RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

AGGREGATE REPORT

Q1- Q2 2018

JANUARY 1, 2018 – JUNE 30, 2018

PATIENT SAFETY WORK PRODUCT

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RO-ILS® RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM
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AGGREGATE REPORT CARD – Q1-Q2 2018

January 1, 2018 – June 30, 2018

METRIC	Q1 2018	Q2 2018	Historical Sum
Reported Events	**798**	**648**	**6375**
Therapeutic Radiation Incidents	84	83	1253
Other Safety Incidents	133	95	672
Near Miss	149	152	1526
Unsafe Conditions	108	64	1239
Operational/Process Improvement	324	254	1685
Most Commonly Identified Workflow Step Where Event *Occurred*	**Treatment Planning:** 34% (272/798)	**Treatment Planning:** 37% (240/648)	**Treatment Planning:** 30% (1931/6375)
Most Commonly Identified Workflow Step Where Event was *Discovered*	**Pre-Treatment QA Review:** 31% (247/798)	**Treatment Delivery Including Imaging:** 32% (207/648)	**Treatment Delivery Including Imaging:** 29% (1867/6375)
Most Commonly Identified Treatment Technique	**IMRT/VMAT:** 32% (256/798)	**IMRT/VMAT:** 34% (218/648)	**3-D:** 26% (1631/6375)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents that Did Not Effect Multiple Patients	**≤5% Maximum Dose Deviation to Target:** 60% (42/70)	**≤5% Maximum Dose Deviation to Target:** 42% (31/74)	**≤5% Maximum Dose Deviation to Target:** 65% (601/920)

ANALYSIS & COMMENTARY

INTRODUCTION

This Aggregate Report contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System®. The report contains the featured theme: *the treatment planning process and hand-offs during transitions of care*. This highlights an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS.

FEATURED THEME: TREATMENT PLANNING PROCESS

The treatment planning process is a series of complex tasks performed by multiple individuals. The planner-physician interaction lies at the heart of the process, which is most often a dosimetrist but, in some instances, may be the medical physicist or other clinical staff. The specific details and order of the process varies by institution, but in general entails the following steps and include multiple transfer of tasks:

1. Clinical staff import and prepare simulation imaging data set,

2. The physician contours the target(s),

3. The planner contours the organ(s) at risk (OAR(s)),

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,

7a. The physician gives plan feedback to the planner and

7b. If necessary, the planner revises the treatment plan to achieve a plan that better manages the compromise between target dose and normal tissue sparing, per physician instructions,

8. The physician approves the plan.

Given the complexity of the planning process and the number of times that a task is passed back and forth between the physician and planner, it is obvious that clear, accurate, timely and effective documented communication is required for success. This critical demand for complex, multi-phase communication leaves little wonder as to why treatment planning errors comprise roughly one-third of all events reported to the RO-ILS database. The following summary of RO-ILS data provides insight into those events that occurred during treatment planning.

SUMMARY OF RO-ILS DATA: EVENTS THAT OCCURRED DURING TREATMENT PLANNING

From Q1 2014 to Q2 2018, 6,375 events have been entered into RO-ILS and reported to Clarity PSO. Of those, 1,931 events were documented as having occurred within the treatment planning workflow step. The following graphs provide insight into those 1931 events.

Figure 1 depicts the event's classification, RO-ILS data element *Classification* (#104). This graph reveals that approximately 15 percent of the events that occurred during treatment planning were classified as therapeutic radiation incidents. RO-ILS defines a therapeutic radiation incident as a safety event in which the radiation dose was not delivered as intended, with or without harm to the patient(s). Existing QA processes did not catch these errors before they reached the patient(s) and therefore there is an opportunity for improvement.

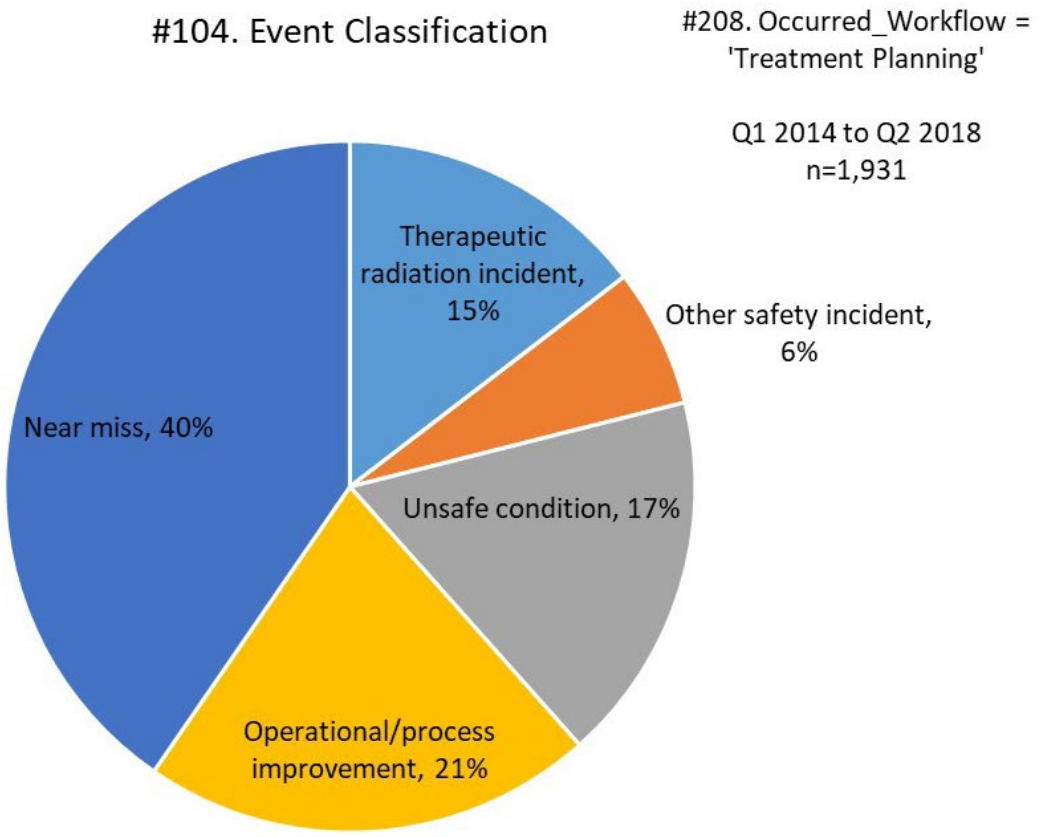


Figure 1: Event Classification for Events that Occurred During Treatment Planning (Q1 2014 - Q2 2018)

Figure 2 shows RO-ILS data element *Significance_Scale* (#225), "In terms of risk to patient safety, how significant was this event?" This data element was added to RO-ILS 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.

