SRS/SBRT Errors and Causes

Ryan Foster, Ph.D.
Department of Radiation Oncology
Levine Cancer Institute
Atrium Health NorthEast
Concord, NC

Disclosures

• Nothing to disclose.
Outline of Presentation

- Introduction
- Summary of accidents and misadministrations
- Resources and guidance
- Conclusions

Learning Objectives

- To learn from previous accidents and misadministrations during SRS/SBRT
- To understand the types of errors that can occur
- To understand how to prevent these errors from happening to you!
What are the sources of errors?

Figure 4: Radiotherapy Incidents (1976-2007) by the stages of treatment process

WHO Radiotherapy Risk Profile 2008

Updated source for this information

Q1 2018 | Q2-2018: Workflow Step Where Event Occurred

ROILS reports available at https://www.astro.org/RO-ILS-Education.aspx
Communication is key!

ANALYSIS & COMMENTARY

INTRODUCTION
This inaugural report contains case studies derived from events submitted to RO-ELS. Radiation Oncology Event Learning System. This report contains the broadened themes of the treatment planning process and hand off during transitions of care. It highlights an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ELS.

FEATURED THEME: TREATMENT PLANNING PROCESS
The treatment planning process is a team-oriented activity performed by multiple individuals. The physician-physician interaction is at the heart of the process, which is most often a documented one in some centers. This is the medical physicist and the clinical staff. The radiologist and other members of the radiation oncology team, but in general remains the following steps and include multiple transfer of studies:

1. Clinical staff report and propose simulations (using data set,
2. The physician selects the target(s),
3. The planner creates the plan(s) of care (OPA/TPA),
4. The physician documents target and normal tissue goals and constraints for the planner,
5. The planner generates a treatment plan,
6. The physician reviews the plan,
7. The physician gives plan feedback to the planner and
8. If necessary the planner reviews the treatment plan to achieve a plan that better manages the compromise between target dose and normal tissue sparing.

Given the complexity of the planning process and the number of times that a setup is passed back and forth between the physician and planner, it is obvious that clear, accurate, timely and effective documentation and communication is necessary. This is important to ensure that the patient is adequately treated, that potential health risks are not overlooked, and that lessons learned are transferred to prevent future errors. The following summary of RO-ELS data provides insight into these events that occurred during treatment planning.

Significance of events

Figure 2 shows RO-ELS data element “Significance Scale (225), “In terms of risk to patient safety, how significant was this event?” This data element was added to RO-ELS in the August 2016 data element update. Figure 2 depicts the percentage of events that occurred during treatment planning since Q3 2016 and the associated significance. As can be seen, approximately 17 percent of the data has been categorized as having moderate to severe significance.

#225. How significant was this event?

- Severe: 3%
- Unknown: 2%
- Moderate: 14%
- Minor: 80%

Figure 2: Significance of Events that Occurred During Treatment Planning (Q3 2016 - Q2 2018)
More communication!

Within the “Communication” category above, contributing factors are broken down into subcategories as displayed in Figure 5. The most common response is “Poor, incomplete unclear or missing,” followed by “Written documentation in EMR incorrect/incomplete/absent” and “Inadequate communication patterns designed.”

SUMMARY OF INCIDENTS
Small field commissioning

Radiation Errors Reported in Missouri

A study conducted by the Missouri State Radiation Control Division found that 71% of the 18,514 surveys conducted in the state were non-compliant with federal and state regulations. The survey was conducted in 2017 and involved 1,602 radiation devices.

**Radiation incident highlights the need to go above and beyond.**

This happened in France in 2007 and was reported in 2008!

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**FIGURE 3. 6-MV output factors at 10 and 80 cm for box collimator.**

**FIGURE 4. 6-MV output factors at 10 and 80 cm for box collimator.**

**FIGURE 5. 6-MV output factors at 10 and 80 cm for box collimator.**

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**Table 1. Comparison of output factors for different collimator sizes.**

<table>
<thead>
<tr>
<th>Collimator Size</th>
<th>Output Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 cm</td>
<td>0.93</td>
</tr>
<tr>
<td>20 cm</td>
<td>0.87</td>
</tr>
<tr>
<td>30 cm</td>
<td>0.82</td>
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</tbody>
</table>

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**Figure 1.** Diagram showing the relationship between output factor and collimator size. The output factor decreases as the collimator size increases.

