RO·ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY
PSO
A Patient Safety Organization

QUARTERLY REPORT
PATIENT SAFETY WORK PRODUCT

Q4 2016
OCTOBER 1, 2016 – DECEMBER 31, 2016

TABLE OF CONTENTS

AGGREGATE REPORT CARD –
Q4 2016
October 1, 2016 - December 31, 2016

METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE HISTORICAL SUM
Reported Events	**271**	**2681**
Therapeutic Radiation Incidents	67	733
Other Safety Incidents	33	167
Near Miss	49	836
Unsafe Conditions	56	744
Operational/Process Improvement	66	201
Most Commonly Identified Workflow Step Where Event *Occurred*	**Treatment Delivery Including Imaging:** 37% (100/271)	**Treatment Planning:** 28% (756/2681)
Most Commonly Identified Workflow Step Where Event was *Discovered*	**Treatment Delivery Including Imaging:** 43% (116/271)	**Treatment Delivery Including Imaging:** 26% (709/2681)
Most Commonly Identified Treatment Technique	**3-D:** 34% (91/271)	**3-D:** 21% (565/2681)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents/Other Safety Incidents that Did Not Effect Multiple Patients	**≤5% Maximum Dose Deviation to Target:** 51% (50/98)	**≤5% Maximum Dose Deviation to Target:** 69% (352/512)

ANALYSIS & COMMENTARY

INTRODUCTION

The following content contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System®. This quarterly report contains several featured themes in which the report and case studies are separated into: Triage and Severity Assessment of Q4 2016 Radiation Oncology Incidents, Level 5 Incidents and Electron Beam Radiotherapy, and Best Practices. Each of these sections contain focus topics that are interconnected to highlight an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS. The events presented here are excellent examples of providers utilizing the RO-ILS program to share information about error pathways that exist within the daily practice of radiation oncology.

FEATURED THEME I: TRIAGE AND SEVERITY ASSESSMENT OF Q4 2016 RADIATION ONCOLOGY INCIDENTS

The current RO-ILS workflow includes two distinct systems of event triage/prioritization. Throughout the history of RO-ILS, event triage has been a major discussion point within the Radiation Oncology Healthcare Advisory Council (RO-HAC), and the process continues to undergo revision. What follows is a description of the current Triage Bin System and current RO-HAC Severity Scoring. We expect these processes to continue to evolve.

    1. Triage Bin System:

        Events are first classified by the reporting institution into one of five categories: "Therapeutic Radiation Incident", "Other Safety Incident", "Near-miss", "Unsafe Condition", and "Operational/Process Improvement". Beginning with these event classifications, automatic triggers place each event into one of five bins (See Table 1 for a description of the triggers for each bin):

        The triggers are based upon RO-ILS data elements, and the data entered by the reporting institution determines which bin the reported event is placed.

Table 1. *Event triggers and descriptions and their corresponding bin assignments.*

BIN	TRIGGERS AND EVENTS' DESCRIPTIONS
Bin A: Operational/Process Improvement Events	1. Operational/Process Improvement Events
Bin B: Non-radiation Patient Safety Events	1. Other Safety Incident Events
Bin C: High Priority Radiation Near Miss Events or Unsafe Conditions	1. Near Miss Events or Unsafe Conditions that were classified as 'severe' by the reporter's assessment of the significance of the event.

Bin D: High Priority Radiation Misadministration Events	1. Therapeutic Radiation Safety Incidents that were identified as a systematic error affecting multiple patients. 2. Therapeutic Radiation Safety Incidents that had a dose deviation to target greater than 5 percent and/or OAR(s) that exceeded tolerance levels. 3. Therapeutic Radiation Safety Incidents that had a dose deviation to target less than or equal to 5 percent and/or OAR(s) that received more than intended but within tolerance levels, more than 1 fraction/treatment delivered incorrectly, regardless of the number of total fractions/treatments prescribed. 4. Therapeutic Radiation Safety Incidents that had a dose deviation to target less than or equal to 5 percent and/or OAR(s) that received more than intended but within tolerance levels, had 1 fraction/treatment delivered incorrectly out of 5 or less total fractions/treatments prescribed.
Bin E: Low Priority Radiation Misadministration Events	1. Near Miss Events or Unsafe Conditions that were not classified as 'severe' by the reporter's assessment of the event's significance. 2. Therapeutic Radiation Safety Incidents that had a dose deviation to target less than or equal to 5 percent and/or OAR(s) that received more than intended but within tolerance levels, had 1 fraction/treatment delivered incorrectly out of more than 5 total fractions/treatments prescribed.

2. RO-HAC Severity Score:

A member of the RO-HAC reviews each event and assigns a severity score (low to high) from 1-5, refer to figure 2, which was adapted from Nyflot et al. work (2015).

Figure 2. *Event Prioritization Score/Event Severity Index. Adapted from Nyflot (2015).*

SEVERITY INDEX	SEVERITY DESCRIPTION	CRITERIA
1	No potential or real harm	Event does not pose downstream risk in workflow. Event is not related to patient safety or quality of treatment.
2	Mild potential or real harm	Event may enhance the risk of other downstream errors. Event may cause emotional distress or inconvenience to patient with no clinical impact.
3	Moderate potential or real harm	Event enhances the risk of other critical downstream errors. Temporary pain or discomfort for patient. Deviations from best practices, but with no obvious clinical impact.
4	Severe potential or real harm	Limited barriers to prevention of problem. Event with potential clinical impact that is non-critical.
5	Critical potential or real harm	Extremely limited barriers to prevention of problem. Event with potentially critical clinical impact.

FEATURED THEME II: LEVEL 5 INCIDENTS AND ELECTRON BEAM RADIOTHERAPY (RT)

As described above, RO-HAC utilizes the current incident severity system to assign a score of 1-5 to each event submitted to Clarity PSO. For Q4 2016, there were 21 cases (8%) out of 271 total classified as severity level 5 (critical severity) events. Of these 21 critical severity events, 11 were incidents that reached the patient and all 11 resulted in unintended dose deviations. Eight of these dose deviations were ≤5 percent maximum dose deviation to the target and 3 cases were 5-25 percent dose deviation. The 11 critical severity incidents that reached the patient included the modalities listed in Table 2. Of the 10 critical severity incidents that did not reach the patient (i.e., near miss), all were IMRT/VMAT or 3-D modalities.

Table 3. *Level 5 (critical severity) Incidents that reached the patient, Q4 2016*

MODALITY	NUMBER OF LEVEL 5 CASES
Electron beam RT	4
HDR Brachytherapy	3
3-D Radiotherapy	2
IMRT/VMAT	2

The current RO-ILS system does not capture the proportion of each modality treated by the reporting institutions. However, it is telling that more than half (7 of 11) of the severity level 5 incidents that reached the patient involved electron beam RT or HDR brachytherapy. We believe that electron beam and HDR brachytherapy represent a smaller proportion of total cases treated in the US than the other modalities listed. We have chosen to focus some attention on the risks of electron beam RT this quarter.

The following includes several brief case studies on electron beam incidents that reached the patient and were reported to RO-ILS during Q4 2016.

CASE 1: INCORRECT ELECTRON ENERGY WAS DELIVERED
During the patient's first weekly chart check, physics discovered that the patient received 6 of 30 fractions using 6MeV electrons while the physician's intent and the plan documentation all indicated 9MeV electrons.

CASE 2: ELECTRON BLOCK NOT PROPERLY ALIGNED TO THE TARGET
An electron breast boost cutout was planned with no collimator rotation. However, the cutout was poured for collimator 90 degrees. The patient was treated at collimator 0 degrees and this was approved by the covering physician (not the treating physician) on the first day. During fraction 3 of electron beam therapy, the treatment team noted that the electron block did not match the reference documentation. The collimator angle was incorrect and the electron block was misaligned.

CASE 3: UNINTENDED SKIN LESION TREATED WITH ELECTRONS (INCORRECT TARGET)
A patient was set up to receive electron beam RT to 8 skin targets. On day 4, a member of the treatment team noted that one of the treatment sites was not the same as prior fractions. On review, they noted they had been treating an incorrect site.

CASE 4: SEPARATE ELECTRON SKIN SITES TREATMENT AT SAME SCHEDULE
Two electron skin sites were being treated at the same schedule when the intent called for different schedules. The physician intent included electron RT to two distinct targets treating each with a different schedule/fractionation. Both were treated with the same schedule until this was noted by the physician during the weekly on treatment visit.

In electron beam RT, the chosen energy often represents a significant decision in how well, or how poorly, the target is covered with the intended dose. As most electrons are delivered *en face*, the deep margin of target coverage is typically chosen by altering the electron energy, among other factors (bolus, SSD, etc.). This makes the choice of electron energy particularly important.

The delivery of an incorrect electron energy may represent an error in treatment volume just as a misalignment (incorrect targeting) may occur with photon radiotherapy. Modern photon radiotherapy targeting is also commonly verified with portal or advanced imaging. Such imaging for photons serves as a second check on targeting for both the therapists at the treatment console, and the physician reviewing alignment images. Treatment teams should recognize that such a second check does not readily exist for electron radiotherapy.

Also, at many clinics, electron treatments are often generated without 3-D imaging and outside the workflow of standard photon plans. These differences in workflow should be acknowledged. All clinics should formally review their processes for prescribing electrons and verifying that the intended energy is delivered. Simply asking, "How do we know that the same electron energy prescribed by the physician is used in dose calculation, and then used in treatment delivery?" can begin a productive dialog between physicians, physicists, dosimetrists and therapists.

Actions and Recommendations:
- All clinics should formally review their processes for prescribing, calculating and delivering electrons.

In one the of the above-referenced electron beam cases, an incorrect skin target was treated. Incorrect treatment site is a risk for many radiation modalities, especially when more than one target is being considered. In electron beam radiotherapy for skin malignancies, the problem may be confounded by multiple candidate sites, removal of the gross tumor at the time of biopsy, possibly lack of imaging (biopsy site photography) and other factors.

Struggles identifying the correct surgical site represent common problems for dermatologic surgeons and the dermatology literature contains a healthy discussion of these issues (Nemeth 2012) (St John 2016). In one series, patients incorrectly identified 17 percent of surgical sites, dermatologists incorrectly identified 6 percent of sites, and both physicians and patients incorrectly identified 4 percent of sites (McGinness 2010). With biopsy site photographs, all surgical sites were correctly identified (McGinness 2010). In dermatology, risk factors for site misidentification include more than 6 weeks between biopsy and surgery, patient inability to see the biopsy site, biopsy specimens from multiple sites and the absence of biopsy site photographs (Zhang 2016).

Actions and Recommendations:
- All clinics that treat skin malignancies with radiotherapy should have a formal process to ensure correct site identification at every step along the workflow from initial consultation, to simulation to daily treatment delivery. This process should include biopsy site, simulation and other photographs.

FEATURED THEME III: BEST PRACTICES

PATIENT SAFETY EVENT REPORTING

Q4 2016 saw a decrease in reported events compared to prior quarters. A total of 271 events were reported which represents a 30 percent decline in the number of quarterly events compared to the historical maximum during Q2 2016. This is concerning on several fronts. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. Decreased reporting limits the potential for shared learning. There is also evidence that increases in reporting are linked to increases in patient safety, as evidenced in a large study including 179 hospitals where in-hospital complications and adverse events decreased with increased frequency of event reporting (Mardon 2010).

For many people, the idea that increased events submitted equates to improved safety seems counterintuitive. Some may feel that finding fewer events indicates improved safety. We must understand that, given the complexity of modern medicine and radiotherapy, there will always be risk and the potential for medical events. In practical terms, if we are not finding events then the most likely cause is that we are not looking hard enough. Increased reporting improves patient safety culture and identifies risks that can be mitigated before they cause patient harm. The goal is to increase reporting which, while increasing the total number of reported events, will decrease the severity of events and lead to improved overall patient safety.

Actions and Recommendations for Increasing Event Reporting

- **Culture:**
  The culture of a department and organization is the foundation and underpinning that ultimately influences the degree of safety and quality practiced and delivered. Developing a culture that supports, encourages, and praises staff in pointing out flaws in system design and workflow is of utmost importance. There are three main components to focus on when developing a safety culture (Piotrowski 2017):
  1. A culture of safety: The department values open discussions about concerns and issues. Frontline staff need to be empowered to talk about instances where things went wrong.
  2. A culture of learning: Leadership takes a systems approach (not a person approach) to problems and focuses on asking what happened and how it can be prevented. Learning from errors and incidents needs to be made a core tenant of the department and organization.
  3. A culture of justice: Leadership, frontline staff and other employees need to hold themselves and each other accountable for making and sustaining safety and quality improvement efforts.

- **Tracking Events Submitted:**
  We recommend that each institution actively track the number of events submitted at their clinics on a regular basis. A wealth of experience across a range of disciplines has taught us that with measurement comes improvement. At regular quality meetings, each clinic should display the total events reported and discuss any changes in the frequency of event reporting.

- **Education:**
  Recurrent training and re-education should highlight the connection between event reporting and patient safety for all team members. Simply stated, we need everyone on the radiation team to internalize the goal that we can become safer by increasing event reporting. We must emphasize the non-punitive nature of reporting and create a safety culture to support the reporting infrastructure. This quarterly report includes a premade PowerPoint slide set (Q4 2016 RO-ILS Report Training Slides) that clinics may use to teach these principals to their team members. This slide set is available to RO-ILS participants within the RO-ILS Portal Library.

IMPLEMENTING CHANGE

The RO-HAC reviews and analyzes RO-ILS events that have been submitted to Clarity PSO. Quarterly reports, training slides and Tips of the Month are created and published based upon the learnings gleaned from the submitted events. This output provides a wealth of knowledge that can be used in your department to make necessary changes that will improve patient safety and reduce the likelihood of severe incidents. This section describes common facilitators in implementing change. To be effective, incident learning must not simply collect and analyze data, but must become the catalyst and facilitator behind real change. When staff understand why a change is made, and are part of the process for planning and implementing the change, it allows for a better chance of successful implementation.

Support from Administration
Assure you have support from administration. Administration and staff need to be constantly aware of how processes and systems affect the organization. It is critical that administration shows support for change and demonstrates that support when communicating and interacting with staff. The more information shared with staff, the more attentive of the situation they become. Staff will develop a comfort level and confidence in the change when they see management leading and supporting the change process.

Initiating awareness through improved communication can easily be done by using rounding. Rounding can be a formal or informal meeting where clinical problems are discussed. Observing processes and department procedures firsthand can assist department leaders in developing a better understanding of processes and workflows within the department, thus promoting open, purposeful communication. Leaders should ask questions about the process that is in place as this will promote proactive discussions to ensure that staff concerns are heard. Rounding creates a cultural practice in which the team can define objectives, which will lead to improvements in the quality of care, and better utilization of medical resources.

Describe the Change
Clearly define the problem and change to be made. A case for change can come from different sources. It can be a result of data collected on all levels such as data entered into RO-ILS. Using data is the best way to identify areas that need to improve and change initiatives. This can easily be done by utilizing the RO-ILS Quarterly Report Training Slides during department meetings.

As data is examined and reviewed, administration and leaders must be willing to examine old habits and opinions. It is vital to define new initiatives, articulate them clearly, involve as many people as practical and as early as possible.

Communicating

Communicate the change to all staff. Communicating change should be structured and systematic. Being proactive in communications can minimize resistance by including staff in part of the change process. It is important to be clear when communicating the changes as well as communicating them often to educate staff, assisting them in understanding the changes necessary. Many forms of effective communication can be used; face to face, staff meetings, presentations, forums, emails, etc. Make sure to provide opportunities for staff to ask questions regarding the changes taking place.

Involvement

Involve a range of team members in implementing the change. When administration and leaders fail to listen to staff about current workflows, processes and operations within the department, the development of standardized and consistent processes or operations becomes increasingly challenging. Since staff are typically closest to the process that needs to change, it is important that they understand the "why" behind a change and participate in creating the new process.

Create a group and empower champions to lead change. This group should include staff within various roles as well as leaders. Do not limit this change group to only your department, consider other departments that may be impacted or may be necessary to facilitate the change and invite them to participate. These other roles may include IT, the quality/safety/risk department(s), volunteers, administrative assistants, etc.

Implementation

Implement the change using a logical order and defined timeline. Implementing without a logical order can create frustration for those responsible for the work process. A timeline should be made for the implementation of the change and leaders should make changes in the order that affect the process and the staff who manage the process. Using a timeline will also define support for staff with training, mentoring and feedback during the implementation of a change.

Evaluation of Change and Process

Evaluate how effective your change has been. After implementation of any change, it is important to evaluate after a period of time the effectiveness of the change, and if the intended results were achieved. Has the change shown improvement in competence, accuracy, outcomes, reliability, efficiency or patient satisfaction?

Evaluating the process can provide understanding on how to streamline future changes to ensure success. What went well in initiating, handling and completing this change? What could have been done better? What else can be done so that future changes are successful? It is also vital to determine and monitor the sustainability of the change. The Institute for Healthcare Improvement (IHI) provides a variety of resources on the science of improvement and includes the essentials on how to improve.

Difficulties
Expect difficulties and resistance and be prepared to rework your solution. When change is imposed, active and passive resistance can expose resentments and lack of commitment to the change from staff which can lead back to old habits.

It is management's responsibility to ensure that staff can implement change without obstacles and resistance. These can be described in many forms.

- **Inadequate communication and information.** If communication is poor and news of a change spreads through the department, details are sometimes skewed and staff end up receiving inaccurate, second-hand information. This can lead staff to lack the desire to change or prevents them from seeing the need for change.

- **Feeling Excluded.** When staff feel they had no input in the change, they will feel excluded from the decision making process and will often be resistant to the change. Communication and staff involvement provide an opportunity to turn frontline staff into champions and advocates for the change process.

- **Lack of Trust with Administration.** This will also hamper the change process and prevent sustainability of any improvement.

- **Lack of Skills or Resources.** When change requires learning new skills, resistance is likely. Providing adequate education and training is important.

Celebrate
Celebrate your success and let your staff see and feel real improvement. Celebrate successes along the way as changes are made. Celebrating the small changes and building momentum for bigger changes are what makes staff want to participate in the process. When planning your improvement project, purposely identify portions of the project's evolution that can be declared small wins or successes. Focus on encouraging your team to work towards each of these small wins and then follow through on celebrating those wins.

When change initiatives are successful, people are more apt to adapt to change. They become confident in the change process overall. Small wins or successes assist staff in seeing the benefit of the change as the project unfolds and increases both staff acceptance and participation in the change.

Implementing modifications in the clinical environment is difficult but true incident learning means making changes.

RESOURCES

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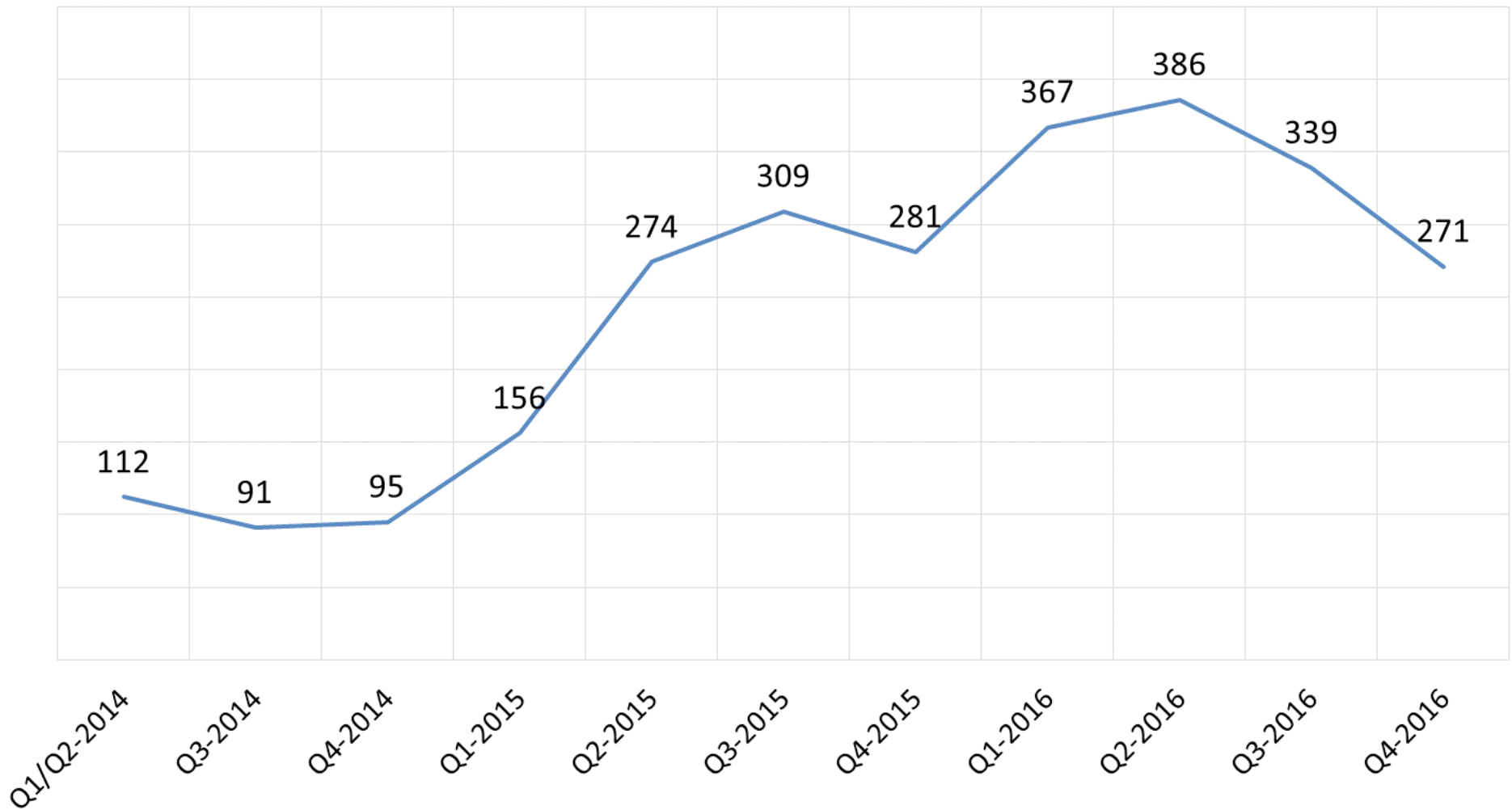ncbi.nlm.nih.gov/pmc/articles/PMC1070929/pdf/wjm17200393.pdf.

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AGGREGATE ANALYSIS GRAPHS

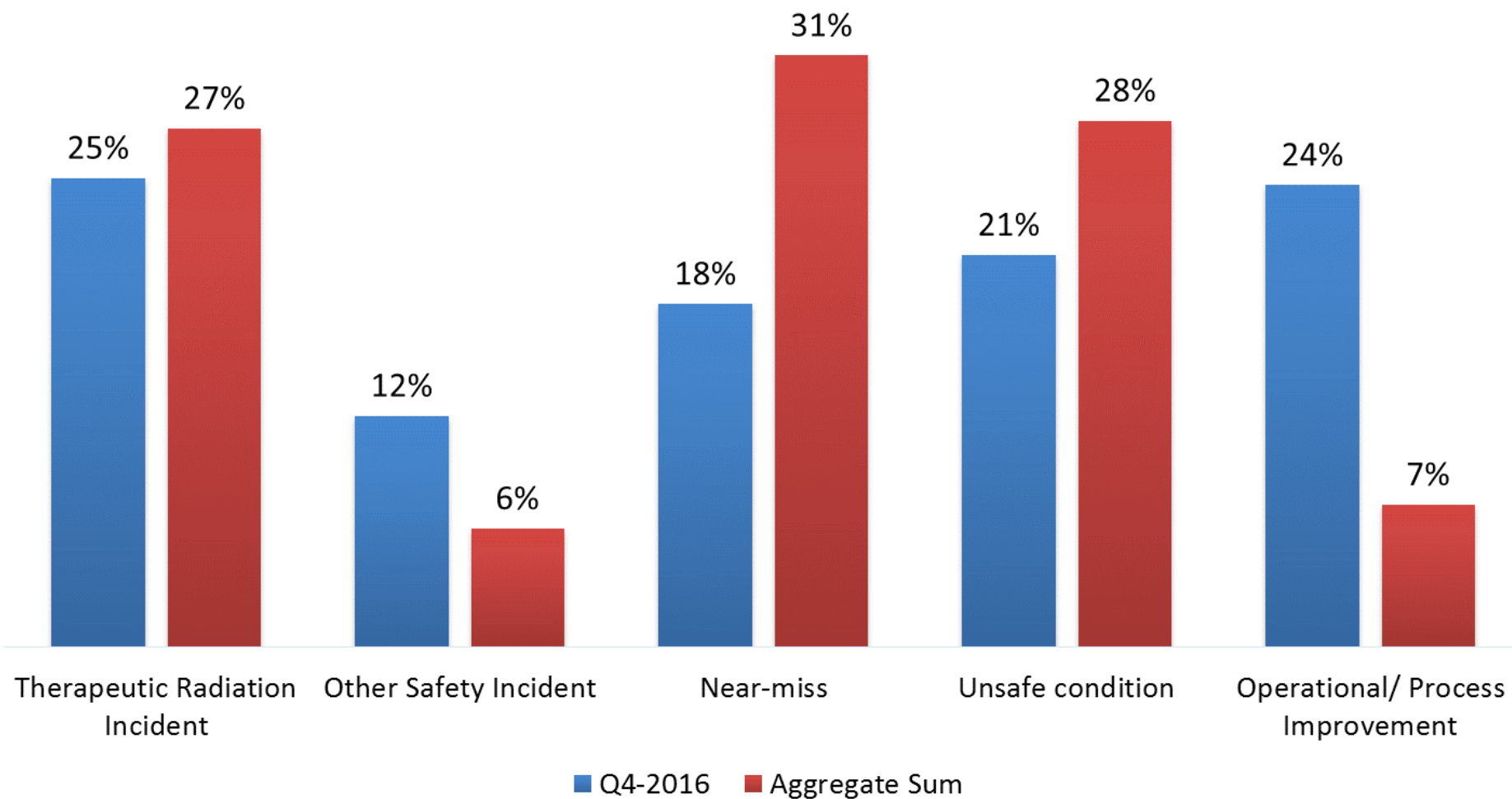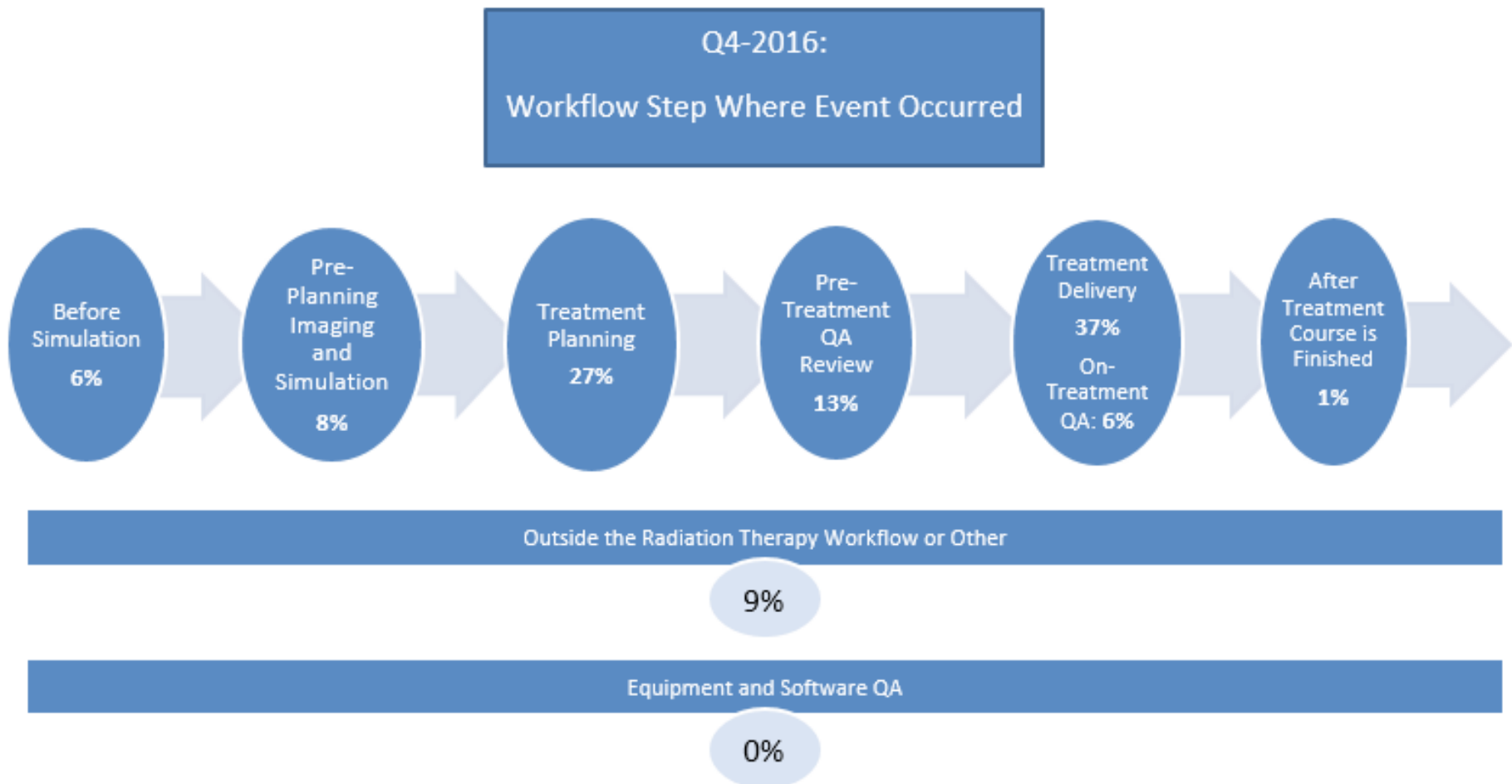**Aggregate: Total Number of Events**

Aggregate: Reported Event Type

Q4-2016:

Workflow Step Where Event Occurred

Before Simulation 6%

Pre-Planning Imaging and Simulation 8%

Treatment Planning 27%

Pre-Treatment QA Review 13%

Treatment Delivery 37% On-Treatment QA: 6%

After Treatment Course is Finished 1%

Outside the Radiation Therapy Workflow or Other
9%

Equipment and Software QA
0%

AGGREGATE ANALYSIS GRAPHS | continued

Aggregate Sum:

Workflow Step Where Event Occurred

Before Simulation 7% → Pre-Planning Imaging and Simulation 9% → Treatment Planning 28% → Pre-Treatment QA Review 15% → Treatment Delivery 23% On-Treatment QA: 5% → After Treatment Course is Finished 1% →

Outside the Radiation Therapy Workflow or Other
1%

Equipment and Software QA
1%

Q4-2016:

Workflow Step Where Event Discovered

Before Simulation 3% → Pre-Planning Imaging and Simulation 4% → Treatment Planning 11% → Pre-Treatment QA Review 13% → Treatment Delivery 43% On-Treatment QA: 14% → After Treatment Course is Finished 4%

Outside the Radiation Therapy Workflow or Other
9%

Equipment and Software QA
1%

Aggregate Sum:

Workflow Step Where Event Discovered

Before Simulation 3%

Pre-Planning Imaging and Simulation 6%

Treatment Planning 6%

Pre-Treatment QA Review 23%

Treatment Delivery 26% On-Treatment QA: 10%

After Treatment Course is Finished 3%

Outside the Radiation Therapy Workflow or Other

1%

Equipment and Software QA

1%

Aggregate: Treatment Techniques
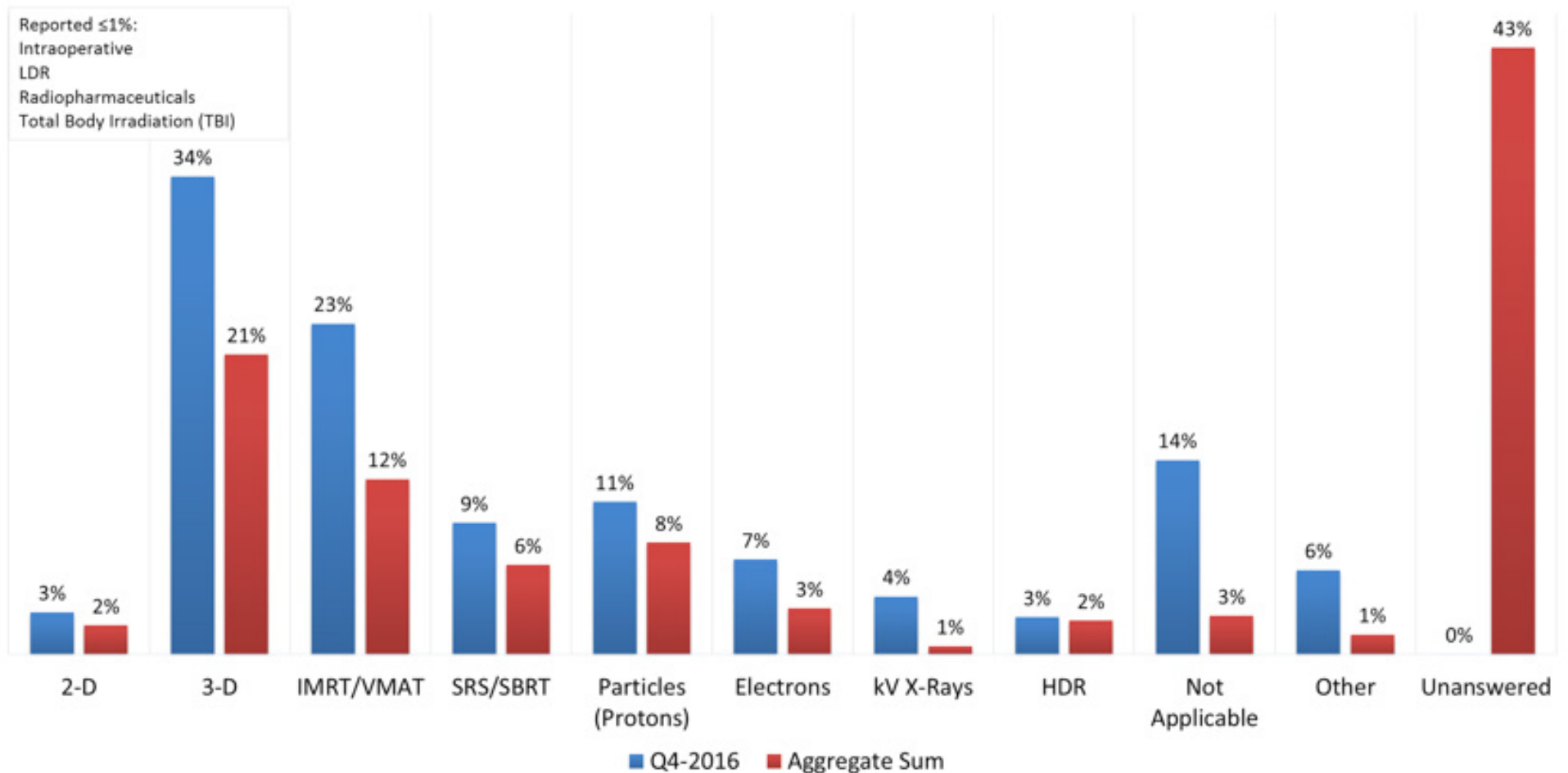
Aggregate: Contributing Factors - Top Factor Per Category