Module 2.10: Accident update – some newer events (UK, USA, France)
Questions

Do you think the accidents have not happened in recent years?

Do you think well-developed centres are immune to these accidents?
Overview

It should be noted that the intent is certainly not to reflect the quoted centres in this presentation in poor light.

Instead, the purpose is to draw lessons.

In many cases, the centres have a quality system in place.

The events are reconstructed from information in the public domain, and might differ from actual events due to gaps in this information.
Overview

Newer examples of accidents in radiotherapy from 2004 to 2007

- 1st example: Incorrect manual parameter transfer (UK)
- 2nd example: Reversal of images (USA)
- 3rd example: Inappropriate measuring device (France)
- 4th example: Erroneous calculation for soft wedges (France)
- 5th example: Incorrect IMRT planning (USA)
- 6th example: More information needed…
1st example: Incorrect manual parameter transfer (UK)
Background

• January 2006 at the Beatson Oncology Centre (BOC) in Glasgow, Scotland
  • At the time: Radiotherapy physics staffing levels in Scotland less than 60% of the recommended level
  • “Glasgow has problems with recruiting physicists, as shown by their high number of vacancies.”
Background

- Treatment planning at BOC:
  - 14.5 whole time equivalent (WTE) staff were available for between 4500 and 5000 new treatment plans per year.
  - When staffing levels were compared with guidelines from IPEM, it was seen that 18 WTE staff would be the recommended level.
Background

- Treatment planning at BOC:
  - Planning staff members and planning procedures were both categorized
  - A to C denotes senior to junior staff
  - A to E denotes simple to complex plans
  - The main duties per staff category is outlined in column 4

<table>
<thead>
<tr>
<th>Staff planning category</th>
<th>Number of staff members in each category</th>
<th>WTE(^a) allocation to treatment planning for Dec 2005</th>
<th>Categories of plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>5</td>
<td>3.2</td>
<td>D and E (as checker)</td>
</tr>
<tr>
<td>A2</td>
<td>2</td>
<td>1</td>
<td>C, D and E as planner and checker</td>
</tr>
<tr>
<td>A3</td>
<td>4</td>
<td>2.3</td>
<td>C and D as planner and checker</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>3.3</td>
<td>B, C and D as planner</td>
</tr>
<tr>
<td>C</td>
<td>7</td>
<td>4.7</td>
<td>A, B and C checker</td>
</tr>
<tr>
<td>Totals</td>
<td>23</td>
<td>14.5</td>
<td>A, B and C as planner</td>
</tr>
</tbody>
</table>

\(^a\)WTE: Work Time Equivalent

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

• Treatment planning at BOC:
  • Practice prior to 2005 had been to let the treatment planning system (TPS) calculate the Monitor Units (MU) for 1 Gy followed by manual multiplication with the intended dose per fraction for the correct MU-setting to use.
Background

• Treatment planning at BOC:
  • In May 2005, the Record and Verify (RV) system was upgraded to be a more integrated platform.
  • The centre decided to input the dose per fraction already in the TPS, for most but not all treatment techniques.
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?

- The bulk of the planning was done by “Planner X” in Dec’05, a junior planner.
- “Planner X” had not yet been registered internally to be competent to plan whole CNS, or to train on these.
- “Planner X” got initial instructions and the opportunity to be supervised when creating the plan.
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.

Table from: “Report of an investigation by the Inspector appointed by the Scottish Ministers for The Ionising Radiation (Medical Exposures) Regulations 2000”
What happened?

- 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

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

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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”**
Discovery of 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 calculations for Lisa Norris was also identified
Impact of 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
Lessons to learn

• Ensure that all staff
  • Are properly trained in safety 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
  • Independent MU checking of ALL treatment plans

• Review staffing levels and competencies
References


2nd example: Reversal of images (USA)
What happened?

- October 2007 at the Karmanos Cancer Center (KCC) in midtown Detroit, Michigan, USA
  - At the Gamma Knife treatment facility, a patient was set up for MRI imaging
  - Standard practice is to position the patient “head first”
  - The patient was positioned “head first”, but “feet first” scan technique was chosen on the unit
What happened?

