



RO•ILS[®]

**RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM**

Sponsored by ASTRO and AAPM



QUARTERLY REPORT

PATIENT SAFETY WORK PRODUCT

Q1 2016

JANUARY 1, 2016 – MARCH 31, 2016

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AGGREGATE REPORT CARD –
Q1 2016
 January 1, 2016 – March 31, 2016

METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE PREVIOUS QUARTER	AGGREGATE HISTORICAL SUM
Total Number of Events	297	289	1632
Patient Incident	110	104	589
Near Miss	95	102	555
Unsafe Conditions	92	83	488
Most Commonly Identified Characterization of Event	Not Sure How to Characterize: 29% (86/297)	Not Sure How to Characterize: 33% (95/289)	Not Sure How to Characterize: 26% (421/1632)
	Unanswered/Not Sure: 37% (111/297)	Unanswered/Not Sure: 39% (112/289)	Unanswered/Not Sure: 37% (598/1632)
Most Commonly Identified Workflow Step Where Event Occurred	Treatment Planning: 27% (80/297)	Treatment Planning: 32% (92/289)	Treatment Planning: 30% (494/1632)
	Unanswered: 24% (72/297)	Unanswered: 19% (55/289)	Unanswered: 24% (389/1632)
Most Commonly Identified Treatment Technique	3D: 23% (67/297)	3D: 19% (56/289)	3D: 21% (343/1632)
	Unanswered: 44% (132/297)	Unanswered: 47% (135/289)	Unanswered: 48% (776/1632)
Characterization of Dosimetric Severity for Events That Reached the Patient	Desired Procedure Omitted: 39% (13/33)	Incorrect Dose to All or Part of Body: 56% (10/18)	Incorrect Dose to All or Part of Body: 37% (67/179)
Potential Future Toxicity Within Events That Reached the Patient	None or mild: 55% (60/110)	None or mild: 39% (41/104)	None or mild: 50% (296/589)
	Unanswered: 45% (49/110)	Unanswered: 58% (60/104)	Unanswered: 45% (267/589)

ANALYSIS & COMMENTARY

INTRODUCTION

Within this Q1 2016 report, there are two main content sections: Featured Themes and Data Analysis. Each of these sections provides deeper analysis and case studies derived from the events submitted to the database. These events directly relate to the correlating themes discussed within each section.

The shared learning from RO-ILS: Radiation Oncology Incident Learning System®, which subsequently leads to safer, higher quality care, is dependent upon the submission of events by providers. The first event, within the “high-dose-rate (HDR) with equipment from different vendors” section, in particular, is an excellent example of a provider utilizing this program to reach out to the community and share information about an error pathway that affected patients. RO-ILS provides a safe environment for such dissemination. The events described in this report are valuable examples of the expectation set for this program.

FEATURED THEMES

HDR with equipment from different vendors

This quarter there were two events reported that related to the positioning of HDR brachytherapy sources in a treatment applicator. In one case, there was confusion about the proper method for manually inserting a dummy marker to indicate the treatment position, leading to a geographic miss of approximately 4.6 cm for two endobronchial treatments on one patient. Subsequent investigation revealed that the same error had been made on two other patients. The problem arose because of uncertainty in how to use dummy markers in a new HDR system that had replaced one from a different vendor. The old system required that the treatment adapter be attached to the endobronchial catheter before the dummy markers were inserted, while the new system required that the treatment adapter not be attached. Deficiencies in training and vendor documentation were identified as contributing factors. The facility reported the events to the relevant regulators. In its internal analysis of the event, the facility staff highlighted the importance of **involving the people who actually perform the various steps in the process in the end to end tests of new procedures**. In this case, some members of the therapist and physics groups had different understandings about how to use the dummy markers. An end-to-end test performed solely by physicists would not have revealed that ambiguity. It is also worth emphasizing that *the problem was identified and solved after a team member saw something that did not seem right and asked the question*.

In the other case, the planning system used for HDR planning applied a default value for the applicator length that is 20 cm shorter than the actual catheter, and that was not corrected during planning. The mismatch was found and corrected by a physicist before treatment.

These two cases involving HDR afterloaders illustrate the importance of revealing, and if necessary correcting, assumptions that exist in our minds or in our software, and these can often be manifested when transitioning from or mixing systems from different vendors. It is of utmost importance to challenge ourselves and ask questions even when the system and process appear “correct”.

ANALYSIS & COMMENTARY | continued

Laterality errors

Additionally, there were two events this quarter of laterality errors made by physicians prescribing treatment that were recognized and corrected by technical staff before treatment. In one case the dosimetrist reviewed the medical record before beginning planning to check the laterality and in the other case the radiation therapists recognized that the wrong hip was targeted and called for a correction. **These last two events demonstrate the value of having fully engaged staff who are empowered to take initiative to prevent treatment errors.**

Manual data entry

Not surprisingly, a common feature of many events is that some information that requires manual data entry was entered incorrectly. When the error is identified and corrected at the first available quality assurance (QA) step, it indicates that the QA step is necessary and is functioning. However, it often happens that the error is not found until later in the process, and that then indicates a need to improve the QA process (or better yet change the system to remove the need for manual data entry).

A frequent issue seen is that shift instructions are incorrect. In this quarter, there were six events involving shift instructions. While none of the events this quarter led to an incorrect treatment, manual entry surrounding shifts requires added attention.

Case 1: In one case, a 0.3 cm shift was transcribed as 3 cm, but the discrepancy was identified by the cone beam computed tomography (CBCT) used for image guidance.

Case 2: In another case, the shift direction was given as “right” when “left” was correct; this was also found early by the physics plan check.

Case 3: In a cautionary near miss event, the desired isocenter for the CBCT was manually entered 5 cm off, so when the therapists imaged the patient this large shift was needed to align the images. They made the shift, and then, because this patient had 3-D conformal ports, they took portal images that revealed the error. Had the patient not had portal images, the error may have gone unnoticed.

This near miss event highlights an issue pertinent to quality and safety: **when there is a manual step that is critical to the process there needs to be a highly reliable QA step designed to test it.** When a manual step is used to set up the image guidance reference there is the possibility for a systematic error. Relying on a plan checker to catch the mistake is not sufficient. A post-shift image, not subject to the same error mode as the original reference, is a better tool and should be considered as part of the sequence when starting treatment. These near miss events also highlight the issue of something happening that is “out of the norm” (e.g. a 5 cm shift on a patient indicated by CBCT). A questioning attitude is crucial in such a situation. Such issues can also sometimes be addressed at the level of policy and procedures, **for example, a policy requiring a second check by an attending or other staff when there is a shift indicated that is larger than some predefined value.**

ANALYSIS & COMMENTARY | continued

Patient orientation

Another example of manual data entry being a source of error is selection of patient orientation (e.g. feet-first supine). This can be required at multiple steps in the radiation oncology workflow: at the CT simulation, in the treatment planning system, and in the treatment guidance system. It is always manual at the time of simulation because the imaging device cannot detect the patient orientation. It can also happen at later stages, if direct digital data transfer is not available for that parameter.

This quarter there was one event of a patient being treated feet-first who was entered as head-first into the image guidance system. In this case the patient was treated correctly but the left/right directions were reversed in the image labeling, meaning the image displayed had the incorrect orientation labels.

There have been multiple events in other quarters related to patient orientation being entered incorrectly at the time of CT simulation. All of these particular events were identified and corrected, although in one event the patient was on the table for the first treatment which then had to be postponed.

One facility reported that they have started a **special time-out procedure in CT simulation whenever the patient orientation is not head-first, supine**. This involves not only confirming that the labeling is correct but also that the oncologist marking the isocenter is aware of any change in left/right display.

Approved plan different from intent

There were three events reported this quarter in which a treatment plan was created and approved that used a different fractionation scheme than the physician actually intended.

Case 4: The prescription was for five fractions, but the approved plan was for three. This was noted by the therapists after the patient was brought into the room for the first treatment.

Case 5: The patient was told she would have 16 treatments, but the physician wrote the prescription for 28. After the first treatment, the patient was given her full schedule and she noted the change from her expectation. The plan was changed before the next treatment so she could be completed in 16 fractions total.

Case 6: The plan was prepared and approved for a prescription of 4500 cGy (45 Gy) in 25 fractions, but the physicist checking the plan noted that the physician's intent document, created before the prescription, indicated 4500 cGy (45 Gy) in 15 fractions. The plan was revised after the patient's verification appointment had occurred, but before the first treatment.

ANALYSIS & COMMENTARY | continued

This is a recurring issue that was discussed in detail in the Q4 2015 Quarterly Report. However, there is a specific failure pathway that has not yet been highlighted. In at least six cases within the database, the narrative either states or implies that the planner wrote the prescription that the physician approved, but the planner's understanding of the intent was incorrect. In one case a patient with breast cancer had her supraclavicular region targeted in error and treated twice before the case was reviewed in chart rounds and the field discontinued. In another case, the physician verbally ordered "12 in 2", intending 2 fractions of 6 Gy, but the planner assumed the intent was 6 fractions of 2 Gy. The plan was prepared and approved for 2 Gy/fraction and one treatment was delivered. This error was also discovered at chart rounds.

Facilities that permit a planner to prepare the final prescription for the physician to approve may wish to consider workflows that reduce the chance for error. In those situations, and in general, a physician who verbalizes the key elements of the prescription before approving it is more likely to recognize and prevent a contradiction. This is only one suggestion and should be discussed internally.

While it is well understood that one should not rely solely on verbal communication for critical matters, we should also consider the potential weakness of relying solely on written communication. A combination of both verbal and written communication engages the attention more completely. It is especially beneficial to have a standard sequence when expressing the elements of a dose prescription, as that can reduce the chance of misunderstanding.

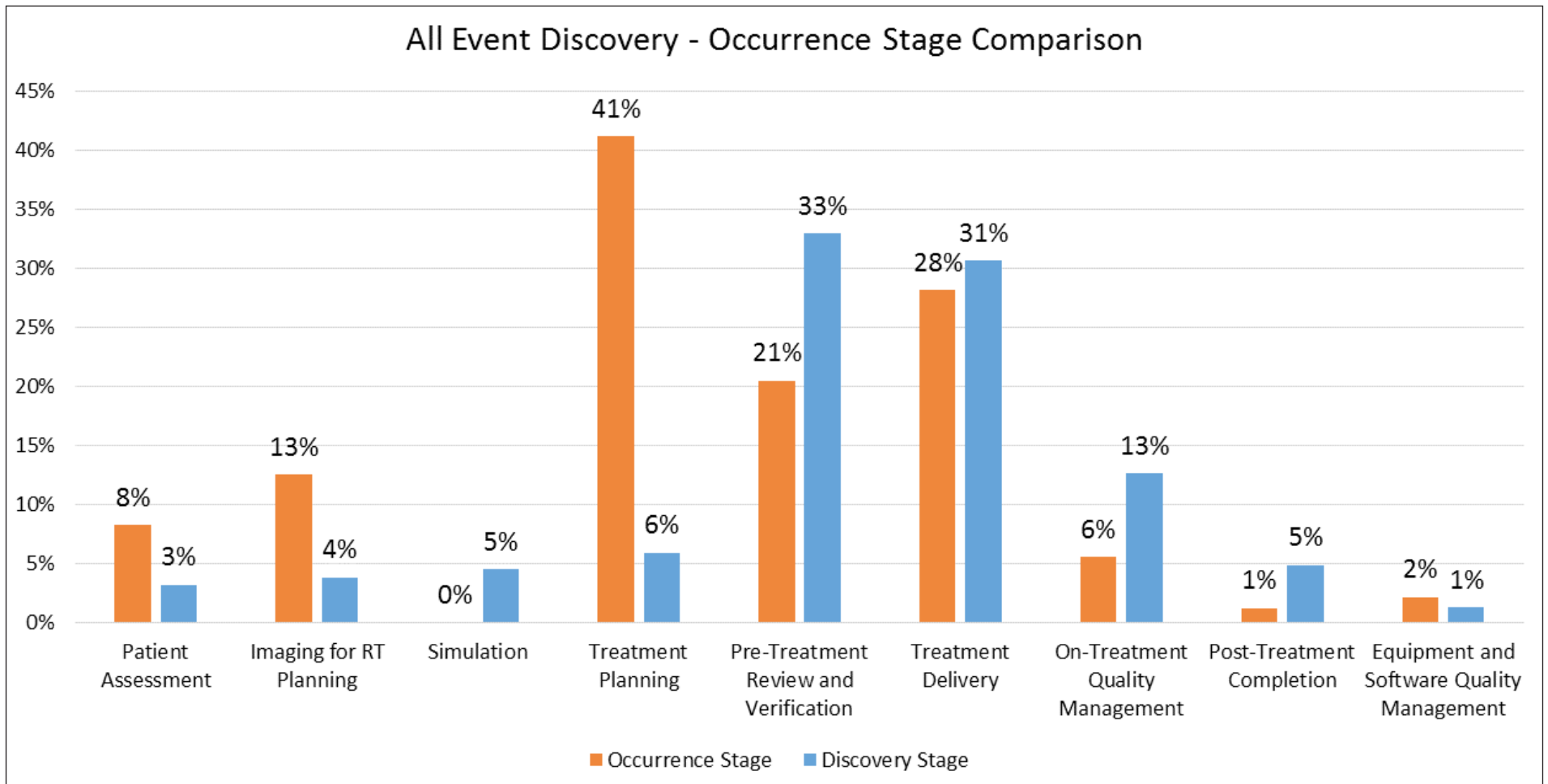
This fall, ASTRO will be publish a manuscript titled "Standardizing Dose Prescription: An ASTRO White Paper" to help create a consistent format for presenting the dose prescription.

DATA ANALYSIS: OCCURRENCE AND DISCOVERY OF ERRORS WITHIN THE WORKFLOW PROCESS

"In what workflow step(s) did the event occur" and "in what workflow step(s) was the event discovered" are both asked during the follow-up review of the event. These questions are not mandatory. The following graph demonstrates how these events (in which one or both of these data elements are answered) are distributed throughout the workflow steps. Occurrence refers to when or where an event *happened*. Discovery refers to when or where an event was *found*. Therefore, an event could (and often does) happen earlier in the process, but is not caught until later.

ANALYSIS & COMMENTARY | continued

FIGURE 1. EVENT OCCURRENCE AND DISCOVERY FOR ALL EVENTS (N =1146)



ANALYSIS & COMMENTARY | continued

Of the 1632 events in the database through Q1 2016, 70 percent (1146/1632) had *both* the data elements for *occurrence* and *discovery* filled out. It is of particular interest to look at the number of cases in which the event occurred early in the process, i.e., in Treatment Planning or earlier, but the event was not discovered until Treatment Delivery or later (i.e., “early occurrence, late discovery”). These are the cases that passed through QA steps that—in principle—should have found the problem. Table 1 and Figure 2 highlights this subset of events.

Table 1. Events that occurred during “Treatment Planning” or earlier and in what workflow step those events were discovered.

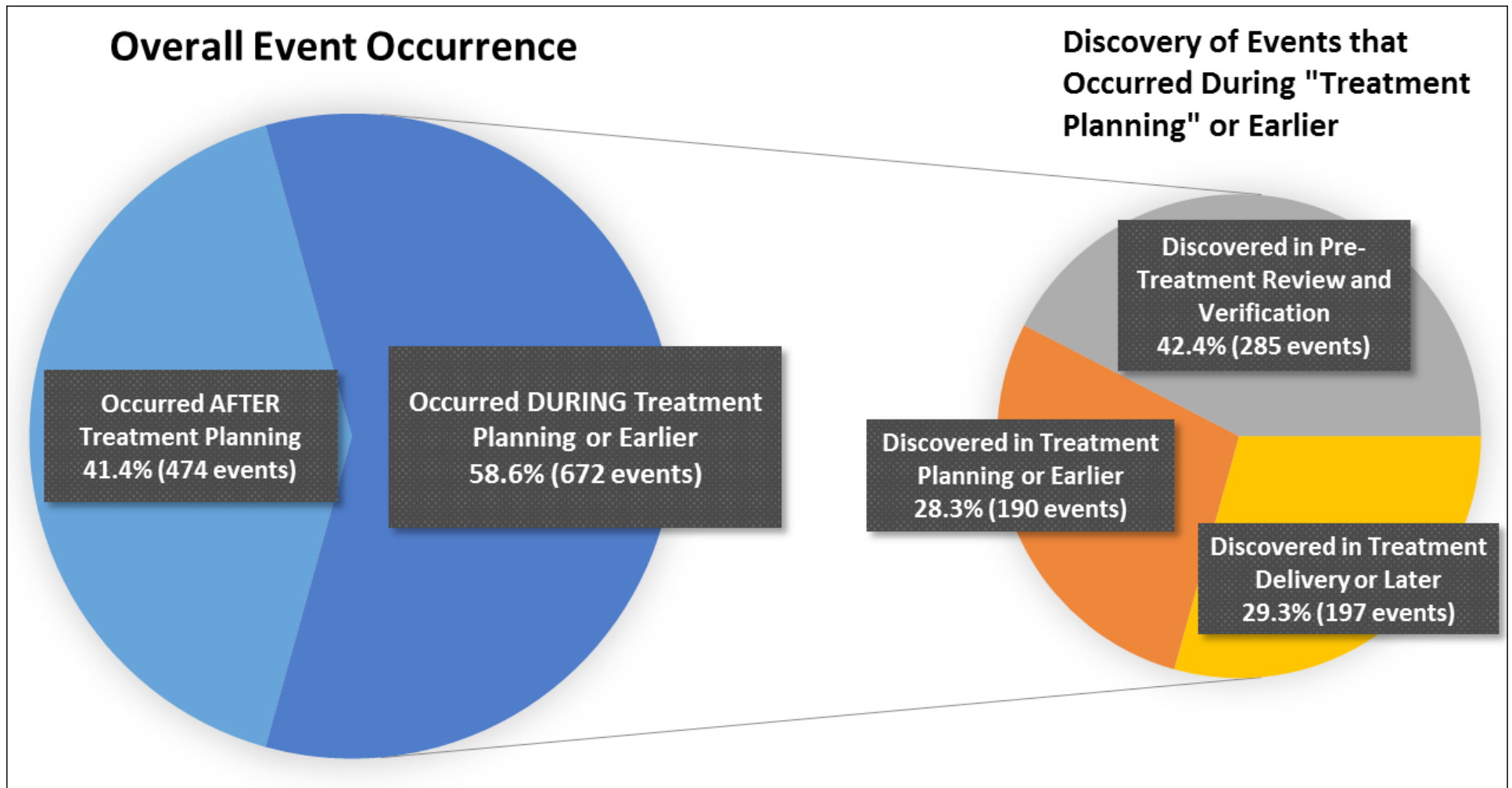
Type	Number	Percent
Discovered in Treatment Planning or Earlier	190	28.3%
Discovered in Pre-treatment Review and Verification	285	42.4%
Discovered in Treatment Delivery or Later	197	29.3%
Total Occurred During Treatment Planning or Earlier	672	100%

We see from this subset of data that 58.6 percent (672/1146) of events occurred early in the process, and 29.3 percent (197/672) of those were not discovered until Treatment Delivery or later. As discussed in the Q4 2015 Quarterly Report, the Radiation Oncology Healthcare Advisory Council (RO-HAC) scores events as perceived risk on a 1-5 scale, where 1 is low and 5 is critical. Of the 29.3 percent (197/672) of events that made it through the pre-treatment checks, 47.7 percent (94/197) were scored as moderate risk or higher (3-5) and 23.4 percent (46/197) were scored as severe or critical (4-5).

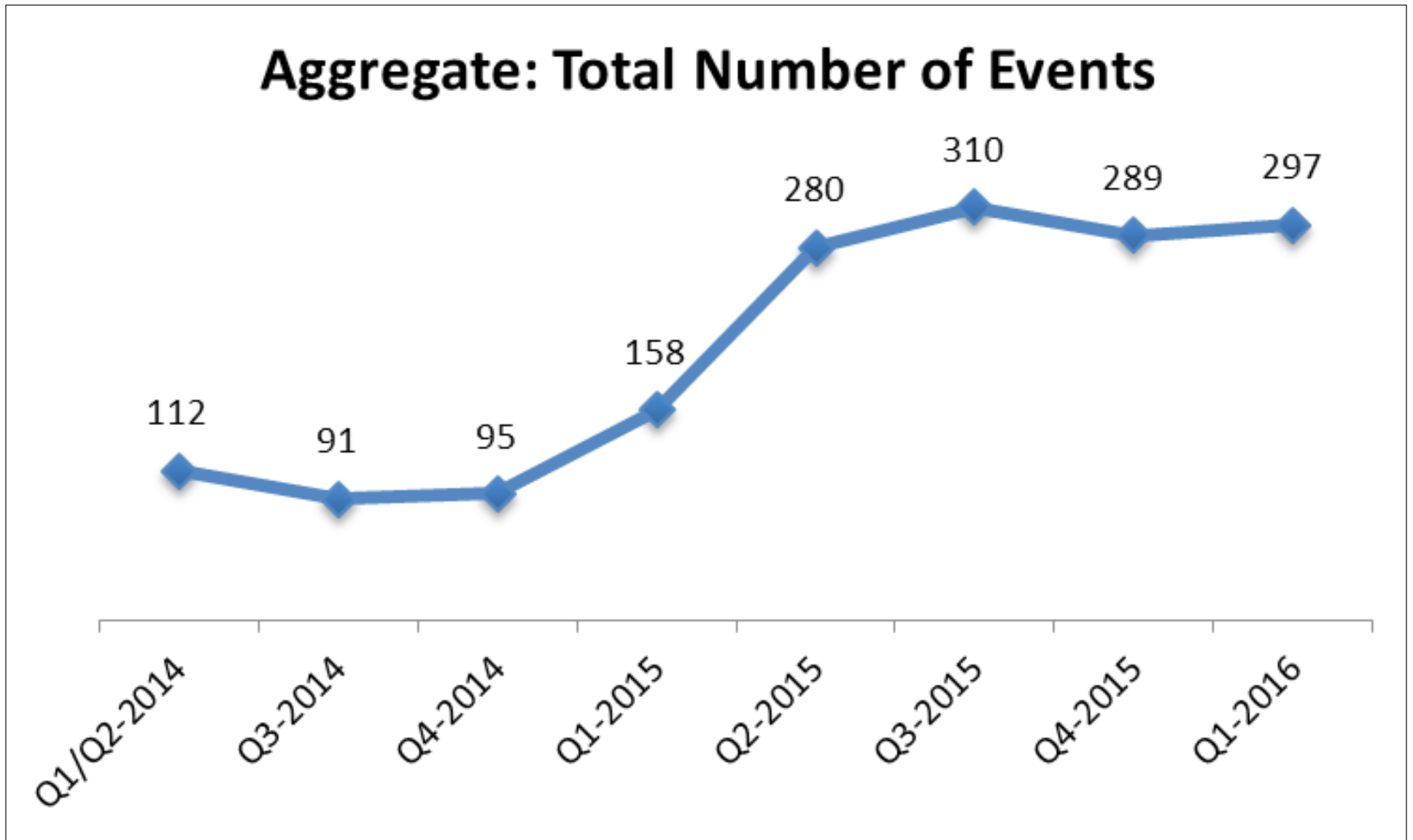
Examine your internal events through this context. **Compare where events occur and where those same events are discovered within the workflow process.** This investigation will lead to insight regarding process failures and functioning fail safes.

ANALYSIS & COMMENTARY | continued

FIGURE 2. "EARLY OCCURRENCE, LATE DISCOVERY"



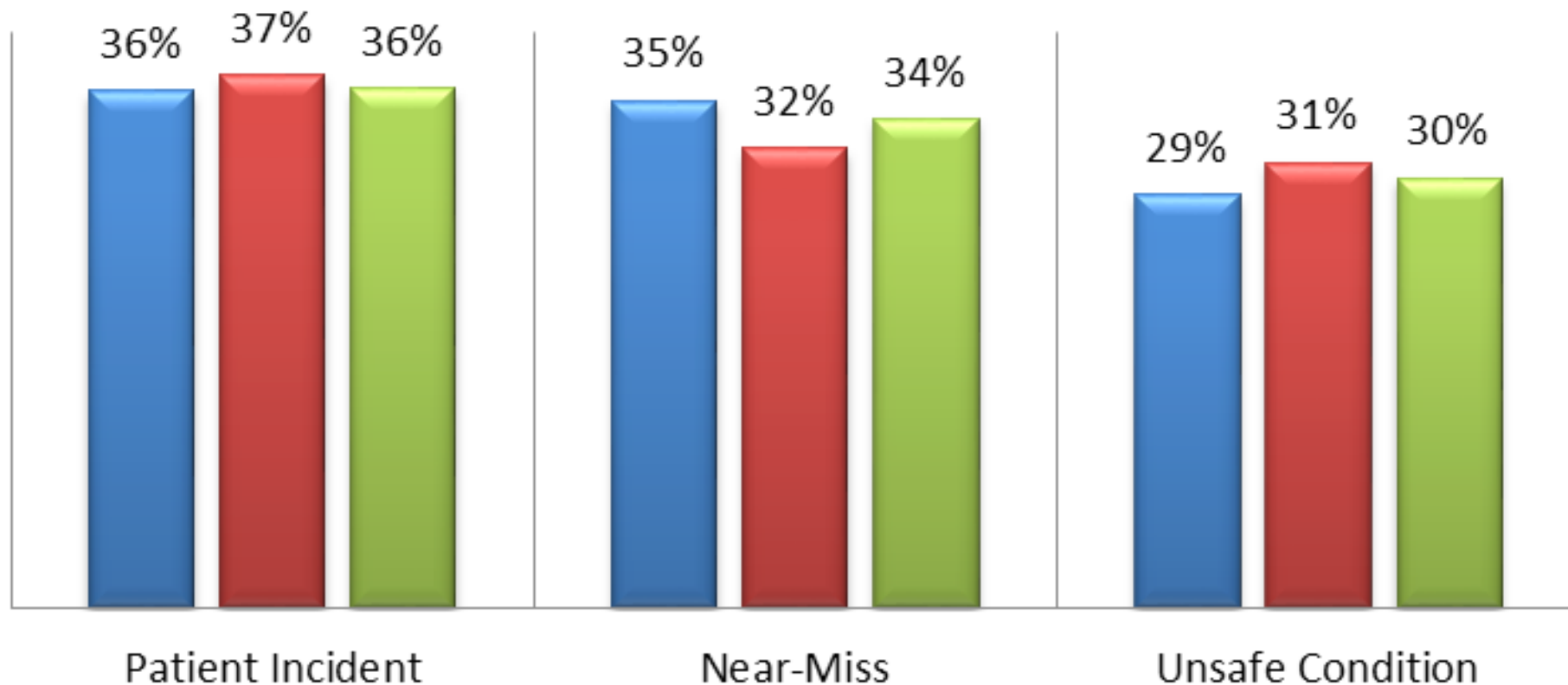
AGGREGATE ANALYSIS GRAPHS



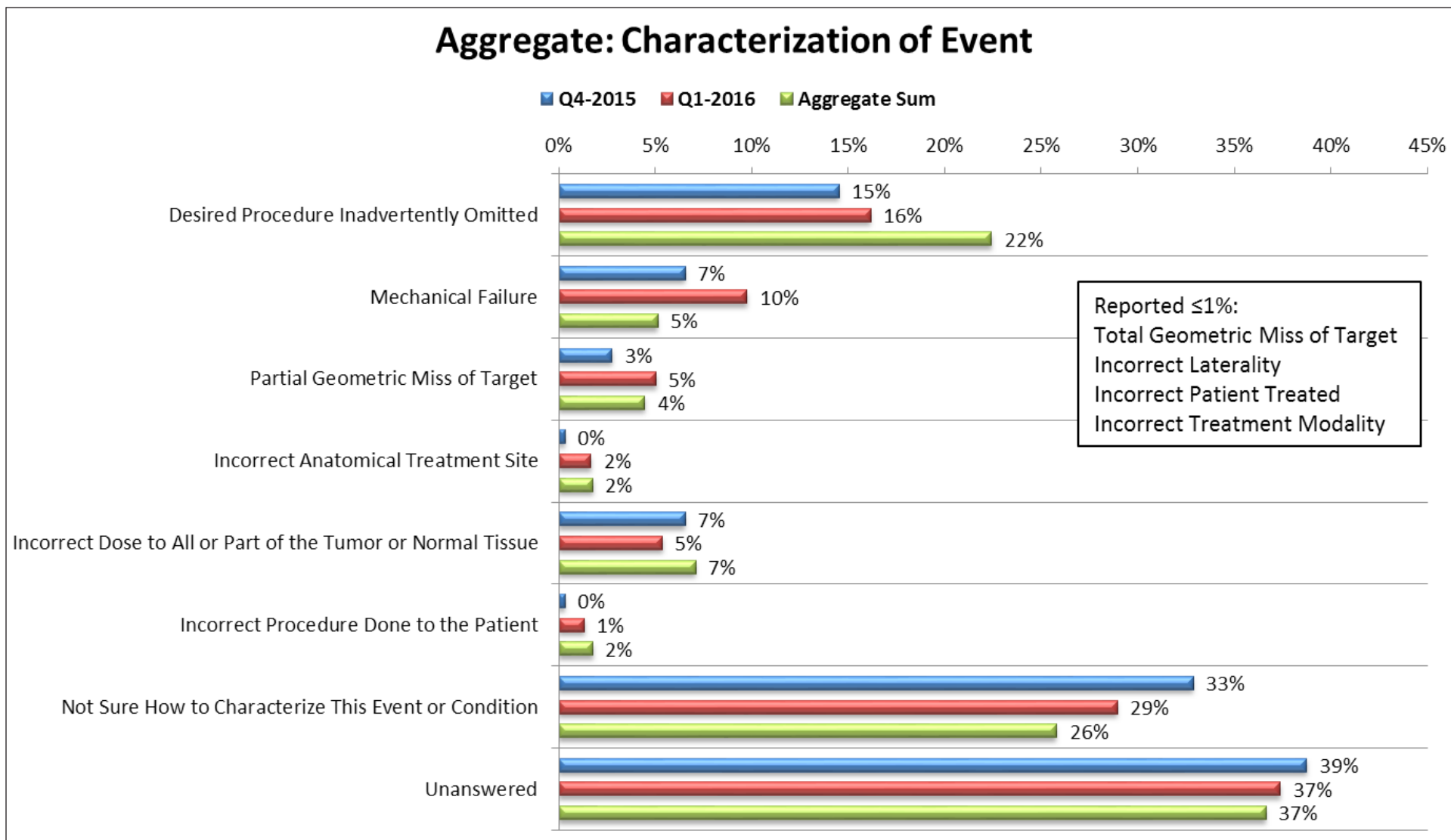
AGGREGATE ANALYSIS GRAPHS | continued

Aggregate: What Is Being Reported

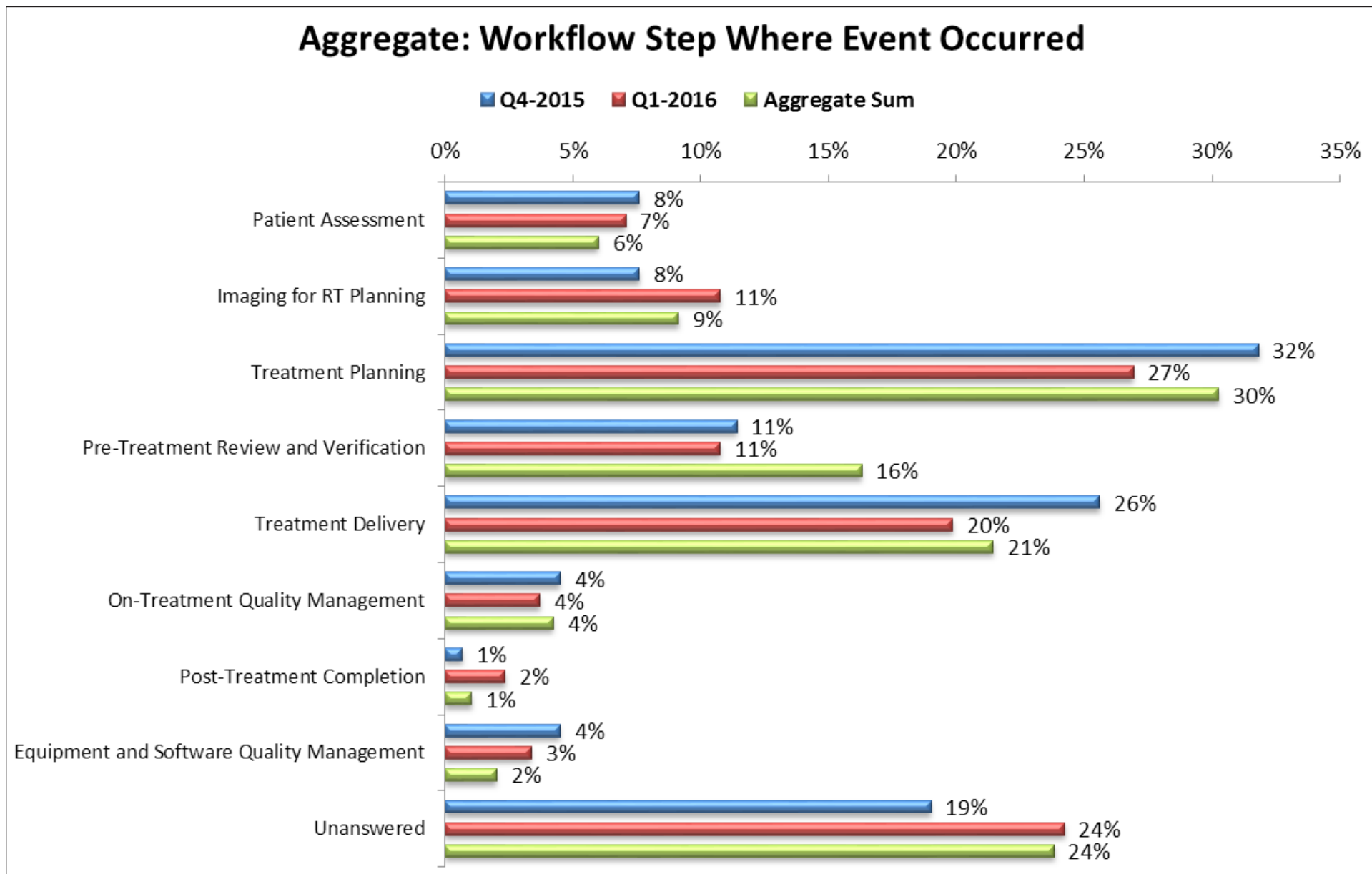
■ Q4-2015 ■ Q1-2016 ■ Aggregate Sum



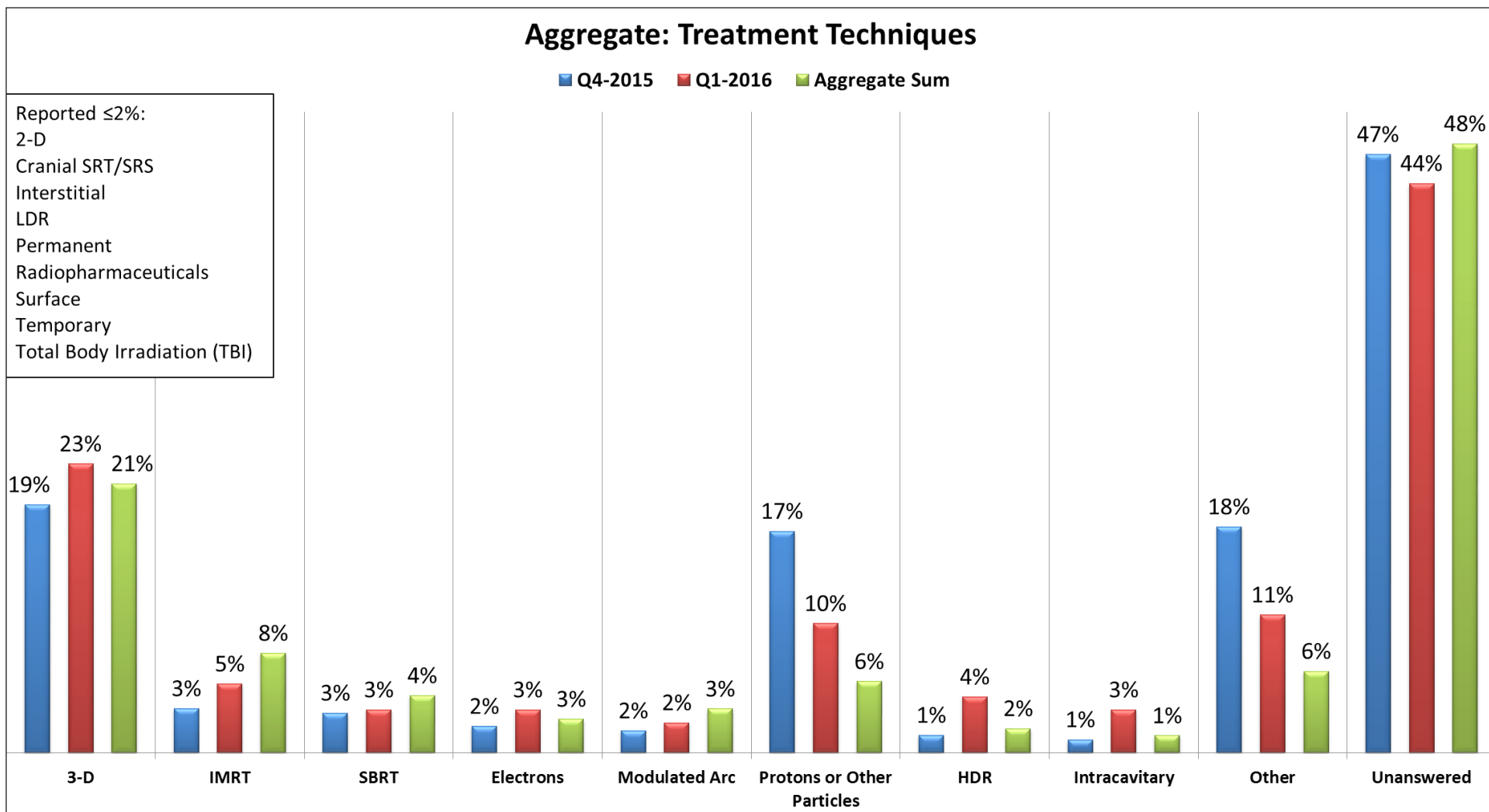
AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued



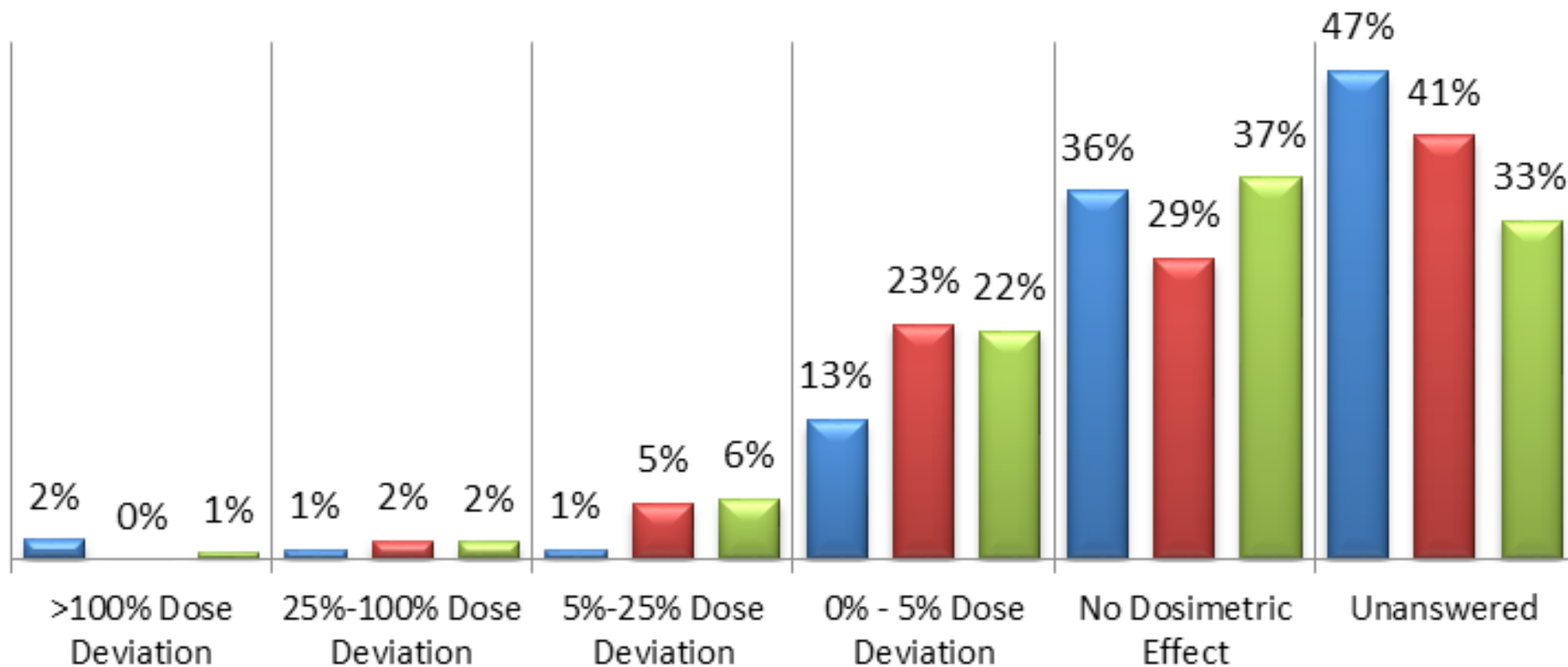
AGGREGATE ANALYSIS GRAPHS | continued



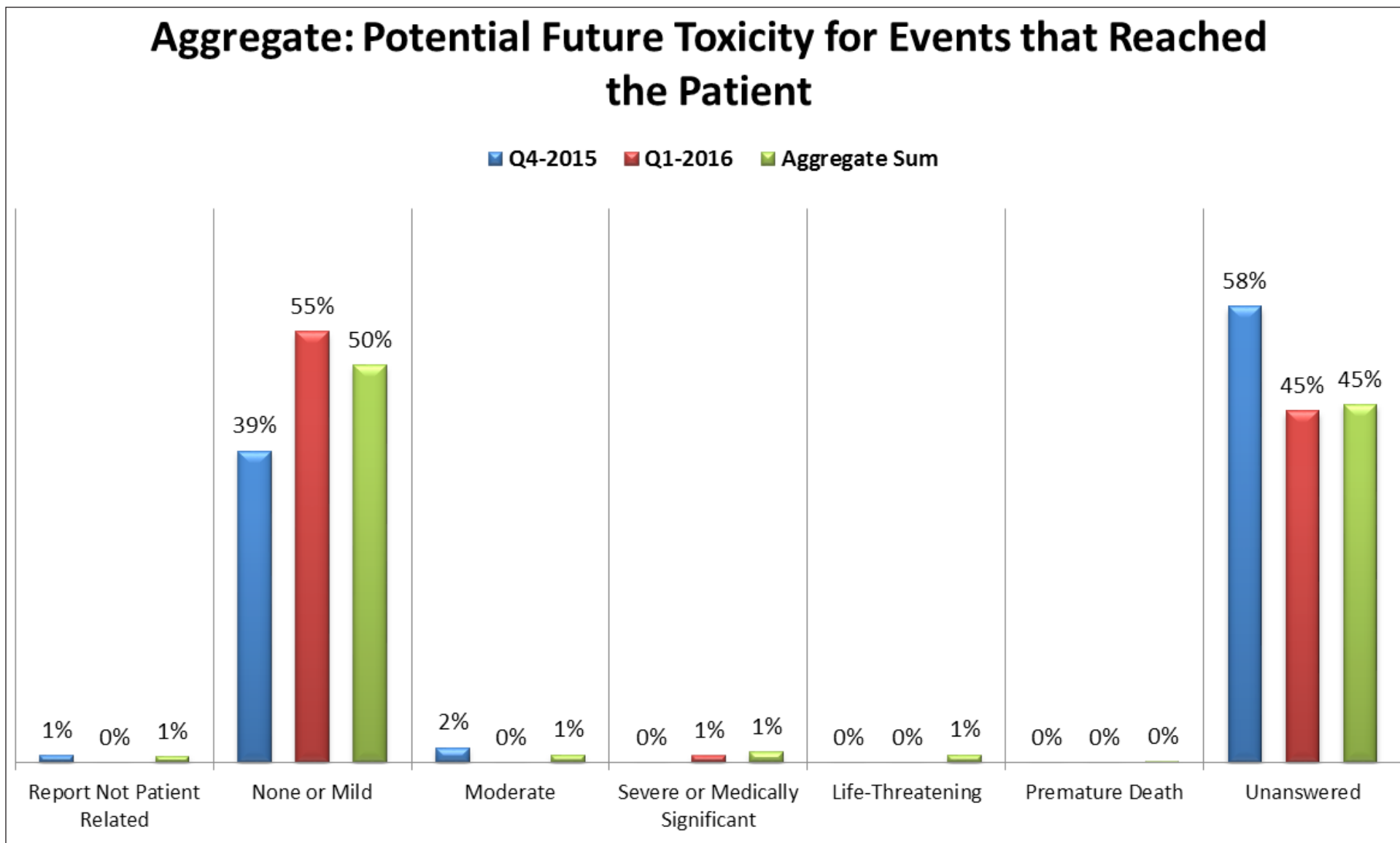
AGGREGATE ANALYSIS GRAPHS | continued

Aggregate: Dosimetric Severity for Events that Reached the Patient

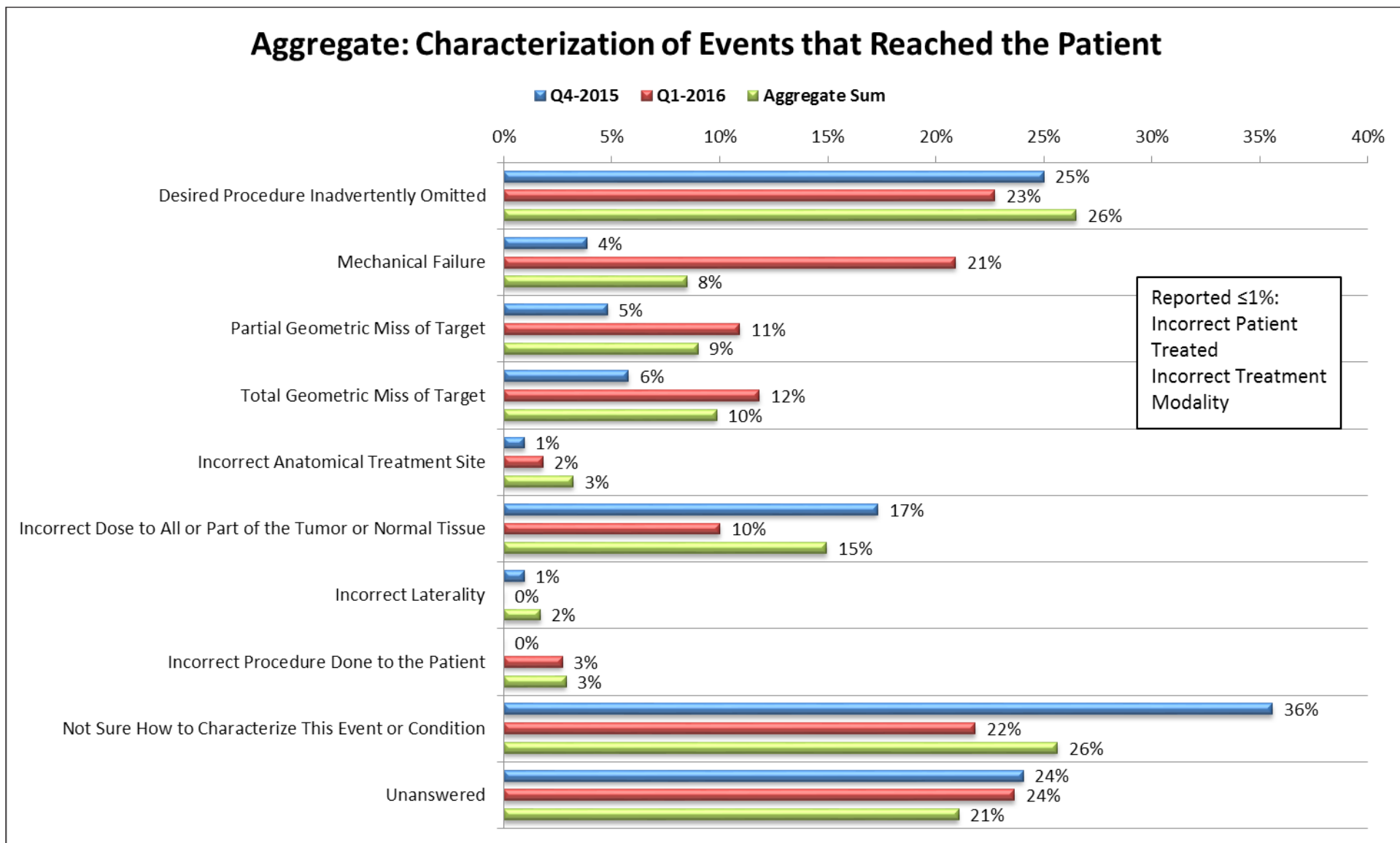
■ Q4-2015 ■ Q1-2016 ■ Aggregate Sum



AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued