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**Figure 2.** Graph illustrating the impact of collimator size on beam quality.

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**Figure 3.** Graph showing the variation of output factor with collimator size.

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**Figure 4.** Graph depicting the change in output factor with field size for different collimator sizes.

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**Figure 5.** Graph illustrating the relationship between output factor and field size for a given collimator size.
No communication

“A There were strong similarities between what happened in Missouri and what happened in Toulouse,” said Dr. Ola Holmberg, who heads the radiation protection unit for patients at the International Atomic Energy Agency.

But without a requirement that accidents and near-misses be reported, other hospitals cannot learn from these mistakes, Dr. Holmberg said.

“T There is no effective way now of sharing the information or learning in a systematic way,” Dr. Holmberg said. “If something happens, such as Evanston, I would have wanted to know about it at the time.”

The patients in Missouri could have been treated correctly if the incident in France had been more widely reported.

Small field measurement issues persist

detector. The response at different SSDs was within ±0.35% and ±0.26% with farmer chamber. For field sizes greater than 5x5cm², output factors measured with array chamber were within ±0.12% and ±0.17% with farmer chamber. However, for 2x2cm², the difference was 17.95% and 16.61%. In all the cases, array over-estimated the output factors. WFs measured with array were
### How do you know if your data is good? Compare with Other Institutions / Machines

<table>
<thead>
<tr>
<th>Field size (cm x cm)</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
<th>Proper 15 Gy</th>
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<td>(0.003)</td>
<td>(0.003)</td>
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<tr>
<td></td>
<td>(3.1%)</td>
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<td>(3.1%)</td>
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<td>(n=145)</td>
<td>(n=152)</td>
<td>(n=145)</td>
<td>(n=145)</td>
<td>(n=145)</td>
</tr>
</tbody>
</table>

Followill et al. JACMP 2012 and Erratum, JACMP Vol 15, No 2, 2014

### Improper Jaw Size During SRS

In 2004, physicist told therapist to set a “40x40” for cone SRS treatment; therapist set 40x40 cm²

Some normal tissue received more dose than the target; developed “fibrosis and oeso-tracheal fistula” requiring surgery; patient died from “brutal haemorrhage” a few days after surgery

Improper Jaw Size During SRS

This occurred in France in 2004!

Marc Faber was one of the three patients. She had gone to Evanston Hospital in Illinois seeking treatment for pain emanating from a nerve deep inside her head. Today, she is in a nursing home, nearly comatose, unable to speak, eat or walk, leaving her husband to care for their three young daughters.

SRS Cone Left Out

On June 5, 2012, the licensee notified the Agency that a medical event had occurred at its facility on June 5, 2012. A technician failed to insert a conical collimator prior to a stereotactic surgery procedure which had resulted in a dose being delivered to a patient that varied greater than 10% from the prescribed dose. An investigation into this event is ongoing.

File open.
State of Texas Response

- Appendix of Solberg et al. PRO 2011 provides excellent examples of checklists for SRS, SBRT, simulation and treatment planning.

But what’s even better than checklists?

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>MIB:</th>
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<tbody>
<tr>
<td>Date of Implant:</td>
<td>Target Area:</td>
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<tr>
<td>Rad Osteorad:</td>
<td></td>
</tr>
</tbody>
</table>

**SBRT Spine Worklist:**

- Markers for surgery (per neural foramen)
- Markers for needle (corrected) or MRI
- Level 1-5, MIB, or Pelvis

**Normal Tissue Constraints:**

- DVT (25% of PTU length)
- LTV (25% of PTU length)
- Nerve (25% of PTU length)
- Other Nerves (25% of PTU length)
- Abdominal Aorta (25% of PTU length)
- Renal Vein (25% of PTU length)
- Renal Artery (25% of PTU length)
- Liver (25% of PTU length)
- Bladder (25% of PTU length)
- Small Bowel (25% of PTU length)
- Large Bowel (25% of PTU length)

**But what’s even better than checklists?**

- FlexiCheck
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- FlexiCheck
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- FlexiCheck
**Interlocks!**

- Trigeminal nerve SRS on CyberKnife
- Patient referred for left side treatment
- Patient received 60 Gy to the right trigeminal nerve
- Oncologist and neurosurgeon approved plan
- Corrective action taken: Laterality signed/verified by radiation oncologist and attending physician on all new trigeminal neuralgia patients

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**Wrong side treated**

- Trigeminal nerve SRS on CyberKnife
- Patient referred for left side treatment
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- Oncologist and neurosurgeon approved plan
- Corrective action taken: Laterality signed/verified by radiation oncologist and attending physician on all new trigeminal neuralgia patients

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*Amy Carlson, FL DOH, http://hpschapters.org/florida/fallppts.htm*
Wrong Site SBRT

Summary
Stereotactic body radiation therapy (SBRT) that was meant for a patient’s malignant liver tumor was instead delivered to a benign tumor in a different part of the liver. The patient received the entire prescribed dose (50 Gy in 5 fractions) to the unintended liver lesion. Follow-up imaging was performed four months after the treatment and it was noted that the liver metastasis had increased in size. It was then discovered that the wrong lesion had been treated.

Root Cause
The gross tumor volume (GTV) contour initially created by a resident covered the wrong liver lesion (a benign hemangioma instead of the metastasis). During the approval of the GTV contour by the prescribing physician, a check against the primary diagnostic imaging was not performed.

Corrective Action
The facility will henceforth require physicians to attest to confirming treatment locations using diagnostic images and that an additional attending physician will independently verify correct treatment.

Effect on Patient
An unintended dose of 50 Gy was delivered to a benign liver hemangioma. While the patient did not experience any toxicity from the unintended treatment, the untreated liver metastasis increased in size. The patient was notified and a new treatment plan was created considering the doses already delivered to the surrounding structures and was delivered to the patient.

GammaKnife Misadministrations

Describes circumstances for 15 misadministrations.
GammaKnife Misadministrations

- 5 transposed Y and Z coordinates
- 3 wrong side treated
- 2 treatments delivered to incorrect lesion
- 1 incorrect collimator helmet
- 1 failure to enter prescribed dose in TPS
- 1 incorrect date in TPS
- 1 incorrect Y coordinate
- 1 incorrect exposure time

Gamma Knife

U.S. FOOD & DRUG ADMINISTRATION

Elekta has become aware that the latches may be locked before they have been fully turned resulting in a poorly locked frame.

Device Design

Elekta sent an Important Field Safety Notice distributed on October 6, 2014, to all affected customers. The letter identified the product problem and the action needed to be taken by the customer.

This Important Field Safety Notice describes the problem and possible workarounds for customers to follow until a permanent solution can be developed. They are:

* Always assure that the plastic lever is only operated when at a right angle with the frame adapter.
* Do not force the plastic lever in place if it meets significant resistance when turned.
* Ensure that the plastic lever is completely flush with the frame adapter and that no angulations are present.

Corrective Action #2: Elekta will check and replace as necessary affected frame adapters in the field. This will be released at the end of October 2014, and Elekta will have six months to complete the checks and replacements for those products in the field.
RECENT NEAR MISSES

Potential

CIVCO PROTRUSION
Event Type: Rotation
Event Description:
A Protrus software issue was recently discovered when using the Protrus system with the configuration of splitting the shifts between the Protrus (rotations) and variator potential (translations). The issue presents the opportunity for non-sub-millimeter positioning when making large translations (i.e., x/cm).

The accuracy issue when using the split shifts feature will be resolved in the next Protrus software release. The accuracy issue does not impact the Protrus system for all 6 degrees of freedom corrections. If you are currently using the system with "All 6 degrees Protrus", there are no issues or required configuration changes at this time.

The issue was discovered during a system QA at a customer site. A phantom was set up on isocenter with translation offsets of 3-5 cm in all three directions, along with a rotation of 2.5-3.0 degrees. When sending the correction values through Protrus to the variator (translations) and Protrus (rotations), the phantom was 3.1-2.9 cm off in vertical and lateral directions after the correction. It was found the Protrus rotations were not accounting for the variator translation values when making a rotation about isocenter. Therefore, Protrus’s rotation algorithm was providing rotation axis based on the actual couch position, rather than the target couch position (since translations are applied). Translation values are considered for isocentric rotation when performing all 6 shifts with Protrus.