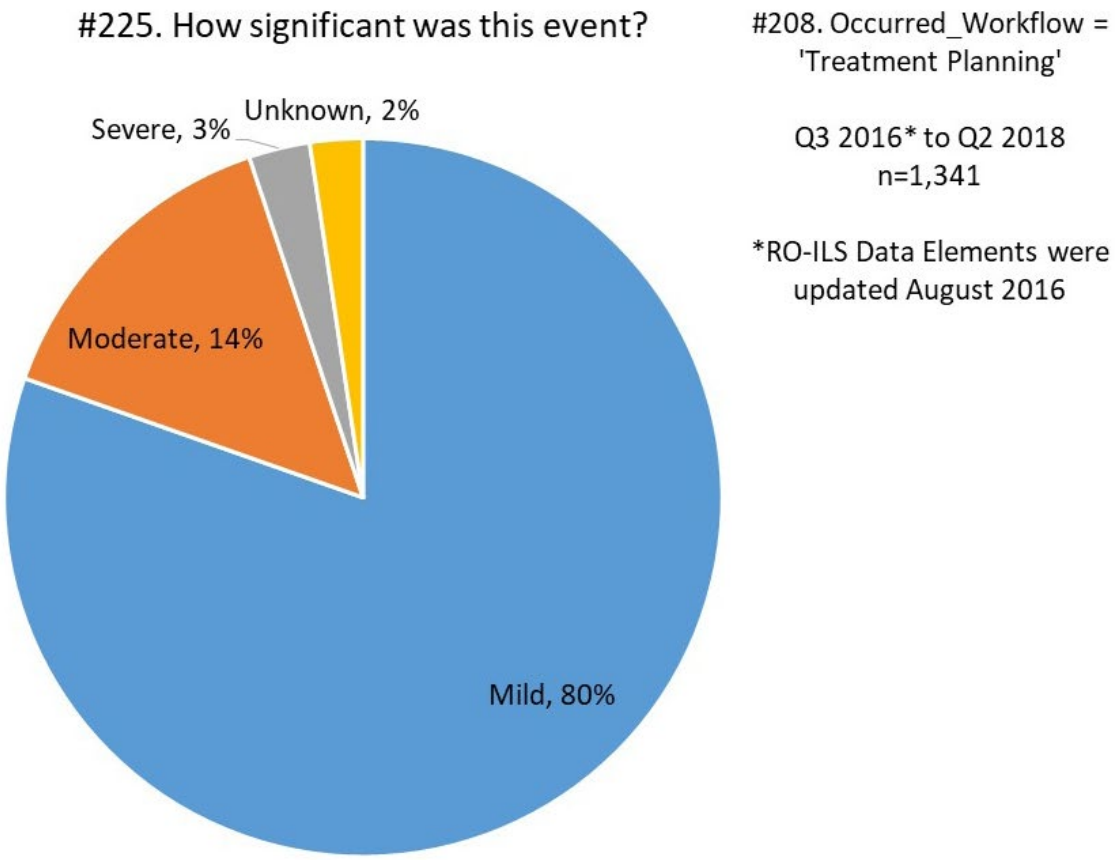


Figure 2: Significance of Events that Occurred During Treatment Planning (Q3 2016 - Q2 2018)

Figure 3 shows RO-ILS data element *Discoverer_Role* (#202), "Role of Person Who Discovered the Event". Figure 3 reveals 39 percent of events that occurred during treatment planning were discovered by radiation therapists.

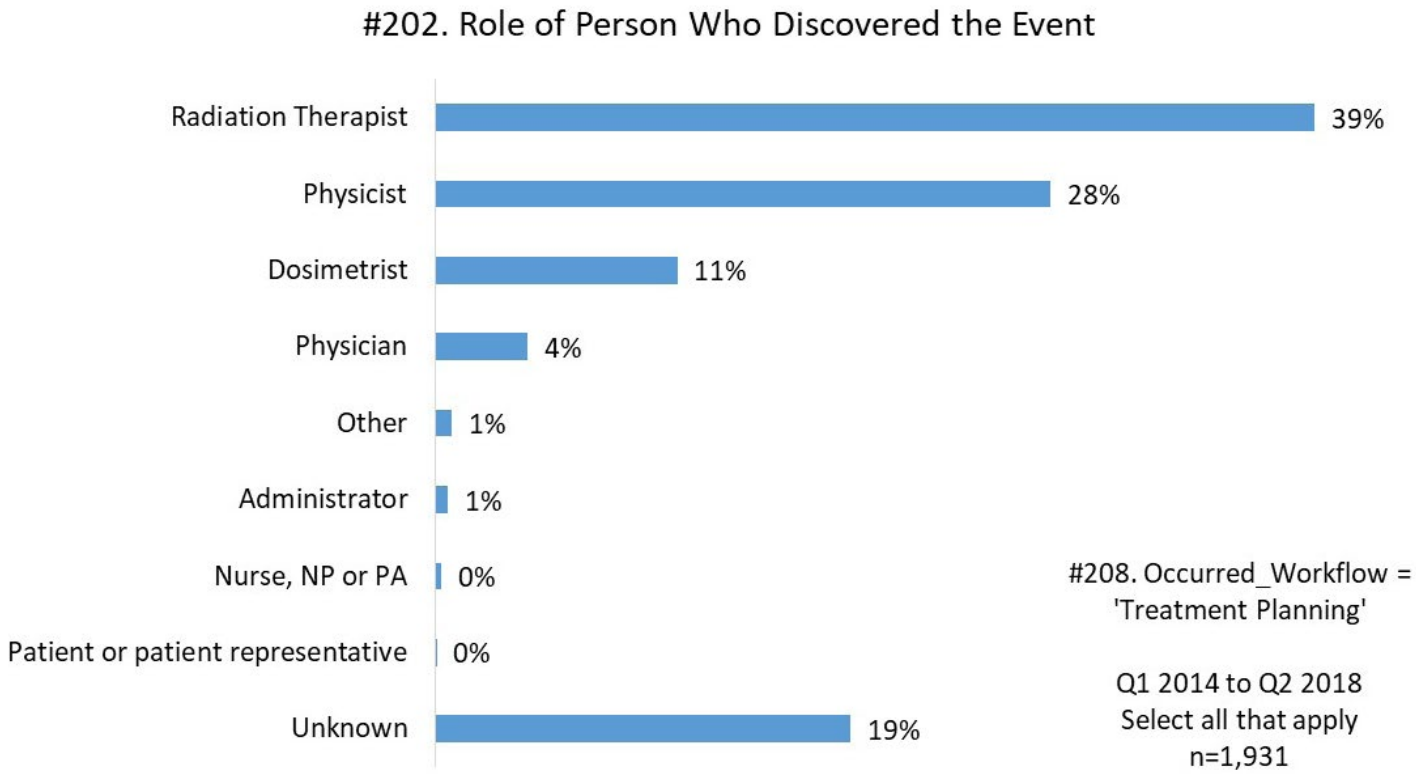


Figure 3: Role of Person Who Discovered Event for Events that Occurred During Treatment Planning (Q1 2014 - Q2 2018)

The following two figures depict the RO-ILS data element *Contributing_Factors* (#231). The contributing factors data element is divided into seven overarching categories: organizational management, communication, procedural issues, technical, human behavior involving staff, patient-focused circumstance and other. Except for the last two categories, these overarching topics are then further sub-divided.

