Case histories of radiotherapy accidents
& clinical consequences

Ben Mijnheer
Accidents happen everywhere.....
Erroneous calibration, Exeter, UK, 1988

- Installation of a new cobalt source

- A physicist calibrated the new source
O/P calibration of new source

Spectra: Source 2570 with probe in water tank at depth 5 cm.
Water tank outside dimensions (purpose): 32 x 32 x 21 cm, T = 2.93
S.S.D. = 800 mm, 100 x 100 mm field

Source left on for 45 minutes before any measurements.
Water tank filled and left to come to room temp overnight.

Source readings (0.8 min): 90.95, 90.92, 90.90, 90.90, 90.90 - 90.905
(0.4 min) 46.47, 46.40, 46.40, 46.42, 46.42 - 46.42

Steady-state 0.4 min reading 44.48

At 800 mm, 100 x 100 = 2 x 2.93 x 760 x 0.947 x 100 = 44.48
79.0

\[ = 106.7 \text{ cGy/min} \]

\[ \frac{1}{0.4} = 2.5 \text{ not 2!!!} \]
Should have been 133.4 cGy/min

Dose effective min = \[ 90.905 - 2 \times 44.48 \]
\[ \frac{2}{2} = 44.48 \]
\[ = 0.0218 \text{ mins} \]
What went wrong and how was it detected?

- The physicist has multiplied by the wrong factor (2.0 instead of 2.5) to achieve an equivalent exposure for one full minute. Tragically, this inaccuracy was then not recognised, possibly because the physicist was working on his own and his data may not have been checked.
- Commonly afterwards only relative dose calculations are used to calculate the treatment time for an individual patient.
- As a result of this calibration error, 205 patients were significantly overdosed (by about 25%) with increased morbidity and possible deaths as a consequence.
- The Institute of Physical Sciences in Medicine performed a National multicentre dosimetric comparison (external audit) and discovered this error.
Lessons

• One clear lesson from this accident is that a calibration of a new cobalt source or linear accelerator must be checked and rechecked (and rechecked…).

• It is certainly possible to cross check a new installation by asking a colleague. It might even be sensible to repeat the calibration of a new source a month after its first use in case of contamination with other isotopes which might have unexpected patterns of decay.

• Participate in an external audit, e.g. the IAEA TLD audit system
Miscalibration
The Ottawa Hospital Cancer Centre
2008
What happened?

• The centre reported a calculation error with one of its radiation machines – an orthovoltage machine (kV-range) – April 2008
• The calculation error took place during re-commissioning after the unit was moved from the General Campus to the Civic Campus – Nov 2004
• Checks of the calibration of the unit showed that measurements and calculations had been performed correctly at that moment – Nov 2007
To make it short!

• The last step of generating output tables should have been to calculate the output for all cones from the absorbed dose to water in water under reference conditions, through the application of ratios of distance corrected in-air charge measurements and ratios of backscatter factors.

• The re-commissioning covered only a 10x10 cm² field!
To make it short!

- The last step of generating output tables should have been to calculate the output for all cones. This was to calculate the absorbed dose to water in water under reference conditions, through the application of ratios of distance corrected in-air charge mAs factors and ratios of backscatter factors.

- The re-commissioning covered only a 10x10 cm² field! Ratios of backscatter factors were not applied in this final step and this is the error which led to the under-dosing of 326 patients.
Affected Patients

- The treatment charts of all 326 patients affected were reviewed by their respective treating physicians and the patients were contacted for an immediate follow up appointment.
- The error did only involve patients with basal cell and squamous cell carcinomas:
  - Patients were treated between November 2004-November 2007
  - Patients were treated at the Civic Campus
  - In some cases, patients received radiation up to 17% less than the prescribed dose.
- Patients who received radiation therapy for any other type of cancer were not affected.
External review by experts

• The basis of this review and analysis of the events focused on the following questions:
  – Why were the incorrect output tables prepared during re-commissioning?
  – Why was an independent second check not done prior to release of the output tables?
  – Why was the error not detected for 3 years?

• Root causes
  – Incorrect output tables were released for clinical use
  – Multiple significant tasks were assigned to the physicists
  – A comprehensive, independent second check was not performed
### Staffing shortage behind radiation error: probe

Skim cancer patients at Civic given wrong dosages between 2004 and 2007

BY PAULINE TAM

A critical shortage of medical physicists at The Ottawa Hospital played a key role in an error that left 326 skin cancer patients with less than the recommended radon therapy dosages to destroy their tumors, a provincial investigation into the incident has found.

