Safety and Quality in Radiation Therapy

Indrin J. Chetty, PhD
Henry Ford Health System
Disclosure

My department receives research support from:

• NIH/NCI
• Varian Medical Systems
• Philips HealthCare
Learning Objectives/Outline

To understand complexity in radiotherapy

To review causes of errors – emphasis on human factors

To discuss the role of the physician in the culture of safety

What should we be doing to improve safety in RT?
Pre Test Question

Research studies have shown that human factors can be attributed to ____% of safety-related incidents in radiation therapy.

A. 0-20
B. 20-40
C. 40-60
D. 60-80
E. 80-100
In 2010 a series of articles in the NY times challenged safety in Radiation Oncology

December 28, 2010: The New York Times published an article titled "A Pinpoint Beam Strays Invisibly, Harming Instead of Healing." ASTRO submitted a Letter to the Editor and developed a more comprehensive response to the article in an ASTROgram from Dr. Zietman (ASTRO Chair), sent to the membership

“All available evidence indicates that errors like the ones described in this article are extremely rare. However, as with flying a plane, even a single error is one too many and our specialty is working to eliminate them.”
In 2004, ASTRO established IHE-RO (Integrating the Healthcare Enterprise-Radiation Oncology) in recognition of the risks associated with new and advanced technologies unless “there was perfect communication between software and hardware, regardless of the manufacturer.”...Significant resources have been committed to ensure that medical technologies from different manufacturers can seamlessly transfer information, though the “lack of connectivity among systems is still a problem.”
In January 2010, ASTRO launched its Target Safely campaign, a comprehensive plan to help to ratchet patient safety up even further.” ASTRO has proposed federal legislation to develop a national medical error reporting system and a patient safety database for radiation oncology. Error and near-miss reporting will not only detect sporadic problems and find patterns but will allow for the rapid and wide dissemination of alerts when problems occur.”
Response letter from Dr. Zietman (ASTRO Chair)……..

A culture of safety

“Every individual on the radiation oncology team has to be immersed in the culture of quality assurance and quality improvement. To this end, we have fortified our educational program for radiation oncologists wishing to maintain their physician certification… We are producing a series of consensus-based white papers on safety and quality, with a specific focus on newer technologies such as stereotactic radiosurgery.” Reports on IMRT and SRS/SBRT are now on-line out for public comment.
Response letter from Dr. Zietman (ASTRO Chair)……..

Patient Advocacy

What is a patient to do? How can they know whether their radiation oncology facility is operating at the safest level? ASTRO has worked with patient supports groups, cancer survivors and other medical organizations to create a list of questions patients should ask their physicians and cancer centers when considering radiation therapy ....We have made these questions available for download on our patient website rtanswers.org and to view as videos posted on YouTube.
Other ASTRO/AAPM sponsored safety initiatives

June 2010, ASTRO and AAPM co-sponsored a symposium: “Safety in Radiation Therapy – A call to action” – co-chaired by Dr. Williams (ASTRO president), Dr. Herman (AAPM president) and Dr. Hendee (AAPM)

ASTRO (Dr. Zietman) leading a multi-society initiative to update the Bluebook (May 2011) – recommendations on basic safety and quality standards in RT, including staffing levels
ASTRO/AAPM Safety Symposium: June 2010

- Complexity in RT
- What can go wrong in RT
- Errors in RT – perspective of the manufacturers
- Errors in RT - perspective of the regulators
- The function of the RT team
- The culture of patient safety
- Education, Experience and MOC – what is needed?
- What are we doing to address patient safety?
- Complex Systems and the Human Interface
- Accreditation, Regulation and Event Reporting
RT: A Simple Goal: Optimize the Therapeutic Ratio

In a Highly Complex Environment

- Different types of cancer
- Different Tx techniques
- Multi- vs. single-vendor environments
  - Clinical
  - Research

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

Technological Innovations:
- EPID
- kV localize
- CBCT
- Other IGRT
- Off line/on-line

Adapted from M. Herm...
IMRT: AAPM TG-100 (Huq et al.)
(failure mode effects analysis FMEA)
Complex Tx Devices:

- Dual energy photon + 6X (SRS mode), 6 e’ energies + HD-MLC
- Two entirely independent Tx planning systems
- 6D Couch is controlled by one control system and the standard couch by the other vendors control system

INTERCONNECTIVITY

http://www.novalistxradiosurgery.com/technology/delivery-system/
What causes errors to occur?

<table>
<thead>
<tr>
<th>Incident Learning System (Calgary)</th>
<th>Radiation Oncology Safety Information System (ROSIS, Europe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards/Procedures/Practices (~67%)</td>
<td>Standards/Procedures/Practices (~54%)</td>
</tr>
<tr>
<td>Communication (~17%)</td>
<td>Planning (~16%)</td>
</tr>
<tr>
<td>Judgment (~11%)</td>
<td>Communication (~13%)</td>
</tr>
<tr>
<td>Materials/Tools/Equipment (~9%)</td>
<td>Materials/Tools/Equipment (~12%)</td>
</tr>
<tr>
<td>Knowledge/Skill (~7%)</td>
<td>Knowledge/Skill (~12%)</td>
</tr>
<tr>
<td>Planning (~4%)</td>
<td>Judgment (~6%)</td>
</tr>
<tr>
<td>Design (~3%)</td>
<td>Design (&lt;1%)</td>
</tr>
<tr>
<td>Capabilities (~2%)</td>
<td>Capabilities (0)</td>
</tr>
</tbody>
</table>

Courtesy: P. Dunscomb
Causes of Errors

Research studies have shown that 60 – 80% of incidents can be attributed to human factors, related primarily to policies/procedures.

What can we do to address human factors issues?

A lot! Human Factors Engineering...

Minimize human interaction in complex processes

Improve behavior, attitude, enhance education and information to improve human performance

From P. Dunscore
Human Factors Engineering: Example

Princess Margaret Hospital [Chan et al.: “The use of human factors to identify and mitigate safety issues in radiation therapy: Radiotherapy Oncology, 97 2010]

Objective: to determine whether evaluating and re-designing technology to improve workflow and work environment can have a positive influence on human-machine interaction, and reduce errors.
Human Factors Engineering: Example

Field observations - observe how users interact with the delivery system over a 3-month period at the Tx facilities.

Workflow analysis – identify areas associated with a high likelihood of incidents.

Existing system was redesigned using a user-centered approach.

16 RT students participated in usability testing to compare the current and redesigned interfaces. Three errors were evaluated: (1) overlooking an important note, (2) shifting the treatment couch incorrectly, and (3) overlooking a change of approval dates.
Human Factors Engineering: Example: Results

Workflow analysis - particular concern was the checking process performed by therapists prior to TX delivery. Due to the multiple Tx checks required (workflow) and the **environment clutter** (multiple screens in the R/V, TX process) pre-Tx checking process found to be inefficient and inconvenient. New system **redesigned to include efficient structure with fewer steps; workflow environment improved**: reduce clutter, highlight important info..

---

**Chan et al.:** Radioth. Onc. 97, 2010
How do we develop and foster a culture of safety?

We must first Admit there is a Problem!

“Hardware breaks, software always has bugs, processes mutate and devolve, and people make mistakes!”

Clinics everywhere are susceptible to many kinds of errors (i.e., including big ones)!

Adapted from B Fraas
A Culture of Safety: The role of the Physician

Patient safety and quality must be driven from the TOP, i.e. the physicians and other senior institutional leaders.

The Physician’s role is Unique

• Societal Responsibility
• Clinical Perspective
• Role as a leader

Physician is in a unique role to champion for a culture change.

