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 White Papers
  - "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
T. Solberg et al. Prac Rad Onc, 2, 2-9, 2012

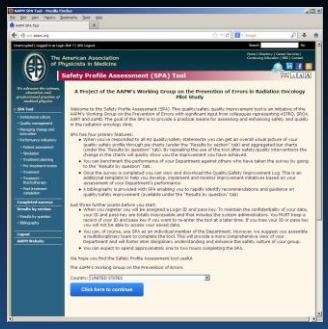
There are MANY prescriptive quality measures.

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

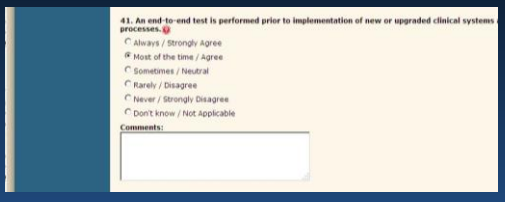
Safety Profile Assessment



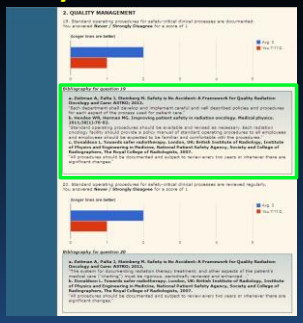
spa.aapm.org

Secure login

Safety Profile Assessment



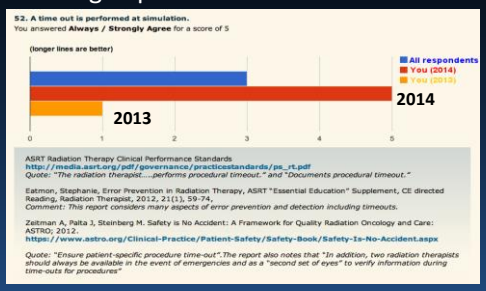
Safety Profile Assessment



Annotated bibliography

Safety Profile Assessment

Tracking improvement over time



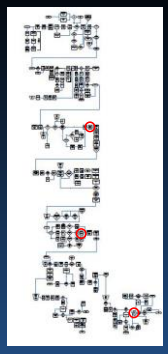
Safety Profile Assessment

- 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?

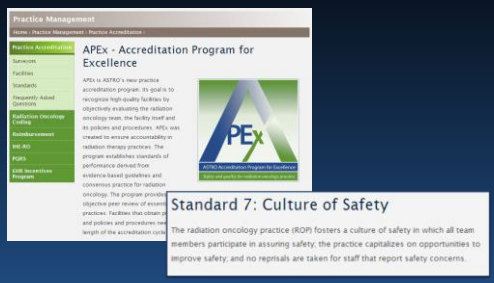
- ✓"Each department should have a department-wide review committee which monitors quality problems, near-misses and errors."

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

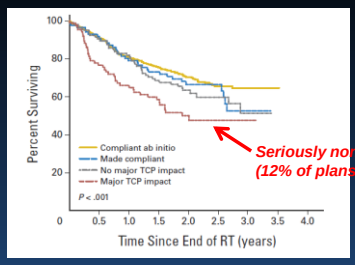
Safety is No Accident, Zietman et al. 2012

Incident Learning: Why Participate?

A key component of practice accreditation



Quality and Outcomes in RO



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

Incident Learning Approaches

Center	System	Review	Feedback	Statistics	Size of center
Mayo Clinic, Scottsdale	In-house + ROILS	Twice per month	Group meeting with minutes to all	10 reports / week	80 patients / day

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Henry Ford Hospital	In-house (pursuing ROILS)	Monthly and as necessary	Monthly + department website	7-10 reports/ week	170 patients / day

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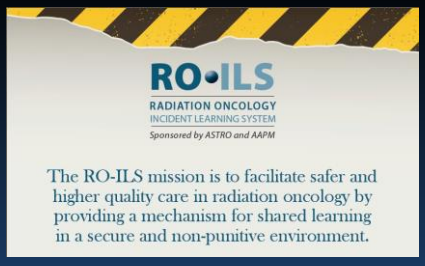
University of Washington	In-house + ROILS	Weekly with advance triage	Monthly "M&M"	25 reports / week	75 patients / day