The staffing crunch, combined with gaps in safety and performance checks, was a "significant contributory factor" behind the improper calibration of a radiation treatment machine that went undetected for three years, the investigation concluded.

The patients were treated at the hospital's Civic campus.

<table>
<thead>
<tr>
<th>Date</th>
<th>Dosage (Gy)</th>
<th>Patients Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2004</td>
<td>230</td>
<td>326</td>
</tr>
<tr>
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### Radiation: Excessive work hours

One panel found staffing shortages of medical physicists personnel was a "significant contributory factor" in the miscalculation of radiation output on the relocated treatment unit.

The independent panel, led by Peter Damscombe, the director of the medical physics department at Calgary's Tom Baker Cancer Centre, also cited the "cultural norm" at the hospital that allowed the scheduling of new treatment programs and equipment without ensuring adequate medical physics staff were available.

The calculation error on the radiation machine at the Ottawa Hospital resulted in 326 skin cancer patients being understored during treatments, according to hospital officials.

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### Ottawa Short-staffing led to dosage error

The radiation department was short-staffed by about half at a time that a calibration error was made, the hospital acknowledged.

### Cancer error well handled

Report says hospital reacted properly following bladder

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### Report blames shortages

Staffing shortages among medical physicists personnel at the Ottawa Hospital contributed to a calculation error on a radiation machine affecting 326 patients over a three-year period, according to an independent review.

In a report released Thursday on the radiation treatment calculation error affecting patients with basal cell and squamous cell cancers at the Civic campus between November 2004 and November 2007, a three-member panel found staffing shortages of medical physicists personnel was a "significant contributory factor" in the miscalculation of radiation output on the relocated treatment unit.

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### Ottawa

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Lack of a QA program or mismanagement of a QA program

How could these accidents happen?
Incorrect manual parameter transfer
Glasgow, Scotland

• Introduced a common data base for linacs, TPS and R/V system in 2005

• Previously all plans were calculated for 1 Gy as prescribed dose and the number of MUs were scaled to correct the dose manually

• Now all plans were made for the correct prescribed dose
What happened?

- 5th January 2006, Lisa Norris, 15 years old, started her whole CNS treatment at BOC
- The treatment plan was divided into head-fields and lower and upper spine-fields
- This is considered to be a complex treatment plan, performed about six times per year at the BOC
What happened?

- Whole CNS plans still went by the “old system”, where the TPS calculates MUs 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.
What happened?

- HOWEVER – “Planner X” let the TPS calculate the MUs 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 MUs entered in the form were 67% too high for each of the head-fields
What happened?

- This error was not found by the more senior planners who checked the plan.
- The radiographer on the unit thus multiplied with the dose per fx a second time.
- 2.92 Gy per fx to the head.
Discovery of the accident

- “Planner X” calculated another plan of the same kind and made the same mistake
- This time, the error was discovered by a senior checker (1st of Feb ‘06)
- The same day, the error in the calculations for Lisa Norris was also identified
Impact of the accident

- 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 and checked the plan her-/himsel)
• No instructions for putting values into the old form
• Could have been avoided by an independent check of the number of MUs
• In vivo dosimetry may have identified the erroneous dose
• Lack of staff (6-7000 patient annually) may have contributed
Lessons to learn

• Ensure that all staff
  – are properly trained in safety of critical procedures
  – are included in training programmes and has supervision as necessary, and that records of training are kept up-to-date
  – understand their responsibilities

• Include in the quality assurance program
  – formal procedures for verifying the risks following the introduction of new technologies and procedures
  – to perform independent MU checking of all treatment plans

• Review staffing levels and competencies
From Pierre Scalliet, Brussels

The incident triangle

- Critical incident: 1
- Major incident: 10
- Serious incident: 30
- Incident: 600
Inappropriate beam calibration
France 2007

• Reported in 2007 at Hôpital de Rangueil in Toulouse, France
• In April 2006, the physicist in the clinic commissioned the new BrainLAB Novalis stereotactic unit
  – This unit can operate with microMLCs (3 mm leaf-width) or conical standard collimators
Background

• Very small fields can be defined with the microMLCs
  – High dose to a 6 mm x 6 mm field is within capability
  – The TPS requires percent depth doses, beam profiles and relative scatter factors down to this field size
  – Care must be taken when measuring small fields!

• Different measuring devices were used by the physicist
  – A measuring device not suitable for calibrating the smallest microbeams was used
  – “…an ionisation chamber of inappropriate dimensions…” according to Nuclear Safety Authority (ASN) inspectors

• The incorrect data was entered into the TPS
  – All patients treated with micro MLC were planned based on this incorrect data
  – Patients treated with conical collimator were not affected
Discovery of the accident

- The BrainLAB company discovered that the measurement files did not match up with those at other comparable centres, during a worldwide intercomparison study.

- It should be noted that the company does not validate or hold any responsibility for local measurements or implementation.
Impact of the accident

- Treatment based on the incorrect data went on for a year (Apr´06 – Apr´07)

- All patients treated with microMLCs were affected (145 of 172 stereotactic patients)

- The dosimetric impact was evaluated as small in most cases, with 6 patients identified for whom over 5% of the volume of healthy organs may have been affected by dose exceeding limits
Lessons to learn

• Ensure that staff
  - understands the properties and limitations of the equipment they are using

• Include in the quality assurance programme
  - an intercomparison with other hospitals, in this case an independent check of the output of a new accelerator by an independent group (using their own equipment) before the equipment is clinically used
Incorrect IMRT planning/delivery

USA, NY – 2005
Discussed in The New York Times
2010
January 2010

• Several articles in the NYT early 2010
• Lot’s of fuzz in the radiotherapy community
• Hearing in the US Senate
• Many meetings in the US on radiation safety
Energy and Commerce - Subcommittee on Health held a hearing entitled "Medical Radiation: An Overview of the Issues" on Friday, February 26, 2010

http://www.youtube.com/watch?v=NcqRgVqeQSg
http://www.youtube.com/watch?v=L_IzTqhghMs
What happened

- **Tuesday - March 8, 2005**
  - The patient begins an IMRT treatment at St Vincent’s Hospital, Manhattan, NY
  - The plan had passed the QC process according to the local protocol
  - The treatment is delivered correctly

- **Friday - March 11, 2005**
  - The physician reviews the case after 4 fractions
    - Wants a modified dose distribution (reducing dose to teeth)

- **Monday - March 14, 2005**
  - Re-planning and re-optimization starts
  - Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved
  - 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

• In this case, data to be saved included
  – actual fluence data
  – a DRR
  – the MLC control points
What happened?

The transaction error message displayed
What happened?
What happened?

• Monday - March 14, 2005, 11.a.m.
  • Within 12 s, another workstation, WS1, is used to open the patient plan. The planner would have seen this:
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 the MLC is not used during treatment:
Discovery of accident

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

- **Tuesday/Wednesday - March 15-16, 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
Lessons to learn

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

• Be alert when a computer crashes or freezes; check the data before you continue working

• Work with awareness at the treatment unit, and keep an eye out on unexpected behaviour of the machine
Mr. Jerome-Parks with his wife, Carmen, on the day he received his diagnosis of tongue cancer. For his treatment, he chose St. Vincent’s Hospital in Manhattan, which was promoting a new linear accelerator and a treatment called Intensity Modulated Radiation Therapy, which could more precisely shape and modulate the radiation beam. Treatment started March 8, 2005.

Sensing that death was near, Mr. Jerome-Parks and his wife summoned his family for a final Christmas together. Friends sent buckets of sand from the beach in Gulfport, Miss., where they had played together, so that he could sink his feet in it and remember happy times. Two month later in Febr. 2007 he died from his injuries.
Swiss cheese model of failure propagation

Some holes due to active failures

Other holes due to latent conditions
Radiotherapy safety layers

Input data check, prescription, volumes etc

Independent monitor unit check

In vivo dosimetry

Chart checks
Summary and lessons to learn

• Work with awareness and alertness
  – Be aware of what you are doing
  – An irradiation can’t be undone

• Procedures
  – Think through if procedures are covering everything that might go wrong

• Training and understanding
  – Have a thorough understanding of equipment and the data that is used for patient treatments

• Responsibilities
  – Make sure all responsibilities are allocated and understood
  – All members of staff are educated according to their tasks and kept up-to-date in their training
Thanks for listening

and thanks particularly to Tommy Knöös for using many of his slides in this presentation

And...
To ensure patient safety we need