RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

AGGREGATE REPORT

PATIENT SAFETY WORK PRODUCT

Q4 2017

OCTOBER 1, 2017 – DECEMBER 31, 2017

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AGGREGATE REPORT CARD – Q4 2017

October 1, 2017 – December 31, 2017

METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE HISTORICAL SUM
Reported Events	**383**	**4,549**
Therapeutic Radiation Incidents	53	1,022
Other Safety Incidents	63	425
Near Miss	85	1,192
Unsafe Conditions	70	1,009
Operational/Process Improvement	112	901
Most Commonly Identified Workflow Step Where Event *Occurred*	**Treatment Planning:** 37% (142/383)	**Treatment Planning:** 29% (1316/4549)
Most Commonly Identified Workflow Step Where Event was *Discovered*	**Treatment Delivery Including Imaging:** 37% (141/383)	**Treatment Delivery Including Imaging:** 29% (1328/4549)
Most Commonly Identified Treatment Technique	**3-D:** 28% (109/383)	**3-D:** 24% (1111/4549)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents that Did Not Effect Multiple Patients	**≤5% Maximum Dose Deviation to Target:** 61% (31/51)	**≤5% Maximum Dose Deviation to Target:** 73% (513/706)

ANALYSIS & COMMENTARY

INTRODUCTION

This quarterly report contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System®. One of the featured themes, human factors engineering and human-computer interface, aims to introduce the overall topic of human factors and highlight the opportunity for learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS. This report also contains results from an anonymous public survey on the workflow and process steps surrounding communication of the prescription and a case study on contouring.

FEATURED THEME: HUMAN FACTORS ENGINEERING/HUMAN-COMPUTER INTERFACE

Human factors engineering considers the design of systems, human behavior and how humans interact with these systems. One example is human-machine interfaces. Radiation oncology clinical staff navigate hundreds of human-machine interfaces in the delivery of radiation therapy. For example, a dosimetrist might input and verify treatment fields in a treatment planning system, a physicist might verify these fields in an oncology information system (OIS), a therapist might schedule out a patient's treatments in the OIS and a physician might review online imaging in the OIS. These are just a few examples of human-computer interaction. In all these cases there is a key role for human factors engineering. The design of these systems can either promote error or prevent it.

The following case studies highlight two near miss events reported to RO-ILS that were influenced by human-computer interaction.

CASE 1: INCORRECT PLAN DUE TO CUT-OFF CT SCAN

A patient is simulated for treatment of a thoracic (T) spine lesion. During the planning process the physician decides to also treat a region of the cervical (C) spine. The relevant C spine region is not fully included in the simulation CT scan, which was performed for a T spine treatment. The dosimetrist proceeds with a plan for the C spine. The result is a plan where there is missing CT data in the beam path as shown in Figure 1.

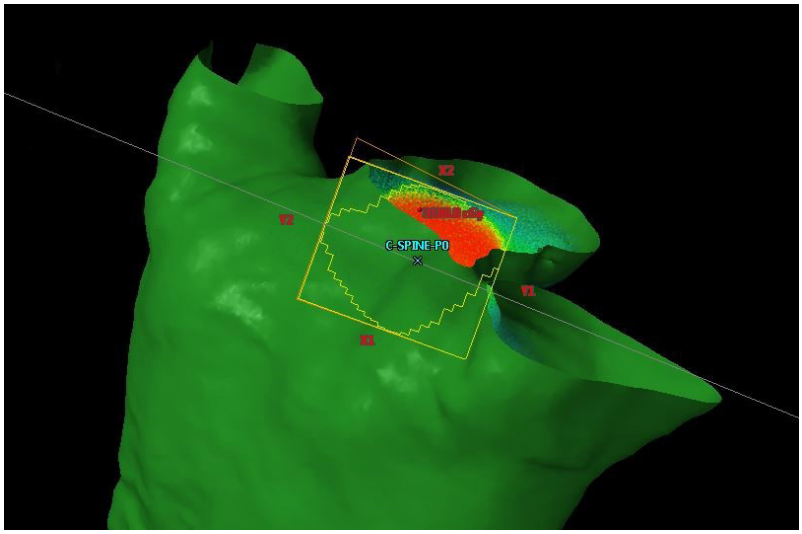


Figure 1. Radiation field for a C spine treatment with missing CT data in the beam path.

The plan is reviewed by a second dosimetrist and approved by the physician. The physicist identifies the problem when inspecting beams-eye-views while reviewing the plan one day prior to treatment. The patient undergoes a second simulation to include the appropriate levels of the C and T spine. If the problem had not been noted the dose would have been significantly different from the intended.

Contributing factors in this case:

There are many potential contributing factors to such a scenario including gaps in policies and procedures, communications, or perhaps training and education. **However, equally important, and perhaps less appreciated, are the human-computer interaction issues that drive this error.** In other words: *What aspects of software design contributed to this error?*

In this case the treatment planning system (TPS) warned the user that there may be a calculation error. In some clinics, however, there was a long history of many warnings of this type which turned out to be minor in nature. Therefore, such warnings were routinely ignored by dosimetrists. (Of note is the fact that new versions of this software eliminated warnings deemed to be unnecessary and/or minor in order to avoid alarm fatigue (also known as alert fatigue). Even though some centers have upgraded software versions, practitioners may still retain old practices and may ignore built-in decision support system (DSS) warnings.)

This error pathway is not unique to this particular treatment planning system software.

This same error is possible in other planning systems. In other systems it is also possible to create a beam that extends outside the CT volume and perform a calculation. Some systems allow the user to compute dose, approve the plan and export it without providing any warnings or interlocks.

Actions and Recommendations to consider:

- When analyzing errors like this consider whether human-factors engineering and human-computer interaction issues are contributing factors.
    - If so, be sure to select "Poor human factors engineering" under the "IV. Technical" "B. Equipment Design and Operations" section on the contributing factor tab in the RO-ILS portal.
    - Events, in which there is a problem with the operations or design of software, be sure to select "Yes" for "Was this event equipment related" (#215).
    - Also consider, are there ways to prevent such an error or make it more obvious to the user? Enter suggestions in the RO-ILS portal under Prevention_Ideas (#226).
- For this particular error pathway there are several suggestions related to software:
    - Software vendors: remove the ability to approve plans if a beam extends outside the CT volume or at least require an explicit override.
    - Clinical users: consider error pathways like this when commissioning a new TPS or upgrade to a TPS, communicate with the vendors, consider developing custom software to flag such issues. An ASTRO's Accreditation Program for Excellence (APEx®) evidence indicator related to information systems training necessitates a plan and process for training staff on system updates and upgrades.

- Barring an elimination of this error pathway, consider workflow and policy changes that might make it more identifiable. Examples include: providing adequate time for review of the plan, working with checklists where applicable, developing a system of managing and discussing error warnings.
- Review the Institute for Healthcare Improvement's (IHI) summary of human factors design principles and how human factors can be addressed in various methods.
- Review The Joint Commission's Human Factors Engineering Strategies from most reliable to least reliable.

CASE 2: RIGHT-LEFT FLIP OF IMAGE FUSION DUE TO SOFTWARE SETTING

A patient being treated for recurrence in the prostate bed receives a PET/CT scan which indicates an area of enhanced uptake to be included in the treatment volume.

Description of standard procedure in some centers: The simulation CT in radiation oncology is performed with the patient aligned feet-first supine (FFS) and the PET/CT scan to be performed with the patient head-first supine (HFS). The images are fused by the medical physicist using image registration software. A setting is available in the software to automatically orient any scan to HFS for viewing purposes. There is also a setting in which the secondary image set is saved with the same patient orientation as the primary data set after registration (i.e., saved as FFS). This setting is enabled for all users on their desktop computers.

In this case the physicist was away from the center performing registration with their laptop. On the laptop the setting to save images as FFS was turned off, unknown to the physicist. The registered image was thus saved as HFS instead of FFS and the physicist transferred this image to the TPS. Only the PET scan from the PET/CT was sent to the TPS and the CT part was not included.