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



RO-ILS Launch

June 19, 2014

Quality and Safety in Radiation Therapy

FMEA & Example SBRT Case

Ellen Yorke, PhD
Memorial Sloan Kettering Cancer Center, New York, NY

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 N Y 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

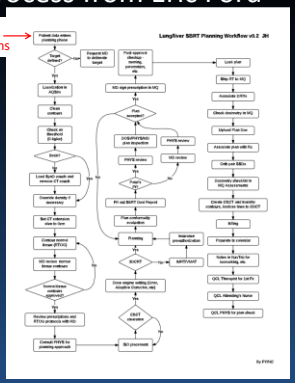
To Start a Real FMEA for SBRT

- 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 <u>treatment planning</u> for lung SBRT

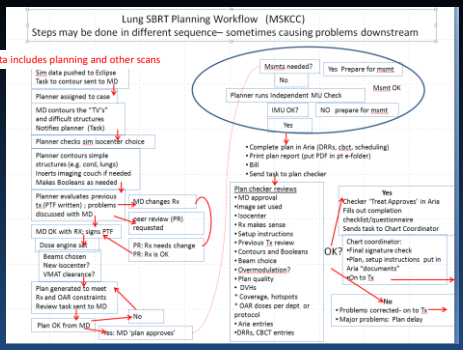
SBRT planning process from Eric Ford

Patient data includes planning and other scans

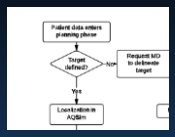


- Done as a project by 2 Physics Residents
- Took ~ a month
- Sent to Department Committee for risk analysis and risk mitigation design
- This process map was used for a true clinical FMEA

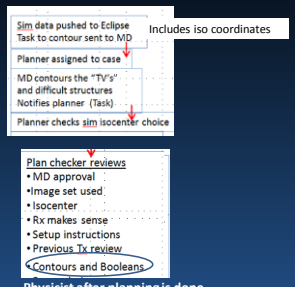
My perception of my department's workflow for lung SBRT planning



Two immediately notable differences (there are others)



MD before planning starts



Physicist after planning is done

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

Table 1. Example scoring system of severity, frequency of occurrence, and detectability for input into failure mode and effects analysis

Score	Severity	Occurrence	Detectability
1	No effect	Less than every 5 years	
2	Dose Δ5%	Every 2–5 years	Very easy to detect
3		Once a year	
4	Minimal delay in care	Several times a year	Easy to detect
5		Once a month	
6	Allergic reaction; moderate delay in care	Several times a month	Mildly difficult to detect
7		Once a week	
8	Dose Δ20%, reportable	Several times a week	
9		Once a day	
10	Patient dies	Several times a day	Impossible to detect

O, S, D scoring from Ford et al

Table II. Descriptions of the O, S, and D values used in the TG-100 FMEA

Rank	Occurrence (O)		Severity(S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01%	No effect		0.01
2		0.02%	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05%			0.5
4		0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5%			5.0
7		<1%	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2%			15
9		<5%	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5%	Catastrophic		>20

O, S, D scoring from TG-100

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

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

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

FMEA on SBRT Planning: Failure Modes (63)

Failure Mode / Cause	Severity	Occurence	Detectability	RPN
SBRT dose constraints not update *Attendings use the generic template (e.g. not include re-irradiation)*	8	7	6	336
Contours not cleaned *Forget or not realize to clean contours (tiny piece of structure not cleaned)*	7	6	8	336
Miscommunication about re-irradiation cases *Attendings do not communicate with Dosi about previous radiation*	7	7	6	294
Wrong scan protocol used (e.g. helical vs. avg) *Unclear direction to Sim esp. with different physicians*	7	8	5	280
Wrong primary image set *Sim put wrong primary image set*	7	8	4	224
Wrong primary image set *Physicians choose the wrong one*	7	5	6	210
Wrong trial sent to MOSAIQ *Multiple trials in the plan*	8	6	4	192
Wrong normal tissue structures used *Multiple or no final version determined*	6	7	4	168
Whole team not aware of pacemaker *Attendings do not inform the team*	8	6	2	96
Whole team not aware of pacemaker *Attendings do not know (do not ask in consult or patients do not know)*	8	6	2	96

Grading scheme of Ford et al

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From Eric Ford Resident's exercise

FMEA on SBRT Planning: Failure Modes (63)

Planner and MD do not consider re-Irradiation;O~ 5

Incorrect contours; estimate D~6

O ~4, D ~ 7; replace scan protocol by reconstruction

Wrong plan finalized in Aria: I'd reverse O and D Same RPN

An O of 3-4 in my experience

In my dept the Planner chooses

Failure Mode / Cause	Severity	Occurence	Detectability	RPN
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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**)

Physics Contribution

Failure Mode and Effect Analysis for Delivery of Lung Stereotactic Body Radiation Therapy

Julian R. Perks, Ph.D., Sinisa Stanic, M.D., Robin L. Stern, Ph.D., Barbara Henk, R.N., M.S.N., Marsha S. Nelson, R.N., M.B.A., Rick D. Harse, R.T.T., Mathew Mathai, B.S., C.M.D., James A. Purdy, Ph.D., Richard K. Valicenti, M.D., M.A., Allan D. Siefkin, M.D., and Allen M. Chen, M.D.

University of California Davis Medical Center, Sacramento, CA

Received Mar 22, 2011, and in revised form Aug 29, 2011. Accepted for publication Sep 12, 2011

Summary

This was a practical study for quality improvement in stereotactic body radiation therapy delivery using an industry-standard model. A failure mode and effects analysis (FMEA) was performed, with the results being implemented to reduce the risk of a treatment incident at several steps along the treatment chain. The study was specific to a clinical practice that treats non–small-cell lung cancer, using abdominal compression for motion management. However, the process of the FMEA was documented in detail to enable other users of high-dose-per-fraction radiotherapy to perform their own analyses, with the aim of quality improvement and error reduction.

Purpose: To improve the quality and safety of our practice of stereotactic body radiation therapy (SBRT), we analyzed the process following the failure mode and effects analysis (FMEA) method.

Methods: The FMEA was performed by a multidisciplinary team. For each step in the SBRT delivery process, a potential failure occurrence was defined and three factors were assessed: the severity of the consequence to the patient, the probability of the occurrence, and the ability to detect the occurrence in time for it to be stopped before reaching the patient. A rank of 1 to 10 was assigned to each factor, and then the multiplied ranks yielded the relative risks (risk priority numbers). The failure modes with the highest risk priority numbers were then considered to implement process improvement measures.

Results: A total of 28 occurrences were derived, of which nine events scored with significantly high risk priority numbers. The risk priority numbers of the highest-ranked events ranged from 27 to 80. These included incorrect use of the stereotactic coordinates and machine failure.

Conclusions: Several areas of our SBRT delivery were reconsidered in terms of process improvement, and safety measures, including treatment checklists and a surgical time-out, were added for our practice of gantry-based image-guided SBRT. This study serves as a guide for other users of SBRT to perform FMEA of their own practice. © 2012 Elsevier Inc.

Keywords: Failure mode and effects analysis; Stereotactic body radiation therapy; Quality assurance; Safety; Process improvement

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(collected by Jennifer Johnson)

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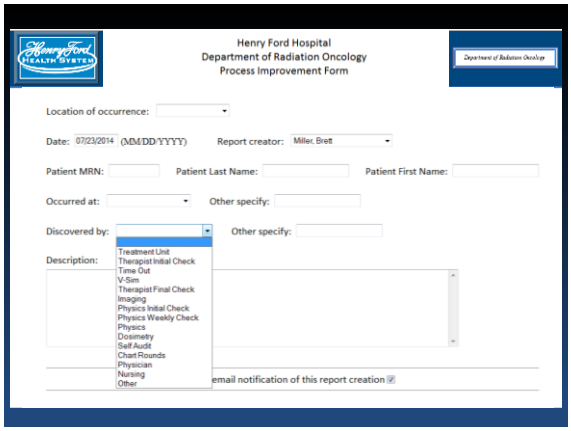
Quality and Safety in Radiation Therapy