Advanced RO-ILS users (i.e., Reviewers), can enter in the contributing factor(s) to an event in the "My Review" section of the RO-ILS portal. Reviewers are instructed to select all the applicable answer options for this data element (checkbox), therefore there may be multiple contributing factors per event. Figures 4 and 5 display the count of contributing factor information for a given number of events (n value). Given the checkbox data field type, allowing for multiple options per event, the percentages may equal more than 100 percent.

Though not all Reviewers are completing this optional section on a routine basis, this contributing factors data element should be used in the reporting of every event. Identifying the contributing factors of an event can be thought of as performing a "mini root cause analysis" of what led to that event regardless of the event classification (incident, near miss or unsafe condition, etc.) or severity. Only by identifying, analyzing and appropriately addressing the root causes of an event can sustainable change occur.

Figure 4 shows the distribution of the contributing factors based on the category level.

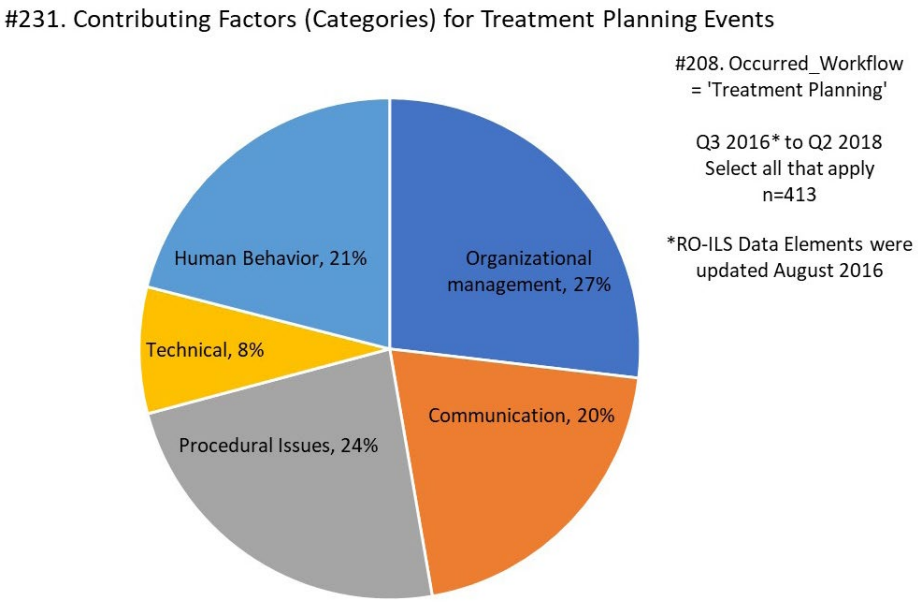


Figure 4: Contributing Factors – Category Distribution for Events that Occurred During Treatment Planning (Q3 2016 - Q2 2018)

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."

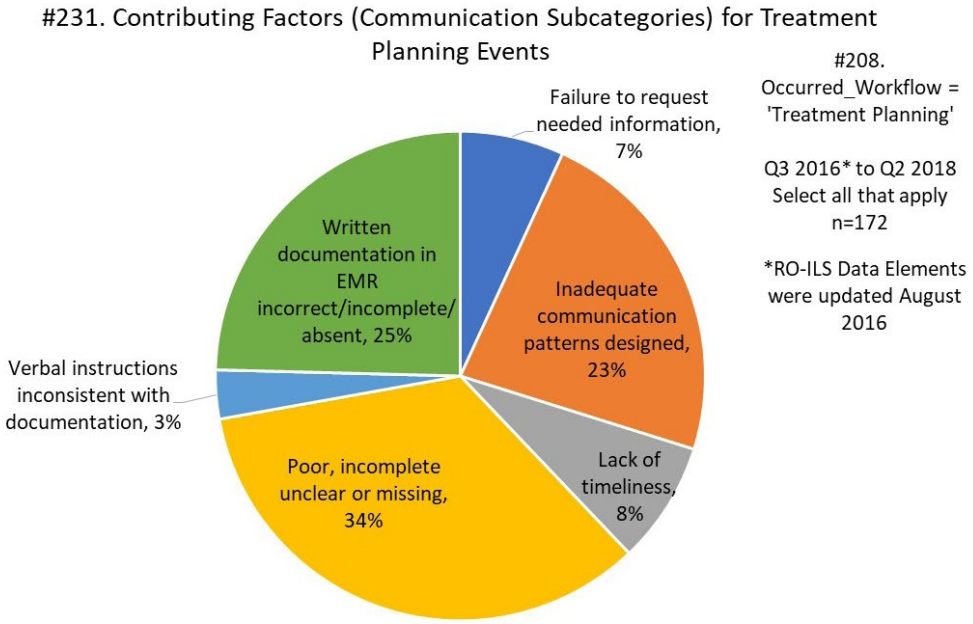


Figure 5: Contributing Factors – Communication Category, Subcategory Distribution (Q3 2016 - Q2 2018)

HAND-OFFS DURING TRANSITIONS OF CARE AND THE PLANNING PROCESS

Given that the treatment planning process is complex and dependent on clear, effective and documented communication, the introduction of additional complicating factors, such as hand-offs between team members, may further complicate and place at-risk an already challenged process. Yet, hand-offs are a common and *necessary* occurrence in the clinical environment. Patients undergo multiple transitions of care from their consultation to treatment. Transitions of care occur within radiation oncology practices at many levels, between radiation oncologists, nurses, dosimetrists, medical physicists and therapists, just to name a few. Below we begin to address the theme of hand-offs during the treatment planning process, along with a presentation of specific examples from the RO-ILS database, a discussion of contributing factors, and possible approaches for mitigation of such events.

> "A hand-off is a transfer and acceptance of patient care responsibility achieved through effective communication. It is a real time process of passing patient specific information from one caregiver to another or from one team of caregivers to another for ensuring the continuity and safety of the patient's care" (The Joint Commission Center for Transforming Healthcare, 2014).