- The axial images were therefore reversed left-to-right
  - The physicist did not see the mistake when importing images into the TPS
  - The error resulted in an 18 mm shift of isocentre across the midline of the brain
Lessons to learn

• Include in the Quality Assurance Program
  • Procedures for verifying left from right in safety critical images, e.g. by using fiducial markers
  • Ensure there are written protocols posted, known and followed, for safety critical procedures
References

3rd example: Inappropriate measuring device (France)
Background

• Reported 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 microMLC’s (3 mm leaf-width) or conical standard collimators
• Very small fields can be defined with the microMLC’s
  • High dose to a 6 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!
What happened?

- 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
What happened?

- 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 accident

- BrainLAB 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 responsibility for local measurements or implementation.
Impact of accident

- Treatment based on the incorrect data went on for a year (Apr´06 – Apr´07)
- All patients treated with microMLC 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**
  - Understand the properties and limitations of the equipment they are using

• **Include in the Quality Assurance Program**
  - Intercomparison with other hospitals, i.e. independent check of new equipment by independent group (using independent equipment) before equipment is clinically used
References

• Report concerning the radiotherapy incident at the university hospital centre (CHU) in Toulouse – Rangueil Hospital. ASN – Autorité de Sûreté Nucléaire (2007)
4th example: Erroneous calculation for soft wedges (France)
Background

• In May 2004 at Centre Hospitalier Jean Monnet in Epinal, France
  • …it was decided to change from static (hard) wedges to dynamic (soft) wedges for prostate cancer patients
  • In a country of few Medical Physicists (MP), this facility had a single MP who was also on call in another clinic

The Jean Monnet Hospital in Epinal
• In preparation for the change in treatment technique, two operators (treatment planners?) were given two brief demo’s
  • The operators did not have any operating manual in their native language
Background

• When the soft wedges were introduced:
  • The independent MU check in use could not be used anymore (unless modified)
  • The diodes used for independent dose check could not be correctly interpreted anymore
What happened?

• Treatment planning with soft wedges started
  • Not all the treatment planners did understand the **interface** to the planning system
What happened?

• Treatment planning with soft wedges started
  • Not all the treatment planners did understand the *interface* to the planning system
  • Some selected the planning for *mechanical* wedge when intending *dynamic* wedge
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the *interface* to the planning system
  - Some selected the planning for *mechanical* wedge when intending *dynamic* wedge
  - Instead they should have selected Dynamic Wedge…
What happened?

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system
  - Some selected the planning for mechanical wedge when intending dynamic wedge
  - Instead they should have selected Dynamic Wedge…
    - …which would have let the correct planning tool appear
What happened?

- When planning was finished and the isodose distribution approved
  - …the parameters were manually transferred to the treatment unit
  - Manually transferred MU’s would have been calculated for mechanical wedges and would be much greater than what is needed for giving the same dose with dynamic wedges
Discovery of accident

• Details not clear, BUT: it might have been when MU check software was replaced and updated to be able to handle independent checking of dynamic wedges.
Impact of accident

- Treatment based on incorrect MU’s went on for over a year (6 May 2004 – 1 Aug 2005)
- At least 23 patients received overdose (20% or more than intended dose)
- Between September 2005 and September 2006, four patients died. At least ten patients show severe radiation complications (symptoms such as intense pain, discharges and fistulas)
Information following accident

• 15 Sep 2005, two doctors from the clinic passed on information that went to the Regional Dept. of Health and Social Security (DDASS)

• 5 Oct 2005 a meeting was held at DDASS. Decisions were not documented or uniformly interpreted.

• National authorities in charge were not informed at this stage, but only a full year after the accident (July 2006)
Information following accident

• 7 patients were informed during the last quarter of 2005.
• 16 other patients were (wrongly) considered no to be affected. Of these …
  • … 3 were informed by another doctor than their radiotherapist
  • … 1 learnt from a third party person
  • … 1 learnt from the press
  • … 1 learnt by overhearing a doctor speaking to a colleague
  • … 4 were informed by management 2 days before press release
  • … 1 died before being informed
Lessons to learn

• Ensure that staff
  • Understand the properties and limitations of the equipment they are using
  • Are properly trained in safety critical procedures
• Include in the Quality Assurance Program
  • Formal procedures for verifying new technologies and procedures before implementation
  • Independent MU checking of ALL treatment plans
  • In vivo dosimetry
• Make sure the clinic has a system in place for
  • Investigation and reporting of accidents
  • Patient management and follow up, including communication to patients
• Instructions should be in a language that is understood
References


Postscript to accident in Epinal

• Going through the records, two further episodes were reported subsequently.

• Reported in Feb 2007:
  • In the time period 2001-2006, portal imaging was used repeatedly without taking into account the added dose (estimated to have been +8% of total) for 412 patients under medical survey.

• Reported in July 2007:
  • In the time period 1989-2000, use of an in-house TPS not updated after change in treatment technique, might have led to 300 patients receiving up to 7% added dose.
5th example: Incorrect IMRT planning (USA)
Background

- March 2005, somewhere in the state of New York, USA
  - A patient is due to be treated with IMRT for head and neck cancer (oropharynx)
What happened?

• March 4 – 7, 2005

• An IMRT plan is prepared: “1 Oropharyn”. A verification plan is created in the TPS and measurements by Portal Dosimetry (with EPID) confirms correctness.

Example of an EPID (Electronic Portal Imaging Device) (Picture: P. Munro)
What happened?

- March 8, 2005
  - The patient begins treatment with the plan “1 Oropharyn”. This treatment is delivered correctly.
What happened?

- March 9-11, 2005
  - Fractions #2, 3 and 4 are also delivered correctly. Verification images for the kV imaging system are created and added to the plan, now called “1A Oropharyn”.

“Model view” of treatment plan (Picture: VMS)
What happened?

• March 11, 2005
  • The physician reviews the case and wants a modified dose distribution (reducing dose to teeth) “1A Oropharyn” is copied and saved to the DB as “1B Oropharyn”.

“Model view” of treatment plan (Picture: VMS)
What happened?

• March 14, 2005
  • Re-optimization work on “1B Oropharyn” starts on workstation 2 (WS2).
  • 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. Normal completion.
What happened?

• March 14, 2005, 11 a.m.
  • “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, and not saved permanently until ALL data elements have been received.
  • In this case, data to be saved included: (1) actual fluence data, (2) a DRR and (3) the MLC control points.
What happened?

- March 14, 2005, 11 a.m.
- The actual fluence data is saved normally.
  - Next in line is the DRR. The “Save all” process continues with this, but is not completed.
  - Saving of MLC control point data would be after the DRR, but will not start because of the above.
What happened?

- March 14, 2005, 11 a.m.
  - An error message is displayed.
  - The user presses “Yes”, which begins a second, separate, save transaction.
  - MLC control point data is moved to the holding area.
What happened?

- March 14, 2005, 11 a.m.
  - The DRR is, however, still locked into the faulty first attempt to save.
  - This means the second save won’t be able to complete.
  - The software would have appeared to be frozen.

The frozen state of the second “Save All” progress indication
What happened?

- March 14, 2005, 11 a.m.
  - The user then terminated the TPS software manually, probably with Ctrl-Alt-Del or Windows Task Manager.
  - At manual termination, the DB performs a “roll-back” to return the data in the holding area to its last known valid state.
  - The treatment plan now contains (1) actual fluence data; (2) not the full DRR; (3) no MLC control point data.

Ctrl-Alt-Del
What happened?

- 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:

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Valid fluences were already saved. Calculation of dose distribution is now done by the planner and saved. MLC control point data is not required for calculation of dose distribution.
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Sagittal view of patient, with fields and dose distribution
What happened?

- March 14, 2005, 11 a.m.
  - No control point data is included in the plan.

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

- March 14, 2005, 11 a.m.
  - No verification plan is generated or used for checking purposes, prior to treatment (should be done according to clinics QA programme)
  - The plan is subsequently prepared for treatment (treatment scheduling, image scheduling, etc) – after several computer crashes.
  - 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, and the MLC shape used.
What happened?

- Would have been seen on verification:
What happened?

• Should have been seen on verification:
What happened?

- 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?

- March 14, 2005, 1 p.m.
- Expected display:
Discovery of accident

• March 15-16, 2005
  • The patient is treated without MLCs for three fractions
  • On 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 plan is loaded and run, with the same result.

Impact of accident

• 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 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
References


6th example: More information needed
Unfortunately, information that professionals could learn from is not readily available sometimes -

- There is the case in Florida (2004), where it seems that a stereotactic unit was miscalibrated, resulting in 50% higher dose than intended for 77 patients with brain tumours.

- We could have learnt a lot here…
Lessons to learn

- ?

References
Questions

Do you think the accidents have not happened in recent years? ANSWER: **NO!** If YES, then think again!

Do you think well-developed centres are immune to these accidents? ANSWER: **NO!** If YES, then think again!