Quality and Safety in Radiation Therapy

SAMs Session

AAPM Annual Meeting, Austin, TX
Thursday

Disclosures

• Eric Ford
  – R18 HS22244-01
• Brett Miller
  – HFHS research agreement, Varian Inc.
• Ellen Yorke
  – None
• Gary Ezzell
  – None

Objectives:
What you will learn in this session

• Essential elements of a good quality management system in radiotherapy
• Value of incident learning and the AAPM/ASTRO RO-ILS incident learning system.
• Appreciate failure mode and effects analysis as a risk assessment tool and its use in resource-limited environments.
• Fundamental principles of good error proofing that extends beyond traditional prescriptive QA measures.
Outline

- Eric Ford, PhD, University of Washington, Seattle
  - Key components of quality management - an overview
- Ellen Yorke, PhD, Memorial Sloan-Kettering, New York
  - Failure Mode and Effects Analysis
- Brett Miller, MS, Henry Ford Health System, Detroit
  - Case presentation: SBRT incident
- Gary Ezzell, PhD, Mayo Clinic, Scottsdale
  - The ASTRO/AAPM Radiation Oncology-ILS
- Panel Discussion – All (30 minutes)

Quality and Safety in Radiation Therapy

Overview of Quality Management

Eric Ford, PhD
University of Washington, Seattle

Tools for Quality Management

- Quality assurance standards & recommendations
- FMEA
- Incident Learning & root cause analysis
Prescriptive Quality Assurance Standards

Some Examples
- TG-51 - Output dosimetry
- TG-142 - QA for linacs (or TG-135, TG-148)
- TG-179 (or TG-226 MPPG) - QA for IGRT
- TG-174 - QA non-radiographic localization
- TG-59 - HDR brachytherapy
- ASTRO / ACR Guidelines
  - ASTRO reports
  - “Safety is No Accident” Report

An example: SBRT

TG101 & SBRT Safety White Paper
- SBRT-specific training and CME
- Independent check of small field OFs
- Independent check of TPS dose calc (e.g. IROC)
- End-to-end tests

S. Benedict et al. Med Phys, 37, 4078-4101, 2010

There are MANY prescriptive quality measures.
How to keep track of them all?
AAPM Safety Profile Assessment (SPA)

• A practical tool to (help) make sense of the plethora of recommendations
• Online survey questionnaire about clinical operations, culture and management
• Product of AAPM Work Group on Prevention of Errors

spa.aapm.org
Secure login

Safety Profile Assessment
Safety Profile Assessment

Annotated bibliography

Safety Profile Assessment

Tracking improvement over time

Safety Profile Assessment

- Launched August 2013
- 82 participants to date
- Feedback results
  - < 1.5 hours to complete
  - Easy or very easy to complete: 70%
  - Will use in the future: 63%
- An approved PQI project for Maintenance of Certification

spa.aapm.org
Prescriptive quality measures have important weaknesses

What can prescriptive QA catch?

Tools for Quality Management

• Quality assurance standards & recommendations
• Failure Mode and Effects Analysis (FMEA)
  ... Identify issues *BEFORE* they manifest
  ... What could possibly go wrong?
  ... Ellen’s talk
• Incident Learning & root cause analysis
What is an “incident”? 

Examples 
- Wrong CT scan used for planning 
- Wrong MR fusion images loaded for contouring 
- Wrong vertebral body treated 
- Confusing policy for online imaging 
- Patients not taking oral chemo at the correct time 

Incident Learning: Why Participate?
Incident Learning: Why Participate?

✓ “Each department should have a department-wide review committee which monitors quality problems, near-misses and errors.”

✓ “Employees should be encouraged to report both errors and near-misses.”

Safety is No Accident, Zietman et al. 2012

Incident Learning: Why Participate?

A key component of practice accreditation

Standard 7: Culture of Safety

The radiation oncology practice (ROP) fosters a culture of safety in which all team members participate in assessing safety; the practice capitalizes on opportunities to improve safety and no reprisals are taken for staff that report safety concerns.