CASE 1: PHYSICIAN TO PHYSICIAN HAND-OFF

Summary of event: A patient was simulated on the day before the attending physician was leaving for a conference and wanted to get the patient started on their treatment as soon as possible. The intention was for a covering physician to approve the plan while the attending physician was at the conference. A treatment plan ("Plan A") was completed on the day following their simulation. Plan A was reviewed remotely by the attending physician and a change to the brachial plexus dose was requested. A new plan with a reduced brachial plexus dose was completed by the dosimetrist ("Plan B") the next day. The attending physician was emailed that Plan B was ready, it was reviewed and deemed acceptable. The attending physician then communicated with the covering physician to say that he was okay with the plan and he would like for it to be approved (approval not being able to occur remotely). The covering physician approved the wrong plan (Plan A with the higher brachial plexus dose). The error was discovered, prior to treatment, when the attending physician returned and saw that the brachial plexus dose was higher than intended on the approved plan.

Several contributing factors identified by the Reviewer included:

- Communication – Inadequate communication patterns designed.
- Communication – Poor, incomplete, unclear or missing.

Possible contributing factors in this case identified by RO-HAC included:

- Rushed or hurried environment due to attending physician leaving for conference.
- A complicated hand-off late in the process. Since the attending physician managed/performed the initial part of treatment planning process (up to the verbal approval step), then communicated to the covering physician very late in the process to approve the plan, the covering physician lacked familiarity with the details of what planning had occurred to that point.
- Ineffective communication of which plan was to be approved.
- Lack of written, specific communication between planning team members to ensure approval of the correct plan.

- Covering physician was presented with unwarranted options. Plan A was not rejected by the dosimetrist and therefore the covering physician could access both Plan A and Plan B, increasing the likelihood the wrong plan would be approved.

Discussion Questions:

- Given how late in the process the handoff occurred, was a handoff necessary?
- Should a remote approval process exist? How does remote approval affect established processes and handoffs?
- Does a policy exist to define how and when handoffs are to be performed?

CASE 2: DOSIMETRIST TO RADIATION THERAPIST HAND-OFF

Summary of event: Patient arrived for their initial setup for a second treatment site. The therapists read the CT simulation order and filmed the patient, verifying shifts and angles for the planned treatment. The implanted cardioverter defibrillator (ICD) was monitored with the nurse present as indicated on the simulation order. On the initial start date, the nurse was called for monitoring of the ICD. She stated that the radiation oncologist referred to a magnet and that the patient would be monitored daily. The electronic medical record was checked for alerts, but there were none regarding the ICD. The nurse indicated that the radiation oncologist had informed the dosimetrist about the patient's ICD. Both the dosimetrist assigned to the case and the radiation oncologist were off that day. The other dosimetrist knew nothing about the patient. Since this was the patient's second treatment site and the patient had previously been monitored for the first three days (the practice's standard protocol), it was assumed that it was safe to treat the patient. The patient was monitored and treated. The following day the therapist was informed that the cath lab needed to be present for monitoring the patient's ICD, which was closer to the current treatment site than the previous treatment.

Several contributing factors identified by the Reviewer included:

- Communication – Poor, incomplete, unclear or missing.
- Communication – Written documentation in EMR incorrect/incomplete/absent.

Possible contributing factors identified by RO-HAC included:

- An alert was not created by the staff to notify the therapists that the patient had an ICD.
- The decision to have cath lab place a magnet on top of the patient's ICD during treatment and monitor the patient was not documented.
- The physician did not document in writing his/her verbal orders.
- The physicist did not enter documentation of the implanted medical device dose evaluation.

Discussion Questions:

- Did the dosimetrist miss the opportunity to discuss this case with either the senior therapists or fellow dosimetrits prior to the planned time off?
- If the radiation oncologist had planned to attend the first setup, did they miss an opportunity to review and hand off this case to a colleague prior to being out of the office?

Experience teaches us that transitions of care do not always go smoothly, and data entered into the RO-ILS database shows that occasionally these events are categorized as moderate to severe in significance. In particular, handoffs increase the *amount* of communication that is required and accentuate the importance of complete, effective and accurate documented communication. In each of the cases listed above, ineffective transitions of patient care by members of the staff led to the potential for significant adverse events to occur. The management of radiation therapy patients always requires a team effort, and hand-offs will always be a part of this process. Therefore, the effective management of the hand-off process can reduce the potential for significant adverse events. Additionally, the prevention of errors is also heavily reliant upon a culture composed of strong communication patterns between all key team members.

ACTIONS AND RECOMMENDATIONS

There are many factors that may contribute to hand-offs or ineffective transitions of patient care within each practice. Below are actions that can be tailored and applied to the causation(s) of ineffective transitions or hand-offs.

- Create standardized procedures to assist in conducting successful hand-offs.
- Do not rely on verbal hand-off/communication methods. Include written documentation in the medical record. Staff should not proceed with any element of a patient's radiation therapy program without written documentation from the physician (e.g., Simulation request, simulation note, special procedure instructions).
- Participate in teamwork and communication training.
  - TeamSTEPPS
  - CUSP: Comprehensive Unit-based Safety Program
- Discuss the practice of internal hand-offs at regularly scheduled quality and safety meetings.
- Define the most common hand-off related errors that occur in your practice and develop methods to mitigate.
- Discuss if certain types of hand-offs could be eliminated completely by approaching planning differently.
- Discuss if performing a complete hand-off of a patient at the start of the process is possible, versus handing off midway or late in the care process.
  - Hand-offs or transitions of care cannot be avoided. It is the nature of the work performed in radiation oncology, and health care in general. Yet, it is worthwhile to consider whether systems or processes could be designed that support hand-offs early on in a patient's care.
- Discuss what role the hurried nature of some hand-offs contributes to the likelihood of errors. Special attention, or a specific policy, should apply to hand-offs that are also "hurried" or urgent in nature.

Below are continued actions and recommendations that pertain to communication, accountability and organizational culture breakdowns.

- Communication breakdowns. Members of the staff do not effectively or completely communicate important information among themselves. The communication method—whether verbal, recorded or written—is ineffective.

- Implement the use of standardized forms, tools and/or methods every time a hand-off occurs. Examples include:
  - Checklists
  - SBAR—Situation, Background, Assessment, Recommendation templates can be used to facilitate accurate communication.
- Identify new and existing technologies within the department's EHR to assist in making the hand-off successful and complete.
- Establish workspace or setting that is conducive for sharing information about a patient without frequent interruptions. More information about a "no interruptions zones" was included in the Q4 2014 report.
- In every radiation oncology practice, it is essential to have a checklist integrated into the patient EHR, where each member of the oncology team can access, document, edit and verify each transition of a patient's multiple tasks. Figure 6 provides a simple example of a checklist utilizing Case 2: Dosimetrist to Radiation Therapist Hand-off.

