RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

QUARTERLY REPORT
PATIENT SAFETY WORK PRODUCT

Q2 2016
APRIL 1, 2016 – JUNE 30, 2016

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AGGREGATE REPORT CARD – Q2 2016

April 1, 2016 – June 30, 2016

METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE PREVIOUS QUARTER	AGGREGATE HISTORICAL SUM
Total Number of Events Patient Incident Near Miss Unsafe Conditions	**297** 96 106 95	**349** 137 108 104	**1982** 711 677 594
Most Commonly Identified Characterization of Event	**Desired Procedure Inadvertently Omitted:** 17% (50/297)	**Desired Procedure Inadvertently Omitted:** 19% (66/349)	**Desired Procedure Inadvertently Omitted:** 22% (434/1982)
Most Commonly Identified Workflow Step Where Event Occurred	**Treatment Planning:** 21% (63/297)	**Treatment Planning:** 26% (92/349)	**Treatment Planning:** 29% (569/1982)
Most Commonly Identified Treatment Technique	**3-D:** 16% (48/297)	**3-D:** 23% (79/349)	**3-D:** 20% (403/1982)
Characterization of Events That Reached the Patient with Dosimetric Severity	**Incorrect Dose to All or Part of the Tumor or Normal Tissue:** 30% (6/20)	**Desired Procedure Inadvertently Omitted:** 43% (15/35)	**Incorrect Dose to All or Part of the Tumor or Normal Tissue:** 37% (73/199)
Potential Future Toxicity of Events That Reached the Patient	**None or mild:** 47% (45/96)	**None or mild:** 49% (67/137)	**None or mild:** 49% (348/711)

ANALYSIS & COMMENTARY

INTRODUCTION

Each of the Featured Themes within the Q2 2016 report describes as well as provides deeper analysis on case studies derived from the events submitted to RO-ILS: Radiation Oncology Incident Learning System®. The shared learning from RO-ILS, which subsequently leads to safer, higher quality care, is dependent upon the submission of events by providers. These events are excellent examples of providers utilizing this program to reach out to the community and share information about error pathways within treatment delivery and those due to communication lapses. 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 THEME I: TREATMENT DELIVERY TO THE WRONG LOCATION

It is self-evident that the effectiveness of radiation therapy is contingent on treatment delivery to the correct location or target. Missing the target not only undermines the ability to achieve the therapeutic goal of treatment, but also potentially places adjacent organs at risk from unintentional radiation.

The following includes representative examples of mistargeted radiation therapy among this quarter's reported cases:

Case 1: Wrong hepatic lesion treated.
Stereotactic body radiation therapy (SBRT) treatment (50Gy in 5 fractions) was delivered to a benign liver hemangioma instead of the intended metastatic liver target.

A patient previously treated with SBRT for two liver metastases returned with a new lesion. The attending radiation oncologist and resident reviewed the imaging and made the decision to treat the new metastasis with SBRT. A simulation directive was performed by the resident complete with axial image snapshots from a diagnostic magnetic resonance (MR) scan as well as a contrast-enhanced computed tomography (CT) scan illustrating the lesion to be treated. After simulation, the gross tumor volume (GTV) contoured by the resident covered the wrong liver lesion. Treatment planning and quality assurance (QA) were completed based on that incorrect target. The error was not detected at the time of attending approval nor in peer-review rounds. Treatment was delivered to the benign liver hemangioma.

Follow-up imaging four months later demonstrated enlargement of the liver metastasis, prompting review of the case and the realization that the five SBRT fractions had been delivered to the incorrect hepatic target. Adjacent normal organs received doses within acceptable tolerances. The correct liver metastasis was subsequently treated with a treatment plan incorporating the contribution from the prior radiation.

As has been previously noted, errors are frequently the result of a confluence of multiple factors, and much less often the result of a single error.

ANALYSIS & COMMENTARY | continued

Contributing factors in this case included:

- Failure to accurately correlate target contouring with diagnostic imaging.
- Hand-offs and extended workflow with multiple people interacting with the plan.
- Safety-critical issue not identified in the review by the attending physician.
- Safety-critical issue not identified in peer review, despite the prospective SBRT-specific peer review being performed.
- Abbreviated treatment course.

Actions and Recommendations:

- The clinic instituted a new policy and procedure which includes the explicit review of diagnostic images by the attending physician (with an accompanying checklist that is reviewed by others in the workflow).
- The role of physician peer review (i.e. chart rounds) is well-recognized and is advocated in the American Society for Radiation Oncology (ASTRO) white paper[1] on this topic.
- This case underscores the need for peer-review and suggests that for SBRT treatments it may take a special form with enhanced safety checks.
- Other suggested actions include setting the isocenter at the time of simulation which may eliminate certain error pathways.

Case 2: Freckle mistaken for setup tattoo.

A breast patient was set up on a freckle instead of the correct central axis tattoo resulting in all 5 beams (supraclavicular, medial and lateral tangents, and two abutting internal mammary fields) being delivered approximately 4 cm superior and 2 cm lateral from the intended position for a single fraction of the total 200 cGy in 30 fractions. There was no imaging required on this fraction per the standard protocol in this clinic and there was no couch tolerance override notice since the couch position was within this clinic's tolerance window (3.5 cm laterally).

The error was noted the following day when the treating therapist noted that the freckle rather than the tattoo had been marked. Remaining fractions were correctly positioned.

Contributing factors in this case included:

- A single therapist was setting up the patient, due to equipment needs for the respiratory gating system which required the other therapist to be in the console area.
- Dim in-room lighting was in use to aid in visualization of the lasers.
- Imaging not required this day of treatment.
- Wide couch tolerances for the breast board.

Actions and Recommendations:

- The clinic used this incident as an educational case for therapists on the importance of setup.
- Re-examination of the couch tolerance levels with the aim of reducing the allowed window.
- Procedural changes enabling the presence of more than one therapist in the room at the time of setup.

Case 3: Incorrect clinically set ear treatment field.

A patient was referred by an outside clinic for ear treatment accompanied by a photo with a "to be treated area" annotation. The radiation treatment field was clinically placed based on the photo. After 13 of 15 fractions, the patient pointed out that the skin reaction was not covering the lesion in question, leading to realization that the photo was ambiguous and the wrong portion of the ear had been treated.

Contributing factors in this case included:

- Reliance on a photo which is subject to misinterpretation.
- Clinical setup for a skin lesion lacking independent confirmation such as with imaging.
- No confirmation of the correct treatment area with the referring physician.

Actions and Recommendations:

- In cases where ambiguity exists regarding the lesion to be treated, the referring clinic can map out the area on the patient prior to the patient arriving in the clinic.
- Photos including a ruler are especially helpful.
- Confirm treatment areas with referring physicians.

Case 4: Incorrect isocenter near-miss.

The isocenter was incorrect on reference digitally reconstructed radiographs (DRRs) for a setup orthogonal pair. The patient was receiving 6,400 cGy in 32 fractions for head and neck cancer. This error did not impact the patient treatment due to the fact that a cone beam computed tomography (CBCT) was used for alignment. The incorrect isocenter on the DRRs was not identified.

On the 12th fraction, the CBCT system was down, therefore orthogonal films were acquired. On these films the incorrect isocenter was noticed. The isocenter on the DRRs was set to the "laser" point in the planning system instead of the planned point "isocenter" (2.0 cm shift). Under a different scenario this may have resulted in an incorrect-location mistreatment.

Contributing factors in this case included:

- Safety-critical issue not identified in the physics plan and chart review.
- Human-computer interface issues.

Actions and Recommendations:

- Change procedures to set the isocenter at the time of simulation to avoid the need for shifts in treatment planning.
- Require a second check of safety-critical items by a therapist prior to treatment, perhaps with a checklist.
- Improve the performance of the physics review, which can include education/training or the use of checklists.

Case 5: Incorrect isocenter near-miss.

There was no communication from the dosimetrist to the therapist regarding a shift for the isocenter as required by the treatment plan. In the normal workflow of this clinic if a shift is required, that information would be typed into the "site setup" area of the Oncology Information System (OIS). In this case no shift information was entered. The error was identified by a radiation therapist on initial chart check when viewing the plan document (which did indicate shifts). The policy and procedures in this clinic include having therapists check shifts prior to the first treatment.

Contributing factors in this case included:

- Critical information in multiple places in the electronic records.
- Reliance on manual data entry.
- Safety-critical issue not identified in the physics plan and chart review.

Actions and Recommendations:

- Reconfigure workflow to avoid reliance on information that is entered manually.
- Require a second check of safety-critical items by a therapist prior to treatment, perhaps with a checklist.
- Improve the performance of the physics review, which can include education/training or the use of checklists.

Please note that Case #4 and Case #5 are both near misses resulting from an incorrect isocenter. While the contributing factors and specifics are different for the two cases, similar actions are recommended and could help avoid two separate error pathways.

