RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

AGGREGATE REPORT

Q3 – Q4 2018

JULY 1, 2018 – DECEMBER 31, 2018

PATIENT SAFETY WORK PRODUCT

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TABLE OF CONTENTS

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AGGREGATE REPORT CARD – Q3 – Q4 2018

July 1, 2018 – December 31, 2018

METRIC	Q3 2018	Q4 2018	AGGREGATE HISTORICAL SUM
Reported Events	**767**	**739**	**7,968**
Therapeutic Radiation Incidents	92	102	1,458
Other Safety Incidents	111	113	906
Near Miss	137	138	1,810
Unsafe Conditions	51	51	1,356
Operational/Process Improvement	376	335	2,438
Most Commonly Identified Workflow Step Where Event *Occurred*	**Treatment Planning:** 29% (223/767)	**Treatment Delivery Including Imaging:** 32% (233/739)	**Treatment Planning:** 30% (2396/7968)
Most Commonly Identified Workflow Step Where Event was *Discovered*	**Treatment Delivery Including Imaging:** 34% (264/767)	**Treatment Delivery Including Imaging:** 35% (257/739)	**Treatment Delivery Including Imaging:** 30% (2421/7968)
Most Commonly Identified Treatment Technique	**IMRT/VMAT:** 30% (233/767)	**IMRT/VMAT:** 33% (244/739)	**3-D:** 25% (2025/7968)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents that Did Not Effect Multiple Patients	**≤5% Maximum Dose Deviation to Target:** 34% (30/88)	**≤5% Maximum Dose Deviation to Target:** 30% (29/98)	**≤5% Maximum Dose Deviation to Target:** 60% (665/1117)

ANALYSIS & COMMENTARY

INTRODUCTION

This Aggregate Report contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System®. The report discusses three featured themes: vertebral body alignment, HDR events and patient identification issues. This highlights an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS.

Events that have been entered into the RO-ILS portal and reported to the patient safety organization (PSO) are reviewed by the Radiation Oncology Healthcare Advisory Council (RO-HAC) and as part of that review, RO-HAC adds specific contributing factors to the events. Case studies exemplifying the report themes are presented below along with possible strategies for mitigation. In certain circumstances, Clarity PSO is able to arrange a conference call between the practice and a RO-HAC member to discuss a specific event for inclusion in RO-ILS education. With Clarity PSO working as the intermediary, these conversations allow for increased engagement with participating practices, promotion of positive safety culture and more in-depth education to share with the radiation oncology community. RO-ILS thanks the practice who reported the event detailed below as Case #1 for their willingness to directly engage with RO-HAC and share their mitigation strategies.

THEME I: VERTEBRAL BODY ALIGNMENT

Identifying the correct vertebral body for alignment can be challenging for various reasons. A few of the obstacles in correctly aligning the spine include the similarities from one vertebral body to the next, the lack of other unique identifying structures adjacent to the spine and patient-specific concerns (e.g., pain associated with spine metastasis).

CASE STUDY #1: VERTEBRAL BODY AND RIB MISALIGNMENT FOR THREE FRACTIONS

During a weekly physics chart check it was noted that a patient's vertebral body and rib were incorrectly aligned for three of their initial 18 fractions of palliative treatment. This incorrect alignment occurred on separate non-consecutive treatment days by three different therapists. The patient's carina was contoured but was poorly visible on the kV images. The patient was not indexed to the table and the shifts were minimal. Physics reviewed the incorrectly aligned images and estimated the offset to be approximately two cm. A plan sum was generated in the treatment planning system (TPS) to demonstrate the dose difference due to the incorrect alignment. This was discussed with the physician who decided to add two additional fractions to account for the lower PTV coverage due to the offset. Critical structure doses were still within acceptable limits. The patient's partial rib was noted during retrospective review so this was contoured to assist in alignment for the remaining treatment fractions.

Contributing factors identified by RO-HAC:

- Low quality kV images.
- Lack of additional contoured structures to assist in alignment.
- Cross-coverage by multiple therapists.
- Confirmation bias.
- Small field of view (FOV) for imaging which did not allow for capturing of nearby relevant anatomy.
- Lack of patient indexing.

CASE STUDY #2: PHYSICAL CONSTRAINTS RESULTED IN MISALIGNMENT FOR ONE FRACTION

During a weekly physics check when performing offline image review, it was noted that the patient was misaligned longitudinally by one vertebral body for one treatment fraction. The physician had reported that the patient had been in a great deal of discomfort at the time the vertebral body was misaligned. A mockup of the incorrect alignment and a plan sum were generated in the TPS for physician review. The team determined that no further action was necessary.

Additional Contributing factors identified by RO-HAC:

- Time pressure due to patient's discomfort.

LESSONS LEARNED AND MITIGATION STRATEGIES

It can be challenging to identify the correct vertebral body on imaging and this likely happens more often than it is reported or caught. Review of images, whether daily by the physician or during weekly physics review, can help catch errors after they have already occurred and revise the patient's future treatment, if necessary. To prevent the error from occurring, a systematic approach should be designed so that visual identification of vertebral bodies is not solely based upon bony anatomy, and the team follows a consistent pattern of matching multiple anatomic points. When designing the process of treating vertebral bodies there should be two component pathways. The first should be a process that indicates standard procedure. The second should be a process for how to approach deviations within that standard procedure (i.e., when a large shift is required, and a potential misalignment may be in process). To minimize the risk of incorrect vertebral body localization, consider the mitigations suggestions below.