Quality and Outcomes in RO

Peters et al. JCO, 28(18), 2996, 2010

Seriously non-compliant (12% of plans)
## Incident Learning Approaches

<table>
<thead>
<tr>
<th>Center</th>
<th>System</th>
<th>Review</th>
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<th>Statistics</th>
<th>Size of center</th>
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<td>Tx Planning - weekly staff meetings Therapists reviewed monthly</td>
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<td>University of Washington</td>
<td>In-house + ROILS</td>
<td>Weekly with advance triage</td>
<td>Monthly “M&amp;M”</td>
<td>25 reports / week</td>
<td>75 patients / day</td>
</tr>
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Summary

• Many prescriptive recommendations exist
• They get you part of the way there … but NOT ALL THE WAY
• Need to be participating in incident learning
• Probably also FMEA
Lung SBRT (aka SABR)

- Increasingly used to treat small lung tumors
- ~ 90% local control at 2 yrs in some studies, remarkably few complications
- Typical prescriptions:
  - 18 Gy x 3 fx, 12 Gy x 4 fx, 10 Gy x 5 fx
- Biology of dose-response not well understood
- More sensitive to errors than conventionally fractionated treatments because:
  - Greater biological effect of misplaced hypofractionated dose
  - Each treatment is a larger percent of the total
    - Less forgiving than conventionally fractionated
• SBRT requires extreme accuracy
  — Accurate target and OAR definition, robust immobilization, meticulous planning, tip-top machine performance, IGRT at treatment
• Up to now, SBRT has been pretty safe
  — No NY Times headlines (yet)
  — Near misses????
• But can we improve safety, efficacy?
• One possibility
  — Systematic analysis of a department’s SBRT process to identify risky areas followed by
  — Devising and implementing measures to plug these holes

Failure Mode and Effects Analysis (FMEA)
• Systematic, proactive approach for identifying possible failures in a design, process or service
  — Failure = any error, either potential or actual
  — Failure modes = ways in which a part of a process might fail
  — Effects analysis = studying the consequences of those failures
• Reduce the risk of harm by proactively correcting the processes to prevent the failures

To Start a Real FMEA for SBRT
• Buy-in from supervisors, other upper-level personnel
• Form a group
  — For SBRT, this should include at least one physicist, MD, dosimetrist and therapist
  — All should be actively involved in SBRT
• Map out/list process steps in their clinical order
  — Flow chart, spreadsheet or a list-up to the group
• Get group consensus on this ‘process map’
• Process mapping is valuable in its own right!
• Different departments have different workflows (different equipment, staffing, departmental ‘culture’) and may have different risks for the same sort of treatment.

• The following two examples specialize to treatment planning for lung SBRT

SBRT planning process from Eric Ford

• Done as a project by 2 Physics Residents
• Took ~ a month
• Sent to Department Committee for risk analysis and risk mitigation design
• This process map was used for a true clinical FMEA

My perception of my department’s workflow for lung SBRT planning

Patient data includes planning and other scans

Sim data includes planning and other scans
Two immediately notable differences (there are others)

Start FMEA After Consensus Process Map

• For each process step ask and get group consensus:
  – What could possibly go wrong?
    • These are the potential failure modes
  – How could it happen?
    • Causes of failure mode
  – How likely is failure due to this cause?
    • Occurrence = O
  – How hard to detect before patient is affected?
    • Detectability = D
  – What are the effects of an undetected failure?
    • Severity = S

• There are quantitatively different O, S, D scales
• They may lead to similar relative ranks
• In the long run, it's the relative ranks that are important
  • You must stick to one scale for a particular analysis

RPN = OxDxS; runs from 1 (extremely low risk) to 1000 (extremely high risk)

Left example is Ford’s scoring; Right example is TG-100’s

O, S, D scoring from Ford et al
O, S, D scoring from TG-100
Assigning O, S, D

• It is argued that you should assign O and D as if no standard QA is in place in order to detect unnecessary QA
  – This is hard to do! I don’t know if it’s necessary in all cases.