A second physicist picked up the case for planning and noticed that the fusion registration seemed "off", though this is very challenging to identify in many circumstances. This event was categorized as a near miss. Near misses are caught generally in two ways: 1) either through chance encounter, which was the case here; or 2) due to a built-in review/check procedure to detect errors before they reach the patient.

Contributing factors in this case:

There are many contributing factors in this case including:

- a change in the work environment (being away from the center),
- a non-standard protocol for patient orientation (orientation differs in different scans),
- a non-standard protocol for system usage, i.e., options turned on/off (such as FFS/HFS), and
- differences in which information is available (PET+CT vs. PET only).

However as with Case #1 there are clearly human-computer interaction issues that drive this error and are perhaps less appreciated. In this case multiple different software systems are used for viewing and manipulating data, the data are presented to the user in different ways depending on how settings are configured, and different data are potentially transferred between systems depending on how settings are configured.

Actions and Recommendations (or what to consider):

- When analyzing errors like this consider whether human-factors engineering and human-computer interaction issues are contributing factors. Are there ways to prevent such an error or make it more obvious to the user?
- For this particular error pathway there are several suggestions related to software:
    - Software vendors: warn the user when image sets are being transferred or saved in an orientation that differs from the primary data set.
    - Clinical users: consider workflow issues that might prevent or identify this error. This might include transferring the CT from the PET/CT scan to improve the identification of the error.
- Review the Institute for Healthcare Improvement's (IHI) summary of human factors design principles and how human factors can be addressed in various methods.
- Review the Joint Commission's Human Factors Engineering Strategies from most reliable to least reliable.

As the above cases illustrate, the process of assessing, planning and treating a patient in radiation oncology requires multiple human and systems interactions. The systems have been designed to deliver safe care to the patient following an accepted care process for each treatment modality. So, if this is followed, as designed with no deviations, a successful outcome should occur every time. As we know, this is not always the case. Why? The system is highly complex with a multitude of interacting pieces, not least of which are the human factors. Human performance, including mental and physiological states (e.g., fatigue, stress, hunger), affect individuals' ability to make decisions and perform to their highest level. The creation of an infrastructure, processes, and tools—a system—that implements human factors principles is necessary in attempting to avoid errors.

The following section provides an overview of the RO-ILS data relating to the contributing factors data element, specifically drilling down to "Poor human factors engineering".

SUMMARY OF RO-ILS DATA: CONTRIBUTING FACTORS FOR HUMAN-FACTORS ENGINEERING AND EQUIPMENT DESIGN AND OPERATIONS

Advanced RO-ILS users (i.e., reviewers), can enter in the contributing factor to an event in the "My Review" section of the RO-ILS portal. Though not all users 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 uncovering, targeting, and appropriately addressing the identified root causes of an event can sustainable change occur.

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. With the exception of the last two categories, these overarching topics are then further sub-divided. An option within the "technical" category of contributing factors is "Poor human factors engineering".

Users are instructed to select all the applicable answer options for this data element (checkbox), therefore there may be multiple contributing factors per event.

Since the data elements were last updated in August 2016, a total of 2,452 events were reported to the PSO (Q3 2016-Q4 2017). In total 768 events (31.3 percent) identified at least one contributing factor and were submitted by 58 different practices. Figures 2-4 display the count of contributing factor information for a given number of events (n value). Given the checkbox data field type, which allows for multiple options per event, the percentages may equal more than 100 percent. Figure 2 depicts the distribution of the contributing factors based on the category level.

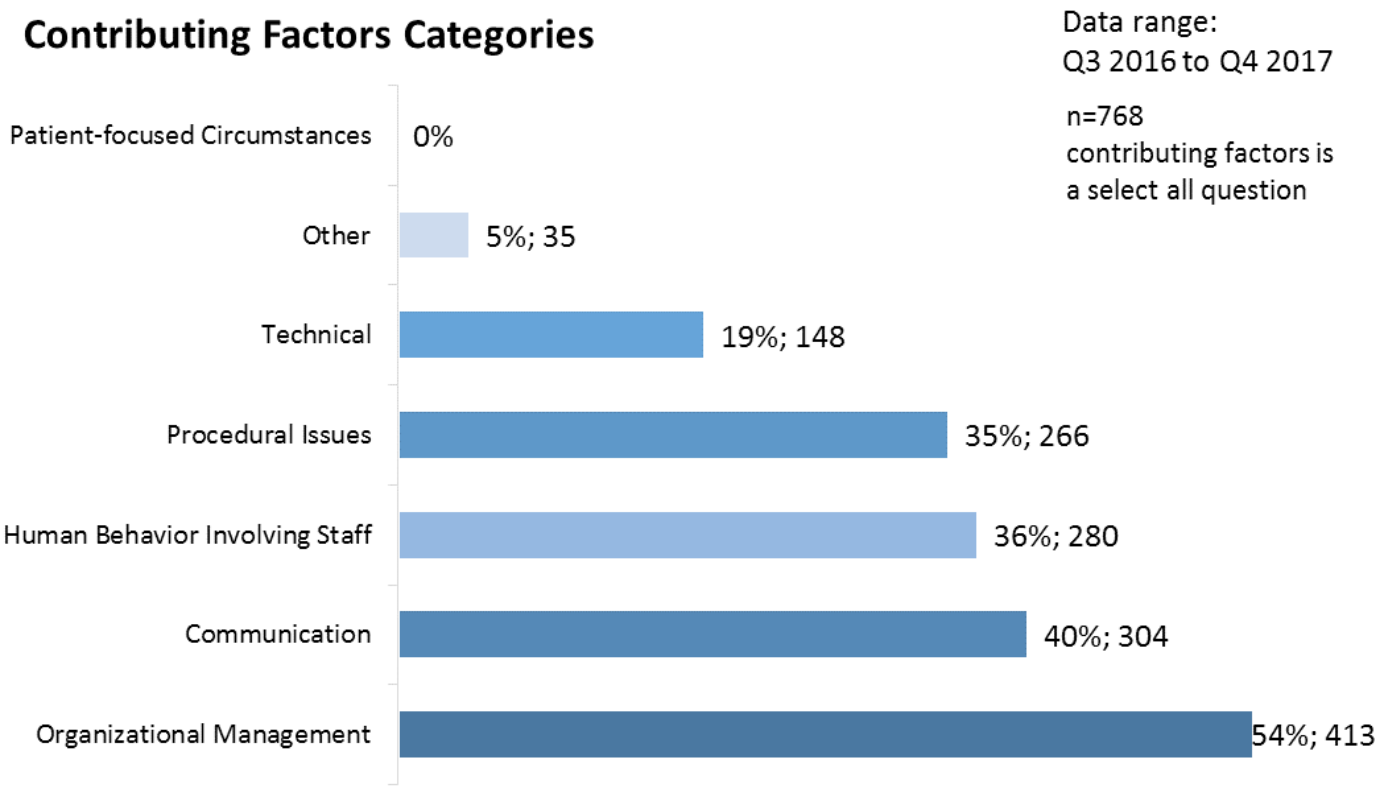


Figure 2. Contributing Factors - Category Distribution (Q3 2016-Q4 2017)

Within the "Technical" category above, contributing factors are broken down into subcategories as displayed in Figure 3. The most common response is "Equipment Design and Operations".

