# Using Event Reporting to Improve Patient Safety

## SAMs Session

*AAPM 2015 Spring Clinical Meeting, St. Louis, MO*

Sunday 7:30-9:30 am

*March 8, 2015*

# Using Event Reporting to Improve Patient Safety

*Case Studies*

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# Case Study List

1. Radiopharmaceutical (NRC)
2. HDR (NRC)
3. Software (my institution)
4. Communication (ROILS)
5. Contouring (ROILS)

# Recalling your regs…

- NRC collects reports from medical byproduct use:
  - Radiopharmaceutical
  - HDR (Ir-192)
  - Cobalt delivery (e.g. GammaKnife)
- ROILS collects ALL incidents
- These two things are not mutually exclusive

# Example Case 1A: Radiopharmaceutical

Problem: Patient pregnant during ablative therapy

- On Dec 11th, 2014, patient received thyroid ablation therapy (97mCi of I-131)
- On Dec 29$^{th}$, patient reported to medical center that she was pregnant on day of treatment (4 weeks)
- Calculated dose to uterus 20.4 rad
- Reportable event – unintended exposure

Cause: Unknown/unconfirmed pregnancy

# Example Case 1A: Radiopharmaceutical

Corrective Actions

- Review counseling/consent with patient
- Possible RX of birth control or alternate means for patients of child-bearing age

Lessons learned

- You can’t control the patient!

# Example Case 1A: Radiopharmaceutical

**Table 1** Summary of events reported from January 1, 2009 to December 31, 2010

| Type of dose delivery (No. of events) | Type of error (No. of events) | Isotope (No. of events) |
|---|---|---|
| Gamma Knife (13) | Wrong site (7) | Co-60 (7) |
| | Wrong dose (5) | Co-60 (5) |
| | Unintended exposure (1) | Co-60 (1) |
| RP (34) | Wrong site (2) | I-125 (1) |
| | | Y-90 (1) |
| | Wrong dose (22) | I-131 (9) |
| | | Y-90 (13) |
| | Unintended exposure (8) | I-131 (8) |
| | Other (2) | P-32 (1) |
| | | Y-90 (1) |

- 6 cases of unintended exposure to the fetus
  - In 4 of those, the patient tested negative directly before treatment
- In 2 cases, the patient was already pregnant
  - one was approximately 6 months along when she received her therapy

**S Richardson**. A two year review of recent NRC events – What errors occur in the modern brachytherapy era? *Pract Rad Onc*, Vol 2(3), 157–163, 2012.

# Example Case 1B: Radiopharmaceutical

Problem: Wrong patient administered therapy

- Dec 17, 2014- patient received 150 mCi instead of prescribed 30 mCi

- Cause: the patient was misidentified

# Example Case 1B: Radiopharmaceutical

Corrective Actions

- JCAHO time out training – 2 identifiers
- Two individuals read vial/activity

Lessons learned

- Patients can (and will) have the same name
- Labels can be switched even from vendor! Buyer beware.

# Radiopharmaceutical examples

**Table 1** Summary of events reported from January 1, 2009 to December 31, 2010

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| | Wrong dose (22) | I-131 (9) |
| | | Y-90 (13) |
| | Unintended exposure (8) | I-131 (8) |
| | Other (2) | P-32 (1) |
| | | Y-90 (1) |

- Five cases involved the wrong dose of radiation being administered to an I-131 ablation patient.
  - Switched vials
  - Ordered wrong dose

**S Richardson**. A two year review of recent NRC events – What errors occur in the modern brachytherapy era? *Pract Rad Onc*, Vol 2(3), 157–163, 2012.

# I Cannot get left!

“Hey look kids, there's Big Ben, and there's Parliament... again.”

# What to learn

- Never get comfortable
- Some factors are beyond control
- Mistakes differ depending on workload
  - Few patients
    - What are we supposed to do?
    - Lack of knowledge, practice
  - Many patients
    - Switching of vials
    - Confusing prescriptions
    - Communication transfer/split shift work
- What can we do about it?

# Example Case 2A: HDR

Problem: Patient received overdose during HDR brachytherapy treatment

- Dec 2, 2014, patient received Ir-192 HDR brachytherapy treatment to the vaginal cuff with a single channel cylinder
- Prescription- 3 cm cylinder, 400cGy. Treated: 5cm cylinder, 700cGy
- Cause: the next patient's plan was being reviewed on the workstation, that plan initiated/treated
- Cause (2): Patient's identification was not verified

# Example Case 2A: HDR

Corrective Actions

- Identify patient
- Appropriate time out can include dose and applicator
- Engage other people on your team

Lessons learned

- Working ahead can get you in trouble!
- Don’t multi-task
  - At least in highly dangerous situations

# Example 2B: HDR

Problem: Stuck HDR source/unintended exposure

- Staff performing daily QA on HDR after loader when source became stuck in the ‘safe’ position
- When vendor RSO attempted to free source, it because stuck in unshielded position
- Service manager used hand crank used to return source to normal positioning.
- RSO received approximately 9mR, manager received 27mR.