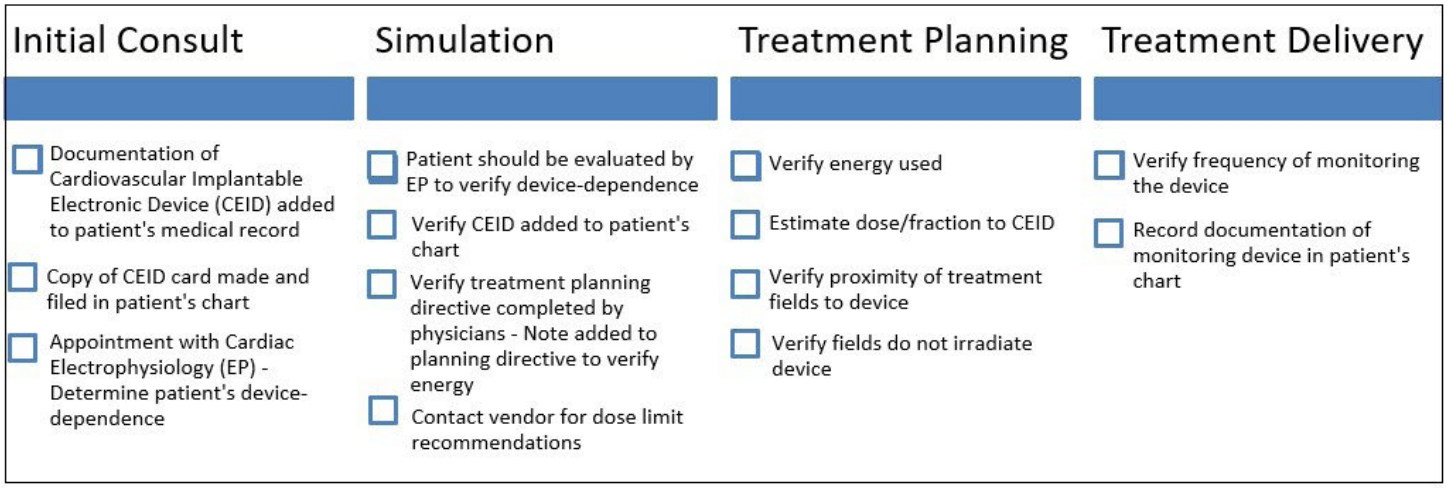


Figure 6: Case 2 Example Checklist

- Accountability breakdowns. With multiple individuals involved with patient care it is important that each person takes responsibility to assure it is coordinated across various settings and among different disciplines within the practice.

  - A formally defined policy should exist for how and when hand-offs are to occur.
    - Hand-offs are often associated with a compressed timeline. This further complicates the situation by combining the communication challenges of a hand-off, with the increased likelihood of errors known to be associated when we hurry the planning process. A policy should define the time frames that are allowable for hand-off scenarios.
    - Consider the timing of the handoff. Confusion occurs when hand-offs happen midway through the process versus a more orderly hand-off at the beginning of the care process.

- Culture (e.g., teamwork and respect) significantly impacts the success of a hand-off.
    - Make successful hand-offs a practice's priority and performance expectation.
    - Educate staff on what constitutes a successful hand-off.
    - Standardize training on how to conduct a hand-off.
        - See teamwork and communication training and hand-off standardization tools above (TeamSTEPPS, CUSP, SBAR).
    - Cultivate a safety culture, one that allows staff to speak up in unsafe scenarios and then provides a supportive infrastructure to hold one another accountable to the safety standard.

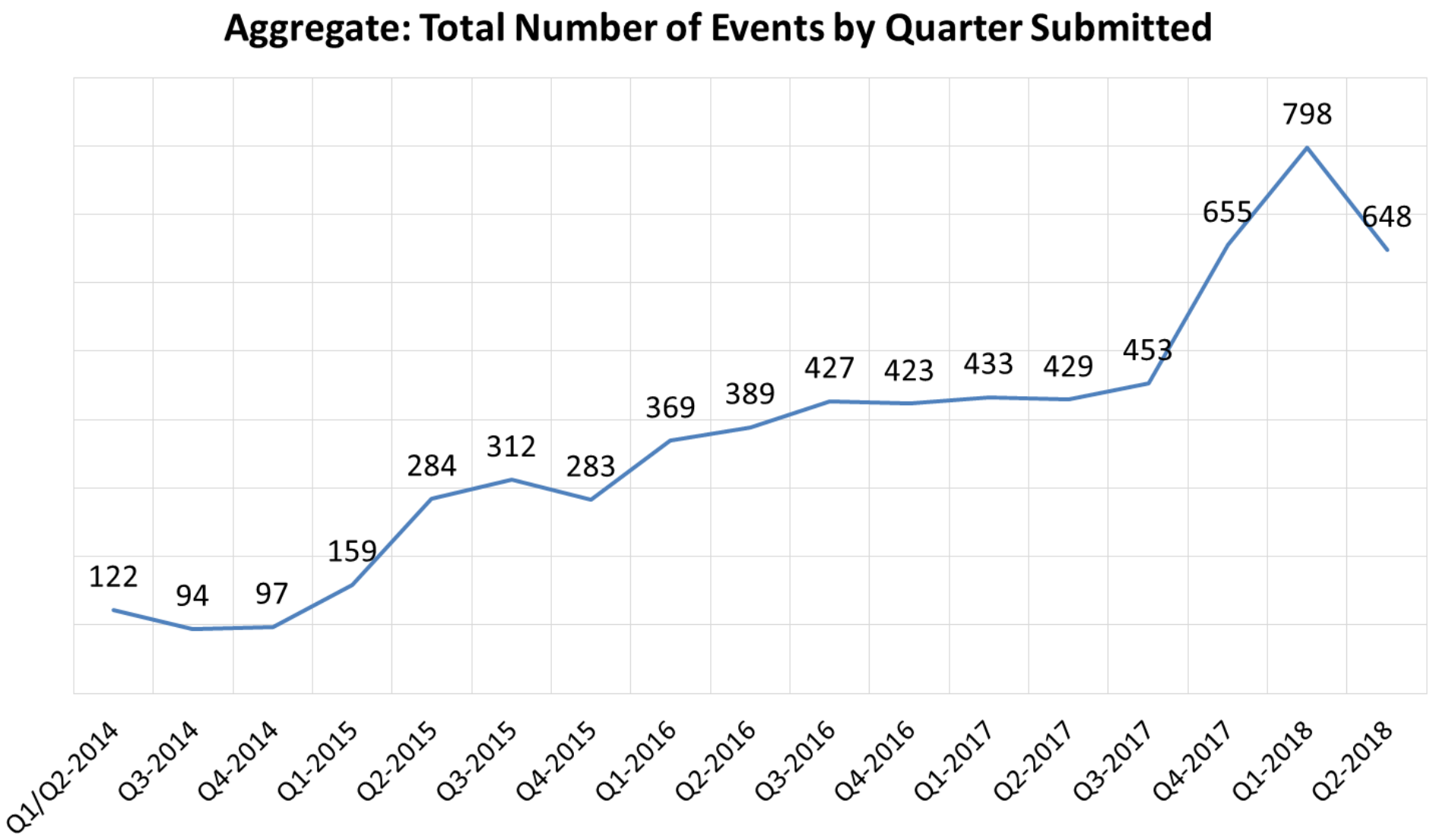
RESOURCES

- The Joint Commission Resources on:
    - 2017 Sentinel Event Alert on Hand-offs
    - Infographic on Hand-offs
- Institute for Healthcare Improvement Resources on:
    - How to Improve (PDSA Cycles)
    - Develop a Culture of Safety
    - SBAR
- Agency for Healthcare Research and Quality Resource on:
    - SBAR
    - TeamSTEPPS
    - CUSP: Comprehensive Unit-based Safety Program