After shifting the couch position, the target couch position moved away from the actual couch position, as no isocentric shifts were applied. Therefore, the target couch position moved away from the actual couch position, as no isocentric shifts were applied.

The issue was resolved by adjusting the Protrus rotation algorithm to account for the variator translation values when making a rotation about isocenter. The updated algorithm now provides the correct rotation axis based on the target couch position, ensuring accurate positioning even with large translations.
Gamma Knife Near Miss

Manufacturer Narrative

The manufacturer’s investigation concluded that volumes of type treated can become misplaced in lps 11. 0. 0 and lps 11. 0. 1. These volumes are intended to indicate targets already having been treated previously, and are generated by the system from the prescription isodose volumes of the targets in previous treatments. This could in the worst case lead to over treatment due to a target being unintentionally re-treated a few months after a prior treatment. The patient related to the reported case was not mistreated since the problem was detected during planning. The reported issue is caused by a bug in the isocentric planning (Ips) version 11. 0. 0 and 11. 0. 1 when doing re-treatment (import data from previous examination) based on another re-treatment examination already containing volumes of type treated generated in an Ips version prior to 11. 0. 0. The bug causes those volumes to end up around 100 mm off or more from where they should be. They may also become enlarged depending on the voxel size of the image study they were connected to when they were generated. The enlargement in the x, y, respectively the z direction is the inverse of the voxel size in corresponding direction. When investigating the involved modelling in a broader perspective after discovering the bug described above, the following similar lps in Ips version 11. 0. 0 and 11. 0. 1 were also discovered: when doing re-treatment (import data from previous examination) based on another re-treatment examination already containing volumes of type treated generated in Ips version 11. 0. 0 or 11. 0. 1, those volumes will end up in the wrong place as well. How wrong depends on how much the anatomy has moved in relation to the isocentric coordinate system between the different examinations. This means that they would normally end up somewhere between 0 and 50-60 mm from where they should. Their size will however not change in contrast to the first bug described above. When replacing the skull definition any volumes of type treated will end up in the wrong place if a non-identity anatomy transformation has been performed, i.e. if the isocentric reference is replaced or a pre-plan reference is replaced by a stereotactic reference, on the skull definition being replaced. How wrong depends on how much the anatomy has moved in relation to the isocentric coordinate system due to the anatomy transformation. This means that they would normally end up somewhere between 0 and 50-60 mm from where they should be. Their size will not change in this case. The risk assessment for this was determined to be remote x critical. A field safety corrective action will be implemented before December 2015 under reference: FOA-EAB 0003. This will recommend that until the problem has been resolved in a new version of the software, previously treated volumes should be reviewed before planning a new treatment.

Near miss due to change in units

![Graph showing dose volume histogram](image)

**Fig. 2.** Dose volume histograms showing the intended dose (solid lines) and the dose which would have been delivered had the error not been caught (dashed lines) to the target (blue) and the brain stem (purple). This error could yield damage of 40% of the brainstem with dose of >20 Gy while leaving the entire target untreated with its maximum dose of only 10 Gy.
Near miss from my clinic

• I was doing an initial review of an SBRT plan
• I don’t remember there being two plans
• But the dosimetrist had done two for the MD to evaluate
• I checked the wrong one and printed the dose constraint document
• I performed QA on the wrong plan
• It was caught by a second physicist when he noticed that the plan name in the chart did not match what was on the dose constraint document
• QA was performed on correct plan and patient was treated
• There was no indication from the MD or dosimetrist which plan I was supposed to check and QA

Beam data acquisition for SRS / SBRT is challenging and time consuming

Small fields
Sharp gradients
Detector position-orientation effects
Loss of lateral electron equilibrium

Must get this right!

Commissioning errors affect all patients treated with the device – not just a select few!
Dosimetric commissioning: Do your calculations agree with measurement?