• Most failure modes in lung SBRT treatment planning can happen with the same O’s and D’s in planning for conventionally fractionated treatment

• BUT for SBRT, S might be higher
  – If an incorrectly contoured structure underestimates the OAR metric used as a constraint, an unsafe plan might be thought safe
  – If the SBRT dose-response is steeper than for conventional fractionation, this failure is more dangerous for SBRT

• Lung SBRT has potential for local control and complications profile that are superior to conventional fractionation

• A poor quality plan may compromise both of these more for SBRT than for conventionally fractionated RT

Example

• Plan on the wrong image set
  – A failure at the very start of planning

• Failure Modes
  – Import/use a scan from a previous simulation
  – Import/use the wrong scan from a simulation that includes several scans
    • (e.g. different compression levels, breath-hold vs free-breathing)
  – Import/use a scan which is not optimally reconstructed
  – Use scan from a previous simulation that is in the TPS
  – Use a scan which is too short sup-inf (most lung toxicity predictors require the entire lung volume)
  – Use a scan with too narrow a scan diameter
  – Can you think of more failure modes at this step?

Using FMEA

• Score and prioritize the overall risk of each failure mode by the Risk Probability Number (RPN)
  – RPN=O  x  S  x  D

• Group pools and discusses the results

• First attack the highest RPN and any high severity failure modes

• A good FMEA helps identify where corrective actions are most needed

• The FMEA sensitizes the group to weak points in the analyzed process

• A first successful FMEA can lead to FMEA-guided interventions in other processes
FMEA from Eric Ford's Residents' exercise

Grading scheme of Ford et al

Incorrect contours; estimate D~6

From Eric Ford Resident's exercise

FMEA on SBRT Planning: Failure Modes (63)

| Failure Mode / Failure Description | Priority | Consequence | Likelihood | Data
|-----------------------------------|----------|-------------|------------|-----
| Missing contours of organs         | 7        | 6           | 336        | 1   |
| Incorrect contour; estimate D~6   |          |             |            |     |
| O~4, D~7; replace scan protocol by reconstruction | 7 | 5 | 280 | 1 |
| Wrong plan finalized in Aria; I'd reverse O and D | 7 | 3 | 224 | 1 |
| Same RPN                           | 7        |             | 210        | 1   |
| An O of 3-4 in my experience      | 7        |             | 192        | 1   |

The same FMs or close relatives also occur in my dept's process

Comments: estimates of O and D from experience with my process

Once the FMEA is done

- Work backwards from each chosen FM to identify its precursor causes
- This is Fault Tree Analysis (FTA)
  - Need not require elaborate diagrams
  - See Ford et al, Med Phys 2014
- Identify causes that are poorly covered by your existing procedures or QM program
- Devise feasible and efficient mitigations
  - Often tighter procedures, naming conventions, checklists, education, adding extra checks
  - Hard interlocks are seldom available
  - Are there interlocks to prevent use of the "wrong scan"?
- Implement mitigating QM changes
- And re-evaluate after a reasonable time
Recommended Reading

( compare with your observations for sbrt treatment delivery)

References

(collected by Jennifer Johnson)


Quality and Safety in Radiation Therapy

SBRT Case Presentation

Brett Miller, MS
Henry Ford Health System, Detroit, MI
Outline

- Notification
  - HFHS In-house Incident Learning System
- Root Cause Analysis (RCA) and FMEA
  - Gather information. What? How? Why?
  - Develop plan of corrective action
  - Update checklists, update policies and procedures, etc.
  - Communicate to staff
QAC Review

- Reports submitted at any of our 5 sites via the intra-department website.
- Reviewed by leads (physician, physicist and therapist) at each site.
  - Keeps leaders informed
  - Distributes workload
  - Allows for information gathering prior to QAC meeting
- Reviewed on a monthly basis by QAC.