Elements to include in the standard procedure:

- **Contour adjacent structures** (i.e., ribs, cricoid, ilium, carina, any unique identifier) to the treatment field. This will act as a reference while localizing the field with imaging.
- **Increase the FOV** length to include either the superior or inferior portion of the section of spine being treated (e.g., include C7 or L1 if treating the t-spine). This would allow therapists the ability to more clearly identify which vertebral body they are aligning.
- **Institute maximum shift tolerances** allowed between set-up and treatment. A practice's policy may contain varying maximum shift tolerances depending on technique (e.g., IMRT, 3-D CRT, SBRT), fractionation scheme, immobilization method, etc. For example, practices may want therapists to call a physician or other staff to assist and review shifts greater than 2 cm for standard fractionation treatments. Practices may also want to set more stringent parameters for shift tolerances.
- **Do not use CBCT only** for alignment of vertebral bodies. When possible, use orthogonal images and CBCT to localize the target. The initial imaging technique is used for the alignment of the target and the second imaging technique is used for verification and very minimal shifts if needed. The order of CBCT and orthogonal images varies.
- Whenever possible, **index immobilization devices** to the table and capture the table position in the oncology information system (OIS) on the first day of treatment. If the immobilization is indexed to the table, treatment shifts should always be in the appropriate tolerance window. Any shift larger than the determined tolerance would be a red flag to the staff that something may not be aligned correctly.

- **Minimize rotating staff mid-treatment.** Employing two therapists to be present for treatment improves continuity of care and allows for intradisciplinary peer review of the patient's set-up. Multiple staff changes can cause confusion (e.g., see Case 2 in the Q1 2017 Report). If a hand-off between treatment therapists is necessary, detailed set-up instructions should be documented in the patient's medical record and extra communication may be necessary regarding difficult cases/set-ups.
- **Include alignment structures on imaging orders.** This written documentation can help physicians clearly communicate to therapists which structures should be referenced when reviewing images. For instance, when treating C1-C7, the physician may direct therapy to align to C3, close to isocenter.
- **Standardize the image review process.** Therapists may first align the vertebral bodies based on the shape of the vertebral bodies, then check this against adjacent structures (e.g., carina, ilium, last rib), and pass the computer mouse to a colleague for them to independently verify the alignment, rather than looking over another's shoulder.

Elements for circumstances that deviate from the standard procedure:

- **Formalize an action plan when the shift tolerances are reached or exceeded** that align with the practice's maximum shift policy. The action plan should detail expectations, including who to notify, what to do and how to document. Implement this action plan by ensuring staff are aware of the follow-up process, especially those who will be notified when tolerances are reached.
- **Ensure that the shift tolerance policy includes process steps that address discrepancies in alignment between the two imaging techniques** (CBCT and orthogonal images). These process steps should include components such as referring staff to a physician for verification, repositioning the patient and beginning the process again. It is vital that leadership hold all staff and clinicians accountable to following the policy.
- **Encourage a culture of safety** by allowing staff to take a pause when something seems "off". One may wish to formalize a "code phrase" for staff to use when they are concerned an error may be taking place, without alarming the patient. Some institutions use the phrase "I need clarity" to indicate that a team member is uncomfortable and wants to stop the line. Encourage dialog and communication between staff members to walk through a situation when someone feels uncomfortable about a treatment. If an incident or near miss does occur, use that as a teaching moment to see what could have been done to prevent the error and what can be done in the future to reduce the likelihood of it happening again. Focus on the process, not the people when discussing root cause analysis. In the instance of Case 1, the practice discussed the event the very next day during their daily huddle, which includes interdisciplinary representatives from dosimetry, physics, etc. Additionally, leadership asked therapists for suggestions on how processes could be improved to minimize the error pathway. As a result, the practice revised the physician's imaging order to specify which primary structured should be utilized as a reference for alignment. These are great examples of how to operationalize a positive safety culture.

RESOURCES

- The American Society of Radiologic Technologists (ASRT) provides numerous educational offerings for therapists. Specifically related to the topic of vertebral alignment, ASRT offers a course titled 'Sectional Anatomy Essentials Module 4: The Spine'.
- Vertebral alignment has previously been discussed in RO-ILS reports (See Case 3 in the Q2 2015 Report and Case 1 in the Q3 2015 Report).
- Other organization outside of the United States have also discussed vertebra identification errors, including the French Nuclear Safety Authority (Autorite de surete nucleaire – ASN) and the Public Health England.
- An i.TreatSafely Video recreates an incident involving patient positioning and can be utilized as a teaching tool. Play the video for staff and discuss the event. What multiple factors influenced the outcome? What could have been done differently? Could a similar event occur at your practice? Why or why not? Do local processes need to be changed? The i.TreatSafetly video can be found by searching "Therapists at the Linac" or "118350878" on the website.

THEME II: HDR TREATMENT LENGTH AND DWELL TIMES

In February 2019, a cancer center outside of the United States suspended brachytherapy treatment for cervical patients after discovering that 25 patients over the past two years were treated using the guide tubes of the incorrect length. The ultimate cause of this systematic error that affected numerous patients has not yet been identified and/or released. This prompted RO-HAC to review RO-ILS events related to high-dose-rate (HDR) brachytherapy. As is the case with vertebral body misalignment, HDR brachytherapy have been previously featured in RO-ILS reports. The Q1 2016 Report discussed an event in which there was a discrepancy in length measurements involving equipment from multiple vendors. Additionally, the Q1 2017 Report included an event in which a patient was treated with the incorrect cylinder diameter.

Because of the increased dose per fraction and smaller number of fractions, incidents occurring during HDR procedures can have a larger overall effect on a patient's course of treatment and must be given more thought, similar to stereotactic and hypo-fractionated external beam treatments.

