Patient Safety

Brett Miller, M.S.
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Outline

- Simple Goal
- What can go wrong?
- What can’t we control?
- What can we do?
Simple Goal

- Treat patients safely and as planned
- Treat the tumor, spare the normal tissue
- Simple process???
Steps in IMRT Process

Fig. 1. An intensity-modulated radiation therapy (IMRT) process tree. MD = physician; QA = quality assurance; RTP = radiation therapy planning; Tx = treatment; H&P = history and physical.

Huq et al, IJROBP, Vol 71, S1 ppS170-S173
Complexity of Radiation Therapy

- Many steps
- Many computer systems
- Complex technology
- Chaotic environment
- Increasingly complex interactions
- Many different people involved
- Beware of oversimplification of the process
People Involved in Radiotherapy Process

- Therapists
- Dosimetrists
- Physicists
- Physicians
- Nurses
- IT
- Administrators
Complexity of the Workspace
Complexity of the Workspace
Outline

- Simple Goal – not really
- What can go wrong?
- What can’t we control?
- What can we do?
What can go wrong?

- **Error** – an act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done

- **Incident** – an unwanted or unexpected change from a normal system behavior, which causes, or has the potential to cause, an adverse effect to persons or equipment
What does going wrong mean?

Consequences of an Incident/Error

- **No effect on the safety or quality of treatment**
- **Erosion of quality**
- **A clinically significant adverse event**

Deviation from optimum dose
What does going wrong mean?

- Unsafe = extreme compromise of quality.
- Let’s not forget the patients caught in the “quality trap”.

Peter Dunscombe, PhD, University of Alberta, Tom Baker Cancer Center
The Quality Trap

If you believe this distribution there must be patients who, due to departures from quality, receive treatments that do not result in obvious injuries but for whom the probability of the desired outcome is compromised.
Contributing factors

- Lack of training, competence or experience
- Fatigue and stress/time pressure
- Poor design and documentation of procedures
- Over-reliance on automated procedures
Contributing factors (cont.)

- Poor communication and lack of teamwork
- Hierarchical departmental structure
- Staffing and skill levels
- Working environment
- Changes in the process
What we can’t control

- Vendors
  - Increasing complexity of technology
- Regulatory agencies
  - NRC
  - State of Michigan – LARA
What can we do?

- Failure Mode and Effects Analysis
- Develop thorough QA policies and procedures
  - Continually update
- Review UMDC, CTB and product recalls
- Learn from experts in the field
- Learn from incidents in the field
- Staff
  - Educate staff/Learn from others
  - Provide with adequate tools, training and time
  - Maintain appropriate staffing levels
- Program Review
- Foster a Culture of Patient Safety
Failure Modes and Effects Analysis

- Process trees – helps to understand the steps in a process or procedure
- Fault trees – illustrates paths that can lead to errors
- Three categories:
  - O – probability that a specific cause will result in a failure mode
  - S – the severity of the effects from a specific failure mode
  - D – the probability that the effect from a failure mode will go undetected

Huq et al, IJROBP, Vol 71, S1 ppS170-S173
Failure Modes and Effects Analysis

- Product of the three values is the Risk Probability Number (RPN)

\[ \text{RPN} = O \times S \times D \]

- The higher the RPN, the higher the risk
- TG-100 to define values for O, S and D

Huq et al, IJROBP, Vol 71, S1 ppS170-S173
Hierarchy of Effectiveness

1. Training and Education
2. Policies and Procedures
3. Checklists, reminders, double checks
4. Simplify/Standardize
5. Automation
6. Interlocks/Forcing Functions
Hierarchy of Effectiveness

Least Useful

Training and Education

Policies and Procedures

Checklists, reminders, double checks

Simplify/Standardize

Automation

Interlocks/Forcing Functions

Most Useful
Hierarchy of Effectiveness

Most Useful

Tech Focus

People Focus

Least Useful

Interlocks/Forcing Functions

Automation

Simplify/Standardize

Checklists, reminders, double checks

Policies and Procedures

Training and Education
Policies and Procedures

ACT
Plan the next cycle
Decide whether the change can be implemented

PLAN
Define the objective, questions and predictions. Plan to answer the questions (who? what? where? when?)
Plan data collection to answer the questions

STUDY
Complete the analysis of the data
Compare data to predictions
Summarize what was learned

DO
Carry out the plan
Collect the data
Begin analysis of the data
What can we do?

- Failure Mode and Effects Analysis
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Review notices from vendors

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject: Potential Detachment of Gantry Center Throat Cover
Commercial Name of Affected Product: Varian High-Energy Clinac® linear accelerator (H14, H27, H29)
Reference / FSCA Identifier: CP-03412
Date of Notification: 2011-05-24
Type of Action: Notification and Correction
Details on Affected Devices: Refer to appendix page.
Sources of Information
Sources of Information

- www.ipem.ac.uk/docimages/2329.pdf
- www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf
Sources of Information
Sources of information
Radiation Oncology Safety Information System

Established in 2001 under the auspices of ESTRO

Voluntary web based safety information system for radiotherapy

Annual Meeting in Dublin, Ireland

http://www.rosis.info/
Radiotherapy, the treatment of disease using ionizing radiation, is mainly associated with cancer treatment but is - to a limited extent - also used for the treatment of some non-malignant diseases. In external beam radiotherapy, radiation beams originating externally to the patient are directed towards the treatment site. These beams are usually created through the use of a linear accelerator or a cobalt unit. In brachytherapy, small and encapsulated radioactive sources are placed directly into or near the volume to be treated. Endovascular brachytherapy, finally, is used for prevention of restenosis in arteries following coronary arterial angioplasty.
“SAFRON (Safety in Radiation Oncology) is a global safety reporting system being developed for radiotherapy. The system aims to enable reporting and learning from accidents / incidents and near incidents; integrate with existing systems while complementing national and mandatory systems; and integrate retrospective reporting and prospective risk analysis.”
In the process of staffing a Committee that would:

- Develop a definition of reportable events to include radiation therapy using linear accelerators and e-brachytherapy technology, as well as high dose diagnostic procedures such as computed tomography (CT) and fluoroscopy.
- Develop/maintain a format and mechanism for state programs to provide the committee with details of reportable events.
- Review submitted reports for completeness and accuracy, and develop notices to the state programs when necessary.
- Oversee the development and maintenance of a CRCPD database of reportable events.
- Prepare an annual summary report for the CRCPD Board and the Newsbrief.
- Provide a verbal report at the Annual Meeting.
What can we do?

- Failure Mode and Effects Analysis
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- Program Review
- Foster a Culture of Patient Safety
Staff Education

- Periodic Review of updated Policies and Procedures
- Just-in-time training
- In-service for new equipment, technology and procedures
## Staffing Levels – ACR recommendations

<table>
<thead>
<tr>
<th>Academic/CCC</th>
<th>Comprehensive Cancer Center or main teaching hospital of a medical school</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1 Hospital based; 600 or more patients</td>
<td>F1 Freestanding; 600 or more patients</td>
</tr>
<tr>
<td>H2 Hospital based; 201-599 patients</td>
<td>F2 Freestanding; 201-599 patients</td>
</tr>
<tr>
<td>H3 Hospital based; 200 or fewer patients</td>
<td>F3 Freestanding; 200 or fewer patients</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>ALL ACR ACCREDITED FACILITIES</th>
<th>ACADEMIC / CCC</th>
<th>H1</th>
<th>H2</th>
<th>H3</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
</tr>
</thead>
<tbody>
<tr>
<td>New patients/radiation oncologist</td>
<td>208</td>
<td>213</td>
<td>253</td>
<td>221</td>
<td>151</td>
<td>248</td>
<td>221</td>
<td>141</td>
</tr>
<tr>
<td>New patients/Physicist</td>
<td>278</td>
<td>196</td>
<td>220</td>
<td>292</td>
<td>153</td>
<td>378</td>
<td>340</td>
<td>226</td>
</tr>
<tr>
<td>New patients/FTE dosimetrist</td>
<td>262</td>
<td>296</td>
<td>348</td>
<td>279</td>
<td>192</td>
<td>287</td>
<td>257</td>
<td>198</td>
</tr>
<tr>
<td>New patients/FTE therapist</td>
<td>71</td>
<td>72</td>
<td>67</td>
<td>75</td>
<td>51</td>
<td>81</td>
<td>73</td>
<td>58</td>
</tr>
<tr>
<td>FTE therapist/Rx machine</td>
<td>3.3</td>
<td>4.1</td>
<td>2</td>
<td>3.4</td>
<td>3</td>
<td>3.9</td>
<td>3.3</td>
<td>2.5</td>
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<tr>
<td>New patients/Rx machines</td>
<td>187</td>
<td>287</td>
<td>206</td>
<td>241</td>
<td>146</td>
<td>321</td>
<td>258</td>
<td>134</td>
</tr>
</tbody>
</table>

(Updated by: Dr. Jane Smith | Date: April 15, 2023)
Program Audit/Review

- RPC/RDC
  - OSLD
  - Site visits
- Peer Review/Self Audit
- External Audit
- ACR Accreditation
What can we do?

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Culture of Patient Safety: What we need to do

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality
Culture of Patient Safety

- **Start at the top**
  - Every process needs a leader who must lead by example
  - Everyone, including the leader, must look at their work with a critical eye

- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality
Culture of Patient Safety

- Start at the top
- **Work as a Team**
  - Therapist, Dosimetrist, Physicist, Physician, Nurse IT Professionals, Administrators
  - Remove Hierarchy
  - Anyone on the team can prevent an error
  - Everyone member of the team needs to have the appropriate tools, training and time to do their job correctly
  - Communication; Flow of Information
- Accountability not blame
- Policies and Procedures
- Measurement of Quality
Culture of Patient Safety

- Start at the top
- Work as a Team
- **Accountability not blame**
  - Talk about errors as a learning experience
  - Must be a non-punitive, nurturing environment
- Policies and Procedures
- Measurement of Quality
Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- **Policies and Procedures**
  - Clear, consistent and thorough
  - Willingness to delay a treatment if not safe
  - Continually updated and modified with feedback from staff and monitoring of variance
  - Review of incidents when policies are not followed
- Measurement of Quality
Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures

**Measurement of Quality**
- Error Analysis and Variance Reporting
- Key Quality Indicators
How can we reduce errors?

- Simplify the human interface
- Improve human performance
  - Establish and maintain (continually update) clear and thorough Policies and Procedures
  - Education – professional meetings and reports, training,
  - Make sure staff has the necessary tools, training and time
  - Error reporting and analysis
- Establish a Culture of Patient Safety
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Thank You