REFERENCES

The Joint Commission. 8 Tips for high-quality hand-offs. 2017.
https://www.jointcommission.org/assets/1/6/SEA_58_HOC_Infographic_8_Tips_FINAL_w_CR.pdf

AGGREGATE ANALYSIS GRAPHS



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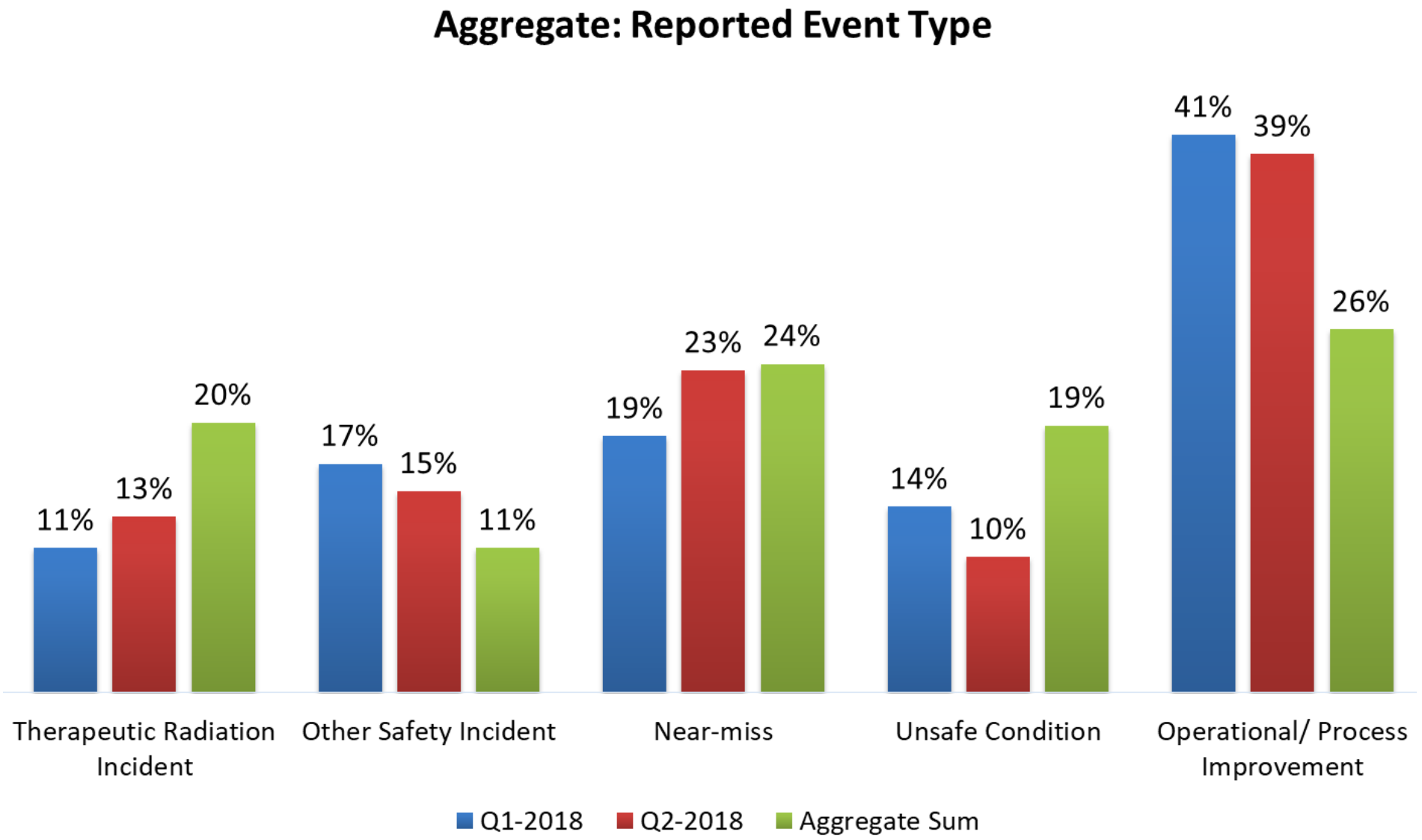

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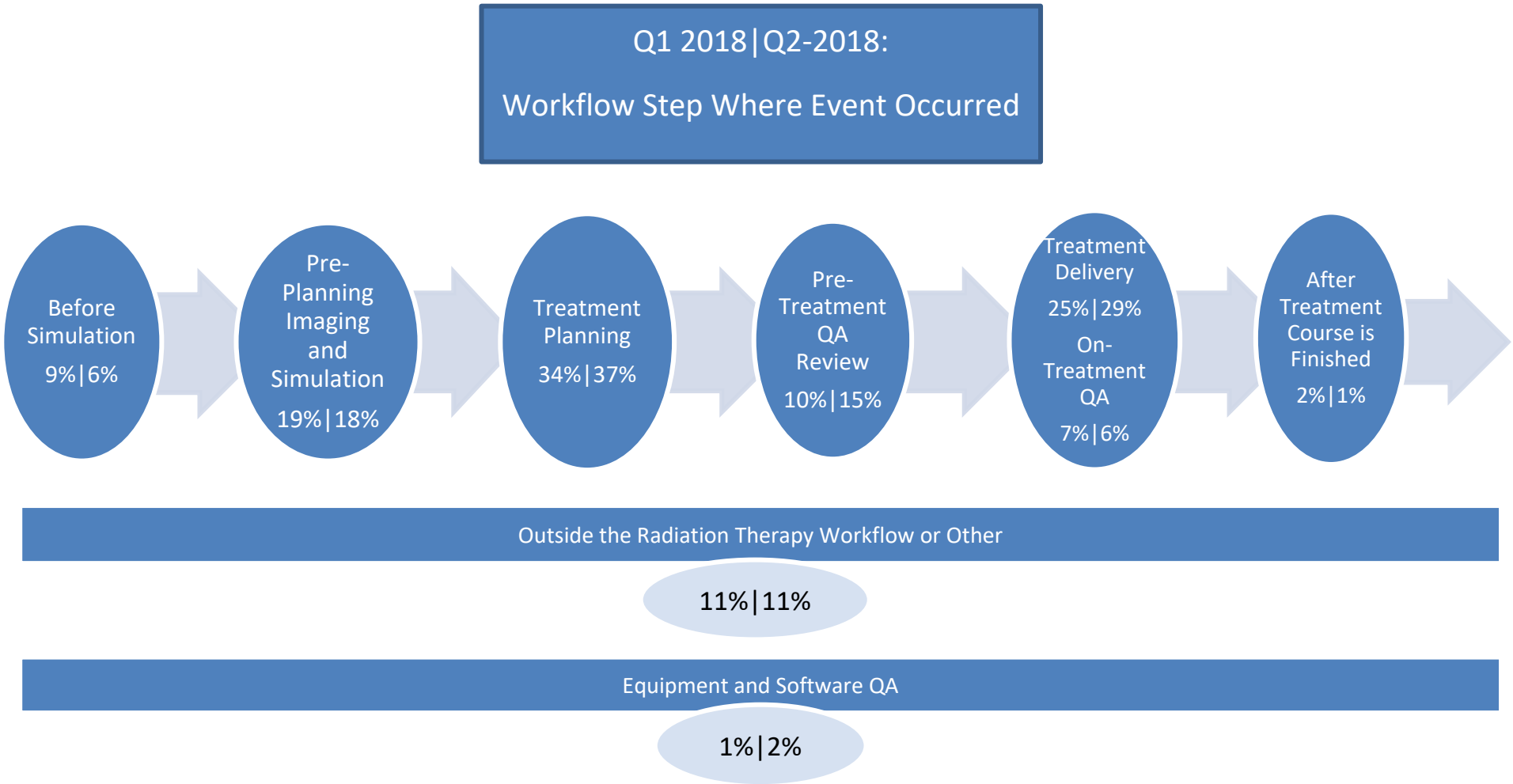

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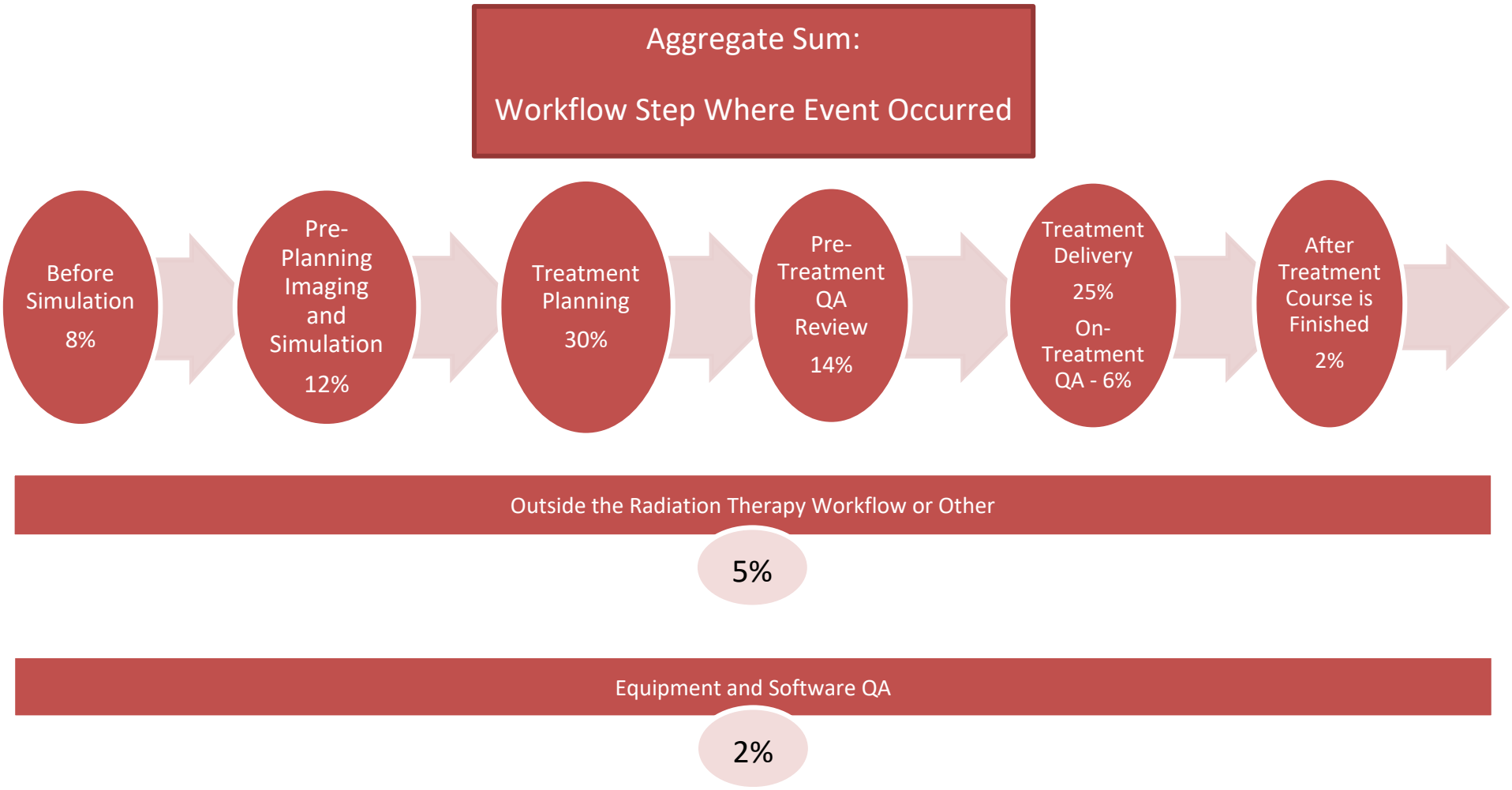