CASE STUDY #3: NEAR MISS, WRONG NEEDLE LENGTH FOR AN HDR PROSTATE TREATMENT

As a part of a prostate HDR procedure the physician cut one of the needles shorter than the others. This was neither documented nor communicated to other staff involved in the procedure. Prior to treatment and during the machine check of the catheter pathways, the treatment unit showed multiple obstruction interlocks for the channel with the needle that was cut shorter. The physicist requested that all needles be re-measured which discovered the needle that was cut shorter.

Contributing factors identified by RO-HAC:

- Missing written communication.
- Deviating from standard processes.
- Expectation bias.

CASE STUDY #4: INCORRECT DWELL TIMES UTILIZED FOR AN HDR TREATMENT

Case was planned for 650 cGy x 3 fractions to a depth of 5 mm. The prescription at the treatment unit indicated that a dose of 700 cGy was to be delivered. The physicist checking the plan, noted the discrepancy and, assuming the 700 cGy was incorrect, deleted the plan, changed the prescription in the planning system to be 650 cGy and re-loaded the plan at the treatment unit. Unbeknownst to the physicist, this action rescaled the dwell times by a factor of 650/700 = 7 percent. During pre-treatment checks it was noted that the dwell times of the re-loaded plan were about 7% lower than the original plan but no action was taken. It was not realized that the prescription change actually scaled down the dwell times and the patient was treated. This resulted in the delivered dose to be 7% less than what was intended. The error was discovered after treatment delivery when the discrepancy was further investigated.

Contributing factors identified by RO-HAC:

- Incomplete or insufficient HDR treatment procedures.
- Expectation bias.
- Unclear, incomplete or missing communication.
- Compressed time scale.
- Lack of interface between the treatment planning computer and HDR treatment unit.

LESSONS LEARNED AND MITIGATION STRATEGIES

Mitigation of the many systemic treatment errors, like the one initially described that affected 25 patients, often begin with thorough acceptance and commissioning policies and procedures. Acceptance testing and commissioning must be well documented and reviewed by another qualified individual prior to using any equipment in the clinic. This process should include verifying the geometric properties of the equipment using both physical measurements and imaging, when applicable. Additionally, periodic testing should be done on all equipment at appropriate intervals. The American Association of Physicists in Medicine (AAPM) Task Group Report 56 "Code of Practice for Brachytherapy Physics" contains acceptance testing and daily, quarterly and annual quality assurance guidelines for equipment used in brachytherapy procedures. Additional documentation regarding the per treatment, quarterly and annual quality assurance tests can be found in the Canadian Partnership for Quality Radiotherapy document "Technical Quality Control Guidelines for Brachytherapy Remote Afterloaders".

Items that should be documented and reviewed as part of equipment acceptance and commissioning include, but are not limited to:

- Visual inspection of the equipment and accessories;
- Verification of the proper functionality of equipment and accessories;
- Characterization of the physical, geometric and radiographic (if applicable) properties of the equipment and accessories;
- Review of the manufacturer's instruction manuals;
- Review of ASTRO, AAPM, American Brachytherapy Society (ABS), etc. reports relevant to the use of the equipment and accessories;
- Education and training of staff using of equipment; and
- Update of relevant policies and procedures.

Both systematic errors and errors that affected only one patient can greatly benefit from a detailed review of a practice's policies and procedures for simulation, treatment planning and treatment delivery. These thorough policies and procedures must ensure the necessary information needed to treat the patient correctly is documented during simulation and communicated to treatment planning and then communicated to the treatment delivery team. The integrity of this information (e.g., dose per fraction, number of fractions and total dose) should be checked by a second qualified individual prior to treatment and compared against the written directive/prescription for agreement. Specifically, for HDR, applicator dimensions and treatment lengths must be documented and verified, throughout the entire process. For treatments in which a transfer guide tube is used, the applicator/transfer guide tube system must be evaluated to verify the correct geometry is used for treatment planning and treatment delivery. Some events can be avoided if the dimensions of the applicator are reviewed on the CT scan prior to treatment. Additionally, the integrity of the dwell positions and dwell times should be verified between treatment planning and treatment delivery. Generally, staff should not rely on expected values when entering or checking data in the TPS or treatment delivery system. Expectation bias can mislead clinical staff and therefore physical measurements should be done whenever possible.

RESOURCES

- The AAPM TG report #59 "High-dose-rate brachytherapy treatment delivery" contains guidelines for HDR treatment procedures.
- The Canadian Partnership for Quality Radiotherapy released "Technical Quality Control Guidelines for Brachytherapy Remote Afterloaders" in 2015.
- The ABS collected corrective and preventive actions from their membership related to an wrong source transfer tube length safety event.

THEME III: PATIENT IDENTIFICATION AND COMMUNICATION

A benefit of systems and programs like RO-ILS is that clinical staff can learn from events at other practices in addition to their own errors and personal experiences. It is tempting and also important to focus on the specifics of an error and to understand the intricacies of involved equipment, software and human factors. At the same time, the more fundamental aspects of patient safety must not be forgotten as those factors seem to permeate many, if not most, safety events. Communication is one of those fundamental factors. The following case studies focus on some communication-related events centered around patient identification.