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Planned Dose (Gy)</th>
<th>Measured Dose (Gy)</th>
<th>Diff (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single 10x10 field AP, SAD</td>
<td>1.527</td>
<td>1.521</td>
<td>-0.39</td>
</tr>
<tr>
<td>AP-PA (same Td, same MU) 10x10</td>
<td>1.502</td>
<td>1.487</td>
<td>-1.00</td>
</tr>
<tr>
<td>AP-PA (same Td, same MU) 5x5</td>
<td>1.761</td>
<td>1.747</td>
<td>-0.80</td>
</tr>
<tr>
<td>4-field box</td>
<td>2.707</td>
<td>2.742</td>
<td>1.39</td>
</tr>
<tr>
<td>Whole Brain</td>
<td>2.012</td>
<td>2.027</td>
<td>0.25</td>
</tr>
<tr>
<td>3-D Cylindrical</td>
<td>3.628</td>
<td>3.623</td>
<td>0.42</td>
</tr>
<tr>
<td>Breast</td>
<td>3.228</td>
<td>3.183</td>
<td>1.39</td>
</tr>
<tr>
<td>SBRT Lung (course 10) IMRT phantom</td>
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<td>1.01</td>
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<td>SBRT Lung (course 10) solid water</td>
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<td>-1.00</td>
</tr>
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<td>1.42</td>
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<td>SmartArc iMRT</td>
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<td>1.575</td>
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</tr>
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<td>Average</td>
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<td>-0.19</td>
</tr>
<tr>
<td>SD</td>
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<td>1.27</td>
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</table>

Dosimetric commissioning: Do your calculation agree with measurement?

![MU Verification / Point Dose Measurement Table]

- **Field #1:** Energy (MV) 6, MU 76, IC, N 1.19, D 0.822, DC 0.674
- **Field #2:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #3:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #4:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #5:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #6:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #7:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #8:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #9:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674
- **Field #10:** Energy (MV) 6, MU 77, IC, N 1.13, D 0.822, DC 0.674

**Validation Tables:**
- **Energy (MV):** 6
- **MU:** 76, 77, 77, 77, 77, 77, 77, 77, 77, 77
- **IC, N:** 1.19, 1.13, 1.13, 1.13, 1.13, 1.13, 1.13, 1.13, 1.13, 1.13
- **D:** 0.822, 0.822, 0.822, 0.822, 0.822, 0.822, 0.822, 0.822, 0.822, 0.822
- **DC:** 0.674, 0.674, 0.674, 0.674, 0.674, 0.674, 0.674, 0.674, 0.674, 0.674

**Temperature (°C):** 34.10
- **Pressure (mmHg):** 764.80
- **Dose Rate (MU/min):** 1.844
- **Dose Rate (MU/min):** 1.844
- **Dose Rate (MU/min):** 1.844
- **Dose Rate (MU/min):** 1.844
- **Dose Rate (MU/min):** 1.844
IROC Lung Phantom

IROC Spine Phantom

IROC Lung Phantom

IROC Spine Phantom
IROC SRS Phantom

Planning

End to end tests should be performed in a clinically meaningful way

R/V

Do all of your commissioning in clinical mode and through your R/V system

Tx Unit
AAPM/ASTRO Resources

- AAPM Task Group 101
- Target Safely – IMRT Safety White Paper
- Target Safely – SBRT/SRS Safety White Paper
- ASTRO – Safety is no accident – A framework for quality radiation oncology and care – Updated March 2019

SRS/SBRT White Paper

- Solberg et al. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy. PRO 2012.

Safety Considerations for SRS and SBRT

1. Introduction
1.1 Scope of this Document on Patient Safety for SRS and SBRT
1.2 Nomenclature
1.3 Safety Concerns
2. Elements of Successful SRS / SBRT Quality Assurance
2.1 Establishing Program Goals
2.2 Technology Requirements
2.3 Personnel Requirements
3. SRS / SBRT Systems Acceptance and Commissioning
4. SRS / SBRT Quality Assurance
4.1 General QA Concepts
4.2 Equipment QA
4.3 Patient / Process QA
5. Processes for Ongoing Quality Improvement
6. Documentation
7. Other Recommendations
8. Summary
**SRS/SBRT White Paper Key Points**

- Focus on personnel qualifications and technology requirements
- Commissioning/credentialing/QA
- Checklists are helpful, especially for brand new programs
- SRS and SBRT are SPECIALIZED procedures and should be treated as such!

