 25

<table>
<thead>
<tr>
<th>Unit Rate/Minute</th>
<th>Actual</th>
<th>Prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor Units</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Time (Min)</td>
<td>0.27</td>
<td>1.00</td>
</tr>
</tbody>
</table>

- **Gantry Rotation (Deg):** 0.0
- **Collimator Rotation (Deg):** 359.2
- **Collimator X (CM):** 14.2
- **Collimator Y (CM):** 27.2
- **Wedge Number:** 1
- **Accessory Number:** 0

**Date:** 84-Oct-26  
**System:** Beam Ready  
**Op. Mode:** Treat

**Time:** 12:55:8  
**Treat:** Treat Pause  
**Reason:** Operator

**Operating ID:** T25V02-R03  
**Commands like P (proceed) or B (beam on)**
A race condition/hazard is a flaw in an electronic system or process whereby the output and/or result of the process is unexpectedly and critically dependent on the sequence or timing of other events.\(^1\)

The term originates with the idea of two signals racing each other to influence the output first.

- Race conditions were among the flaws in the Therac-25 radiation therapy machine, which led to the death of three patients and injuries to several more.

**Outcome**
- Following treatment, the patients complained of burning sensations, sometimes accompanied by a feeling of electric shock.
- In each case, the patients received doses of between 40 and 250 Gy in a very brief exposure (1-3 seconds).

Do Accidents Still Happens Today?

- Have we learnt from history?
- Are the machines/systems fool-proof today?
- Have we implemented defence in depth i.e. errors are trapped before they reach the patient?
- Are we well trained and experienced and never making any mistakes?
- ...
Accidents still happens!!!

- Data transfer in Scotland (2005/6)
- Treatment data missing in NYC (2005)
Glasgow, Scotland

- Introduced a **new** and common data base for linacs, TPS and R/V system in 2005.
- Thus all plan data are available among all modules
  - Incl TPS and treatment console at the linacs
- Previously all plans were calculated for 1 Gy as prescribed dose
  - The MUs were scaled to correct dose manually
- Now all plans were made for the correct prescribed dose
What happened?

- Whole CNS plans still went by the “old system”, where TPS calculates MU for 1 Gy with subsequent upscaling for dose per fx.
- A “medulla planning form” was used, which is passed to treatment radiographers for final MU calculations.
- HOWEVER – “Planner X” let the TPS calculate the MU for the full dose per fx – not for 1 Gy as intended.
- Since the dose per fx to the head was 1.67 Gy, the MU’s entered in the form were 67% too high for each of the head-fields.

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Table from: “Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposures) Regulations 2000”
Latent threat in the system

- #1 August 2005 – prescription dose not entered into system
- #2 November 2005 – prescription dose equal 1 Gy
- #3 December 2005 – This case
- #4 January 2006 – Planned and dose entered correctly (missed opportunity)
- #5 February 2006 – The output from the planning process was questioned by a senior and this error was found
  - The total dose to Lisa Norris from the Right and Left Lateral head fields was 55.5 Gy (19 x 2.92 Gy)
  - She died nine months after the accident
  - Probably due to recurring disease
Lessons to learn

- The experienced planner supervised the “trainee” and checked the plan i.e. **checking her/him self**
- No instructions for putting values into the form, **Old form**
- Could have been avoided by **independent** check of **MU**
- **In-vivo dosimetry** may have identified the erroneous dose
- Lack of staff (6-7000 patient annually)
Incorrect IMRT planning/delivery

USA, NY – 2005

Discussed in

The New York Times

2010
New York Times Jan 2010

- Several articles in NYT early 2010
- Lot’s of fuzz in the community
- Congressional hearing in US
- Meetings etc...

THE RADIATION BOOM
Radiation Offers New Cures, and Ways to Do Harm
By WALT BOGDANICH
Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: a radiation overdose — which left him deaf, struggling to swallow, burned, with his teeth falling out, with null mouth and throat, nauseated, in severe pain and finally breathe — be studied and talked about publicly so that not have to live his nightmare.

Sensing death was near, Parks summoned his family to Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days.
What happened?

- **Tuesday March 8, 2005**
  - The patient begins an IMRT treatment at St Vincent’s Hospital, Manhattan, NY.
  - This treatment is delivered correctly.
  - The plan had passed the QC process FOR imrt

- **Friday March 11, 2005**
  - The physician reviews the case after 4 Tx
    - Wants a modified dose distribution (reducing dose to teeth)
    - The plan is copied and saved under a new name

- **Monday March 14, 2005**
  - Re-optimization work starts
  - Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved to DB.
  - Final calculations are started, where MLC motion control points for IMRT are generated.
What happened?

- “Save all” is started. All new and modified data should be saved to the DB.
  - In this process, data is sent to a holding area on the server (cache), and not saved permanently until ALL data elements have been received.
- In this case, data to be saved included
  - actual fluence data
  - a DRR
  - the MLC control points
What happened?

The transaction error message displayed

Please note the following messages and inform your System Administrator:
Failed to access volume cache file <C:\Program Files\Varian\RV71\Cache\504.MImageDRR>.
Possible reasons are:
- Directory not existing or write-protected
- Disk full

Do you want to save your changes before application aborts?