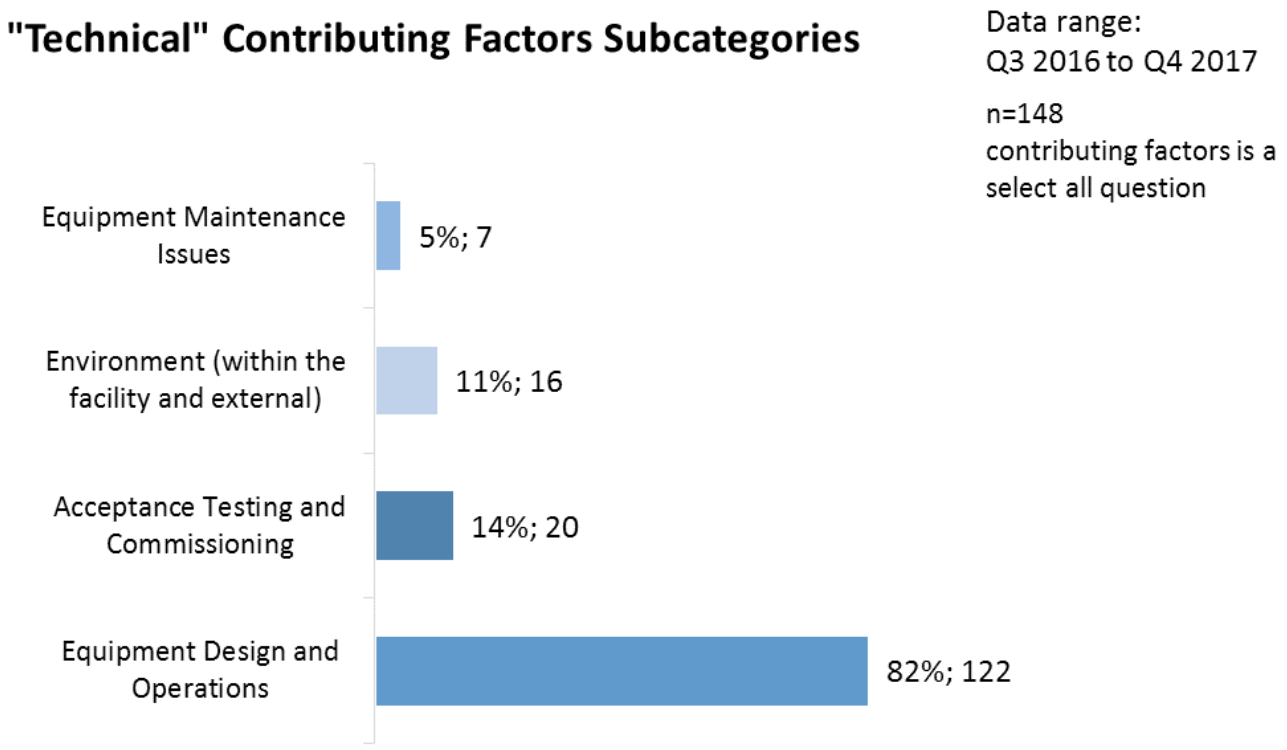


Figure 3. Contributing Factors – Technical Category, Subcategory Distribution (Q3 2016-Q4 2017)

Within "Equipment Design and Operations" there are five contributing factors that the reviewer can select for an event. Figure 4 depicts the frequency with which the contributing factor, "Poor Human Factors Engineering", was chosen within the Equipment Design and Operations subcategory. Within this subcategory, it is the most commonly reported contributing factor.

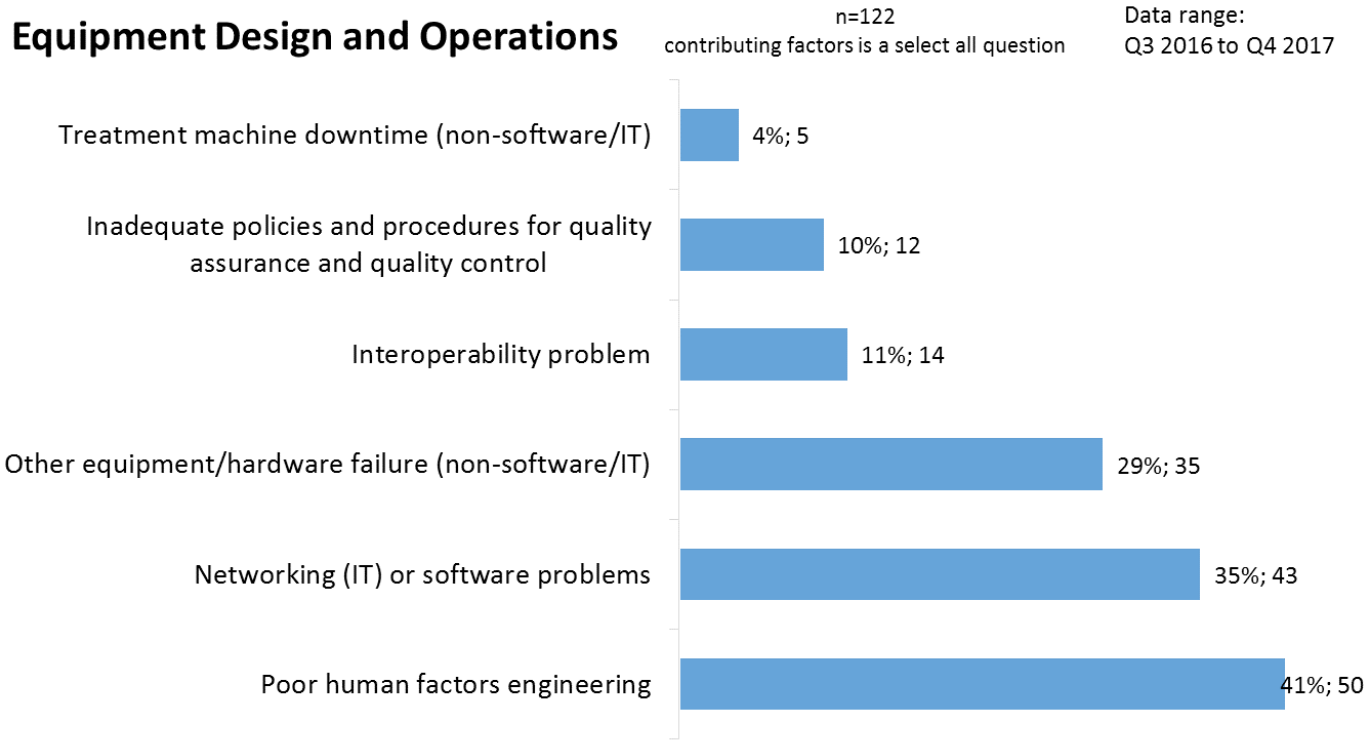


Figure 4. Contributing Factors – Technical Category, Equipment Design and Operations Subcategory, Factor Distribution (Q3 2016-Q4 2017)

Figure 5 depicts the event classification (therapeutic radiation incident, near miss, etc.) for the 50 events reported between August 2016 and December 2017 that indicated poor human factoring engineering was a contributing event. A total of 18 different practices submitted these events.

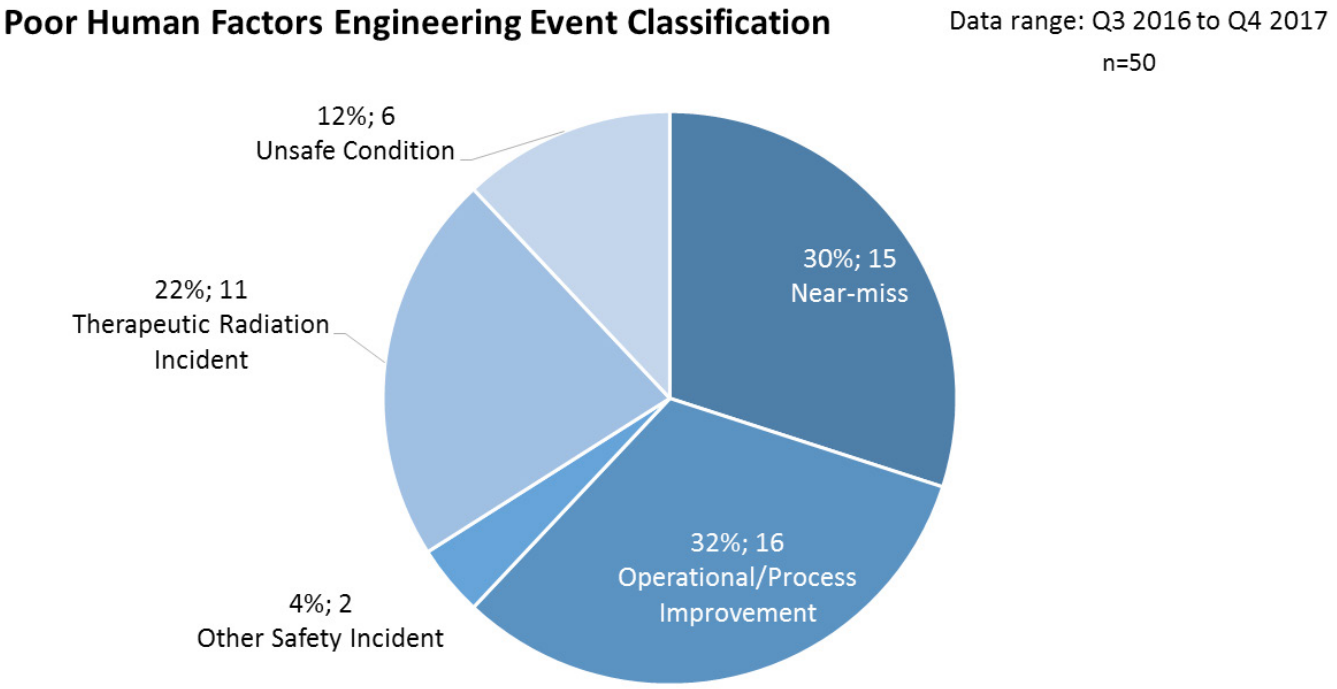


Figure 5. Event Classification for Poor Human Factor Engineering Events (Q3 2016-Q4 2017)

The two case studies previously discussed identified poor human factors engineering as a contributing factor within the near miss events. Case 1 reported that the event occurred during treatment planning and was discovered on pre-treatment QA review. Case 2 reported that the event occurred during pre-planning imaging and simulation and was discovered during pre-planning imaging and simulation.

The significance of this investigation is two-fold. Firstly, health care delivery requires the involvement and interaction of humans—patients, providers and other staff members. Thus, the influence of human factors must be accounted for when prospectively or retrospectively designing, enhancing, reforming, adding, and/or investigating a process, an event, or new technology. Secondly, the thorough reporting of an event to RO-ILS allows for larger analysis to be conducted. At a national level, the types of contributing factors that impact/influence radiation oncology events can investigated. This can then assist in narrowing focus and cultivating learning about how those factors can be countered as well as why they may occur, ultimately evolving into safety improvements at the local level.

Resources for further reading on human-factors engineering and human-computer interface

- Agency for Healthcare Research and Quality (AHRQ): The Implications and Applications of Human Factors Engineering
- Middleton et al. Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA, J Am Med Inform Assoc, 2013, 20, e2-e8
- "Safety of Health IT: Clinical Case Studies", Ed. Abha Agrawal, Pub: Springer International, Switzerland, 2016.
- World Health Organization (WHO): What is human factors and why is it important to patient safety?
- The Joint Commission's Human Factors Engineering Strategies
- WHO: Human factors in patient safety review of topics and tools
- Institute for Healthcare Improvement (IHI): Human factors design principles
- IHI Presentation Slides on Human Factors

FEATURED THEME II: CONTOURING

The accuracy of identifying and contouring treatment volumes and normal structures requires vast knowledge and understanding of gross anatomy and cross-sectional anatomy. Imaging modalities, such as CT, MRI and PET can assist with the contouring of gross anatomy and molecular processes and is vital for effective outcomes. However, available imaging modalities utilized can vary from program to program which can then impact contouring. The following case study provides insight into one issue seen from contouring events submitted to RO-ILS.

CASE 3: CONTOURING SMALL BOWEL

A patient was under treatment with SBRT to the adrenal gland. The target volume was adjacent/in close proximity to the small bowel. The small bowel was not correctly contoured, underestimating the dose to the structure. During setup imaging of fraction #3, small bowel was visible on CBCT overlapping with the PTV. The fraction was cancelled for the day, the small bowel contours were corrected, and the remaining 3 fractions were re-planned to account for the change in anatomic volumes from the original planning imaging.

It is known that the position of the patient's internal anatomy is dependent upon patient positioning (supine, prone, etc.), contents in the small bowel and time of day. Normal small bowel moves through peristalsis. However, if the patient has had abdominal surgery, adhesions can form and prevent the bowel from moving. If this is not taken into account during identification of target volumes, the radiation dose can be misplaced.

In this case, it is unknown whether oral contrast medium was used during imaging to enhance bowel visualization. This could also potentially lead to a contouring oversight.

Suboptimal plan quality is strongly dependent on:

- Allotted time to plan
- Skills and experience of the planner and radiation oncologist
- Subjective preferences and priorities of the planner

Today CT imaging is the minimum standard for radiation therapy treatment planning. The addition of Magnetic Resonance (MR) and Positron Emission Tomography (PET) imaging can improve the delineation of treatment targets and normal structures. However, care must be taken when registering and fusing the individual datasets. Placing the patient in the same position with proper immobilization devices during imaging where possible reduces this issue.

Contouring errors are a high-risk part of the radiation oncology procedure, due partly to the limited amount of review they receive. As such it is very important to try to minimize the occurrence of these errors through training, competency assessment, time management, software systems design and standardized procedures, etc. Additionally, communication between the planner and physician including review and approval are critical to the process. The radiation oncologist specifies the normal tissues requiring segmentation and is ultimately responsible for ensuring the accurate delineation of the OARs.

Q3 2017 RO-ILS REPORT SURVEY SUMMARY

In order for RO-ILS to understand the workflow that initiates prescription errors, a survey was conducted through the Q3 2017 RO-ILS Report. The survey results were managed by Clarity PSO under the auspices of the Patient Safety Act.

This survey focused on procedures and practices related to the radiation dose prescription, a theme of the Q3 2017 RO-ILS Report. The survey received a total of 160 responses.

Respondents were asked to select all the methods physicians utilize to initially convey the intended prescription information to the planner. While a majority (74 percent; 119) of respondents reported that physicians electronically convey this information via a record and verify system (e.g., MOSAIQ, ARIA, etc.), a significant number (41 percent, 66 respondents) indicated that verbal instructions are given (See Figure 6).

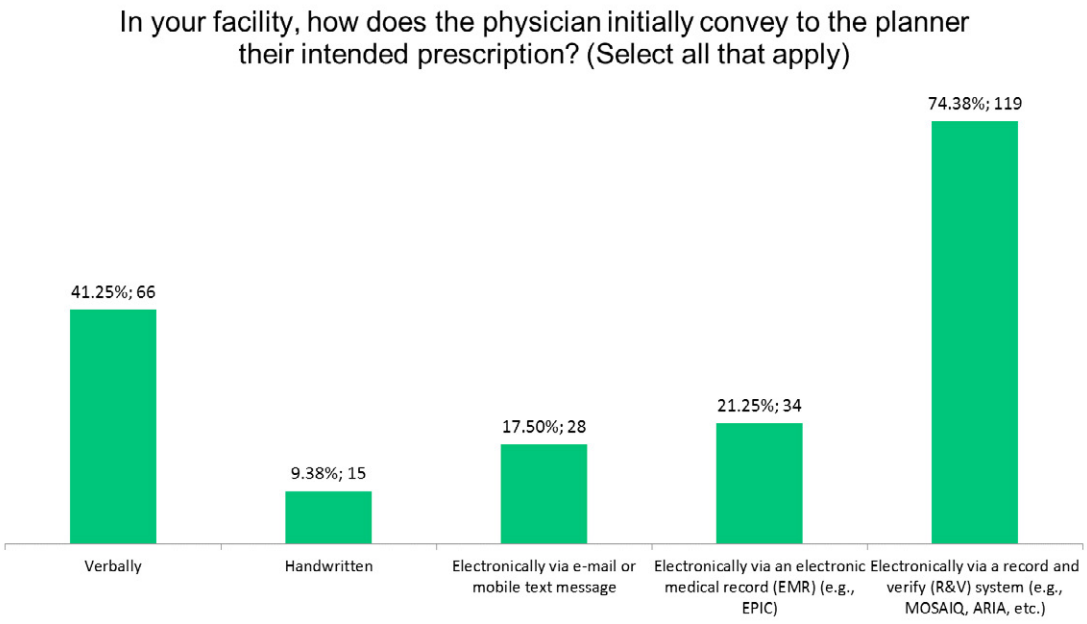


Figure 6. Initial Method of Prescription Communication (n=160)

Almost half of respondents (48 percent, 77) reported that only the attending physician drafts the formal prescription (i.e., dose/fraction, number of fractions, and total dose) for signature/approval. Thirty two percent of respondents indicated non-uniform process whereby the attending, resident physician, or planner may draft the formal prescription for the physician's approval. Figure 7 depicts the reasons someone other than the attending physician (i.e., the resident physician or the planner) drafts the formal prescription. Reasons include process efficiency, time restrictions, familiarity with the software.

