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Beatson, Scotland

Incorrect manual parameter transfer
Background

- January 2006

- At the time: Radiotherapy physics staffing levels in Scotland were 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 for between 4500 and 5000 new treatment plans per year
  - IPEM guidelines: 18 WTE staff would be the recommended level for the workload
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* 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>

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 1Gy 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.
The accident

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

- Dec 2005: The bulk of the planning was done by “Planner X” (a junior planner)
- “Planner X” had not been registered internally to be competent to plan whole CNS, or to train on these
- “Planner X” was given initial instructions and the opportunity to be supervised when creating the plan
The accident

- Whole CNS plans still went by the “old system”, where TPS calculates MU for 1Gy with subsequent upscaling for dose per fraction
- A “medulla planning form” was used, which is passed to treatment radiographers for final MU calculations
The accident

- HOWEVER – “Planner X” let the TPS calculate the MU for the full dose per fraction – not for 1Gy as intended

- Since the dose per fraction to the head was 1.67Gy, the MU’s entered in the form were 67% too high for each of the head-fields
The accident

- 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 fraction a second time.
- 2.92Gy per fraction to the head.
“Planner X” calculated another plan of the same kind and made the same mistake.

1st Feb 2006: the error was discovered by a senior checker.

The same day, the error in calculations for Lisa Norris was also identified.
Impact of the accident

- The total dose Lisa received from the Right and Left Lateral head fields was 55.5Gy (19 x 2.92Gy)

- She died nine months after the accident
References


Epinal, France

Erroneous calculation for soft wedges (2004)
May 2004

...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
In preparation for the change in treatment technique, two operators (treatment planners?) were given two brief demo’s

- The operators did not have an operating manual in their native language
Background

- When the soft wedges were introduced
  - The independent MU check could not be used without modification
  - The diodes used for independent dose check could no longer be correctly interpreted
The accident

- Treatment planning with soft wedges started
  - Not all the treatment planners understood the **interface** to the planning system
The accident

- Treatment planning with soft wedges started
  - Not all the treatment planners understood the interface to the planning system
  - Some selected the planning for mechanical wedge when intending dynamic wedge
The accident

- Treatment planning with soft wedges started
  - Not all the treatment planners did understand the interface to the planning system
The accident

- Treatment planning with soft wedges started
  - 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
When planning was finished and the isodose distribution approved
- ...the parameters were manually transferred to the treatment unit
The accident

- When planning was finished and the isodose distribution approved
  - Manually transferred MU’s would have been calculated for mechanical wedges and would be much greater than what is needed to give the same dose with dynamic wedges
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 the accident

- Treatment based on incorrect MU’s went on for over a year (6 May 2004 – 1 Aug 2005)

- At least 23 patients received an overdose (20% or more than intended dose)
Impact of the accident

- 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)
Post accident

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

- 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).
7 patients were informed during the last quarter of 2005

16 other patients were (wrongly) considered not to be affected. Of these

- ... 3 were informed by a doctor other 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
References


New York, USA

Incorrect IMRT Planning
(2005)
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)
The accident

- 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) confirm it is correct.
The accident

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

“Model view” of treatment plan (Picture: VMS)
The accident

- 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)
The accident

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”
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.
The accident

- 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

A Digitally Reconstructed Radiograph (DRR) of the patient
The accident

- 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.

A Digitally Reconstructed Radiograph (DRR) of the patient
The accident

- 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.
The accident

- 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.
The accident

- 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) incomplete DRR; (3) no MLC control point data

Ctrl-Alt-Del
The accident

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

Sagittal view of patient, with fields and dose distribution.
The accident

- 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.
The accident

- 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.
The accident

- March 14, 2005, 11 a.m.
  - 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.
The accident

Would have been seen on verification
The accident

Would have been seen on verification
The accident

Should have been seen on verification
The accident

- March 14, 2005, 1 p.m.
  - The patient is treated. The console screen would have indicated that MLC is not being used during treatment:
The accident

- March 14, 2005, 1 p.m.
  - The patient is treated. The console screen would have indicated that MLC is not being used during treatment:
The accident

March 14, 2005, 1 p.m.

- Expected display
Lost MLC after computer crash – another example
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 the accident

- The patient received 13Gy per fraction for three fractions, i.e. **39Gy in 3 fractions**
References


- Walt Bogdanich, New York Times
Contents

- Radiology incidents
  - Over exposure
  - Unnecessary exposure
- Lessons to learn
Top 10 Health Technology Hazards (2013)

1. Alarm hazards
2. Medication administration errors using infusion pumps
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures
4. Patient/data mis-matches in EHRs and other health IT systems
5. Interoperability failures with medical devices and health IT systems
Top 10 Health Technology Hazards (2013)

6. Air embolism hazards
7. Inattention to the needs of pediatric patients when using “adult” technologies
8. Inadequate reprocessing of endoscopic devices and surgical instruments
9. Caregiver distractions from smartphones and other mobile devices
10. Surgical fires

www.ecri.org/2013hazards
Over Exposure

- Two hospitals in the USA – a large well known centre and a small rural hospital
  - 8 times the recommended dose delivered to 206 possible stroke patients over an eighteen month period through CT perfusion scans
  - A child subjected to a CT scan lasting over an hour – CT scanner activated 151 times in the same area
Interventional radiology

- May lead to very high doses
  - Moist desquamation
  - Ulceration
  - necrosis
- Patients are subsequently seen outside of the radiology department
  - Skin damage may not be detected
Over Exposure

- CT perfusion scans - Hospital blames flawed procedures
- Child exposure – no obvious explanation
Discovery

- Patient noted patchy hair loss and contacted the hospital
- Child’s parents reported the event to the State Health Department
  - Radiographer insists she ‘pushed the button like four to six times’
  - ‘Machine must have malfunctioned’
Post scan

- Images unclear so another radiographer repeated the procedure in two minutes using the same equipment

- In both instances the potential for problems in the future is unknown but possible
Post event

- Food and Drug Administration publicly issued its final report on hundreds of overdoses involving brain scans at other hospitals
  - Errors discussed publicly in Congress and by state officials and professional organizations
Subsequent event

- A year later in another hospital
  - Possible stroke patients received ‘grossly and unacceptably abnormal doses’ from CT scans
Over exposure

- At a major Brooklyn hospital in 2007
  - Premature babies had whole-body scans (babygrams) when a simple chest x-ray was requested
  - One baby had ten whole-body scans
  - Radiation levels set too high for infants
  - No shielding used
  - Babies poorly position so hard for doctors to interpret the images
Discovery

- A consultant emailed when he discovered the incidents
- Publication in the New York Times
- State Health Department ordered an enquiry
- 2011 discovered that the hospital were still carrying out some inappropriate x-rays – 27 children irradiated beyond the chest area without proper shielding (27 of 54 images reviewed)
Lessons to learn

- Knowledge and Understanding:
  - (Education, Training, CME, CPD)
- Working with awareness and alertness
  - Applying knowledge and understanding
- Communicating
  - Sharing information
- Documenting
  - Protocols, Procedures
- An effective QMS, QA, QC programme
- Appropriate resources
Lessons to learn - Epinal

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<tr>
<th>Lesson</th>
<th>Application</th>
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<tr>
<td>Knowledge and Understanding</td>
<td>Staff education when new equipment or techniques are introduced – functionality and limitations</td>
</tr>
<tr>
<td>Working with awareness and alertness</td>
<td>Awareness of treatment time differences and any unusual side effects / reactions</td>
</tr>
<tr>
<td>Communicating</td>
<td>Language understood by the staff System for investigating incidents and disseminating information</td>
</tr>
<tr>
<td>Documenting</td>
<td>Clear protocols and procedures</td>
</tr>
<tr>
<td>QMS, QA, QC</td>
<td>Formal procedures for verification of new technologies Independent double checking</td>
</tr>
<tr>
<td>Resources</td>
<td>Sufficient numbers of qualified staff</td>
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# Lessons to learn - Glasgow

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<th>Lesson</th>
<th>Application</th>
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<tbody>
<tr>
<td>Knowledge and Understanding</td>
<td>Staff education for complex techniques</td>
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<tr>
<td>Working with awareness and alertness</td>
<td>Awareness of treatment time differences</td>
</tr>
<tr>
<td>Communicating</td>
<td>Understanding responsibilities and limitations</td>
</tr>
<tr>
<td>Documenting</td>
<td>Training records maintained and regularly updated</td>
</tr>
<tr>
<td>QMS, QA, QC</td>
<td>Formal procedures for risk verification when new technology is introduced</td>
</tr>
<tr>
<td>Resources</td>
<td>Sufficient numbers of qualified staff</td>
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## Lessons to learn – New York

<table>
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<th>Lesson</th>
<th>Application</th>
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<tbody>
<tr>
<td>Knowledge and Understanding</td>
<td>Staff education for complex techniques</td>
</tr>
<tr>
<td>Working with awareness and alertness</td>
<td>Awareness of MLC on the console images</td>
</tr>
<tr>
<td>Communicating</td>
<td>Understanding responsibilities and limitations</td>
</tr>
<tr>
<td>Documenting</td>
<td>Changes, faults</td>
</tr>
<tr>
<td>QMS, QA, QC</td>
<td>Formal procedures must be followed irrespective of pressures exerted</td>
</tr>
<tr>
<td>Resources</td>
<td>Sufficient time to complete complex plans</td>
</tr>
</tbody>
</table>
Lessons to learn – Radiology

<table>
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<th>Lesson</th>
<th>Application</th>
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<tbody>
<tr>
<td>Knowledge and Understanding</td>
<td>Staff education</td>
</tr>
<tr>
<td>Working with awareness and alertness</td>
<td>Awareness of dose and time constraints</td>
</tr>
<tr>
<td>Communicating</td>
<td>Understanding responsibilities and limitations</td>
</tr>
<tr>
<td>Documenting</td>
<td>Changes, faults, doses</td>
</tr>
<tr>
<td>QMS, QA, QC</td>
<td>Formal procedures and protocols in place and followed</td>
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<tr>
<td>Resources</td>
<td>Staff, education</td>
</tr>
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Lessons to learn

- Knowledge and Understanding:
  - (Education, Training, CME, CPD)

- Informs and enables working with awareness and alertness
  - Through the application of knowledge and understanding
Lessons to learn

- Informs and enables working with awareness and alertness
  - Through the application of knowledge and understanding

- Leads to more effective communication
  - Sharing of information with colleagues who understand the context
Lessons to learn

- More effective communication
  - Sharing of information with colleagues who understand the context
  - Accurate clear and appropriate documentation – all staff involved in developing protocols and procedures – bringing their unique knowledge and understanding
Lessons to learn

- Accurate clear and appropriate documentation – all staff involved in developing protocols and procedures – bringing their unique knowledge and understanding

- Effective QMS, QA and QC procedures
- Better use of scarce resources
- A safer and more efficient service
Acknowledgements

- Tommy Knoos
- Ola Holmberg