CASE STUDY #5: PHYSICIAN PERFORMED A CONSULTATION ON THE WRONG PATIENT

The physician was paged to see Patient #1, an inpatient consult. When the physician arrived, there was only one patient within the inpatient holding area. The physician asked the individual if they were Patient #1 (by stating Patient #1's name) and the individual replied by nodding. The physician continued with the consult and the individual continued to nod, which the physician took to indicate agreement. Once the consult concluded, the physician received a second page that Patient #1 was still in the inpatient holding area waiting. The physician spoke with clinic staff that Patient #1 had already be seen. Clinic staff confirmed that the physician had actually completed a consultation on Patient #2 and not the correct inpatient consult, Patient #1. A two-step verification process (name and date of birth) was conducted with Patient #1 and the physician then completed the consultation for Patient #1 as originally intended.

Contributing factors identified by RO-HAC:

- Patient ID not verified (two-step verification process was not performed appropriately).
- Patients should always identify themselves such as by stating their own name and DOB. The staff member must then confirm.
- Miscommunication about the location of Patient #1.
- Patient-specific factors leading to the patient responding to the incorrect name (e.g., poor hearing, altered mental status, distraction).

CASE STUDY #6: WRONG PATIENT WAS ALMOST TREATED

There were two patients with the same last name that both required treatment to the right breast. Patient A was currently under treatment, while Patient B was scheduled to start treatment soon. Patient B's attending requested the scheduled start date to be moved to an earlier date. This request was not given to the appropriate person which led to a delay in moving Patient B's start date until a few days prior to the originally scheduled start date. Patient B subsequently arrived on the originally scheduled start date as opposed to the newly rescheduled date. Patient B was mistakenly checked in under Patient A's appointment because both patients have the same last name and the exact appointment time was provided. Patient B was taken into the waiting room. The therapist, that went to get Patient B, recognized that this was the incorrect person because they had previously treated Patient A.

Contributing factors identified by RO-HAC:

- Patients with the same last name being treated for the same disease site.
- Incorrect communication (incorrect staff member was asked to reschedule Patient B).
- Untimely communication (unclear if Patient B received notice that their treatment was moved).
- Patient ID not verified (front desk staff did not confirm the patient's full name).
- Lack of automated flagging system for patients under treatment with the same/similar name.

Contributing factors identified by practice:

- Applicable policies existed but were not followed.
- Inappropriate assumptions were made, and information was not seen or sought.
- Failure to develop a plan to combat the problem.
- Equipment design and operations were suboptimal – poor human factors engineering.
- Human behavioral error causing a failure in skilled performance.

CASE STUDY #7: WRONG PATIENT HAD THEIR BLOOD DRAWN

A patient arrived for his radiation oncology simulation appointment and checked in at the front desk. The waiting area in this institution was shared by both medical and radiation oncology. The front office staff and clinical staff were all aware that this patient was present, but he had asked that they wait for his wife to arrive before proceeding with the pre-simulation consultation. When the nurse finally went to escort him and his wife to an exam room, they found that he was missing. The radiation oncology team walked around the department, walked outside and made several phone calls before ultimately finding the patient and his wife. They had walked away with a medical oncology nurse who had gone to the waiting room to get a different patient. The radiation oncology patient had undergone an un-ordered blood draw while he was in the medical oncology department and was understandably upset when he learned what had happened.

Contributing factors identified by RO-HAC:

- Patient ID not verified.
- Waiting room shared by multiple departments.

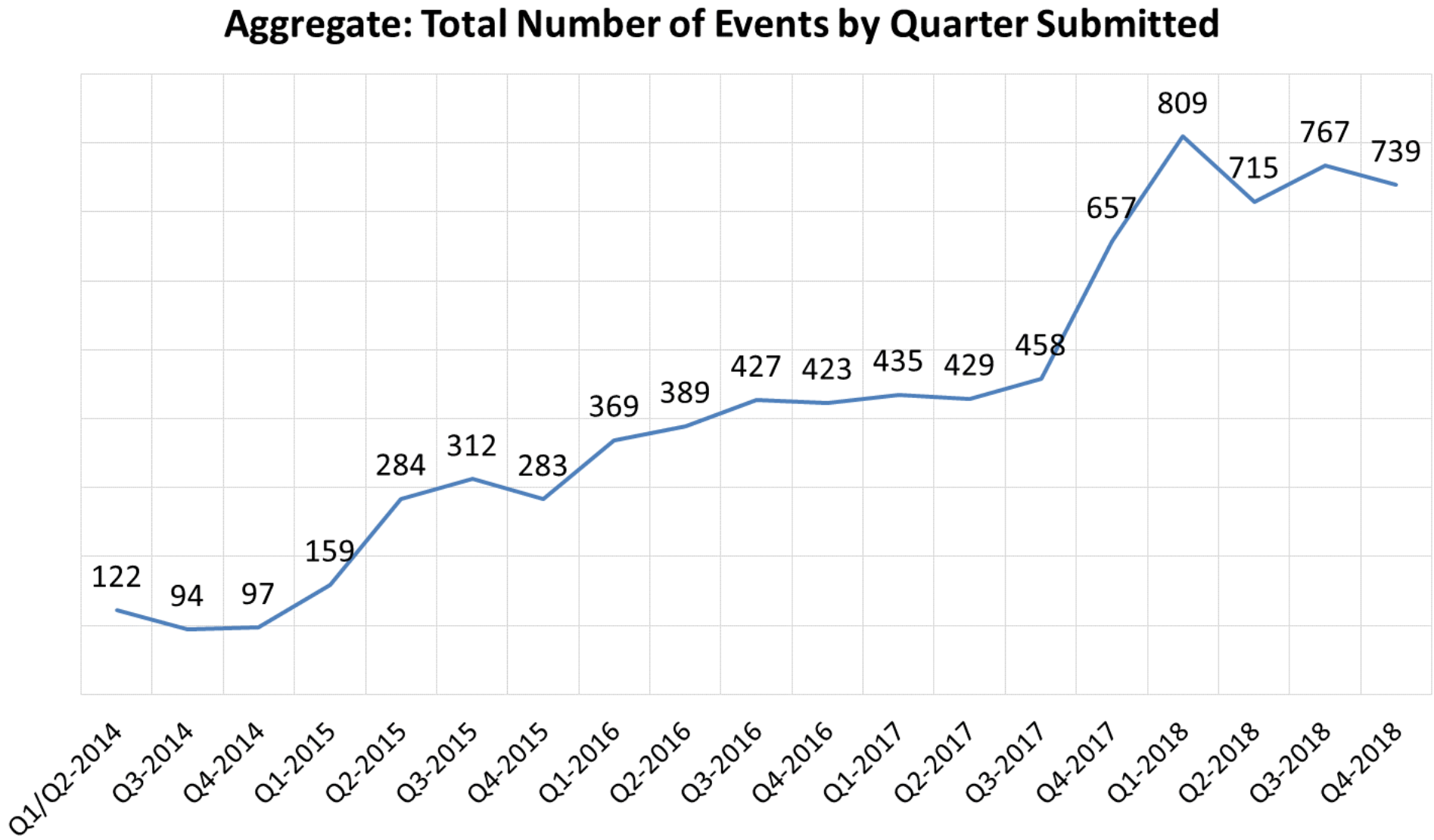
LESSONS LEARNED AND MITIGATION STRATEGIES

Some patients look alike, some have similar sounding names (or the same names), some are hard of hearing, and some are just present at the place and time that staff expect someone else to be there. For all of these reasons and more, it is imperative that practices have identification policies in place that are semi-automated. In other words, dual identification requirements such as by having the patient state their name and date of birth and/or use of an ID bracelet or card should always be upheld even when patients become familiar and it may seem unnecessary. These kinds of standards protect patients and staff from the periodic challenges such as language barriers, an eager yet hearing-impaired patient or a temporary lapse in memory.

Although it is not typically the case that medical and radiation oncology share a waiting room, multidisciplinary practices may share patients and heightened awareness coupled with open communication is critical. Good working relationships, including knowing each other's names, can improve teamwork and foster a safety culture between departments. Contact information should be readily available, and staff should be comfortable asking questions and picking up the phone when something seems off.

Communication may seem like a non-specific and generally applicable contributing factor to many errors. That is certainly the case though its importance should not be underestimated as it leads to pervasive issues from patient delays with increased anxiety to actual patient harm. Awareness of cases such as those described above may help us to recognize unsafe conditions prospectively and will hopefully reduce the risk of similar events happening in the future.

AGGREGATE ANALYSIS GRAPHS



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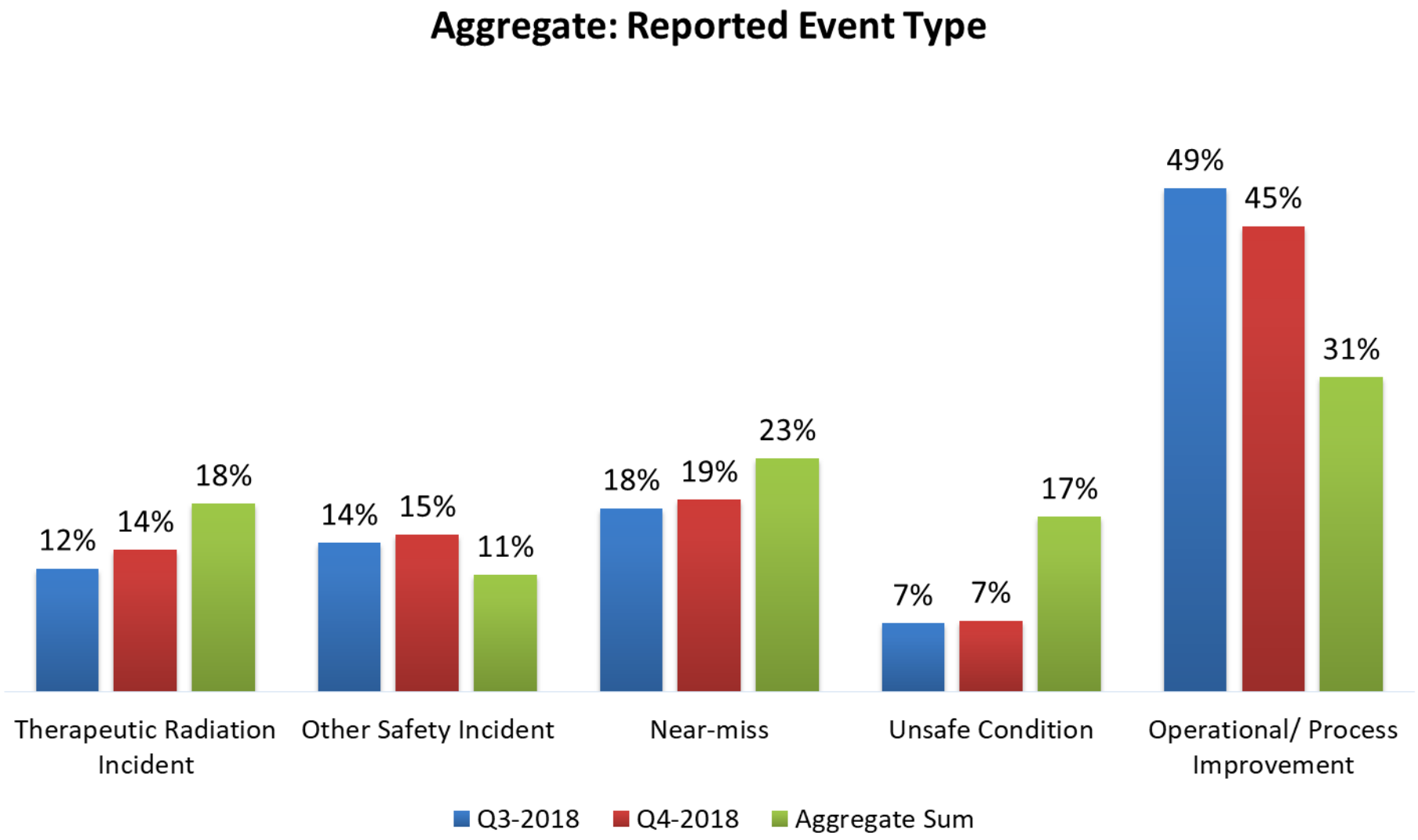
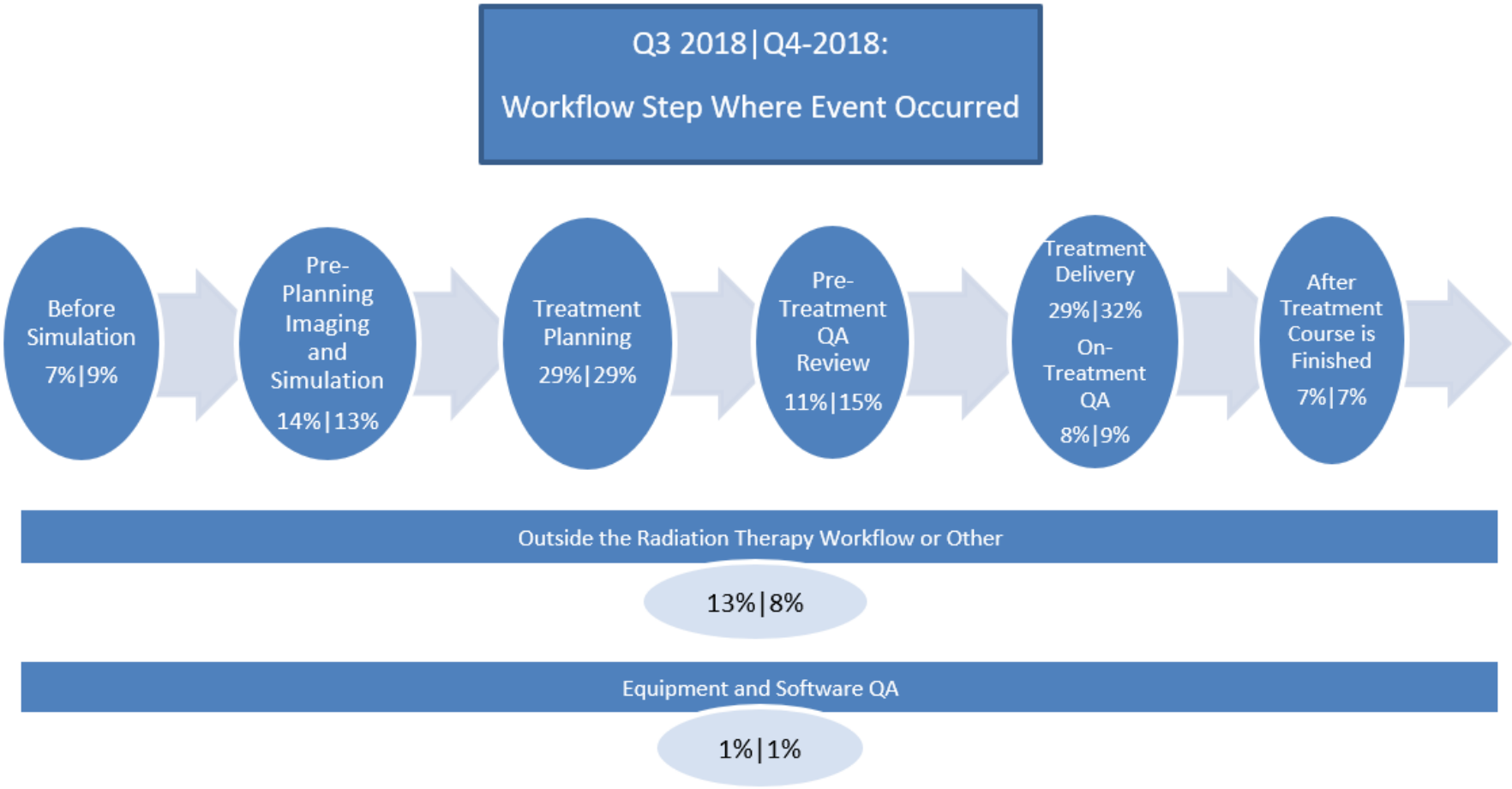