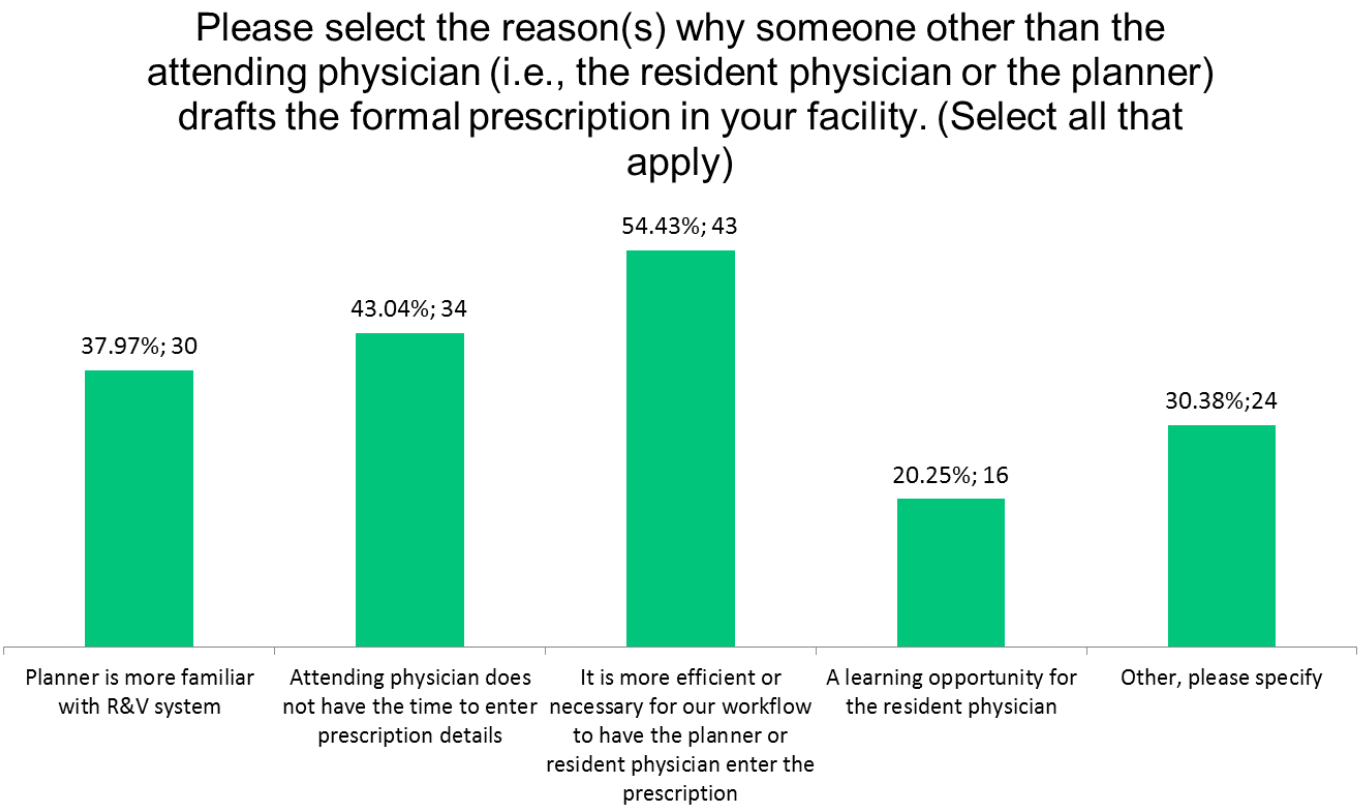


Figure 7. Rationale for Non-Attending Physician Drafting Prescription (n=79)

Figure 8 depicts when in the workflow the prescription is typically entered into the R&V system. Over 60 percent of respondents indicated this is done prior to the start of treatment planning, most commonly after simulation has been completed.

Approximately half of respondents (51 percent; 78) report that their record and verify and treatment planning systems are from the same vendor. Of those who operate with a single-vendor environment, the most frequently reported response (39 percent; 30) was that key components of the prescription (i.e., dose/fraction, number of fractions, and total dose) are entered into the record and verify system and then automatically transferred and populated in the treatment planning system. The 78 single-vendor respondents were given an opportunity to provide free-response comment on their experience with automatically populated prescription information. Overall, users see automating prescription information to be valuable. Specifically, with common disease sites that have consistent treatment parameters (i.e., dose, fractionation, delivery technique). However, it requires more work to make changes at the completion of the planning process. The plan must be approved for it to link the treatment parameters to the record and verify delivery system. It seems that a specific process must be followed to take advantage of this automation. If the prescribing radiation oncologist does not complete the work in this workflow, then issues may arise such as delays in treatment and if the variation in the work is missed a treatment delivery error such as a misadministration may occur. Therefore, to be successful with this automation, a rigid workflow process must be followed, monitored, and staff must be held accountable to reasonable, agreed-upon time frames.

The final question of the survey was an optional free-text response asking all respondents what strategies their facilities have implemented to mitigate error pathways related to an incorrect prescription. The most common response was to have some check in place, either a physician reviewing the plan and prescription and/or the dosimetrist and/or the physicist.

