Patient Risk (Safety) in Radiation Therapy

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Outline

• Radiation Therapy
• What Can/Did Happen?
• Is Patient Safety at Risk?
• What Have We Learned/Done?
Radiation Therapy

- Delivery of therapeutic (2-80Gy) ionizing radiation – photon, electron, proton
- Specifically targeted to conform to tumor and to spare healthy tissue
Radiation Therapy

• Has evolved from manual calculations and analogue delivery systems to computer-optimized preparation and computer – controlled delivery
The Radiation Therapy Process

- Different types of cancer
- Different treatment techniques
- Several technologies

- Multi- vs. single-vendor environments

Different users:
- Physicians
- Physicists
- Therapists
- Dosimetrists
- IS Staff
- Administrative Staff

- Research
- Clinical activities

Technological Innovations:
- EPID
- kV localize
- CBCT
- Other IGRT

Analysis:
- On-line
- Off-line

Paper vs. Paperless

A lot of Information Communication
CUSTOMIZED

5 to 40 Fractions
Radiation Therapy Team

Assessment/Rx: Physician

Simulation: Physician, Therapist

Dosimetric Planning: Physician, Dosimetrist, Physicist

Treatment Verification/QA: Thersapist, Physicist

Treatment Delivery: Therapist (Physician, Physicist)

Follow Up: Dosimetrist

- [Image]
Radiation Therapy IS Safe

• Expectation is that the treatment will be beneficial
• Educated, professional teams deliver millions of treatments safely and effectively each year
• Complex system of technology and humans plus many variables
IS Radiation Therapy Safe?

- The best people + the best technology NOT = the best System!
- SAFE, but not perfect
- There are many causes of errors
- There are many mechanisms by which safety can be improved.
Module 2.3: Accelerator software problems (USA and Canada)
Therac 25
Background

- Mid 1970s - AECL developed a new double-pass concept for electron acceleration
  - needs less space to develop similar energy levels
  - dual-mode linear accelerator
  - more compact and versatile than the older Therac-20
- Therac 25 took advantage of computer’s abilities to control and monitor hardware
Therac 25 Events

- Marietta, GA – June 1985
  - Patient “burned” by radiation
- Hamilton Ontario – July 1985
  - Machine error, multiple retries, severe patient overdose
- Yakima, WA – December 1985
  - Strange skin reddening pattern, no apparent cause
Therac 25 Events

- Tyler, TX – March 1986
  - Operator edited modality at console
  - Electron patient – felt burned/shocked

<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>TREATMENT MODE</th>
<th>BEAM TYPE</th>
<th>ENERGY (MeV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST</td>
<td>FIX</td>
<td>X</td>
<td>25</td>
</tr>
</tbody>
</table>

- Beam type X or E
- Commands like P (proceed) or B (beam on)
Therac 25 Events

March ‘86 Conclusions
– Patient must have received electrical shock!
– No other events known

Tyler, TX – April 1986
– Operator edited modality at console
– Electron patient – felt pain/hit in face
– Medical physicist reproduces error
– All Therac 25 units taken out of service
Summary of Therac 25

Manufacturer recycled software with complete integration testing.

Allowed machine to deliver electron beams with photon currents (>100x)

There was no mechanism for investigating, porting, sharing information on accidents any substantial level.

July 1986 - FDA approved improvements

Therac 25 used without reported incident
OK that was THEN,

1999 - Errors are not caused by bad people, but by bad systems

And Now?
Module 2.10: Accident update – some newer events (UK, USA, France)
More Recently

2005 – Incorrect parameter transfer
  – Team handoff, new process flow, QA miss
  – Dose multiplier occurred twice → 60% O.D.

2007 – Incorrect detector size used
  – Large systematic calibration error

2007 – image reversed – wrong site Tx
Example: Incorrect IMRT planning (USA)
IMRT Error 2005

March 2005 – Head and neck pt begins normal IMRT treatment – plan had been done, approved and checked per standard practice.

On Tx 4, MD requests plan change (to spare teeth)

New plan done, but system crash during data save – incomplete data saved.
IMRT Error 2005

Attempt to recover plan appeared to succeed
- Planner did not notice subtle differences
- Required second check not performed
- Treating team did not notice missing data
- After 3 more Tx, second check done
- **OH NO!!**

Massive overdose to patient
Attention!

Much has been done on error analysis, reduction, .... BUT
Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy
Radiation Therapy is #1!

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2011

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ECRI Institute
The Discipline of Science. The Integrity of Independence.

1. Radiation Overdose and Other Dose Errors during Radiation Therapy

Radiation misadministration during radiation therapy can have devastating health consequences, from causing critical damage to normal tissue and organs, which can lead to severe morbidity and death, to creating an avenue for disease recurrence through improper or incomplete treatment of a tumor. The
~ 1500 mild to moderate injuries per million treatment courses (patients) ....
~1% prove to be fatal
Compare with IOM report where 10s of thousands of injuries/events per million (for adverse drug reaction for example).
We CAN do better.
Why Does It Happen?
Excerpts from

60 – 80% → Human factors
(not) Following policies/procedures

“Errors often follow violations in protocols, particularly failures to perform verification procedures, and indicators that things are not correct are often present yet ignored during events.” Thomadsen 2003

No one knows what happened elsewhere
Why Does It Happen?

Excerpts from

Lack of standards
- practice
- regulatory

Limited training and communication

Excessive complexity, problems hidden

Distractions, confusion

Intimidation
Safety in Radiation Therapy: Recommendations

- As complexity increases, control should be simplified
- Use of FMEA and RCA
- Develop a usable reporting system
- Therapist workstation needs human factors engineering
  - Return control to operator at point of care
  - Provide improved early warnings
  - Minimize cognitive clutter
Decision Tree for Intensity-modulated Radiation Therapy
Safety in Radiation Therapy:
Recommendations (cont’d)

Team covenant and safety commitment
Time outs – called by any team member
Check lists,
Facility accreditation
– audits, SOPs
Profession-sponsored user groups
Safety champions
Safety in Radiation Therapy: Recommendations (cont’d)

Billing process must be simplified
Team member qualifications consistency, recognized.
Improve FDA equipment process
Vendors should address concerns intelligibly
Recommend staffing levels (Blue Book revision)

*Hendee & Herman, PRO, MedPhys 2011*
Safety in RT

Excerpts from

- Safety can **NOT** be improved by
  - A new QA test
  - Doing only simple procedures
  - Creating error free systems
- A big error can happen to anyone
- We need to continually pursue improvement
Recognizing Qualifications
demonstrate competence through nationally recognized and consistent qualifications ..... Accreditation
that qualified people in appropriate staffing numbers perform medical radiation procedures following national consensus best, safe practices.

Event Reporting
Uniform, consistent, quantitative, accessible national reporting and notifications

Improved Manufacturing/FDA Process
Long Term, Ongoing

- Radiation Treatment is very safe, it can be better
- There is no overnight, quick fix to improve safety
- We have been working
- All are responsible to be vigilant and to work together to develop safer, more effective use of radiation in medicine.
THANK YOU!
Solutions

Excerpts from

Central database, updated, analyzed and disseminated – learn from others
Comply with policy, Follow YOUR QA program – practice standards
Be alert – computer crash…
Understand properties/limitations of technology, humans
Independent checks!
Solutions

Excerpts from

- Consistent regulations and reporting for all therapy machines regardless of the type of device
- Only qualified individuals providing radiation therapy
- Team commitment to quality
- Use checklists, time outs, limit access
Solutions

Excerpts from

- Leaders have to own it
- Safety requires
  - Standardization
  - Accountability
  - Mutual respect
- Vigilance for every team member