# Example 2B: HDR

Problem: Stuck HDR source/unintended exposure

- Cause:
  - Service Engineer had just performed the routine source exchange
    - failed to perform or performed incorrectly one step*
    - Source became stuck
    - Physicist is “blind” to this procedure
  - Engineer received retraining from company*

**Per telephone conversation with company representative*

# Example Case 2B: HDR

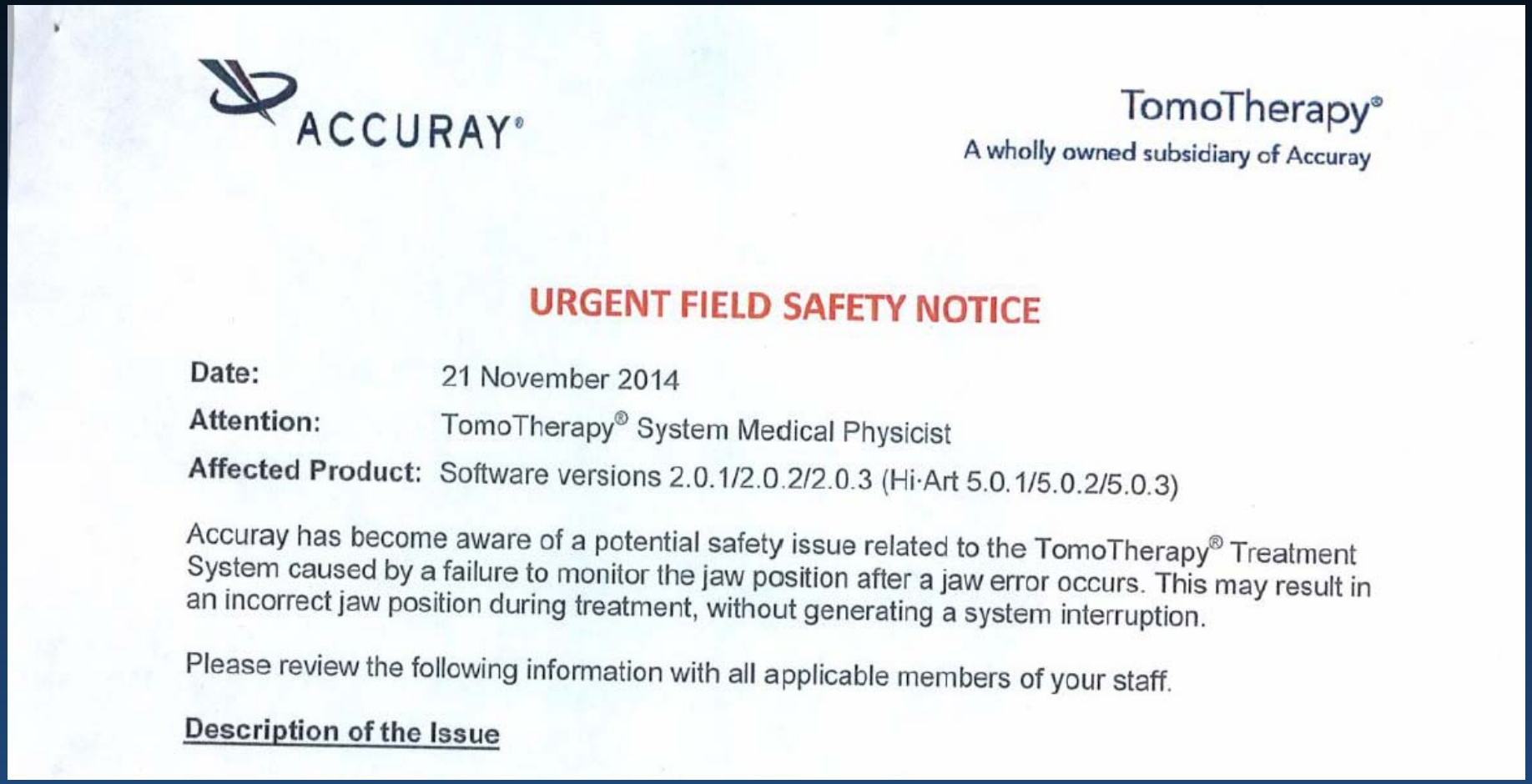
Corrective Actions

- Test your equipment regularly, thoroughly, excessively (?).