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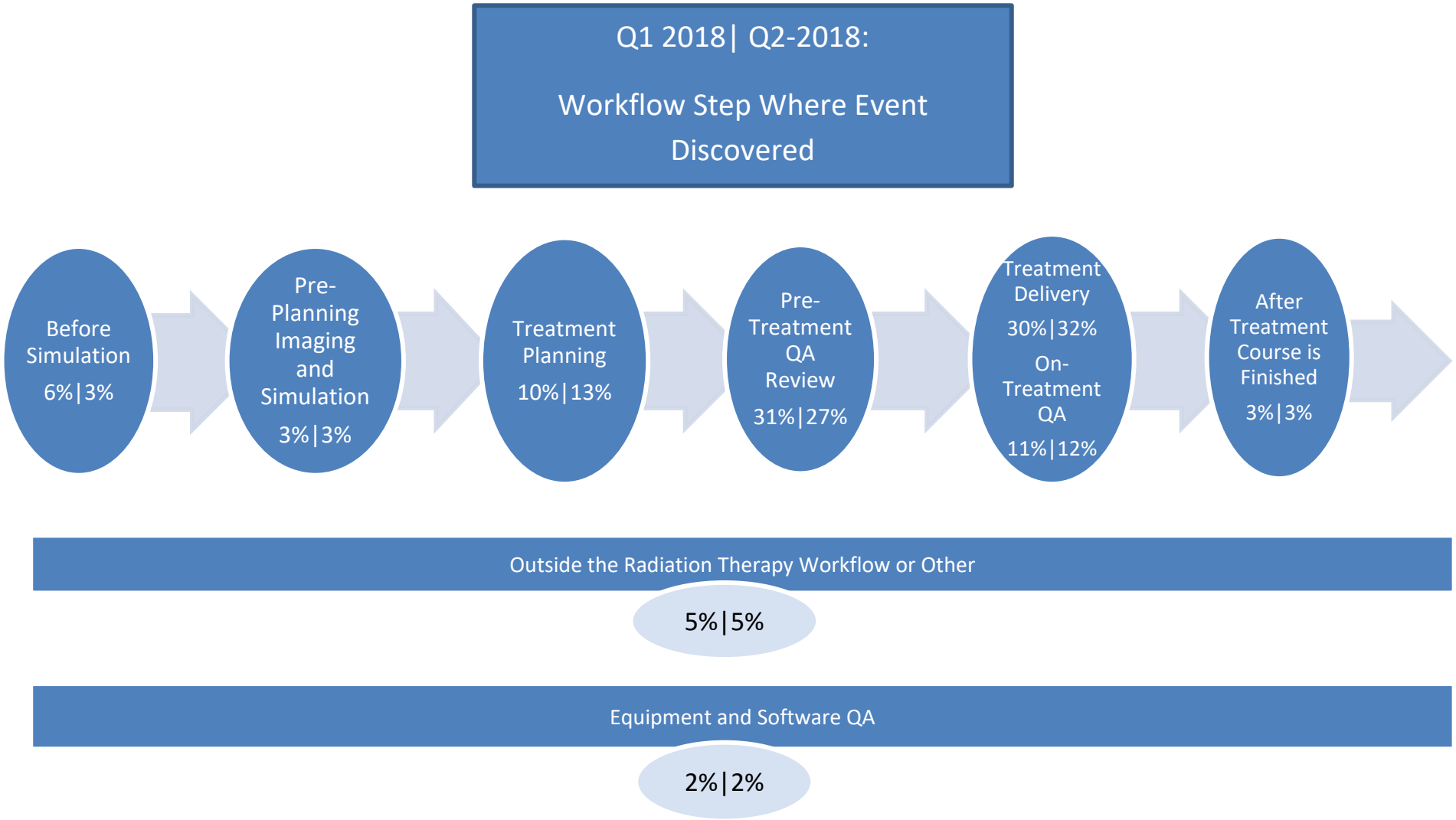

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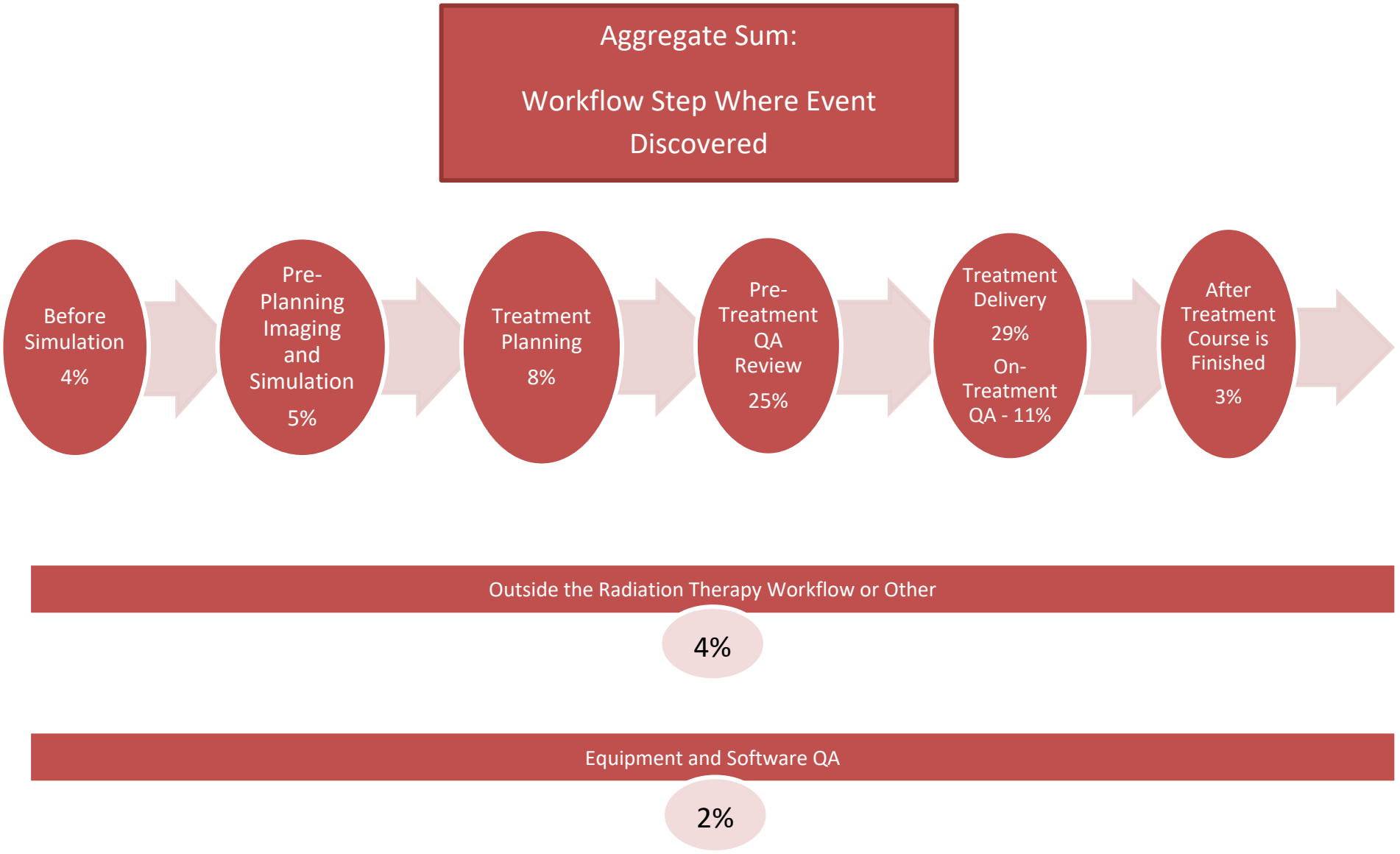

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