Root Cause Analysis

- Gather information about the event
  - Must be done in a non-punitive manner
  - Accountability needs to exist
  - Buy in from entire department
- Develop a process map
- Look for cause and effect relationships
- Identify holes in your clinical process

Root Cause Analysis

- Process Step – Identify where the incident occurred
- Failure Mode – Collect information on what went wrong
- Failure Pathway – How and why did it happen?
- Develop a plan of corrective action
- FMEA – RPN calculated prior to and after corrective action
FMEA and Deming Cycle

Implement change:
- Decrease the probability the incident will reoccur
- Increase the probability of detecting the incident
- Severity remains unchanged

Hierarchy of Effectiveness*

**"Safety Is No Accident", ASTRO 2012**

Example 1 - RCA

- **Failure Mode**: Shift not indicated or incorrect in setup note.
- Discuss with dosimetry and physics to determine why the shift was left out
- **Failure Pathway**
  - Time crunch to get plan done
  - Dosimetry rushed
  - Physics check rushed

*"Safety Is No Accident", ASTRO 2012, AAPM 2013, B. Miller, et al
Example 1 – Corrective Action

• Failure Mode: Shift not indicated or incorrect in setup note.
• Additional checklist items
  – Provides list of items that need to be checked
• Update policies and procedures
  – Provide mechanism to move start date if certain tasks are overdue
• Staff Education
  – In-service on how to recognize and measure a shift

Example 2 - RCA

• Failure Mode: Couch model inserted into the plan but at the incorrect location
• Discuss with dosimetry and physics to determine why couch model was inserted incorrectly.
• Failure Pathway
  – New clinical process
  – Inadequate checklists

Example 2 – Corrective Action

• Failure Mode: Couch model inserted into the plan but at the incorrect location
• Additional checklist items
  – Provides list of items that need to be checked
• Update policies and procedures
• Staff education
Vendor Customer Technical Bulletins

- Information from vendors to identify areas of weakness previously not known by the end user.
- When you receive a Custom Technical Bulletin (CTB) from a vendor it will have several components:
  - Description of the issue
  - User recommended corrective action
  - Vendor corrective action
- Need to understand how YOUR CLINIC’S WORKFLOW is affected by each bulletin

Vendor CTB – Examples

Corrective action example

- Failure pathway:
  - Incorrect position of RT structures and isocenter after DICOM export
- Corrective action:
  - Added checklist item to initial physics chart check to verify DRR’s match between treatment planning and treatment delivery software

AAPM 2013, B. Miller, et al
Staff Notification

• Departmental database for the storing of vendor CTB’s.
• Easily accessible web interface where users upload CTB’s from any of our 5 locations for distribution to the department.
• Contains summary of CTB and corrective actions taken.
• Integration of RPN numbers into the database for quality control.

Advantages

• Ensures failure modes are analyzed for the best understanding
• Justifies the need for rigorous QA program
  – To staff
  – To administration
• Provides quantitative results to support:
  – Proper QA tools
  – Proper staffing levels

Thank You

• Ben Movsas, MD. Department Chair
• Indrin Chetty, PhD. Physics Division Chief
• Salim Siddiqui, MD, PhD. QAC Chair
• Michelle Dickinson, BS RT(T). QA Therapist
• Etc.
Quality and Safety in Radiation Therapy

The RO-ILS System from AAPM and ASTRO

Gary Ezzell, PhD
Mayo Clinic, Scottsdale, AZ

Radiation Oncology Incident Learning System

• What is it?
• Why do it? What is the payoff?
• What does it cost?
• Who sees our mistakes?
• How does it work? Be specific
• What are the obstacles?
• How do we start?

What is it?

• Web-based system for collecting, analyzing, and sharing information about errors and near misses
• A “Patient Safety Organization” (PSO) so data is legally protected by federal law
• Confidential and non-punitive environment
• Hybrid system: National database based on local reports
Each facility will enter local events
- Can analyze and report locally
- Decide which events to upload to national

National group will analyze and report to community

Basic data flow

Local facility
Local database
Send to PSO?
National database
National analysis and reports

Basic flow – Local

First report is brief, could be done by “anyone”

Follow-up information will then be added by facility’s designees
- Uses AAPM taxonomy

What to report to the national ILS?