Lessons learned

- Don’t assume things will work because a vendor touched it last

# Example Case 3: Software/Hardware



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**URGENT FIELD SAFETY NOTICE**

**Date:** 21 November 2014

**Attention:** TomoTherapy® System Medical Physicist

**Affected Product:** Software versions 2.0.1/2.0.2/2.0.3 (Hi·Art 5.0.1/5.0.2/5.0.3)

Accuray has become aware of a potential safety issue related to the TomoTherapy® Treatment System caused by a failure to monitor the jaw position after a jaw error occurs. This may result in an incorrect jaw position during treatment, without generating a system interruption.

Please review the following information with all applicable members of your staff.

**Description of the Issue**

# Example Case 3: Software/Hardware

- “On rare occasions, a jaw communication issue may occur and the jaws will not perform any further planned movement.”

# Example Case 3: Software/Hardware

- A communications issue causes the jaw monitoring system to stop monitoring the jaw position. The jaws will then remain stationary for the remainder of the procedure.
- Upon investigation of our machine log files, Accuray determined that this had occurred during the treatment of one of our patients for one of her 5 beams
- Only occurred on 1 fraction out of 28

# Example Case 3: Software/Hardware

- the effected field was essentially a PAB field treating the elective nodal region of a breast patient.
- The offset was luckily only 1 cm from where it should be.
- 40% underdose for that particular beam

# What to learn?

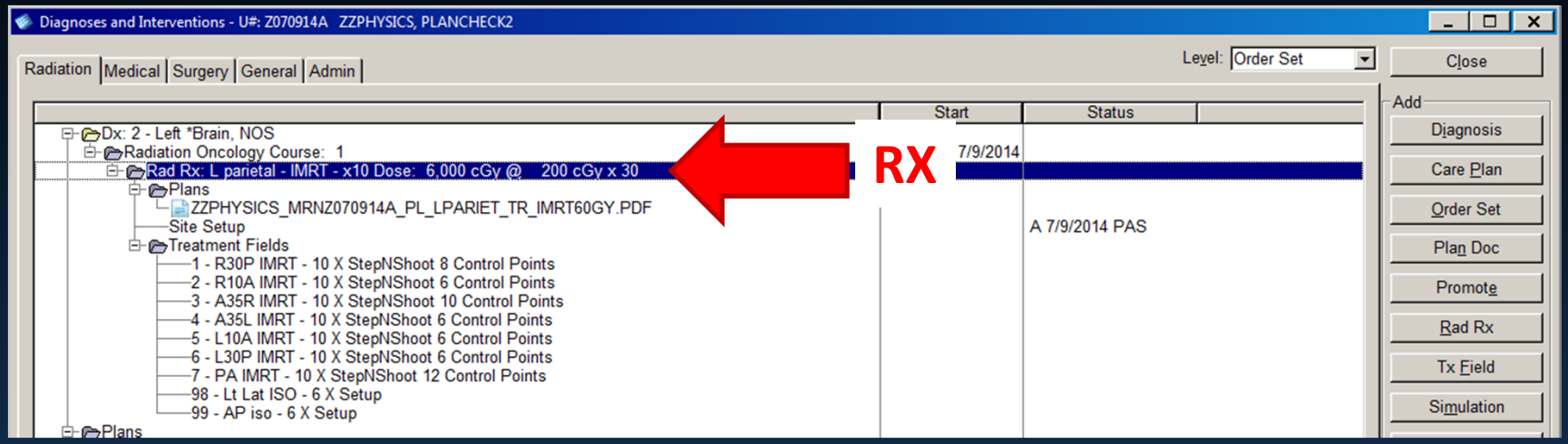
- Software not infallible
- IMRT QA does not catch everything*
- Daily monitoring of MLCs, delivery, etc important

# Example Case 4: Communication

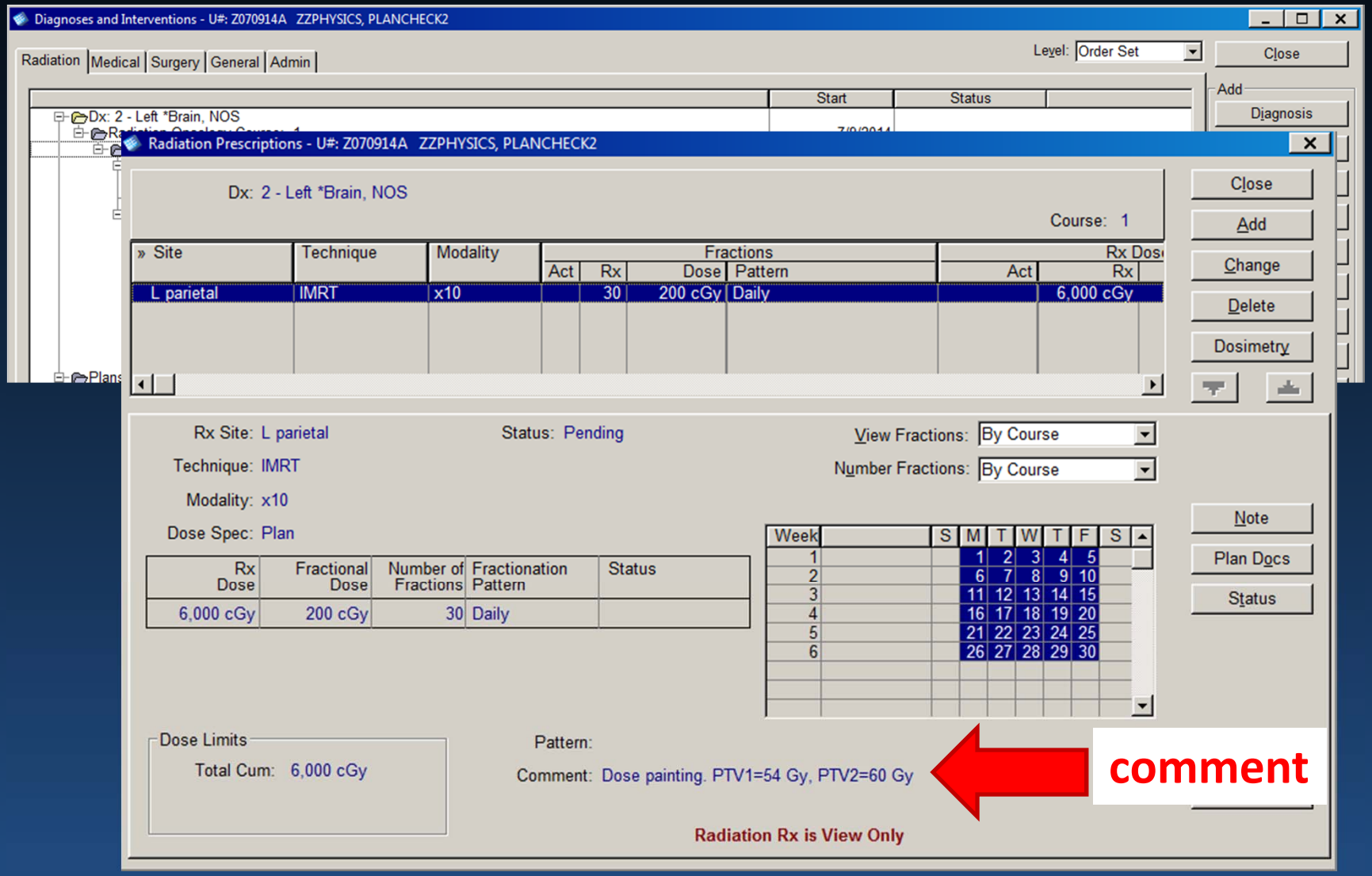
Problem: Miscommunication about physician intent & fractionation scheme

- Patient receiving IMRT treatment
- Physician intends a simultaneous integrated boost (“dose painting”) and indicates this in prescription
- Treatment planner does not notice this