[Yes] [No]
What happened?

The frozen state of the second "Save All" progress indication.
What happened?

- **Monday March 14, 2005, 11 a.m.**
- Within 12 s, another workstation, WS1, is used to open the patients plan. The planner would have seen this:

![Sagittal view of patient, with fields and dose distribution](image)
What happened?

Monday March 14, 2005, 11.a.m.

No MLC control point data is included in the plan, neither required for dose calculation, display and approval !!!

The sagittal view should have looked like the one to the right, with MLCs
What happened?

Monday March 14, 2005, 1 p.m.

The patient is treated. The console screen would have indicated that MLC is not being used during treatment:
What happened?

Monday March 14, 2005, 1 p.m.

Expected display:
Discovery of accident

- **March 14-16, 2005**
  - The patient is treated without MLCs for three fractions
- **Wednesday March 16,** a **verification plan** is created and run on the treatment machine. The operator notices the absence of MLCs.
  - A second verification plan is created and run with the same result
- The patient received 13 Gy per fraction for three fractions, i.e. 39 Gy in 3 fractions

- **Monday March 14, 2005, 11 a.m.**
  - No verification plan is generated or used - should be done according to clinics QA program
  - The plan is subsequently prepared for treatment (treatment scheduling, image scheduling, etc.
  - It is also approved by a physician
  - According to QA programme, a second physicist should then have reviewed the plan
    - including an overview of the irradiated area outline
    - MLC shape
    - Etc
Lessons to learn

• Do what you should be doing according to your QA program
  - The error could have been found through verification plan (normal QA procedure at the facility) or independent review

• Be alert when computer crashes or freezes, when the data worked on is safety critical

• Work with awareness at treatment unit, and keep an eye out for unexpected behaviour of machine
Reason’s Swiss Cheese Model of Failure Propagation

Successive layers of defences, barriers, filters and safe guards

Some holes due to active failures

Other holes due to latent conditions

When holes line up an error will occur
Radiotherapy safety layers

Successive layers of defences, barriers, filters and safe guards

When holes line up an error will occur
Are there recurring themes in the lessons learned?

Lessons learned can be grouped under the following headings:

- Working with Awareness and Alertness
- Procedures
- Training and Understanding
- Responsibilities
Working with Awareness and Alertness

- Maintain awareness for unusual and complex treatments
  - should there be longer or shorter treatment time when the SSD is changed from 80 cm to 70 cm?
- Be alert when there are unusual circumstances during treatment.
  - if the patient claims to have the wrong site treated, follow it up carefully.
  - when you notice that the treatment time is significantly different than it usually is for a certain treatment, ask: why?

Be aware of what you are doing! An irradiation can’t be undone
Procedures

- Use comprehensive acceptance, commissioning, quality control and documentation (including clinical) procedures.
  - when commission treatment units for clinical use, their behavior under clinical circumstances should also be investigated.

- Have procedures for truly independent checking of “critical steps” in the radiotherapy process.

Think through if procedures you have are covering what might go wrong!
Training and Understanding

- Make sure you understand how the equipment you are using works.
  - dosimeters, barometers, asymmetric jaws, TPS etc
- When someone else’s data is used for calibration and calculation, get to know what it means.
  - calibration certificate, atmospheric pressure data.
- Understand the physics and units of radiation treatment.
  - cobalt decay, decimal time units (Costa Rica, 1996)

Have a thorough understanding of equipment and the data that is used for patient treatment!
Responsibilities

- Functions and responsibilities should be allocated and understood.
  - a physicist should take responsibility for all aspects of dosimetry.
- When there are discrepancies in data, there should be a person responsible for thoroughly investigating why.
  - differences in depth dose measurements.

Make sure all responsibilities are allocated and understood and that the members of staff they’ve been allocated to are educated accordingly and kept up to date in training.
ICRP 112

• **International Commission on Radiological Protection (ICRP)**
  - ICRP Publication 112
  - Following on from previous ICRP Publications on prevention of accidents in radiotherapy
  - Focussing on new EBRT technologies

• **Contents of publication**
  - Identification of potential weaknesses with new medical radiation technology
  - Case histories involving new technology
  - Proactive approaches to avoiding accidental exposures
  - Educational PowerPoint presentation also available on ICRP website
Safety in radiation oncology – event reporting system (SAFRON)

- Web-based event reporting system for radiotherapy that has the aim to:
  - Enable reporting and learning from incidents and near-incidents
  - Integrate retrospective reporting and prospective risk analysis
  - Integrate with existing systems, complementing national and mandatory systems
  - Now: IT-structure being devised
Thanks for listening

- Poland 2001, interlock failure linac
- Spain 1990, wrong repair linac
- Panama 2000, TPS
- US 2007, reversal of images
- France 2006, wrong detector choice
- France 2004, Dynamic wedges
- France 2007, repeated MV imaging
- France 2007, error in inhouse TPS
- Denmark, 2001, miscalibration linac
- Australia, 2005 miscalibration linac
- US, 2005 miscalibration SRT (not much known)
- Canada, 2008 miscalibration ortovoltage
- US, 2009 miscalibration of SRT
- US, 2010, seeds mispositioned
- US, 2010 missing wedge filter

AND...