AGGREGATE ANALYSIS GRAPHS | continued



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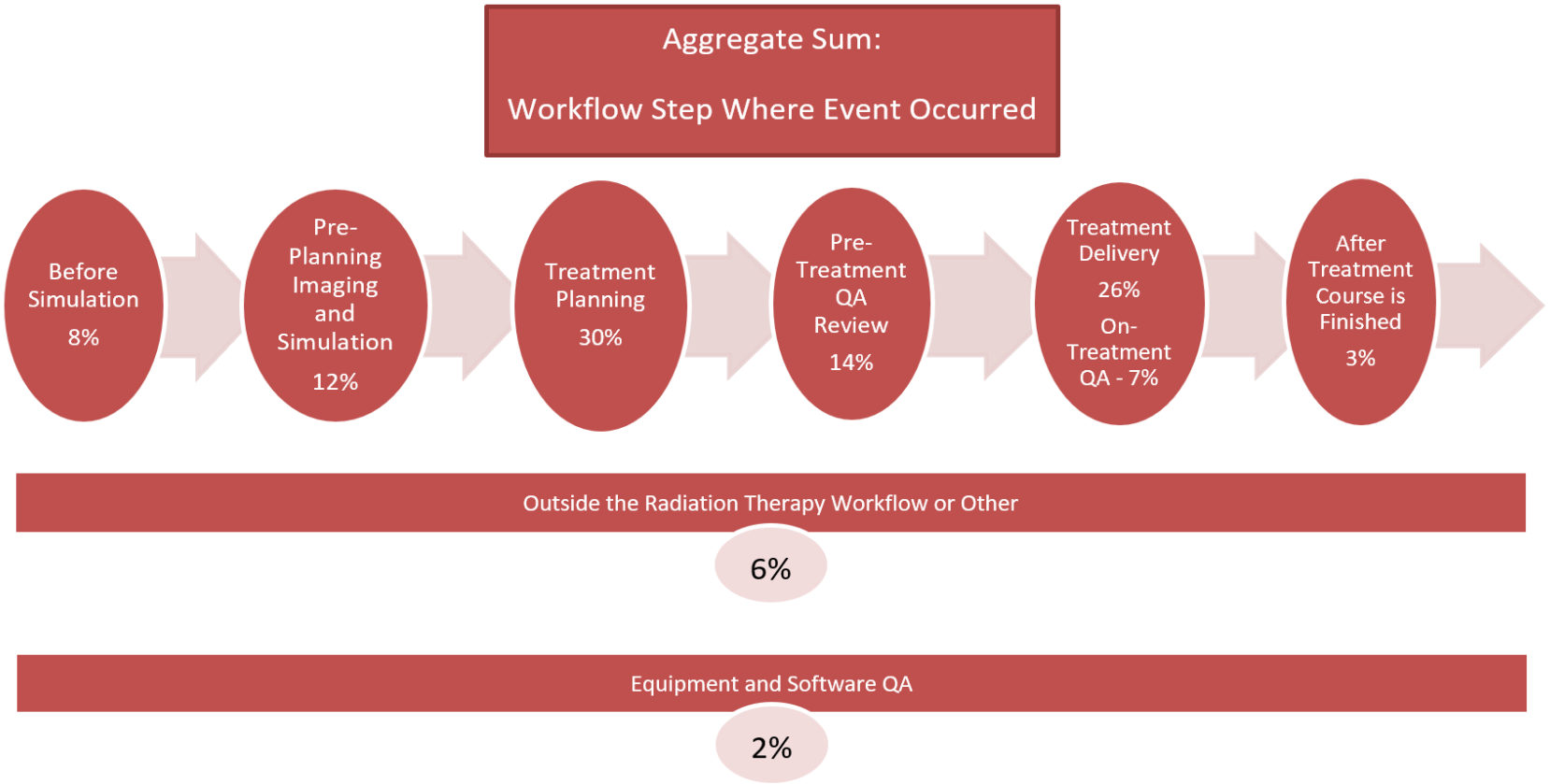

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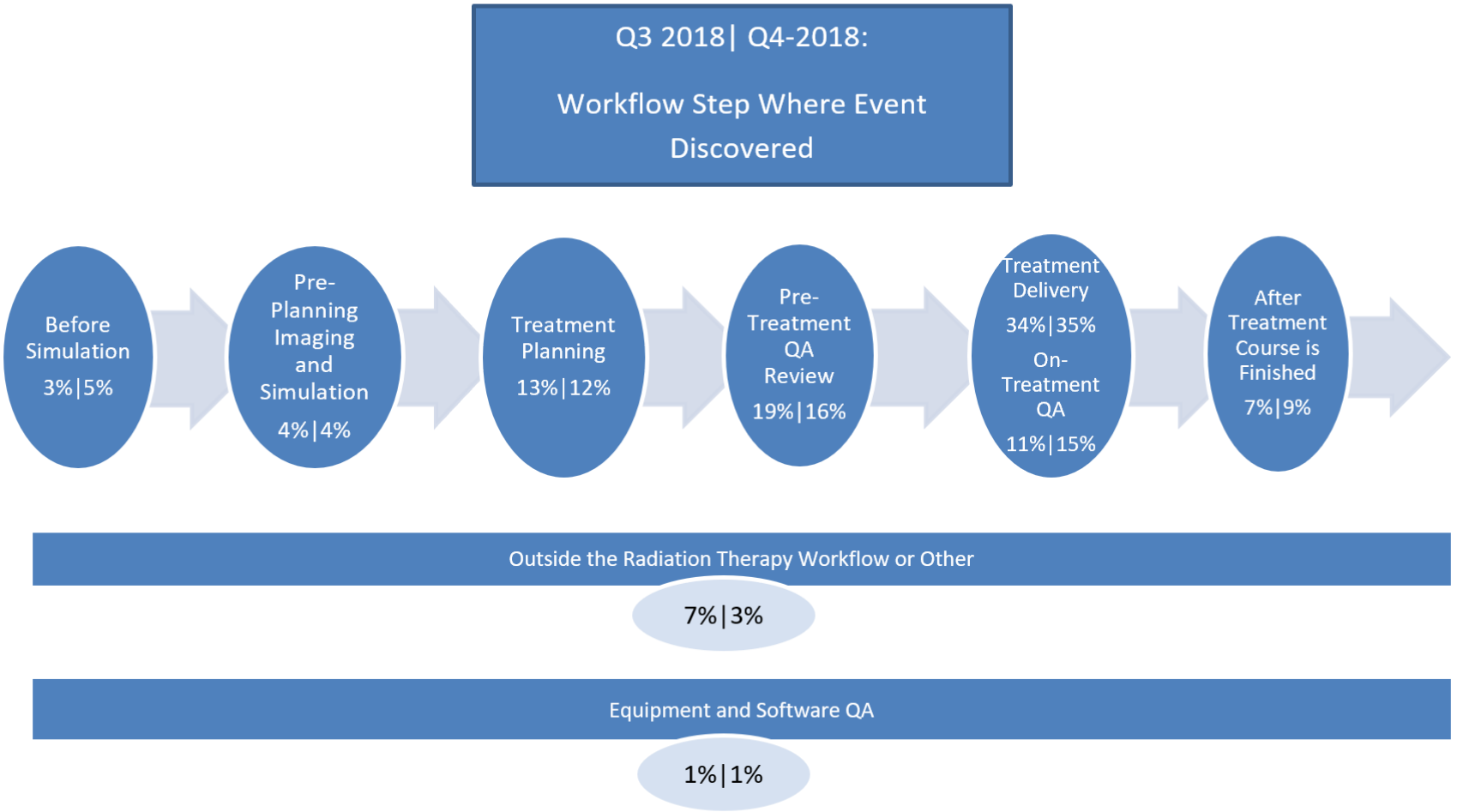