Events of possible general interest

- Events for which there was no safety barrier
  - i.e. “Here is a failure mode we never thought of”

- Events which passed through at least one barrier – indicating need for better systems
  - i.e. “This got through the plan check and made it to the machine”

- Events involving equipment performance or communication between equipment
3 types of events to be reported

- **Incident** that reached the patient with or without harm
- **Near-miss** event that did not reach the patient
- **Unsafe condition** that increases the probability of an event

Why do it? What is the payoff?

- Internally: improve your own practice by studying your own experience
- Nationally: learn from others’ experiences as well  
  – What went (almost) wrong and what did we do about it
- Gain MOC credit

What does it cost?

- No cost to join or participate
- No IT overhead
- Time commitment to collect, upload, and respond to reports
Who sees our mistakes?

- Your own information, with any identifiers you choose to record, is seen only by you
- Information sent up to the national system is anonymized
- Anonymized data is reviewed by a committee of peers for condensation into reports for the community

How does it work? Be specific

- Let’s walk through an example of a report
- Retreatment situation: partial geometric miss caused by the new plan being done on the old scan

Initial report
At save, email goes out to designated people

Follow up by supervisor
Additional optional information

- Dose deviation
- Treatment technique; imaging technique
- Equipment involved
- Likelihood of harm
- Dosimetric severity scale
- Toxicity scale (actual or potential)
- Contributing factors (follows AAPM report)
Reviewing your own events

What will happen to the data in the national system?

- Protected from legal discovery
- Analyzed by...
  - Patient Safety Organization (PSO) staff
  - Subject matter experts: Radiation Oncology Healthcare Advisory Council

- Summarized for reports back to participants and community at large

Initial “RO-HAC”

- Adam Dicker, MD, PhD
  Jefferson Medical College of Thomas Jefferson University
- Gary Ezzell, PhD
  Mayo Clinic Arizona
- Eric Ford, PhD
  University of Washington
- Benedict A. Franas, PhD
  Cedars Sinai Medical Center
- David J. Hoopes, MD
  David Grant Medical Center
- Theresa Kulauskis, CMD, RT
  Rochester General Hospital
- Kathy Lash, RT
  University of Michigan
- Gregory Patton, MD, MBA, MS
  Compass Oncology
Who is in so far? What is the status?

• As of July 17, there were 14 facilities that have signed contracts with 13 more that have started the contracting process
  – 2 freestanding clinics
  – 2 community-based hospitals
  – 10 academic centers
• There have been 80 reports submitted
• The RO-HAC has done a preliminary look at the first 65 events and is developing its methods for analyzing and reporting

Can you give us a peek?

• Some initial data ...

Of the 65 events, 9 (14%) had a common factor: wrong isocenter was identified in a manner that could have led to systematic mistreatments. All were near misses ...

In several cases, the original error made it through a physics plan check before being caught by another check later in the process ...

There were a few events reported in which safety steps were skipped and patients received an erroneous treatment: patient identification not checked leading to the wrong patient’s plan being used; no re-port after a large manual shift being applied that inadvertently was done in the wrong direction.

Best practices suggestion

One facility provided a time-out form they use for emergency treatments that includes simple tables of the ratio of MU to dose as a function of depth for typical circumstances (PA spine, parallel-opposed spine, whole brain).

They use this as a reasonability check: if the calculation for the patient differs from the expected ratio by more than 10%, that is a flag that there is probably something wrong.
What are the obstacles?

- Mistrust – is this really going to be safe?
- Skepticism – is this going to be worthwhile?
- Inertia (and complacency) – we’re OK
- Getting through legal
  - First step is for your facility to sign a contract with the PSO
- Creating an internal culture of safety
  - Rewarding good catches and reporting

How do I start?

- Links on the AAPM and ASTRO websites
  
Which report contains recommendations for safe practices in stereotactic body radiotherapy?

