Future of Radiation Therapy Safety

Disclosures

- Scientific Advisory Board Member of ViewRay
- AERO Board of Directors: Accuray

- Institute of Medicine Report
- 2000
- 44,000 to 98,000 die every year in US as result of medical errors
- Greater than auto accident deaths (43k)
- Updated 2010
Recent Articles Revealed Inadequacies in System

Radiation Oncology Errors Reporting Initiatives

- WHO Radiotherapy Risk Profile (21 actual, 28 potential incidents), 2008
- UK professional bodies: “Towards Safer Radiotherapy” (5 incidents), 2008
- ICRP: “Preventing Accidental Exposures from new External Beam Radiation Therapy Technologies” (11 incidents)

Why Are We Seeing This?

- Greater complexity
- Greater scrutiny
- Greater awareness
What To Do?

- 5 Elements
  - Automation and Redundancy
  - Monitoring
  - Standardization and Rationalization (procedures)
  - Training, Retraining, and Testing
  - Quality QA: Accreditation

- 2 Strategies
  - Coordination and Cooperation
  - Culture

Automation and Redundancy

1. Forcing functions and constraints
2. Automation / Computerization
3. Simplification / Standardization
4. Checks, double checks, checklists
5. Policy and training
RTD Checksum System

Integrated into the beam delivery path
Automatically integrates dose with spatially sensitive detector
Automated workflow, provides both automation and redundancy

RTD Checksum Example

Planning Automation

\[ D_{\text{pred}} = D_{\text{RL}} \left( 0.2 + 0.8 e^{-0.2 V_{\text{overlap}}/V_{\text{OAR}}} \right) \]

- Parotid glands (head and neck)
- Rectum (prostate)

Apparent Lower Limit to Mean Dose

\[ \frac{D_{\text{mean}}}{D_{\text{RL}}} \]
Monitoring

- How well do we do?
  - Error Reporting
  - Results
  - In-room monitoring

Error Reporting: Grass Roots

- UCLA - Wash U. Collaboration Electronic Whiteboard to Enhance Safety
- Electronic whiteboard for reporting and analysis
- All errors and near misses are tracked
- Creates data
- Promotes zero mistake culture with all stakeholders (if implemented correctly)
National Error Registry

- We need to know what is happening
- Where are we making mistakes?
- How often do the mistakes happen?
- What are the consequences of the mistakes?
- National Radiation Oncology Registry (NROR)

Proposal: Black Box

- Develop retrospective recording system
  - Records actions in the treatment room
  - Policies that maintain worker’s and patient’s privacy

Monitoring to Avoid Errors

- Primarily human-based errors
  - Wrong patient
  - Wrong site
  - Missing or wrong accessory
- How?
  - 3D cameras positioned in the room
  - Monitor the patient, accessories, accelerator
  - Compare against programmed values
  - Compare against similar patients
  - Automated feature recognition
  - Expert system: Big Brother Covert Patient Surveillance
FMEA

- For each subprocess, enumerate the possible scenarios, i.e., Failure Modes (FM), that could lead an unsuccessful treatment.
- Identify causes and effect on process outcome.
- Assess risk to successful outcome posed by each FM assuming no QA.

<table>
<thead>
<tr>
<th>Probability of occurrence</th>
<th>Severity of consequences</th>
<th>Probability Error</th>
<th>Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>S</td>
<td>P</td>
<td></td>
</tr>
</tbody>
</table>

Risk Probability Number – RPN = O x S x P

- Assign O, S, and P a value from 1-10.
- 4 Observers: Ibbott, Matic, Williamson, Thomadsen.
- Significant additions/modifications by JFW.
- Reorder list in terms of descending RPN.

Alternative Method

- Nancy Leveson of MIT.
- Evaluated modern accidents (FMEA is more than 30 years old).
- FMEA doesn’t manage software or “migration”.
- Changed emphasis from “prevent errors” to:
  - Enforce safety constraints on system behavior
  - ID safety constraints
  - Design control structure to enforce constraints on system behavior and adaptation.

Training and Retraining

- Ph.D. Exams
- Board exams
- New gizmos
- New techniques

- Practice
- Grad School
- Residency
- Retirement
**Competence**

- Complexity is increasing.
- Flat "minimum" is really increased complexity.
- Doctor X
- Minimal

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**Training and Retraining**

- Re-rationalization
- Simulations
- Performance review
- Frequent re-training

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**QA**

- Accreditation

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**37,691,912**

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**3,580,709**
Coordination and Cooperation

- Informal collaboration with MITA and vendors on a Radiation Oncology Stakeholders group that is working on a series of white papers
- Error Messages
- Standard prescription format

Culture

- Culture of Safety is key ingredient
  - Create the culture that strives to learn what happened
  - Commitment by all personnel
- Current medical culture: “be perfect”
  - Mistake… not what you did was bad, but you are bad
  - You are always supposed to have the right answer
  - Self doubt vs. culture of improvement
    - Errors are ubiquitous
    - Medical events vs. process mistakes
    - Mistakes are inevitable... if we weed out the mistake makers there won’t be anyone left
- Blameless culture

M. Workman, 2009
Radiation Therapy Safety is Now More Challenging Because

1. Investigative reporters are looking over our shoulders
2. Computers entered the picture
3. The number of parameters being defined, transported and used has grown tremendously
4. IMRT is easier to plan than 2D
5. CT scanning makes target definition harder

Correct Answer: 3
- The number of parameters being defined, transported and used has grown tremendously

FMEA is

1. A quantitative way to determine relative risk
2. A way to prioritize risk management according to a combination of occurrence, severity, and detectability
3. A way to prioritize risk management according to severity
4. Only useful for designing factory assembly lines
5. Framed Management Engagement Assurance
Correct Answer: 2

- A way to prioritize risk management according to a combination of occurrence, severity, and detectability

Automation is Important in RT Because

22% 1. It reduces the reliance on expensive employees
21% 2. It allows us to spend less time at the console
21% 3. Therapists are too scarce and need to be replaced by automation
18% 4. The number and speed of parameters we use are too numerous for humans to effectively manage
18% 5. There are no redundant systems in radiation therapy

Correct Answer: 4

- The number and speed of parameters we use are too numerous for humans to effectively manage