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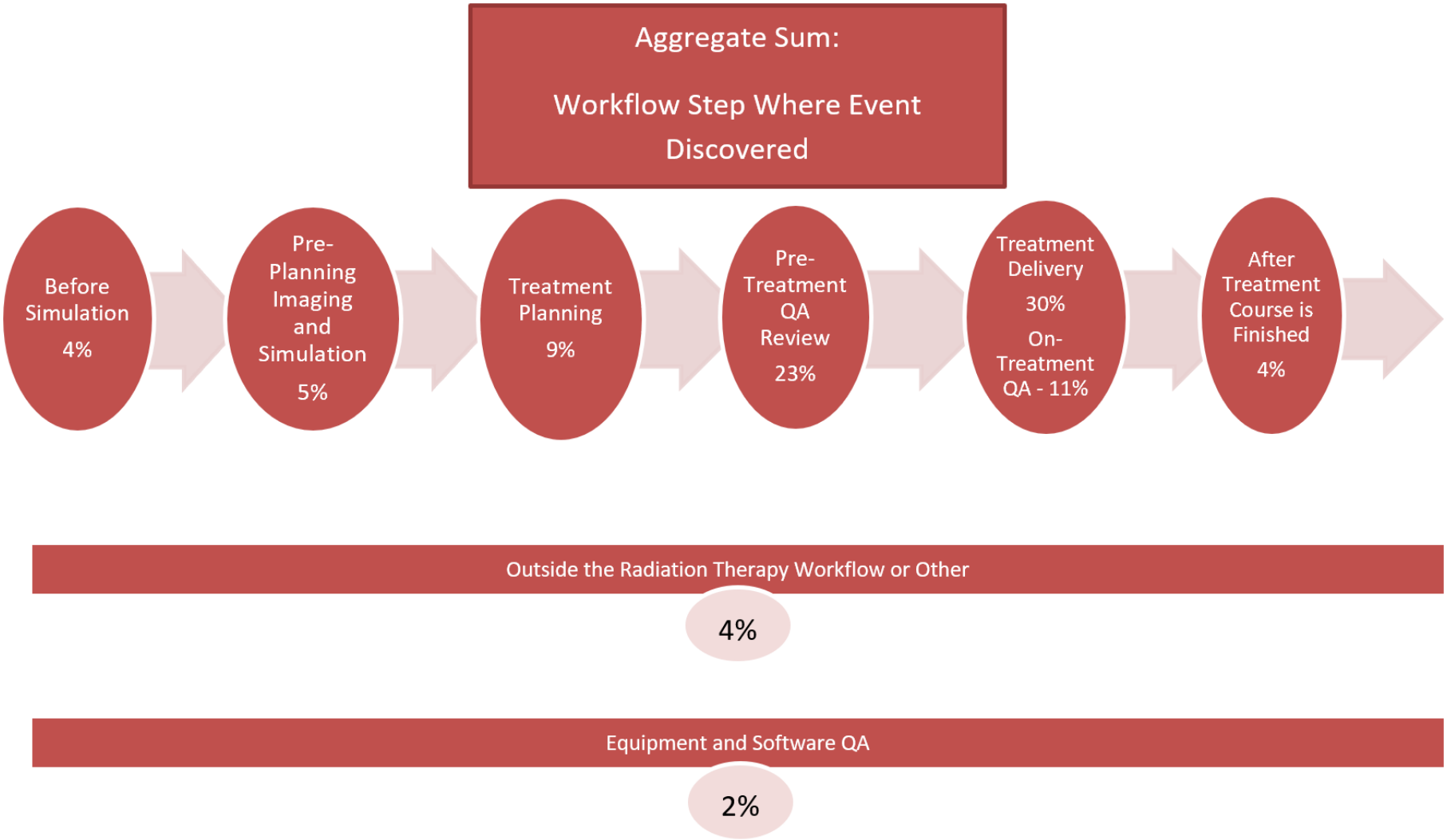

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