1. AAPM TG-176
2. AAPM TG-101
3. ASTRO “Safety is No Accident” report
4. WHO “Radiotherapy Risk Profile” report
5. None of the above


Which quality improvement measure is specifically recommended by current AAPM and ASTRO reports?

1. Failure Mode and Effect Analysis
2. Near-miss incident learning
3. Root cause analysis
4. Field change order tracking
5. Forcing functions
Which quality improvement measure is specifically recommended by current AAPM and ASTRO reports?

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5. Forcing functions


Which attributes of a failure mode are numerically ranked when performing an FMEA?

1. occurrence and difficulty of detecting it
2. occurrence, potential consequences, and difficulty of detecting it
3. occurrence, potential consequences, difficulty of detecting it, and cost to prevent it
4. occurrence, ease of detection, and who was at fault
5. potential consequences if it does affect the patient

Which of the following is true of FMEA in radiation therapy?

1. To be helpful, it must be performed for the entire clinical process at once.
2. It is better for physicians to not be involved in doing an FMEA.
3. It can be useful if performed for well-defined clinical sub-processes.
4. Once an FMEA is performed, it need not be re-evaluated for at least three years.
5. FMEA should be done only for high-risk clinical processes.


After a group performs an FMEA for a limited clinical process, the next step should be:

1. Identify basic causes of the highest risk failure modes and design mitigation procedures.
2. Enter the highest risk failure modes into an ILS.
3. Immediately go on to another clinical process and perform another FMEA.
4. Go out for a beer.
5. Identify basic causes of the lowest risk failure modes and design mitigation procedures.
After a group performs an FMEA for a limited clinical process, the next step should be:

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2. Enter the highest risk failure modes into an ILS.
3. Immediately go on to another clinical process and perform another FMEA.
4. Go out for a beer.
5. Identify basic causes of the lowest risk failure modes and design mitigation procedures.


When performing root cause analysis of an incident:

1. Make sure to intimidate staff to get the best information possible.
2. Identify the process step where an incident occurred, the failure mode and the failure pathway.
3. Developing a process map will most likely not be of help.
4. Implement corrective action only if absolutely necessary.
5. There is no need to monitor activity as long as corrective action is implemented.

Which of the following would be the MOST useful corrective action to implement to reduce errors?

1. Add checklist item to physics chart check (10%)
2. Educate staff on the proper way to do an initial chart check (10%)
3. Require physician to digitally approve a plan before it can be treated (3%)
4. Use software to determine if a planned DVH meets physician constraints (17%)
5. Update policies and procedures and distribute to staff (7%)


What is the cost to a facility for participating in the RO-ILS program?

1. More frequent state inspections. (3%)
2. More frequent lawsuits. (13%)
3. Time committed to the effort, but no fee to participate. (13%)
4. Additional firewalls and specific IT needs. (3%)
5. Higher staff turnover because of all the fault-finding. (17%)

More frequent state inspections.

More frequent lawsuits.

Time committed to the effort, but no fee to participate.

Additional firewalls and specific IT needs.

Higher staff turnover because of all the fault-finding.
What is the cost to a facility for participating in the RO-ILS program?

1. More frequent state inspections.
3. **Time committed to the effort, but no fee to participate.**
4. Additional firewalls and specific IT needs.
5. Higher staff turnover because of all the fault-finding.

Reference: This presentation and www.astro.org/roils

Who is participating in the RO-ILS program?

1. **Only academic centers with surplus staff.**
2. Individual physicists, independent of any employer.
3. **Only facilities with multiple sites.**
4. **Hospital-based and free-standing centers.**
5. Nobody yet.

Reference: This presentation and www.astro.org/roils

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5. Nobody yet.
Which of the following is true about data submitted to the RO-ILS program:

1. It is confidential and privileged.
2. It is subject to Freedom of Information Act requests.
3. It can be used to avoid state reporting requirements.
4. It is available in raw form for all participants to search.
5. It can be accessed via Facebook and Twitter.

Reference: This presentation and www.astro.org/roils

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