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

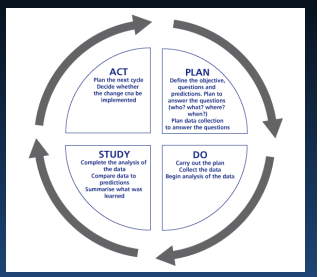
Root Cause Analysis

- 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

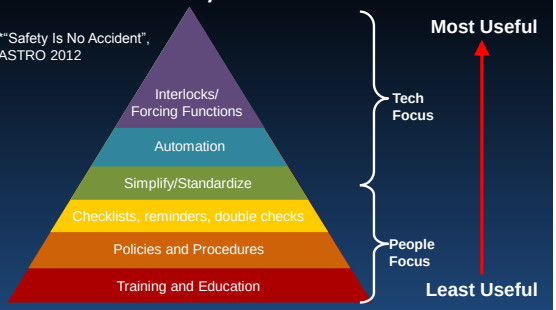
Implement change:

- 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



AAPM 2013, B. Miller, et al

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

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

Subject:	**Exact™ Couch Trapping Zones (pinch points)**
Title	Cannot Image an Unscheduled Plan in 4D ITC v10.1
Subject:	**Wedges May Separate from Wedge Tray**
Subject:	Risk of gantry collision with a patient during automated treatment including couch rotation
Subject:	Possible incorrect position of RT structures and isocenters after DICOM "Full Export"
Title	**Acquisition of Couch Parameters for Multi-Isocenter Plans On The 4D Integrated Treatment Console**

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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.

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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

AAPM 2013, B. Miller, et al

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?

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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

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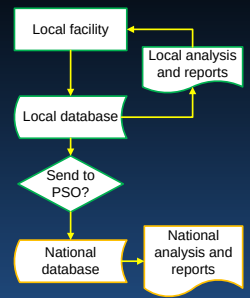
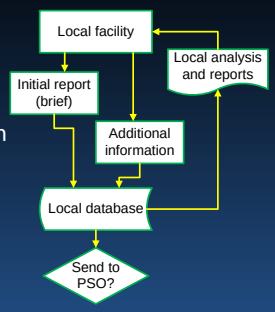
Basic data flow

- 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 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

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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

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What does it cost?

- No cost to join or participate
- No IT overhead
- Time commitment to collect, upload, and respond to reports

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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

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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

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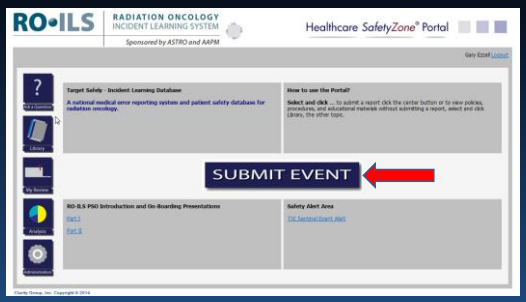
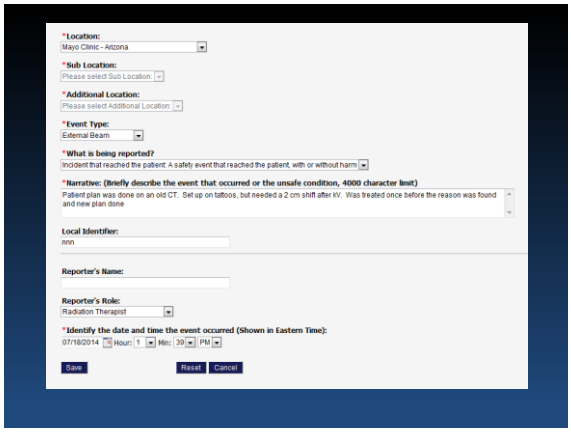
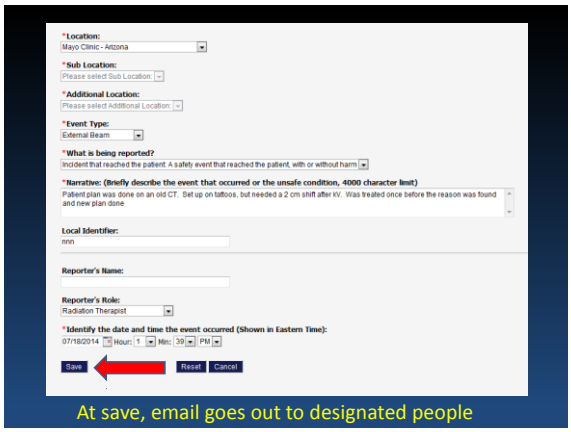
Initial report

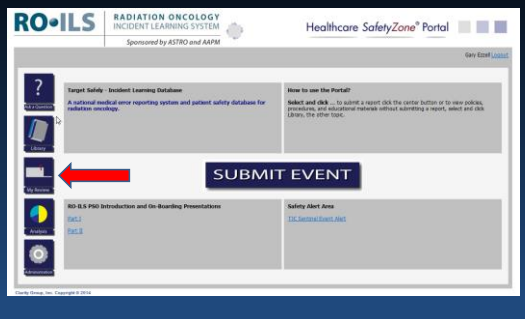


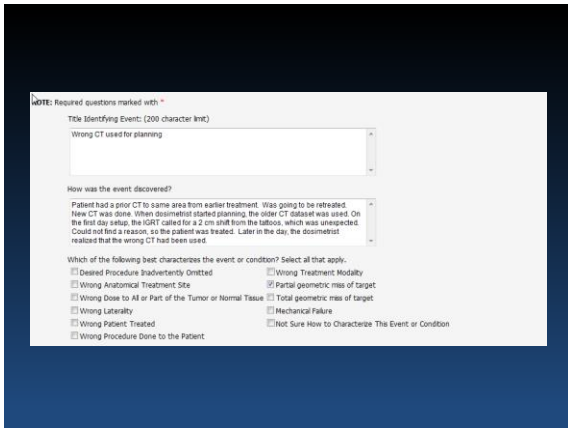


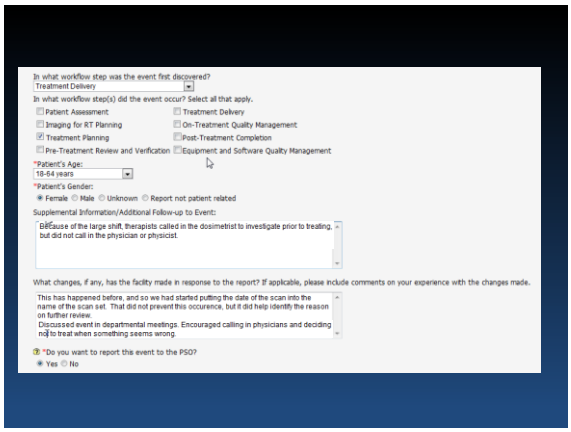


At save, email goes out to designated people

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

#	Submitted Date	Last Name	SubLocation	EventType	Short Description of Event: (200 character limit)
1399	06/27/2014			Brachytherapy	Possible improper insertion of HDR treatment catheter for vaginal cylinder treatment
1398	06/27/2014			External Beam	Previous radiation treatment not considered
1359	06/13/2014			External Beam	Resim, not replan, needs new DRRs
1358	06/13/2014			External Beam	Wrong contrast orders for simulation
1357	06/13/2014			External Beam	Emergency PA field too deep
1277	05/09/2014			External Beam	Gantry rotation to 180
1189	04/15/2014			External Beam	Wrong mark used for planning (DUPLICATE: same as 1184)
1184	04/14/2014			External Beam	Wrong BB chosen for isocenter
1160	03/13/2014			External Beam	Wrong sim orders for brain treatment
1136	02/21/2014			External Beam	Modified treatment field not started on time
1135	02/21/2014			External Beam	Separation measured in error during emergency treatment
1134	02/21/2014			External Beam	Field missed for treatment
1132	02/20/2014			External Beam	Wrong CT used for planning
1131	02/20/2014			External Beam	Defibrillator patient treated with IBX

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

RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM Sponsored by ASTRO and AAPM

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
- **Benedick A. Fraass, PhD**
  Cedars-Sinai Medical Center
- **David J. Hoopes, MD**
  David Grant Medical Center
- **Theresa Kwiatkowski, CMD, RT**
  Rochester General Hospital
- **Kathy Lash, RT**
  University of Michigan
- **Gregory Patton, MD, MBA, MS**
  Compass Oncology

RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM Sponsored by ASTRO and AAPM

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

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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.

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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.

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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

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How do I start?

- Links on the AAPM and ASTRO websites

http://www.astro.org/ROILS

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SAMS QUESTIONS

Which report contains recommendations for safe practices in stereotactic body radiotherapy?