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**Recent Publications**

**Targeting safety improvements through identification of incident origination and detection in a near-miss incident learning system**

Avrey Novak, Matthew J. Nyfot, Ralph P. Ermoian, Loucille E. Jordan, Patricia A. Sponseller, Gabrielle M. Kane, Eric C. Ford, and Jing Zeng

Department of Radiation Oncology, University of Washington Medical Center, 1959 NE Pacific Street, Campus Box 356043, Seattle, Washington 98195

**Adverse Events Involving Radiation Oncology Medical Devices: Comprehensive Analysis of US Food and Drug Administration Data, 1991 to 2015**

Michael J. Connor, BS,*,**† Deborah C. Marshall, MD,* Vitali Moiseenko, PhD,* Kevin Moore, PhD,* Laura Cervino, PhD,* Todd Atwood, PhD,* Parag Sanghvi, MD,* Arno J. Mundt, MD,* Todd Pawlicki, PhD,* Abram Recht, MD,* and Jona A. Hattangadi-Bluth, MD*

*Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, California; †Department of Radiation Oncology, University of California Irvine School of Medicine, Irvine, California; and ‡Department of Radiation Oncology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts
Targeting safety improvements through identification of incident origination and detection in a near-miss incident learning system

<table>
<thead>
<tr>
<th>Safety barrier</th>
<th>Number of events caught at safety barrier (average NMR)</th>
<th>Number of events undetected by safety barrier (average NMR)</th>
<th>Most frequent origination points of events caught at safety barrier</th>
<th>Most frequent point where undetected events were ultimately discovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical plan review</td>
<td>372 [15%] (1.4)</td>
<td>512 [18%] (1.8)</td>
<td>3.14—plan information transfer to radiation oncology information system (11.2)</td>
<td>4.8—therapists chart check (70)</td>
</tr>
<tr>
<td>Therapist chart check</td>
<td>360 [16%] (1.6)</td>
<td>432 [18%] (1.8)</td>
<td>3.2—verification of clinical parameters, treatment consent (94)</td>
<td>5.2—time-out (e.g., verification of clinical parameters, treatment consent) (94)</td>
</tr>
<tr>
<td>Weekly physics chart check</td>
<td>304 [54%] (1.6)</td>
<td>633 [46%] (1.7)</td>
<td>3.15—scheduling, treatment, treatment, treatment protocol (94)</td>
<td>6.5—weekly physics chart check (50)</td>
</tr>
<tr>
<td>Time-out</td>
<td>307 [13%] (1.6)</td>
<td>466 [35%] (1.8)</td>
<td>3.13—plan, prescription, and administration (134)</td>
<td>5.7—patient positioning and immobilization (59)</td>
</tr>
<tr>
<td>Image-guided verification</td>
<td>18 [13%] (1.7)</td>
<td>253 [88%] (1.9)</td>
<td>3.14—plan information transfer to radiation oncology information system (7)</td>
<td>5.14—treatment delivery (46)</td>
</tr>
</tbody>
</table>

Results: There were 4234 ROD and 4,985,698 other device adverse event reports. Adverse event reports increased over time, and events involving RODs peaked in 2011. Most event outcomes differed between RODs and other devices. While most device events involved malfunction, patient injury was less common among RODs (16.3% vs 33.7% in other devices). This finding suggests that while evaluability by the manufacturer must be considered, similar adverse events may be more likely to be recalled (10.5% vs 37.9%) (P<0.001). Device age and time since 510(k) approval were shorter among RODs (P<0.001).

Conclusions: Compared with other devices, RODs may experience adverse events sooner after manufacture and market approval. Close postmarket surveillance, improved software design, and manufacturer–user training may help mitigate these events. © 2016 Elsevier Inc. All rights reserved.
**Specific Lessons Learned from Accidents and Overexposures**

- Get an independent check of machine calibration and commissioning
- Perform end to end commissioning tests, including the R&V system
- Evaluate changes in TPS, R&V and other software thoroughly before implementation
- Our equipment is complicated
- Communication is key!
- Every member of the treatment team plays a role in quality and safety
- Dosimetrists play a vital role in the process
- Don’t assume the MD is right!
Summary | Conclusion

- SRS and SBRT are ABLATIVE treatments!
- Care must be taken during commissioning
- Take your role in safety and quality seriously
- Don’t be afraid to speak up if something seems wrong
- Plan your program carefully!
- Be alert for anything out of the ordinary