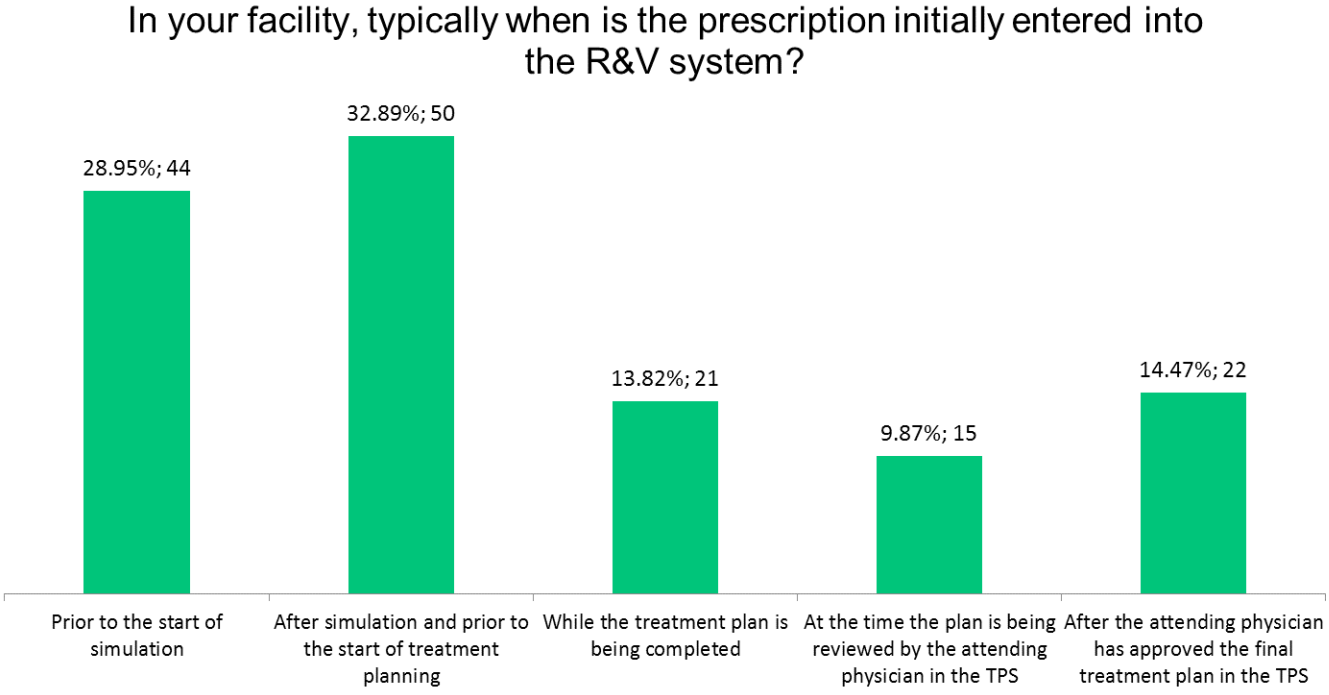
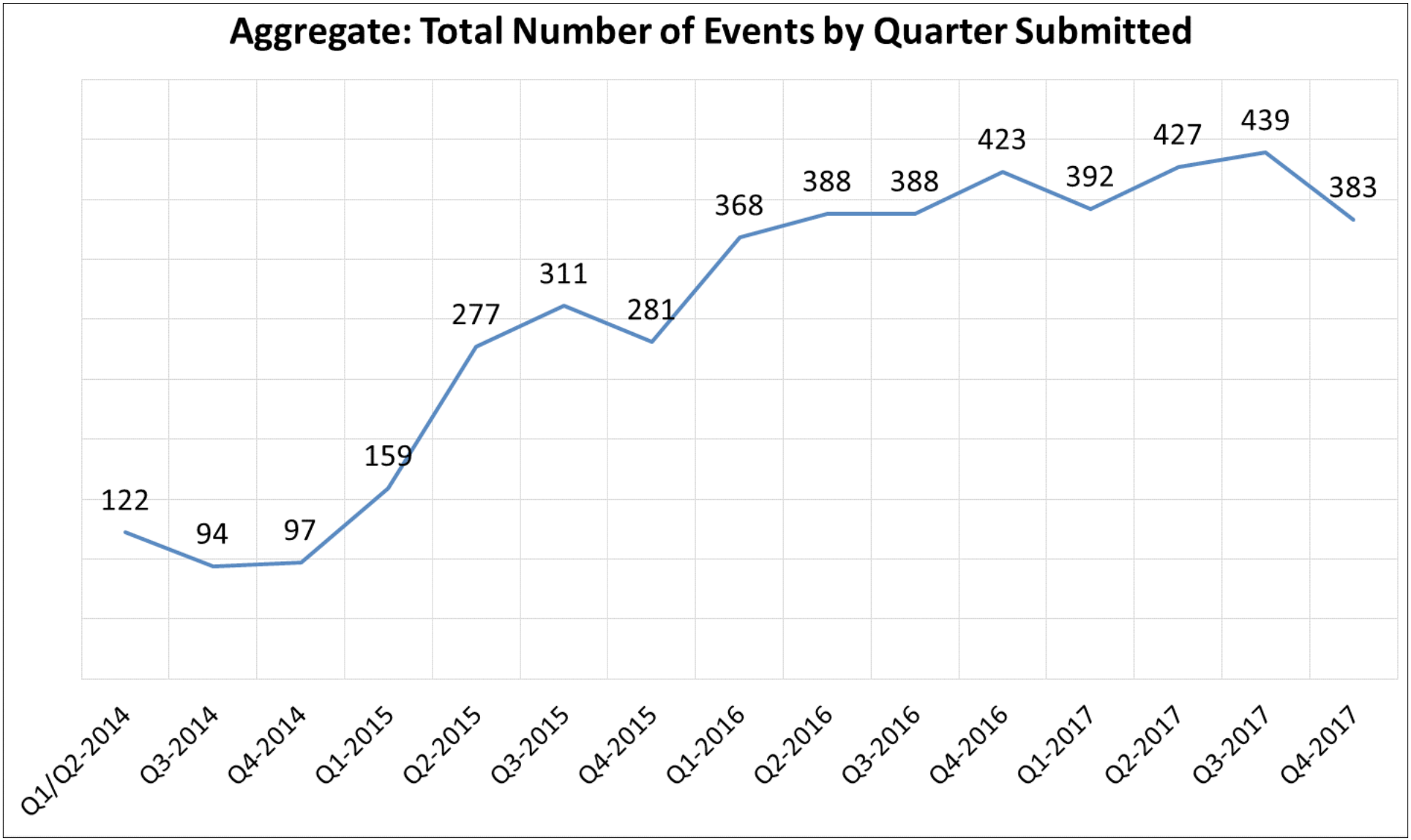


Figure 8. Timing of R&V Prescription Information Entry (n=152)

AGGREGATE ANALYSIS GRAPHS



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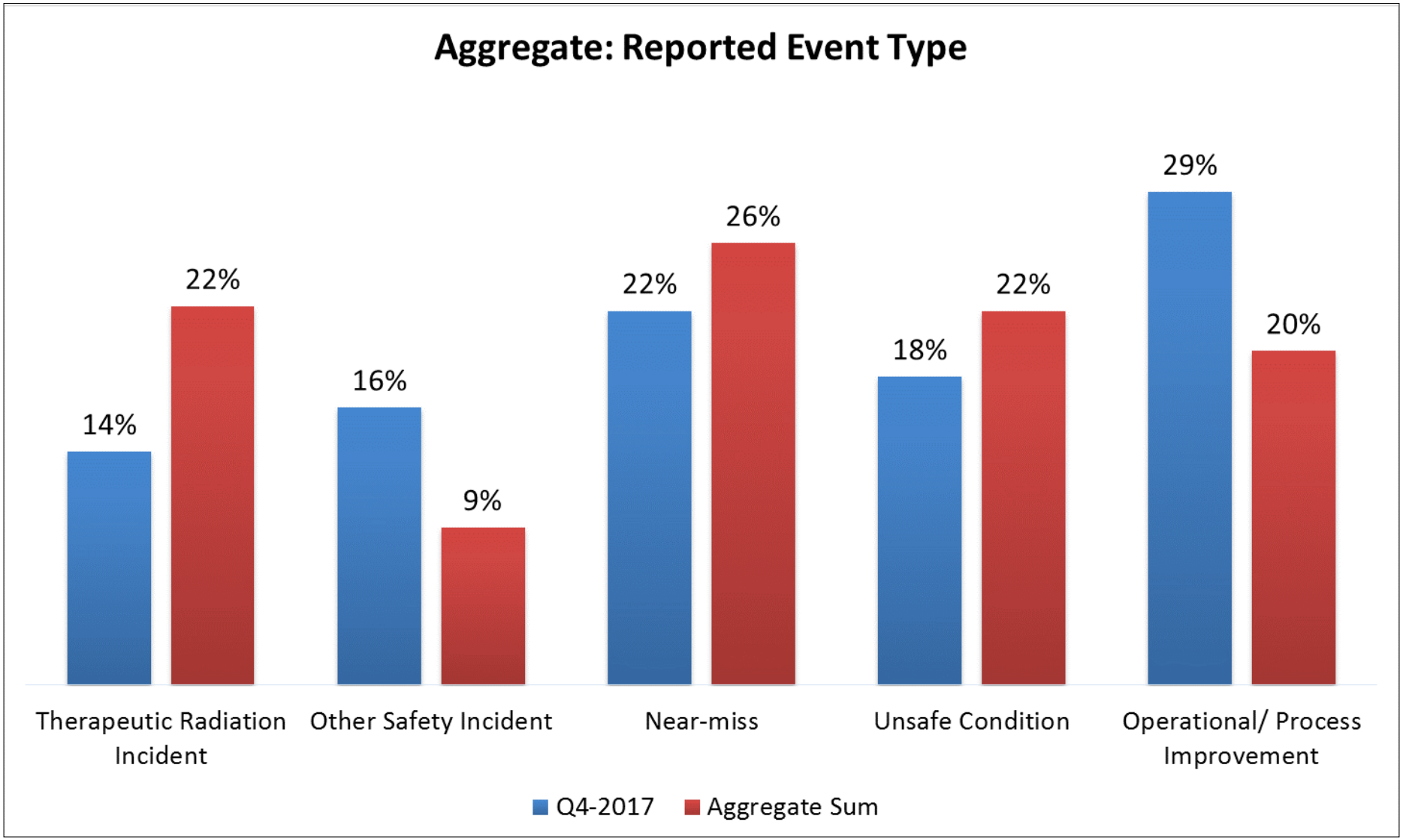

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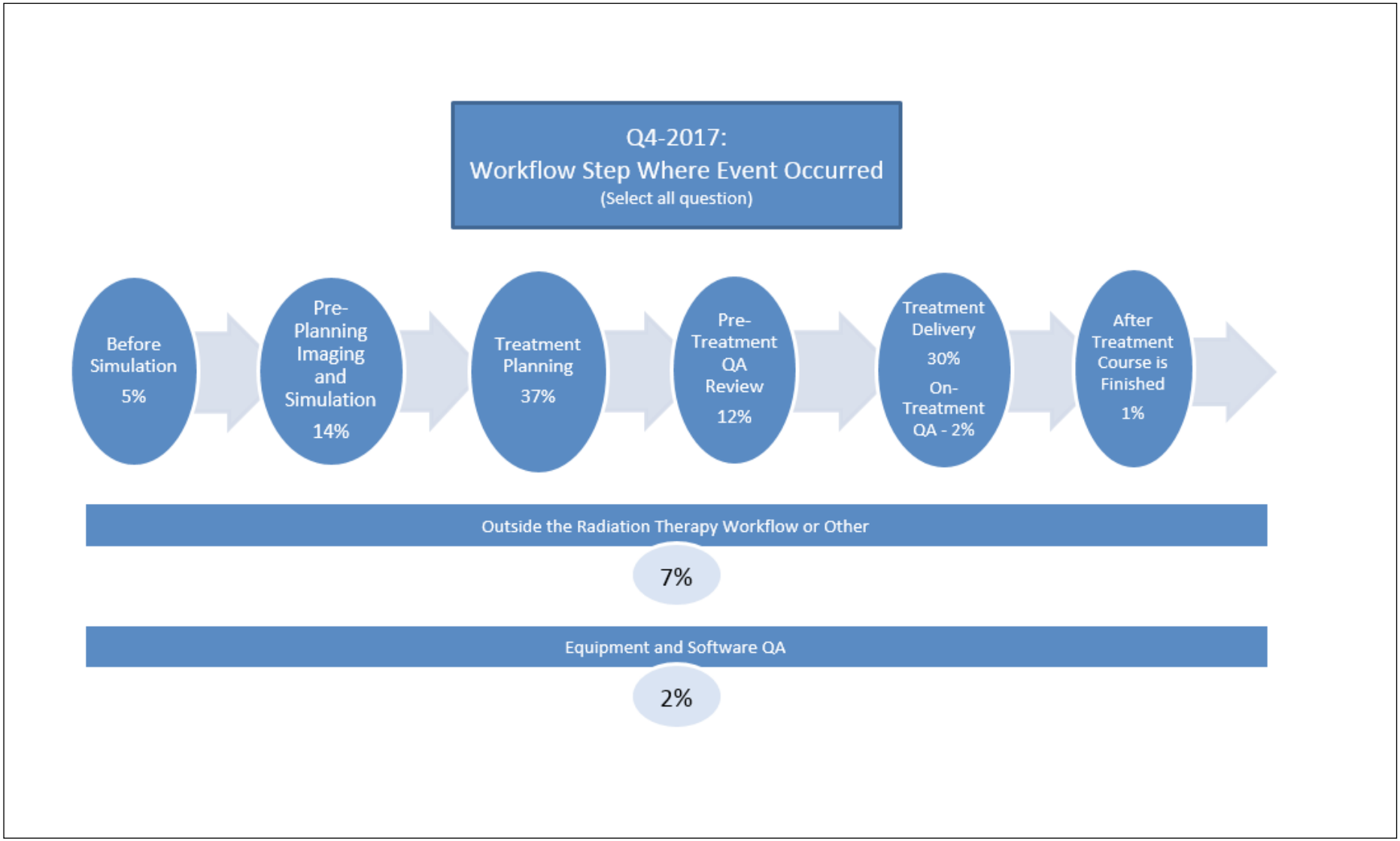

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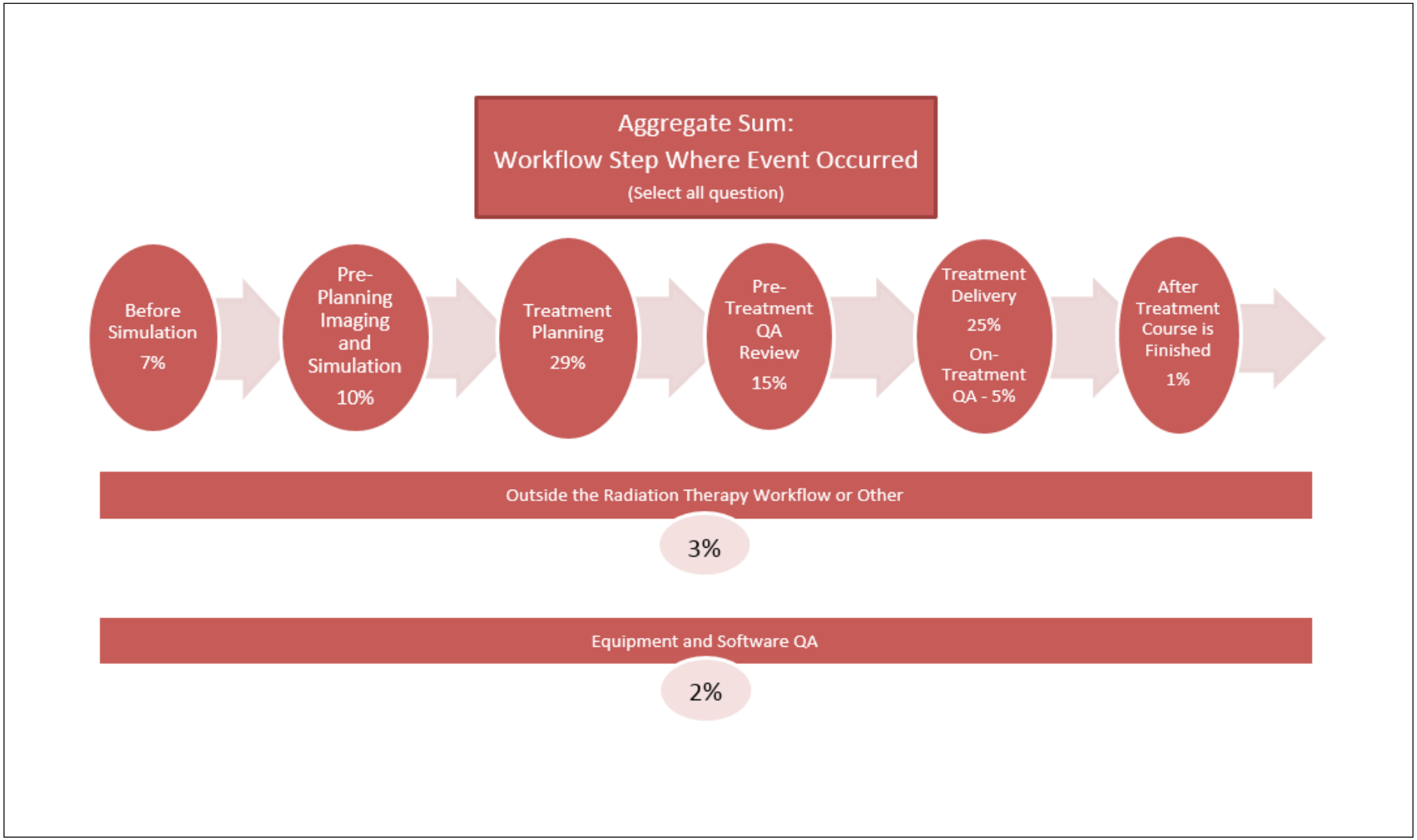

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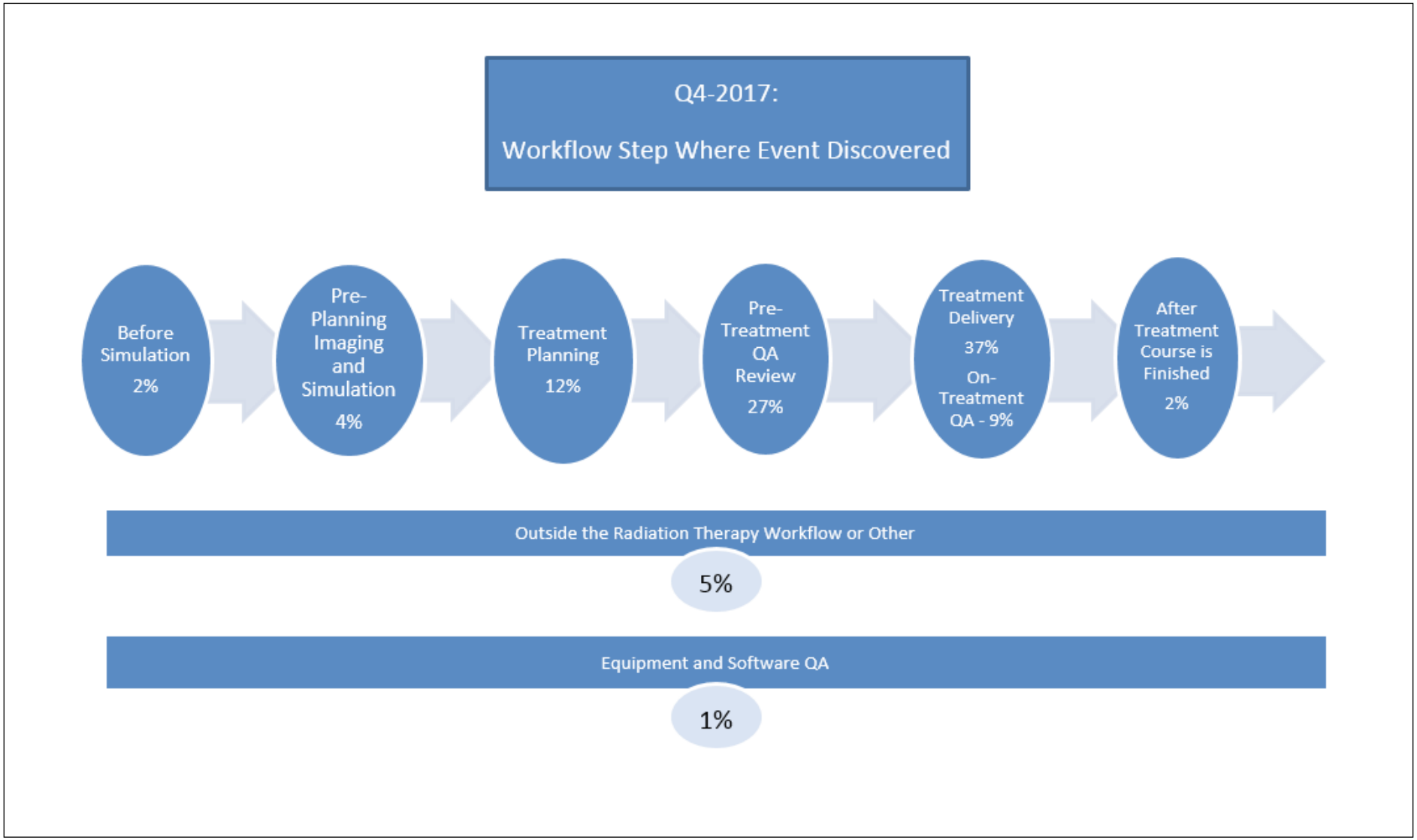

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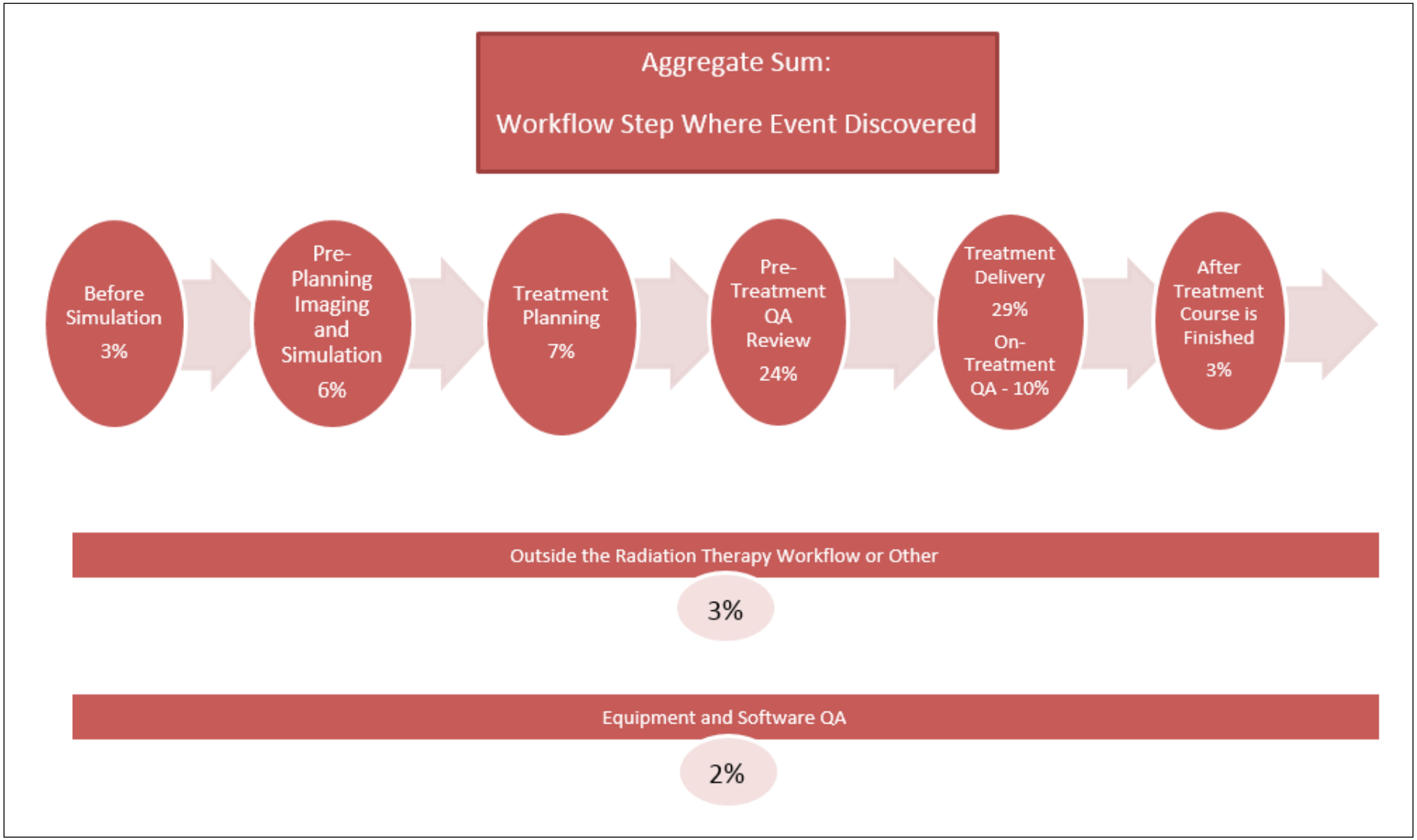

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