Adapted from L Mark
Approaches for championing a culture of safety

– Acknowledge the risks
– Speak openly: staff, administrators, patients
– Foster a non-punitive environment
– Empower and support others
– Celebrate other’s accomplishments in QA arena

Enhance Education: M&M conferences, Safety Rounds, QA meetings, departmental safety engagement retreats

Incorporate safety into all departmental activities

Change is hard  \( \text{Success} = f(\text{leadership}) \)

Adapted from L Mar
Physician’s Role: Trendsetting examples from UNC

Courtesy: L Marks
Physician’s Role: Trendsetting examples from UNC

Suggestion boxes for feedback on improving processes

Courtesy: L Marks
Daily morning conference to review cases in TX planning queue

Respectful questioning, building a team
HFHS Radiation Oncology Variance Reporting Database
Available on the HFHS Radonc Intranet at all TX workstations

HFHS Physics Variance Web Site

Create a Variance Report
View/Update a Variance Report
Search by Physician and Date Range
Search by Date Range
Keyword Search of Description Field
Search Using Patient MRN
Search Using Patient Last Name
Report Menu
Back to medphys.hfhs.org
### Henry Ford Hospital Department of Radiation Oncology

#### Variance Form

- **Site:** Main Campus
- **Source of the Variance:** HFH Rm4

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>3/26/2012</td>
</tr>
<tr>
<td>Variance report creator</td>
<td>Anonymous</td>
</tr>
<tr>
<td>Patient MRN</td>
<td></td>
</tr>
<tr>
<td>Patient Last Name</td>
<td></td>
</tr>
<tr>
<td>Patient First Name</td>
<td></td>
</tr>
<tr>
<td>Patient Physician</td>
<td></td>
</tr>
<tr>
<td>Secondary Physician</td>
<td></td>
</tr>
<tr>
<td>Nature of the Variance</td>
<td></td>
</tr>
<tr>
<td>Specify</td>
<td></td>
</tr>
<tr>
<td>High Priority</td>
<td>No</td>
</tr>
<tr>
<td>Process Variance</td>
<td>No</td>
</tr>
<tr>
<td>Floor physician contacted</td>
<td></td>
</tr>
<tr>
<td>Missed 24 hour approval</td>
<td></td>
</tr>
<tr>
<td>Missed image check</td>
<td></td>
</tr>
<tr>
<td>Missed chart check</td>
<td></td>
</tr>
<tr>
<td>Incomplete documentation</td>
<td></td>
</tr>
</tbody>
</table>

#### Description:

---

#### Check all pertinent tools that helped discover variance:

- Treatment Unit
- Physics Initial Check
- Physics Weekly Check
- Therapist Initial Check
- Therapist Weekly Check
- Chart Rounds
- Imaging
- Other

---

Send email notification of variance report creation
How should we initiate/reevaluate safety programs?

Refer to national guidelines/consensus documents, committee reports, white papers for the basic needs – tailor the program for specific implementation.

ASTRO QA/Safety Sub-committee: Safety White Papers

<table>
<thead>
<tr>
<th>IMRT</th>
<th>SRS/SBRT</th>
<th>HDR</th>
<th>IGRT</th>
<th>Peer Review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>. .</td>
</tr>
<tr>
<td>J Moran PhD</td>
<td>T Solberg PhD</td>
<td>B Thomadsen PhD</td>
<td>D Jaffray PhD</td>
<td>L Marks MD</td>
</tr>
</tbody>
</table>

Published PRO
Published PRO
Published PRO
to expert review
to public review
final edits

Effort supervised by Fraass, Pawlicki, Marks

Adapted by B Fraass
From: “Safety considerations for IMRT”, Moran et al. PRO 1:2011

Recommendations to guard against catastrophic failures for IMRT:

- Halt a procedure if the operator is unclear about what is being done.
- Verify the patient information, treatment site, and prescription.
- Verify correct positioning of the high-dose region of isodose plan relative to targets.
- Verify the recording of reference and shift information from the planning scan in electronic/paper chart.
- Assess pre-treatment localization/portal images with respect to corresponding reference images before first treatment; physician determines frequency of GRT techniques(31).
- Verify that the correct version of the patient’s treatment plan is approved and used for patient-specific QA.
- Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins.
Recommendations to guard against catastrophic failures for IMRT

From: ASTRO IMRT white paper Moran et al. Moran et al. PRO 1:2011

Perform a complete chart check including review of information in treatment management system prior to the start of any treatment and after any change in treatment before changes are used for treatment

Visually review field apertures in treatment management system
Perform a check of dose to verify TPS calculation (measurement or calculation using DICOM export of data from RTP system)
Perform a time out prior to treatment delivery.

Perform a check of treatment parameters before start of and during first treatment against a fixed version of the treatment plan

Includes visual verification of field apertures during first treatment and after any change in treatment

At each fraction, verify motion of leaves (if MLC delivery) and total monitor units

Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (quarterly and after any software or hardware changes)
The Value of Check-Lists

Two Remarkable Books:

1. “The Check-List Manifesto – How to get things right” (Atul Gawande, MD, Harvard Medical School)

2. “Safe Patients, Smart Hospitals – How one Doctors check-list can help us change healthcare from the inside out” (Peter Pronovost, MD, PhD and Eric Vohr, John’s Hopkins University)
The Value of Check-Lists

Check-lists should be developed from detailed procedures to ensure a given process is implemented accurately and consistently.

Must be precise, to the point for efficient implementation but comprehensive to encompass all aspects of the procedure.

Must include “big-picture” checks: (from “Checklist Manifesto”) Example check-list on a single engine Cessna “FLY THE AIRPLANE”

Analogously in RT: “LOOK AT THE MLCs during Beam on”
Check-lists in the electronic environment

![Image of check-lists in electronic environment]

<table>
<thead>
<tr>
<th>Date of Service</th>
<th>Status</th>
<th>Document Type</th>
<th>Preview</th>
<th>Template Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/23/2012 1:32 PM</td>
<td>Approved</td>
<td>Physics - Weekly Chart Check</td>
<td>Weekly Physics Support</td>
<td></td>
</tr>
<tr>
<td>3/23/2012 1:32 PM</td>
<td>Approved</td>
<td>Physics - Weekly Chart Check</td>
<td>Weekly Physics Support</td>
<td></td>
</tr>
<tr>
<td>1/8/2013 3:16 AM</td>
<td>Approved</td>
<td>Physics - Weekly Chart Check</td>
<td>Weekly Physics Support</td>
<td></td>
</tr>
<tr>
<td>3/2/2012 10:22 PM</td>
<td>Approved</td>
<td>Physics - Weekly Chart Check</td>
<td>Weekly Physics Support</td>
<td></td>
</tr>
<tr>
<td>2/24/2012 5:57 PM</td>
<td>Approved</td>
<td>Weekly Chart Check</td>
<td>Weekly Chart Check</td>
<td></td>
</tr>
<tr>
<td>2/22/2012 8:34 AM</td>
<td>Approved</td>
<td>Weekly Chart Check</td>
<td>Weekly Chart Check</td>
<td></td>
</tr>
<tr>
<td>2/21/2012 3:13 PM</td>
<td>Approved</td>
<td>Chart Rounds</td>
<td>ChartRounds Review Radi... First Page (Summary)</td>
<td></td>
</tr>
<tr>
<td>2/17/2012 5:16 PM</td>
<td>Approved</td>
<td>Therapist Initial Chart Check</td>
<td>Initial Chart Check (9/2011)</td>
<td></td>
</tr>
<tr>
<td>2/17/2012 9:48 AM</td>
<td>Approved</td>
<td>Physics, Specialist Consult Work</td>
<td>Special Physics Consult, Report</td>
<td></td>
</tr>
<tr>
<td>2/17/2012 8:07 AM</td>
<td>Approved</td>
<td>Therapist Initial Chart Check</td>
<td>Initial Chart Check (9/2011)</td>
<td></td>
</tr>
<tr>
<td>2/17/2012 8:05 AM</td>
<td>Pending</td>
<td>SSD Log</td>
<td>SSD Sheet</td>
<td></td>
</tr>
<tr>
<td>2/16/2012 10:48 AM</td>
<td>Approved</td>
<td>Physics - Initial Chart Check</td>
<td>Physics - Initial Chart Check</td>
<td></td>
</tr>
<tr>
<td>2/16/2012 10:47 AM</td>
<td>Approved</td>
<td>Special ISO worksheet (Physics)</td>
<td>Special Physics Consult, Request</td>
<td></td>
</tr>
<tr>
<td>2/10/2012 2:51 AM</td>
<td>Pending</td>
<td>Sim Setup Sheet (Physics)</td>
<td>Sim - Generic Set-Up Sheet</td>
<td></td>
</tr>
<tr>
<td>2/10/2012 2:40 AM</td>
<td>Pending</td>
<td>Consent</td>
<td>Consent</td>
<td></td>
</tr>
<tr>
<td>2/7/2012 12:12 PM</td>
<td>Approved</td>
<td>Physics, Specialist Consult Request</td>
<td>Special Physics Consult, Request</td>
<td></td>
</tr>
<tr>
<td>2/7/2012 12:12 PM</td>
<td>Approved</td>
<td>Simulation Note</td>
<td>Simulation Request and Procedure N...</td>
<td></td>
</tr>
</tbody>
</table>
## INITIAL CHART CHECK