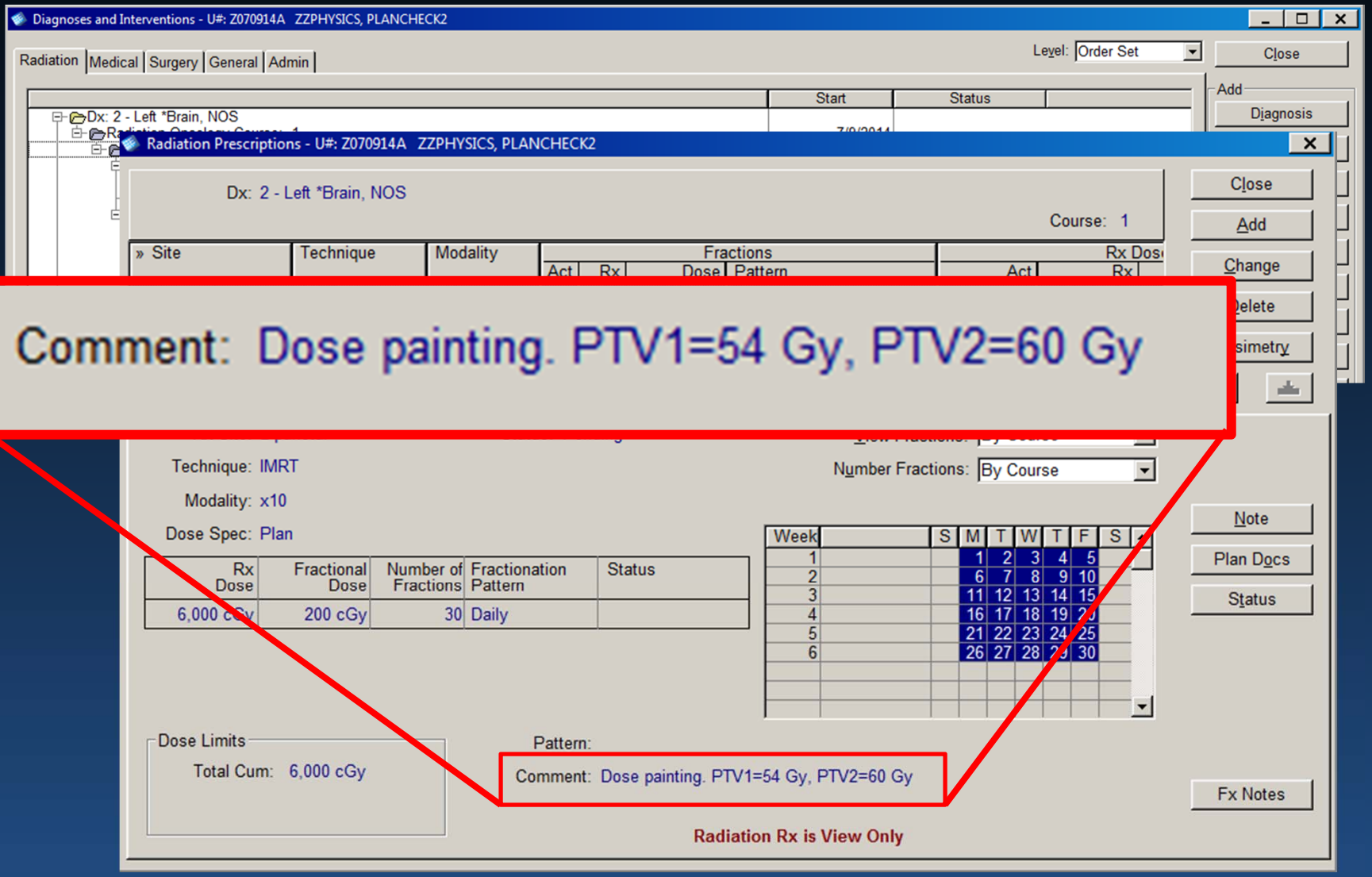
# Example Case 4: Communication



# Example Case 4: Communication



# Example Case 4: Communication



# Example Case 4: Communication

Problem: Miscommunication about physician intent & fractionation scheme

- Patient is planned to 60Gy only
  - no dose painting
- Plan approved by physician
- Plan approved by physicist
- Treatment begins

# Example Case 4: Communication

Problem: Miscommunication about physician intent & fractionation scheme

- On 3rd treatment fraction physicist notes the discrepancy on a weekly physics chart check

# Example Case 4: Communication

Lessons learned

- Communication is essential
- Software design does not promote optimal communications in this case
- Multiple missed opportunities (QA barriers)

# Example Case 4: Communication

Corrective Actions

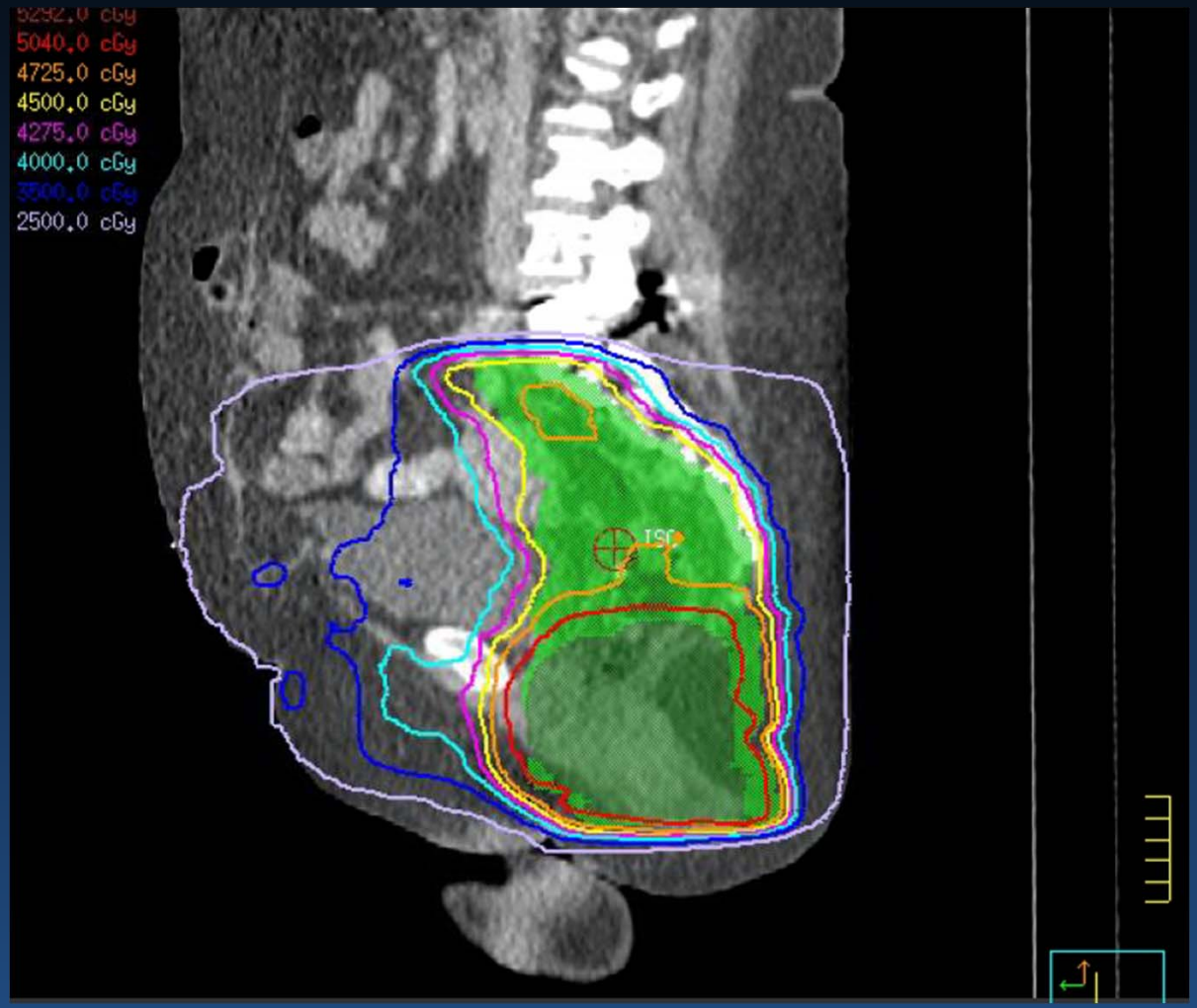
- Clinic uses a physics checklist for new plans
- Checklist modified to include checking the MD notes section of the prescription

# Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

- Patient receiving IMRT for rectal cancer.
- 180x25 followed by 180x3 boost

# Example Case 5: Contouring



# Example Case 5: Contouring

- Resident contours targets and normal tissues in TPS (Pinnacle). Makes “PTV45” and “PTV50”
- Sends study to MIM. (Standard practice).
- Attending reviews contours in MIM, modifies them, deletes resident contours and sends back to TPS

# Example Case 5: Contouring

- TPS now has two sets of contours:
  - “PTV45”, “PTV50” (resident)
  - And “PTV45_1”, “PTV50_1” (attending)
- Treatment planner picks up the case
- Deletes “PTV45_1” and “PTV50_1” volumes
- Plans the case

# Example Case 5: Contouring

- While reviewing final plan in TPS, attending notes that nodal volumes should extend ~4 cm superiorly.
- Plan modified and treated as intended.

# Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

Lessons learned

- Multiple hand-offs (and multiple software packages) can contribute to error
- Residents now label contours with their initials

# Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

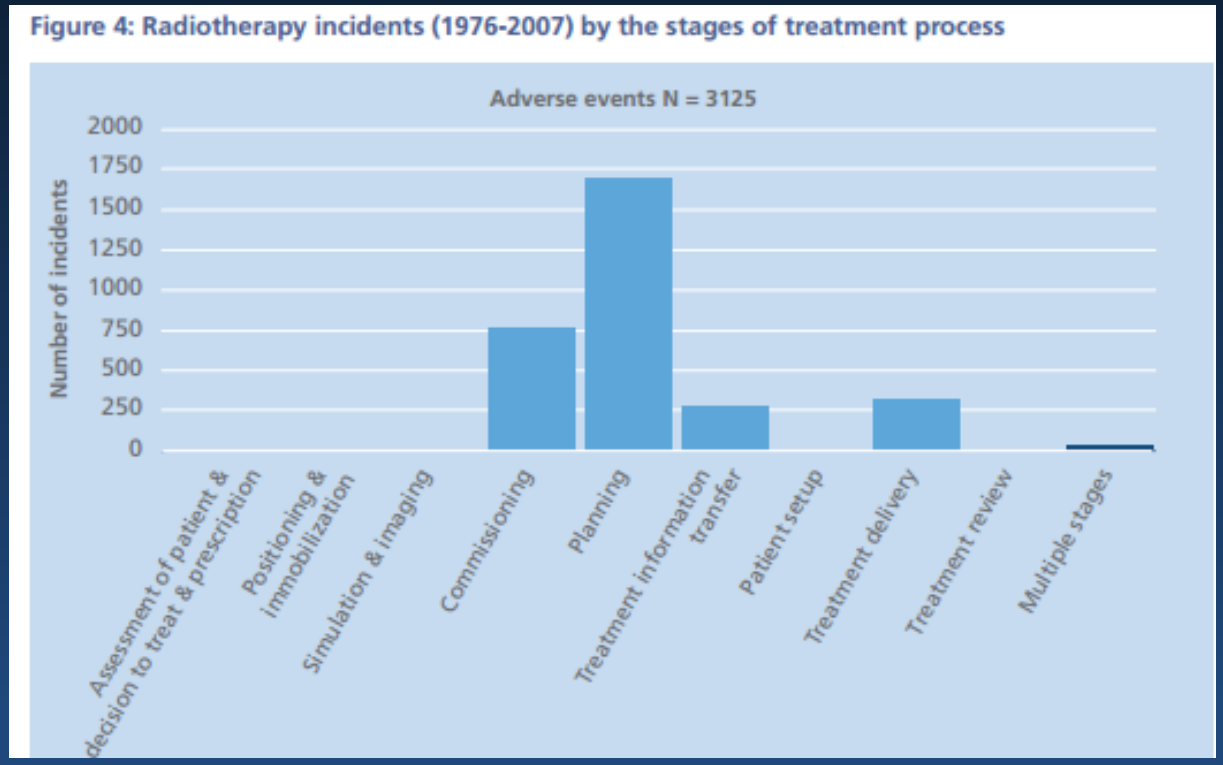
<u>Corrective Actions</u>

- Residents now label contours with their initials

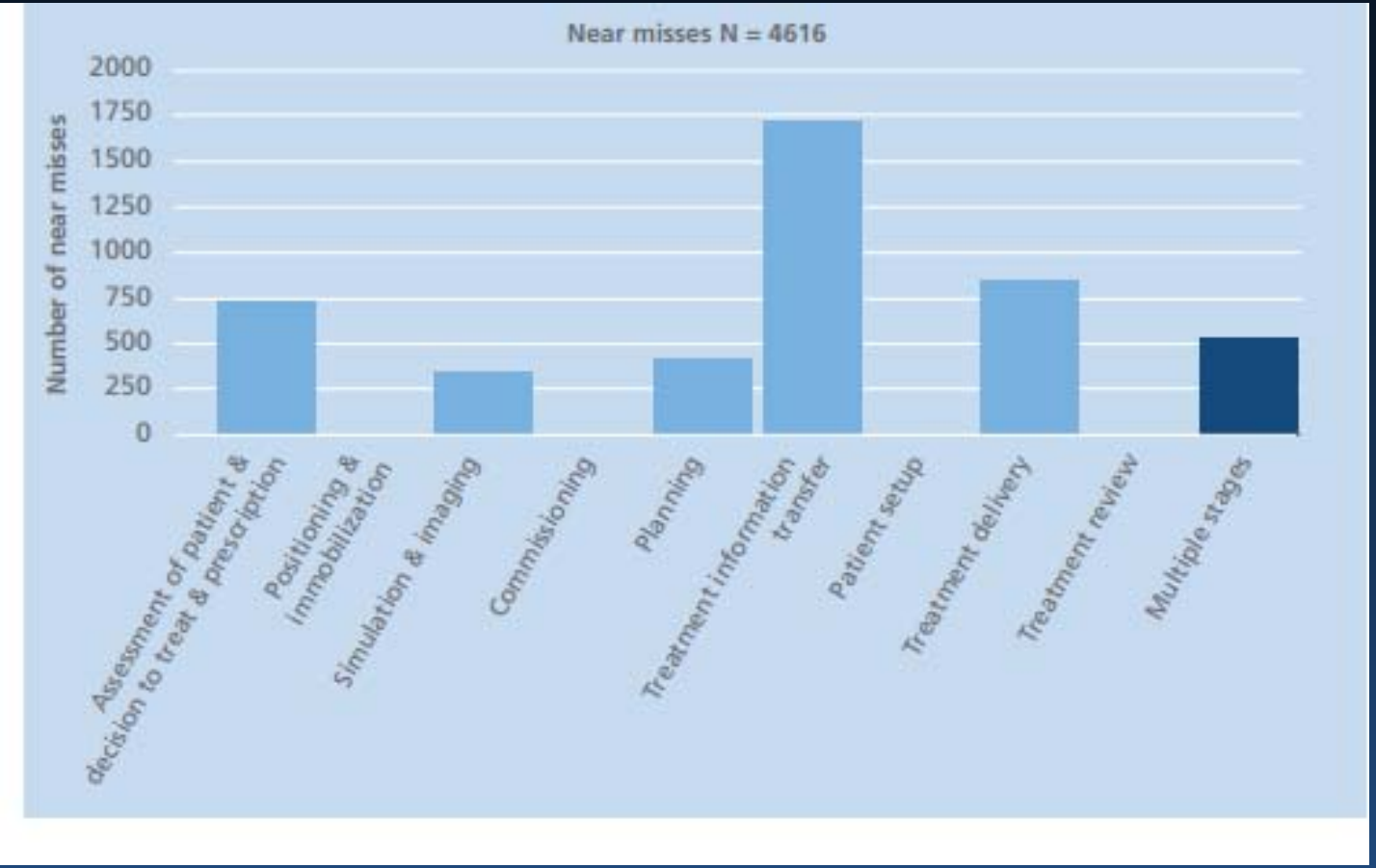
- Standardized nomenclature can help! (TG262)

# Where in the process? Adverse events

- http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf



# Where in the process? Near Misses



# Causes: Linac based errors in NY

The Radiation Safety Journal

**Table 1. NYSDOH LINAC medical events — Causes and contributing factors and staff involved (2001–2009).[a]**

| Cause and contributing factors and staff involved | Frequency of occurrence (%) (N=228) |
|---|---|
| Inadequate QA (Failure to follow policy and procedures) | 145 (63.6%) |
| Documentation/communication error (includes verbal, hardcopy and data flow) | 53 (23.2%) |
| Inadequate policy and procedures (lack of established QA protocols) | 35 (15.4%) |
| Equipment malfunction | 17 (7.5%) |
| Inadequate training | 2 (0.9%) |
| Staff shortage | 4 (1.8%) |
| Physics/dosimetry error | 62 (27.2%) |
| Therapist error | 193 (84.6%) |
| Radiation oncologist error | 28 (12.3%) |

[a]Note: Cause/Contributing Factors add up to more than 228 events and percentages add up to >100% because QA practice has redundancy. Most often, multiple failures result in an event.

Krishnamoorthy J, et al. An Analysis of Radiation Therapy Medical Events in New York State: the Role of the State Radiation Programs in Patient Safety. *The Radiation Safety Journal*, 2014.

# Databases/Resources

- NRC – Nuclear Material Events Database (nrc.gov database)
- http://www.othea.net/ (European incident database)
- http://cars-pso.org/ (Radiotherapy Incident and Analysis System)
- ROILS – Astro.org
- S Richardson. A two year review of recent NRC events – What errors occur in the modern brachytherapy era? *PRO* 2012.
- Krishnamoorthy J, et al. An Analysis of Radiation Therapy Medical Events in New York State: the Role of the State Radiation Programs in Patient Safety. *Rad Safety Journal*, 2014.
- Yorke E, et al. Patient Safety in External Beam Radiation Therapy. *Amer Jour Roent*, 2011.
- Arnold A, et al. The use of categorized time-trend reporting of radiation oncology incidents: A proactive analytical approach to improving quality and safety over time. *IJROBP,* 2010.

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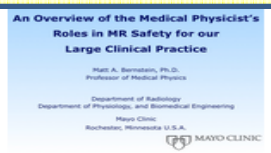


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An Overview of the Medical Physicist's Roles in MR Safety for (our) Large Clinical Practice
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2014 AM
Case Review of Real MRI Safety Incidents
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2014 AM
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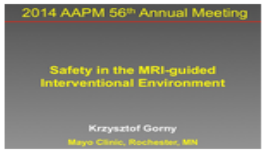


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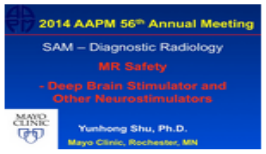


2014 AM
MRI Safety of Deep Brain and Other Stimulators
Presented by Yunhong Shu PhD


2014 AM
Quality and Safety in Radiation Therapy
Presented by Brett Miller MS

100+ Virtual library presentations!

# If a medical event is reported to the NRC or state:

20% 1. It cannot be entered in to RO-ILS

20% 2. The data entered must be exactly the same to the NRC or state

20% 3. It can also be entered into RO-ILS but should be de-identified

20% 4. The NRC will automatically send it to RO-ILS

5. Only near misses are reported to RO-ILS, not actual events

# Incidents that can be submitted to RO-ILS include:

20% 1. Only those due to reports from manufacturers (e.g. customer technical bulletins)

20% 2. Only due to errors involving human factors engineering

20% 3. Only involving external beam incidents

20% 4. Only involving brachytherapy

5. Any event involving radiation therapy (near miss or actual events

# The NRC collects information regarding what types of events?

20% 1. Only those due to reports from manufacturers (e.g. customer technical bulletins)

20% 2. Only medical events involving external beam incidents

20% 3. Near misses and medical events involving brachytherapy

20% 4. Only medical events involving medical byproduct use

5. Any event involving radiation therapy (near mi or actual events)