8% 1. AAPM TG-176
33% 2. AAPM TG-101
8% 3. ASTRO "Safety is No Accident" report
42% 4. WHO "Radiotherapy Risk Profile" report
8% 5. None of the above

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

Reference: Benedict et al. "Stereotactic body radiation therapy: The report of AAPM Task Group 101", Med Phys, 37(8), 4078-4101 (2010)

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

15% 1. Failure Mode and Effect Analysis
5% 2. Near-miss incident learning
20% 3. Root cause analysis
10% 4. Field change order tracking
15% 5. Forcing functions

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

Reference: Zeitman, Palta and Steinberg, "Safety is No Accident: A Framework for Quality Radiation Oncology and Care", ASTRO; 2012

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

14% 1. occurrence and difficulty of detecting it

9% 2. occurrence, potential consequences, and difficulty of detecting it

5% 3. occurrence, potential consequences, difficulty of detecting it, and cost to prevent it

14% 4. occurrence, ease of detection, and who was at fault

5% 5. potential consequences if it does affect the patient

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 detectir 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

References:

Thomadsen B, Dunscombe P, Ford E, et al., editors. Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond. Madison, WI: Medical Physics Publishing; 2013. Chapters: Chs 3,4,9

Ford EC, Gaudette R, Myers L, et al. Evaluation of Safety in a Radiation Oncology Setting Using Failure Mode and Effects Analysis. International Journal of Radiation Oncology Biology Physics 2009;74:852-858

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

7% 1. To be helpful, it must be performed for the entire clinical process at once.

7% 2. It is better for physicians to not be involved in doing an FMEA.

10% 3. It can be useful if performed for well-defined clinical sub-processes

17% 4. Once an FMEA is performed, it need not be re-evaluated for at least three years

14% 5. FMEA should be done only for high-risk clinical processes

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

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Reference: Thomadsen B, Dunscombe P, Ford E, et al., editors. Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond. Madison, WI: Medical Physics Publishing; 2013. Chapters: Chs 3,4,9

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

10% 1. Identify basic causes of the highest risk failure modes and design mitigation procedures.

10% 2. Enter the highest risk failure modes into an ILS

7% 3. Immediately go on to another clinical process and perform another FMEA

23% 4. Go out for a beer

10% 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:

1. **Identify basic causes of the highest risk failure modes and design mitigation procedures.**
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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

Reference: Thomadsen B, Dunscombe P, Ford E, et al., editors. Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond. Madison, WI: Medical Physics Publishing; 2013. Chapters: Chs 3,4,9

When performing root cause analysis of an incident:

13% 1. Make sure to intimidate staff to get the best information possible

13% 2. Identify the process step where an incident occurred, the failure mode and the failure pathway

10% 3. Developing a process map will most likely not be of help

17% 4. Implement corrective action only if absolutely necessary

7% 5. There is no need to monitor activity as long as corrective action is implemented

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Reference: Thomadsen B, Dunscombe P, Ford E, et al., editors. Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond. Madison, WI: Medical Physics Publishing; 2013. Chapters: Chapter 6

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

10% 1. Add checklist item to physics chart check

10% 2. Educate staff on the proper way to do an initial chart check

3% 3. Require physician to digitally approve a plan before it can be treated

17% 4. Use software to determine if a planned DVH meets physician constraints

7% 5. Update policies and procedures and distribute to staff

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4. **Use software to determine if a planned DVH meets physician constraints**
5. Update policies and procedures and distribute to staff

Reference: Vaida AJ. Medication error prevention "toolbox". Medication safety alert: Institute for Safe Medical Practices; 1999.

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

3% 1. More frequent state inspections.

13% 2. More frequent lawsuits.

13% 3. Time committed to the effort, but no fee to participate.

3% 4. Additional firewalls and specific IT needs.

17% 5. Higher staff turnover because of all the fault-finding.

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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?

13% 1. Only academic centers with surplus staff.
20% 2. Individual physicists, independent of any employer.
10% 3. Only facilities with multiple sites.
20% 4. Hospital-based and free-standing centers.
27% 5. Nobody yet.

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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

Which of the following is true about data submitted to the RO-ILS program:

13% 1. It is confidential and privileged.
7% 2. It is subject to Freedom of Information Act requests.
3% 3. It can be used to avoid state reporting requirements.
10% 4. It is available in raw form for all participants to search.
7% 5. It can be accessed via Facebook and Twitter.

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Quality and Safety in Radiation Therapy

SAMs Session

AAPM Annual Meeting, Austin, TX
Thursday