**Patient Name:**  
**Onecologist:** MD

### Parameters:

<table>
<thead>
<tr>
<th>Course ID</th>
<th>Plan ID</th>
<th>Rx Dose (Gy)</th>
<th>Fraction</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>CTV-ESOPHC DCO</td>
<td>56.4</td>
<td>07/28</td>
<td>Planning Approved</td>
</tr>
<tr>
<td>01</td>
<td>CTV-ESOPHC MAIN</td>
<td>56.4</td>
<td>07/28</td>
<td>Treatment Approved</td>
</tr>
</tbody>
</table>

### Cumulative Dose:

- CTV-ESOPHAGUS RX - Planned Dose 100.8Gy
- CTV-ESOPHAGUS NORM - Planned Dose 100.8Gy

#### Patient Manager: Documents (open & view)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Action</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Patient Manager: Registration

- Correct Location/Department Assigned
- ICD-9: Diagnosis matches activity
- Referring Physician is indicated

#### Patient Manager: Journal Reviewed

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Action</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Patient Manager: Health

- Simulation Education documented

#### Patient Manager: CarePath

- Treatment appointments scheduled
- Weekly Physics Support scheduled
- Chart Rounds task scheduled

#### RT Chart & 4DTC: Treatment Parameters

- Setup Note
- Load plan on treatment machine
- Physician Intent matches imaging template
- Verify MU’s present for each field
- Verify Energy present for each field
- Verify MLC for each field
- Open Fields documented by dosimetry

**Approved by:**  
**on:** 2/24/2012 5:56:55 PM
Summary

Patient safety and quality is the responsibility of every individual involved in treating patients with RT.

A culture of safety should be developed and fostered to ensure open communication, reporting of errors (in a non-punitive environment), with the goal of process improvement.

Detailed procedures must be developed and followed, using consensus-based documents and national standards as a foundation: empower your physicists to initiate this.
Summary

Develop check-lists to ensure procedures are being implemented accurately, consistently and efficiently.

Improvement is an on-going process and involves education, evaluation of procedures, and transparent error-reporting.
Acknowledgements

Larry Marks, MD (UNC)
Peter Dunscombe, PhD (Univ. of Calgary, Alberta Health Sciences)
Michael Herman, PhD (Mayo Clinic)
Dick Fraass, PhD (University of Michigan)

ASTRO and AAPM leadership in taking proactive steps toward providing guidance on safe practices

Dr. Akila Viswanathan (Chair) and Dr. Ramesh Rengan (Co-chair)
Cristin Watson and other ASTRO HQ staff

Thank You!
Post Test Question

Research studies have shown that human factors can be attributed to ____% of safety-related incidents in radiation therapy.

A. 0-20
B. 20-40
C. 40-60
D. 60-80
E. 80-100
Test Question Answer

D: Safety incidents are heavily related to human errors; research shows that 60-80% of incidents can be attributed to human factors.

Reference: