



RO•ILS[®]

**RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM**

Sponsored by ASTRO and AAPM



QUARTERLY REPORT

PATIENT SAFETY WORK PRODUCT

Q3 2016

JULY 1, 2016 – SEPTEMBER 30, 2016

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AGGREGATE REPORT CARD – Q3 2016

July 1, 2016 – September 30, 2016

METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE HISTORICAL SUM
Reported Events Therapeutic Radiation Incidents Other Safety Incidents Near Miss Unsafe Conditions Operational/Process Improvement	274 58 21 79 89 27	2345 645 171 773 695 61
Most Commonly Identified Workflow Step Where Event Occurred	Treatment Planning: 30% (83/274)	Treatment Planning: 28% (662/2345)
Most Commonly Identified Workflow Step Where Event was Discovered	Treatment Delivery Including Imaging (e.g. at the machine): 28% (77/274)	Pre-treatment QA Review (e.g. Physics Plan Check): 25% (580/2345)
Most Commonly Identified Treatment Technique	3-D: 27% (101/274)	3-D: 21% (514/2345)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents	≤5% Maximum Dose Deviation to Target: 61% (30/49)	≤5% Maximum Dose Deviation to Target: 78% (307/394)

ANALYSIS & COMMENTARY

INTRODUCTION

The following content contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System®. There are several high-level sections in which the report and case studies are separated into: Example of Incidents with Possible Medical Impact, Featured Themes and Analysis of Other Recurring Themes. Each of these high-level sections contains focus topics displayed through the case studies. The events presented here are excellent examples of providers utilizing the RO-ILS program to reach out to the community and share information about error pathways that exist within the daily practice of radiation oncology.

This is the first quarterly report in which data were reported to RO-ILS using a modified set of data elements in the web portal. The purpose of the data element modification was three-fold: the modified data elements make the system easier and clearer to use; better delineate how events happen within the multi-step planning and delivery process, and help make the events and their results easier to analyze and evaluate.

EXAMPLE OF INCIDENTS WITH POSSIBLE MEDICAL IMPACT

Case 1: Incorrect SBRT Volume Caught by Peer Review

Physician delineated target volume in incorrect location for stereotactic body radiation therapy (SBRT) treatment.

However, this event was caught and mistreatment prevented, as described here:

All SBRT cases are presented at an SBRT conference prior to treatment. In this sense, our process worked—it identified a potentially serious error prior to the initiation of treatment. The case was re-planned with the correct target location.

Stereotactic radiosurgery (SRS) and SBRT cases often strain the standard procedures used to prevent events, typically because of the limited number of fractions used, the high dose per fraction and the need to quickly bring cases through the process to treatment. All of these issues make any error potentially problematic. Clearly, as demonstrated by this case, initial peer review of volumes and other aspects of quality assurance (QA) processes need to be rigorously followed.

Actions and Recommendations:

- An appropriate recommendation arising from this event would be that all SBRT/SRS cases be presented at a peer review conference prior to treatment.

ANALYSIS & COMMENTARY | continued

FEATURED THEME I: POLICIES AND PROCEDURES

There were 116 events this quarter where policies and procedures were identified as the main contributing factor by the Radiation Oncology Healthcare Advisory Council (RO-HAC) members.

Policies and procedures should be written, reviewed and shared with all staff. The goals of such policies are to ensure that the institution's point of view on workflow and delivery of healthcare are standardized and safe. There are certainly some difficult issues related to creation, use and maintenance of policies, as illustrated by a number of events described below. For example, it is clear that policies and procedures can be followed by staff, but then ignored by patients. It is quite common to review and educate employees on policy, but little time is often taken to educate patients, leading to an increasing potential for problems. Cases 2 and 3 are related to this very issue of patient education.

General Theme Actions and Recommendations:

- ASTRO's 2012 *Safety is No Accident: A Framework for Quality Radiation Oncology and Care* 4.1.2.3 "Policies and Procedures" outlines that policies and procedures should be implemented for all aspects of the patient care process, QA process, how staff should behave and any issues that impact the safety of patients and/or staff. Furthermore, the report goes on to detail that every treatment, whether that be SBRT, IMRT, etc., needs to specify through documentation of the treatment planning and delivery process, QA checklists and test procedures, responsibilities and roles of all team members involved within the treatment process, as well as have an outlined method to always address and further quality improvement and safety. It would be wise to verify that these aspects are also addressed within your facility's policies and procedures.

Case 2: Patient became pregnant during course of treatment

A patient being treated for right-sided breast cancer became pregnant while undergoing a course of radiation therapy with 6MV photon tangents. Prior to starting treatment, this patient had tested negative for pregnancy and had documented counseling and consent regarding the dangers of pregnancy during radiation therapy. During a scheduled physician visit, she disclosed that she was late for menses. Radiation was immediately held and she was sent for a urine test and serum HCG which confirmed that she was pregnant. It was determined that she was pregnant for three weeks during her radiation therapy and the embryo was exposed to scatter radiation.

After discussion with the patient, it was determined that she was pregnant during most, if not all, of the treatment. During the three weeks of treatment, she had received 4,800 cGy of a planned 5,000 cGy with photon tangents, but an additional 1,000 cGy electron boost had yet to start. It was estimated that the embryo received between 2.4 and 14.0 cGy (0.05% to 0.30% of the 4,800 cGy delivered dose). The 2.4 cGy estimate was calculated by the treatment planning

ANALYSIS & COMMENTARY | continued

system and the 14.0 cGy estimate was based on American Association of Physicists in Medicine (AAPM) task group 36 (Stovall et al., 1995). Additional publications (NCRP 174 (2013), Antypas (1998)) were used to confirm that these dose estimates were reasonable.

For the first week of her pregnancy, the biggest risk to the embryo was prenatal death. For the following two weeks, risks include organ malformation including small head syndrome, severe mental retardation, growth retardation and development of cancer. A dose below 5 cGy would pose little risk of damage, doses between 5 and 10 cGy have uncertain risk and doses between 10 and 50 cGy would pose a significant risk.

Contributing factors in this case included:

- Failure of the patient to follow recommended pregnancy precautions.
- Patient lacked further information regarding dangers of radiation to pregnancy.

Actions and Recommendations:

- Consent documents were all updated to have additional clarity about the dangers of radiation during pregnancy, as recommended by the various regulatory bodies including the Department of Public Health.
- Consider the shifted paradigm that the Institute of Healthcare Improvement (IHI) has introduced—instead of asking the patient “What’s the matter with you?” during visits, begin by asking “What matters to you?” (Hennessey et al., 2016). This shifted approach not only empowers the patient, but also assists healthcare providers in aligning high quality, safe care with the patient’s priorities.

Case 3: Patient disposed of mesh brachytherapy implant

A patient had an I-125 brachytherapy mesh implant placed. While at home the patient’s tissue graft failed and the seeds fell out. The patient disposed of the seeds. The staff were unable to account for all 50 implanted seeds after surgical procedures for wound dehiscence: 9 seeds were lost.

Contributing factors in this case included:

- Failure of thorough patient education.
- Patient lacked a comprehensive understanding of why it is important to follow the given instructions.

Actions and Recommendations:

- The release instructions to patients for permanent brachytherapy implantation procedures were updated to emphasize the importance of contacting Radiation Oncology and Radiation Safety if seeds fall out of an implant. Appropriate handling of seeds and disposal is described within the instructions.

ANALYSIS & COMMENTARY | continued

- ***As a reminder to all RO-ILS users, be sure to include all appropriate details when submitting reports.*** In this instance, for analysis purposes it would have been helpful to include information about the clinical site, the exposure rate and more information about the type of procedure that would allow a graft failure to make it possible that the “seeds fell out”.

Case 4: Patient scheduled twice

A patient being treated with whole brain radiation was on the schedule twice for one daily treatment. During the first scheduled treatment, physics was called for an override and the second treatment was inadvertently pulled up at the control console. Later that day, physics was called back to the linac to do a dose override on the same patient. After investigating in the treatment management system (TMS), it was noted that the patient had already received a treatment earlier that day. The patient did not receive the second inappropriate treatment.

In this instance, the staff followed policy and were able to identify and avoid a mistreatment by not overriding the dose. The policy and procedure to investigate the override flag that occurred when they prepared for the 2nd (incorrect) treatment that day assisted staff in identifying the error.

Contributing factors in this case included:

- Per the therapists, the patient was on the schedule twice. One radiation therapist (RTT) treated the patient while another RTT was covering the machines.
- The patient’s appointment had been added on, but the other appointment that had been cancelled was not removed, causing the subsequent confusion.
- Failure to follow policy in scheduling and modifying a patient’s appointment.

Actions and Recommendations:

- Review of scheduling policy.
- Examine your workflow process and identify the potential gaps that would allow a patient to receive a treatment that was not indicated (e.g. lack of a process verifying the patient’s last treatment date, etc.).

Case 5: Scheduling can dramatically affect patient treatment

An intraoperative radiation therapy (IORT) patient was scheduled for a lumpectomy in an inappropriately shielded operating room (OR). Prior communication with the OR and scheduling staff was not performed. The case either could not proceed or the patient had to be moved to an appropriately shielded OR after the lumpectomy and while still under sedation. Ultimately, the patient was not treated due to inadequate margins of the lumpectomy.

Here, the scheduling error could have directly affected the way a patient would have been treated, potentially changing the patient’s outcome. Not all scheduling issues are just inconvenient!

ANALYSIS & COMMENTARY | continued

Contributing factors in this case included:

- Lack of communication.

Actions and Recommendations:

- Examine your process and workflow for interacting with the OR.
- Determine how and when IORT cases are highlighted for OR and scheduling staff. Ask how special needs for regular OR cases are made apparent to OR frontline staff (nurses, surgical technicians, those preparing for the cases, etc.) and utilize the same mechanism for emphasizing IORT cases.
- Discuss with the OR manager, OR scheduling staff and several frontline OR staff members (nurses, surgeons, anesthesiologists, etc.) the best method to ensure IORT cases are placed into appropriately shielded ORs.

Case 6: Former employee accessing medical records

Staff detected access into medical records by a former employee (gone several months). Investigation found that there was no standard process to assure access was revoked to the institution's electronic systems when staff leave the facility.

In this time of concern for privacy and security of medical records, this type of problem, and the potential for inappropriate changes into medical records, must be handled carefully by all institutions.

Contributing factors in this case included:

- Lack of a formalized process and policy to remove personnel access.

Actions and Recommendations:

- Ensure that you have a policy and procedure that stipulates the roles and responsibilities of those involved in process.

FEATURED THEME II: QA STEP FAILING TO CATCH A SIGNIFICANT ERROR

QA steps are important, but they have to be performed correctly, and issues they identify must be addressed. An example is described here:

Case 7: Incorrect catheter lengths for breast accelerated partial breast irradiation (APBI)

A patient was planned for a Right Breast APBI treatment using the treatment planning system (TPS). The plan was completed using the default 1,500 mm for the catheter lengths instead of true "sounding" lengths measured during time of the computed tomography (CT) scan. The plan was exported to the Treatment Console and loaded. When the therapist attempted to deliver the first fraction, the dummy test source tried to go to 1,502 mm (1,500+2 mm) and

ANALYSIS & COMMENTARY | continued

immediately hit the catheter end (roughly 1,258 mm). At first the team thought it was an obstruction, but then the therapist noticed the distance was 1,258 mm and said it was hitting the wall. The physicist looked at the plan in the treatment management system (TMS) and confirmed that the catheter lengths were incorrect set at 1,500 mm. The patient was removed from the table and the physicist corrected the plan in the TPS using the appropriate catheter lengths. The plan was double-checked and sent to the Treatment Console. The patient was not harmed nor mistreated in this event.

Contributing factors in this case included:

- A locum physicist developed the treatment plan.
- A second check failed to catch the error.

Actions and Recommendations:

- Incorporate a pre-treatment checklist which includes checks for known error pathways like this (e.g. “Check that default catheter lengths (1,500 mm) are NOT used”).

ANALYSIS OF OTHER RECURRING THEMES

Image-Guided Radiation Therapy (IGRT)/Setup-Related Events

Case 8: 1 of 4 fractions (1,250 cGy/Fx) incorrectly positioned

Misalignment of patient for one out of four fractions in lung SBRT. Intended treatment plan was 5,000 cGy in four fractions to two lesions (each lesion consisting of an individual isocenter). Patient was aligned using cone beam computed tomography (CBCT) daily, with one CBCT taken per isocenter. For fraction A, the daily treatment document did not have physician initials. CBCT for fraction A on that day was approved at the end of the next day. Possible discrepancy of approximately 3 cm superior-inferior for fraction A was discovered on IGRT review during final physics check.

This is one of approximately 28 IGRT events documented this quarter. Clearly we need to increase the attention paid to how to decrease the number of IGRT-related issues throughout the field.

Contributing factors in this case included:

- Failure to follow policy/process on physician initialing the daily treatment document.

Actions and Recommendations:

- Examine the IGRT events that have occurred within your facility. Evaluate your IGRT workflow and identify areas of opportunity within that process. Ask what errors have the potential to develop from your current workflow and review where in the process your IGRT events occurred. Design fail safes within that workflow process to target your identified areas of opportunity.

ANALYSIS & COMMENTARY | continued

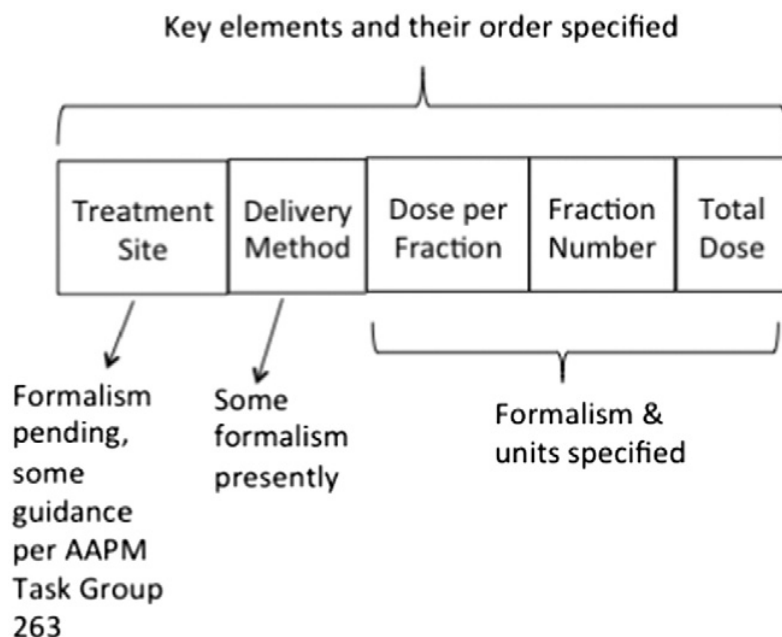
Prescription-Related Events

Events that are related to prescription issues were highlighted several quarters ago. They continue to occur with a list of examples from this quarter below:

- *The prescription in the TMS is 500 cGy in 4 fractions, though intended to be 400 cGy in 5 fractions.*
- *Physician wrote prescription for electrons to 100% isodose line, plan was created using 90% isodose line. Physician approved plan, but did not change prescription in the TMS.*
- *The TMS treatment prescription had the number of fractions changed from the initial physician tab note, but neither the dosimetrist or physician section notes reflected the change in fraction number.*
- *The patient was prescribed 400 cGy x 5 fractions, but the plan was created and approved for 500 cGy x 4 fractions. The discrepancy was not noticed during the physicist or therapist plan checks. Prior to treatment, the therapist at the linac console noticed the discrepancy.*
- *During physician review of TMS prescription, the physician noted that the plan and prescription did not match the physician note. The note requested 5400 cGy at 180 cGy/day and the plan was done with 5,400 cGy at 200 cGy/day. The plan wish list did not match the physician note either, but the plan wish list was also wrong for the given plan (3,420 fractions at 2 cGy/fraction).*
- *Patient started treatment and received the first fraction before the attending physician approved the MU calculation document. This is a big deal for 1,000 cGy/fraction SBRT.*
- *Patient scheduled to receive 15 fractions. After 1 treatment, the plan was changed for the next 14 treatments. As this change was being made, the patient was receiving fraction 2. The TMS recorded the second treatment and scheduled the revised plan for another 14 treatments, which would have resulted in 16 fractions instead of the 15 prescribed. This was caught by a physicist during the weekly chart check.*
- *Patient was prescribed with 600 cGy x 5 fractions IMRT, to be treated every day. However, it was confused as SBRT treatment and was scheduled and delivered every other day.*
- *Patient was supposed to get 13 fractions for a total dose of 3,900 cGy. He had one fraction and then a plan revision; somehow the first fraction was added to the original prescription instead of being subtracted from it.*
- *Prescription changed and not reapproved by the physician. The prescription had to be approved while patient was on the table.*
- *The energy in the prescription was 6 MV. The plan was done using 15 MV and 10 MV, and the plan was approved by the treating physician. Discovered during weekly chart check by physics resident. The planner, the attending physician, the physics double checker, and the therapists all missed the energy difference.*
- *Physician wrote a prescription for specific vertebral bodies, however dosimetry noticed that the vertebral bodies in the prescription did not match the fields. The fields were correct and prescription was wrong.*

Actions and Recommendations:

- Implement a standard prescription within your facility to decrease the risk of miscommunication and enhance patient safety in the delivery of care. The “Standardizing dose prescriptions: An ASTRO white paper” (Evans et al., 2016) provides rationale, challenges of standardization, and the key elements. Please reference the full article as well as the RO-ILS [October 2016 Tip of the Month](#).



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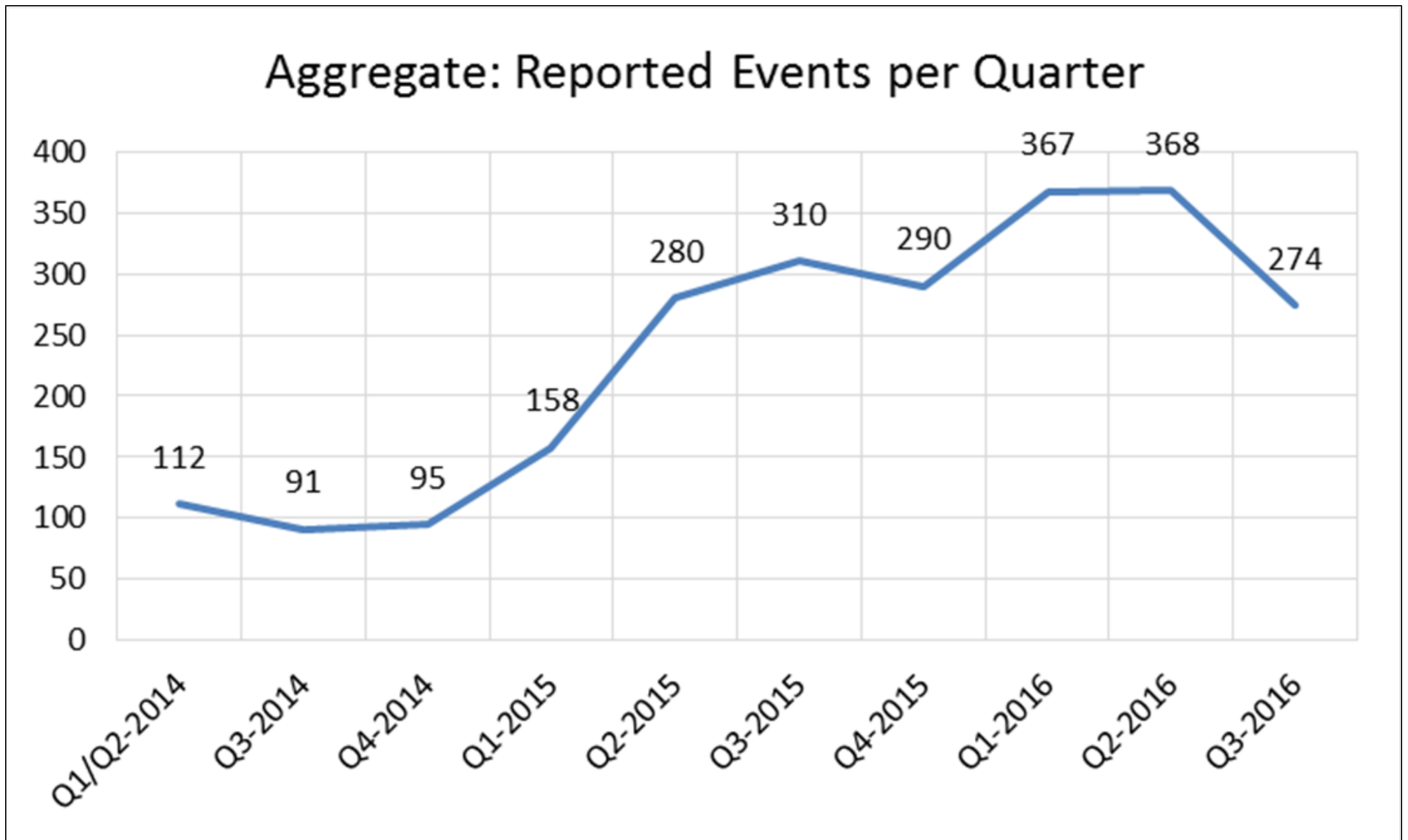
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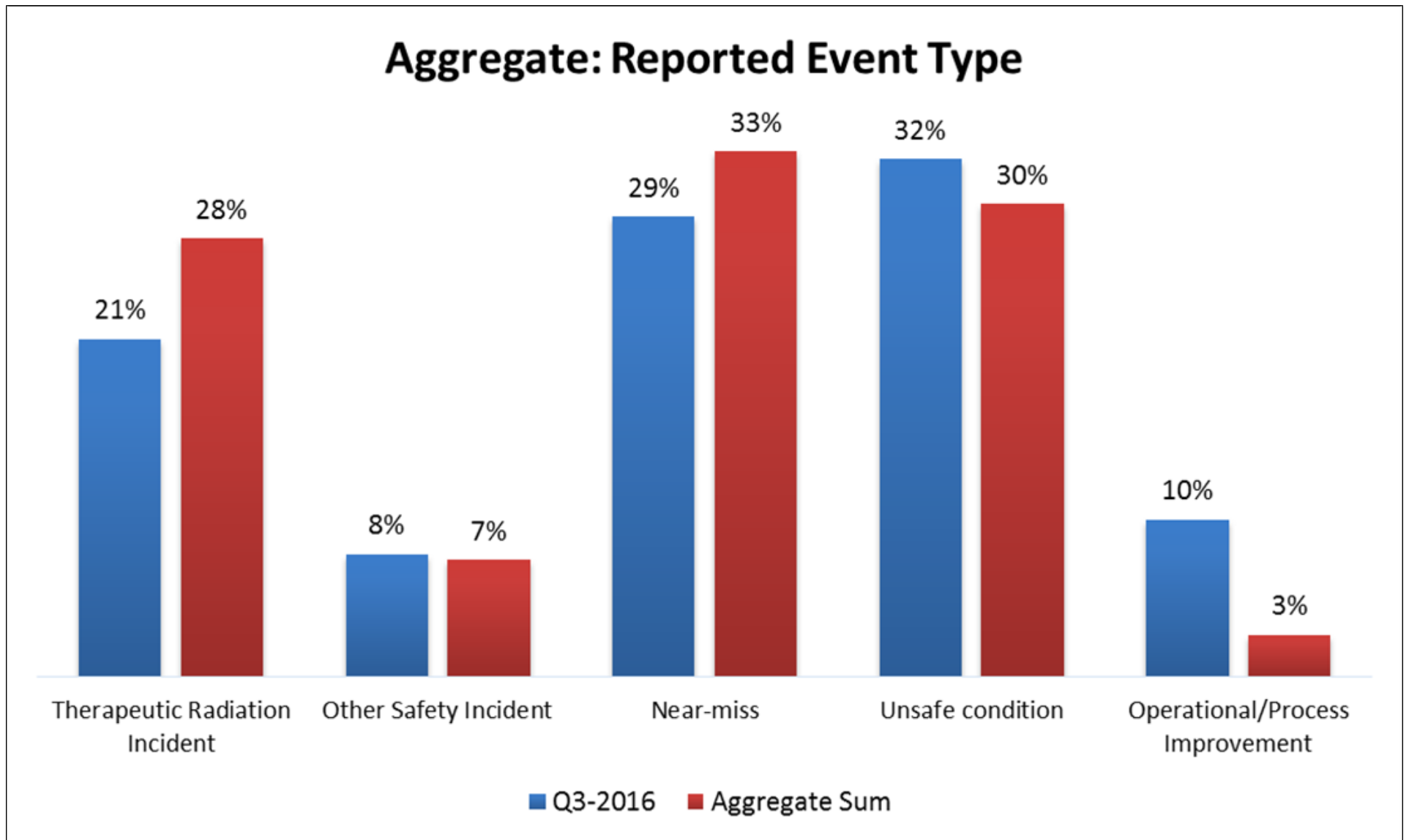
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AGGREGATE ANALYSIS GRAPHS

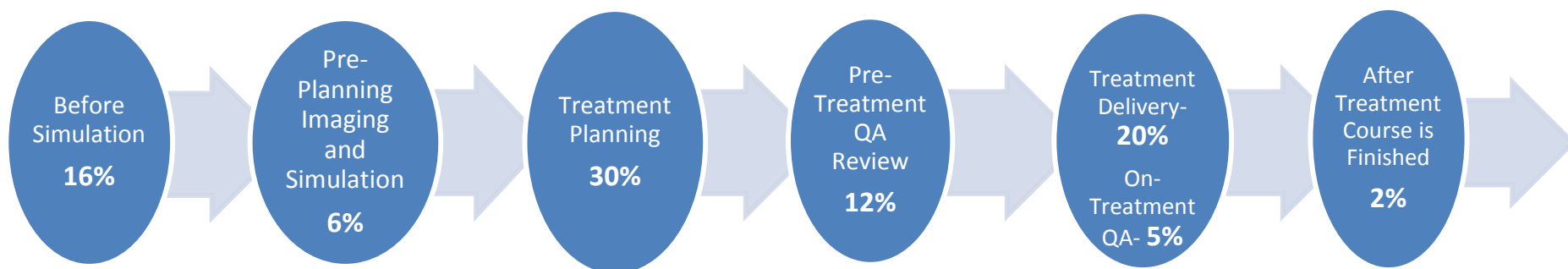


AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued

Q3-2016:
Workflow Step Where Event Occurred



Equipment and Software QA

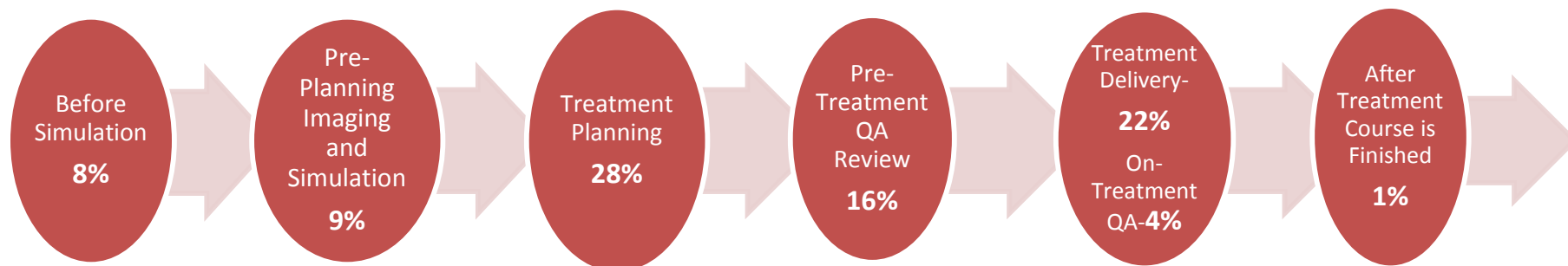
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Outside the Radiation Therapy Workflow or Other

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AGGREGATE ANALYSIS GRAPHS | continued

Aggregate Sum:
Workflow Step Where Event Occurred



Equipment and Software QA

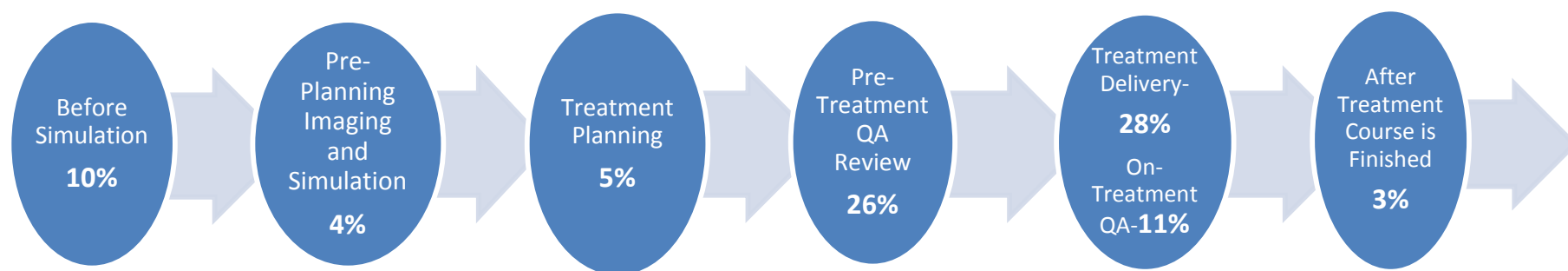
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AGGREGATE ANALYSIS GRAPHS | continued

Q3-2016:
Workflow Step Where Event
Discovered



Equipment and Software QA

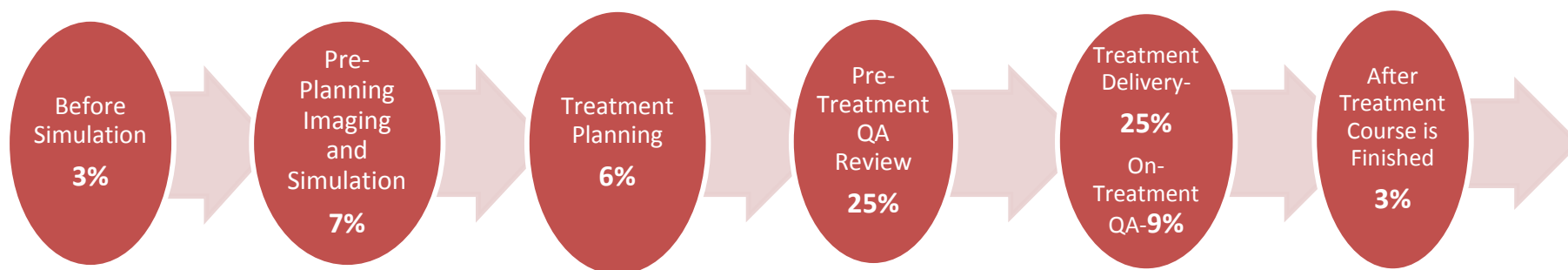
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AGGREGATE ANALYSIS GRAPHS | continued

Aggregate Sum:
Workflow Step Where Event
Discovered



Equipment and Software QA

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Outside the Radiation Therapy Workflow or Other

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AGGREGATE ANALYSIS GRAPHS | continued