RECOMMENDATIONS FOR TREATMENT DELIVERY TO THE WRONG LOCATION:

1. Double checks of safety-critical information are a key component in providing safe and effective treatment. The following checks are relevant to ensuring the correct treatment location:
    a. Verification of intended location by attending physician.
    b. Physician peer-review of the planned target, which may include the referring physician as well.
    c. Physicist review of treatment location, isocenter shifts and communication of those shifts.
    d. Therapist review of treatment location, isocenter shifts prior to treatment. It is important to allow sufficient time for therapists to perform this check.

2. One tool for assisting the above reviews and ensuring that they are performed is a checklist or check document.
3. Sufficient therapist staffing to allow for double checking treatment setups is important. Shifts from skin marks to a treatment isocenter are commonplace, but diligence is essential to ensure that shifts are executed accurately.
4. Workflow should be examined to try to reduce the use of isocenter shifts and reduce the reliance on data that is entered manually.
5. Couch tolerances should be examined and set such that there is an allowance for slight variations in patient positioning but tight enough to identify significant mispositioning prior to treatment delivery.

FEATURED THEME II: COMMUNICATION LAPSES

A common theme seen with many reported cases is communication failure. Given the many steps in the radiation therapy process coupled with the breadth of information that must be accurately shared among the multiple individuals involved in treatment delivery, many opportunities exist for communication failures. The following includes representative examples of communication failures among this quarter's reported cases:

Case 6: Incorrect clinically set ear treatment field (Same case as the above Case 3).
A patient referred by an outside clinic accompanied by a photo with a "to be treated area" annotation for ear treatment resulted in treatment of the wrong portion of the ear.

Locus of communication lapse: Referring clinic to/from radiation oncologist.

Case 7: Incorrect respiratory gating.
A patient receiving lung treatment involving an initial plan followed by boost received 2 fractions within the initial plan under the different respiratory gating parameters chosen for the boost plan.

Locus of communication lapse: Dosimetry/physics to therapists.

Case 8: CT simulation oversight.
A radiation oncologist's CT simulation order to scan three areas was communicated in not one but two documents. Nursing staff transferred the details of the simulation request to the CT simulation schedule, but noted only one form covering two of the three intended areas. The third area was not scanned, requiring the patient to be called back for an additional scanning session.

Locus of communication lapse: From radiation oncologist/nurse to CT tech.

Case 9: Latex allergy overlooked.
A patient was treated with pelvic external beam radiation utilizing a latex condom-covered vaginal dilator for 8 fractions before the patient's vaginal irritation symptoms led to realization that her latex allergy recorded in the EMR was neither recorded in the OIS nor shared with the treating radiation therapists (RTTs).

Locus of communication lapse: From treating radiation oncologist and nursing staff to RTTs.
From EMR to Oncology Information System.

Case 10: Missing shift (Same case as Case 5).
A patient was planned for oblique brain fields incorporating a shift from reference to treatment isocenter, a key detail that was omitted from the radiation OIS site setup instructions.

Locus of communication lapse: From dosimetry to therapists.

Case 11: Wrong patient photo.
A patient's chart included a different patient's photo.

Locus of communication lapse: Unclear from the limited reported details.

RECOMMENDATIONS FOR COMMUNICATION LAPSES:

1. Establish robust procedures to communicate salient details of care to staff.
2. When special circumstances dictate departures from standard processes, prioritize extra communication to staff to ensure accurate treatment delivery.
3. When in doubt, ask for clarification.
4. Tackling communication failures begins with creating a culture of safety.
    a. Consider implementing the Agency for Healthcare Research and Quality's (AHRQ) Survey on Patient Safety Culture within your facility (if not already implemented organization wide).
    b. Make the results clear and easily accessible to every employee throughout the facility.
    c. Discuss and show your plans of action for improvements of the culture.
5. Educate staff and providers on human factors and its integral role in understanding errors.
    a. Identify champions or leaders (create a team within your facility that represents the roles involved, i.e. administration, physics, medicine, nursing).
    b. Train these individuals on AHRQ's TeamSTEPPS®
6. Consider the format of the message – this is central to securing good communication.
    a. Consider the role of briefings, huddles, debriefings and handoffs within your facility.[2]
    b. Develop and enhance individual providers' communication and teamwork skills.[2]
    c. Situational awareness, standardized language, closed-loop communication and shared mental models.[2]

   d. Perform an audit of your facility's policies and procedures. Are these procedures as streamlined, effective, efficient and as easily performed as they can be? What are the barriers to successfully carrying out and communicating these procedures? How can these barriers be removed or overcome?

7. Observe the facility and pay attention to the culture. How do staff communicate amongst each other?
8. Interview lots of people throughout the facility. Ask and listen about the facility's culture. Leave no one out—include the interdisciplinary teams and ancillary staff that interact indirectly with the facility's procedures and care of the patient.
9. Throughout these interviews, ask yourself what behaviors you are looking to see and hear demonstrated within and among your team.

RESOURCES

About TeamSTEPPS®. Content last reviewed August 2015. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/about-teamstepps/index.html.

Comprehensive Unit-based Safety Program (CUSP) Toolkit. Content last reviewed June 2015. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html.

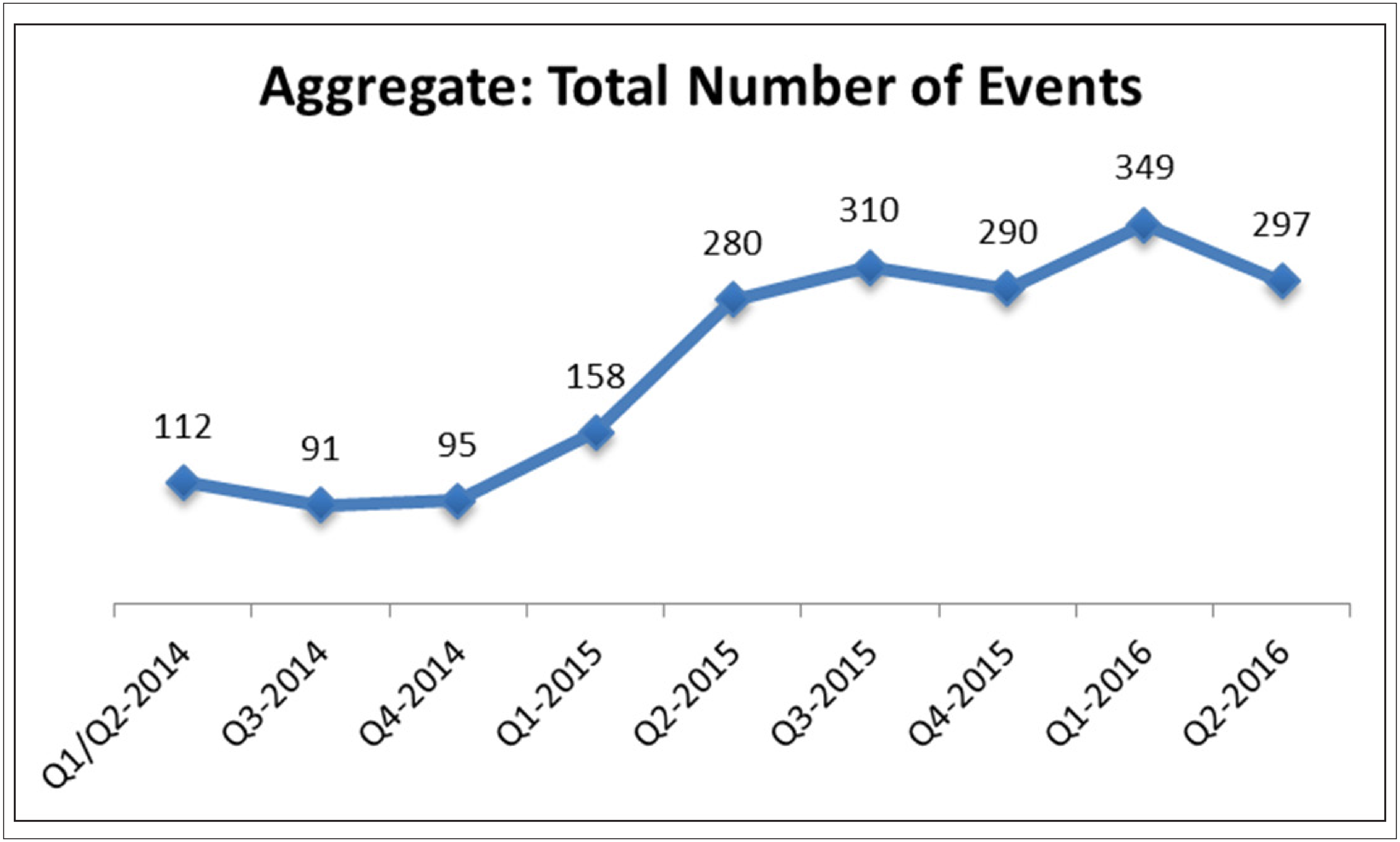
Surveys on Patient Safety Culture. Content last reviewed April 2016. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html.

FOOTNOTE

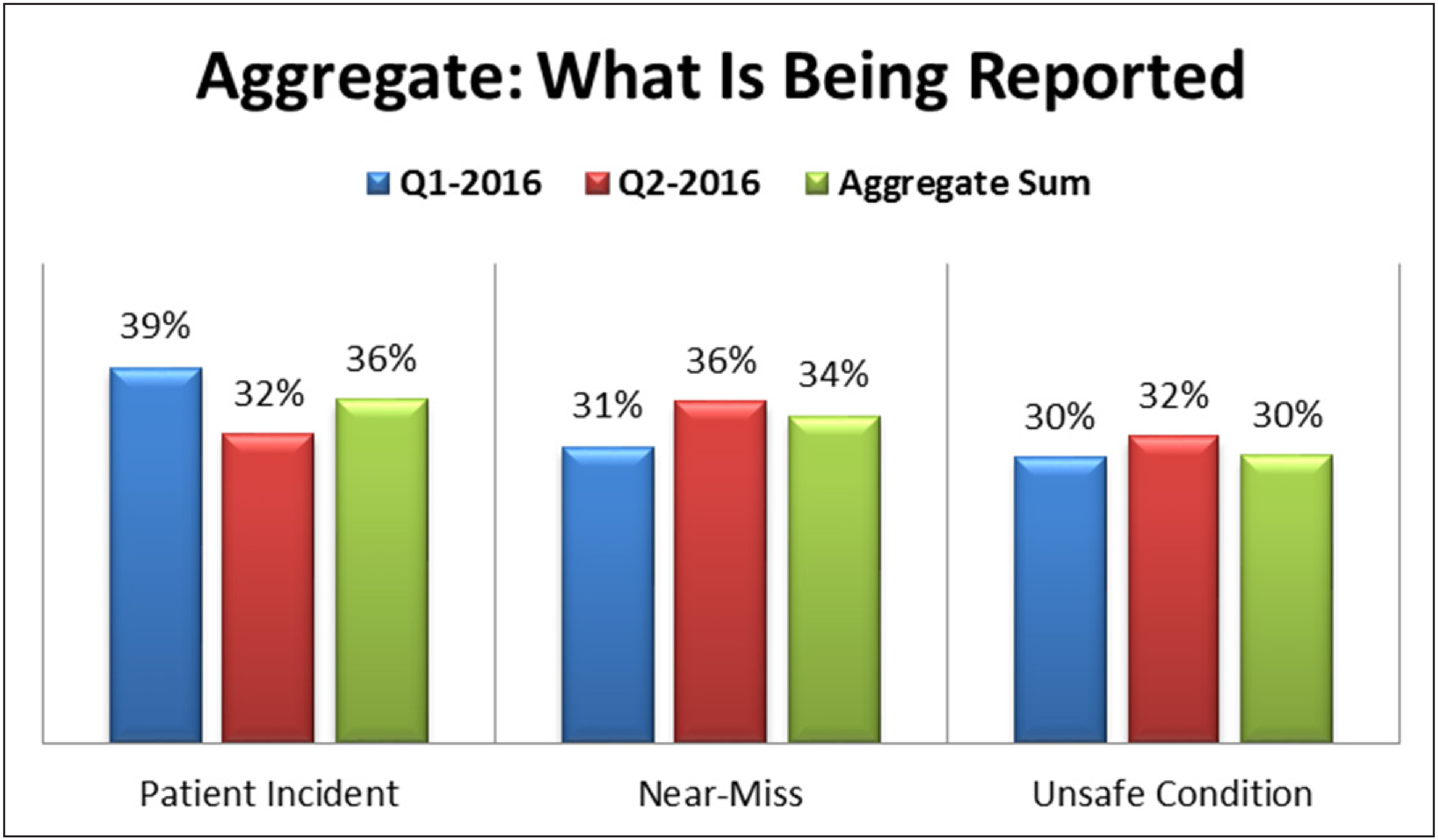
[1] Marks L, Adams R, Pawlicki T, et al. Enhancing the role of case-oriented peer review to improve quality and safety in radiation oncology, ASTRO White Paper. Pract Radiat Oncol 2013;3(3),149-156. http://www.practicalradonc.org/article/S1879-8500(12)00207-X/pdf

[2] Davis S, Piotrowski T. The 3 D's of Debriefing: Define, Deploy, Discover. A Clarity PSO Two-Part Series. June 2016.

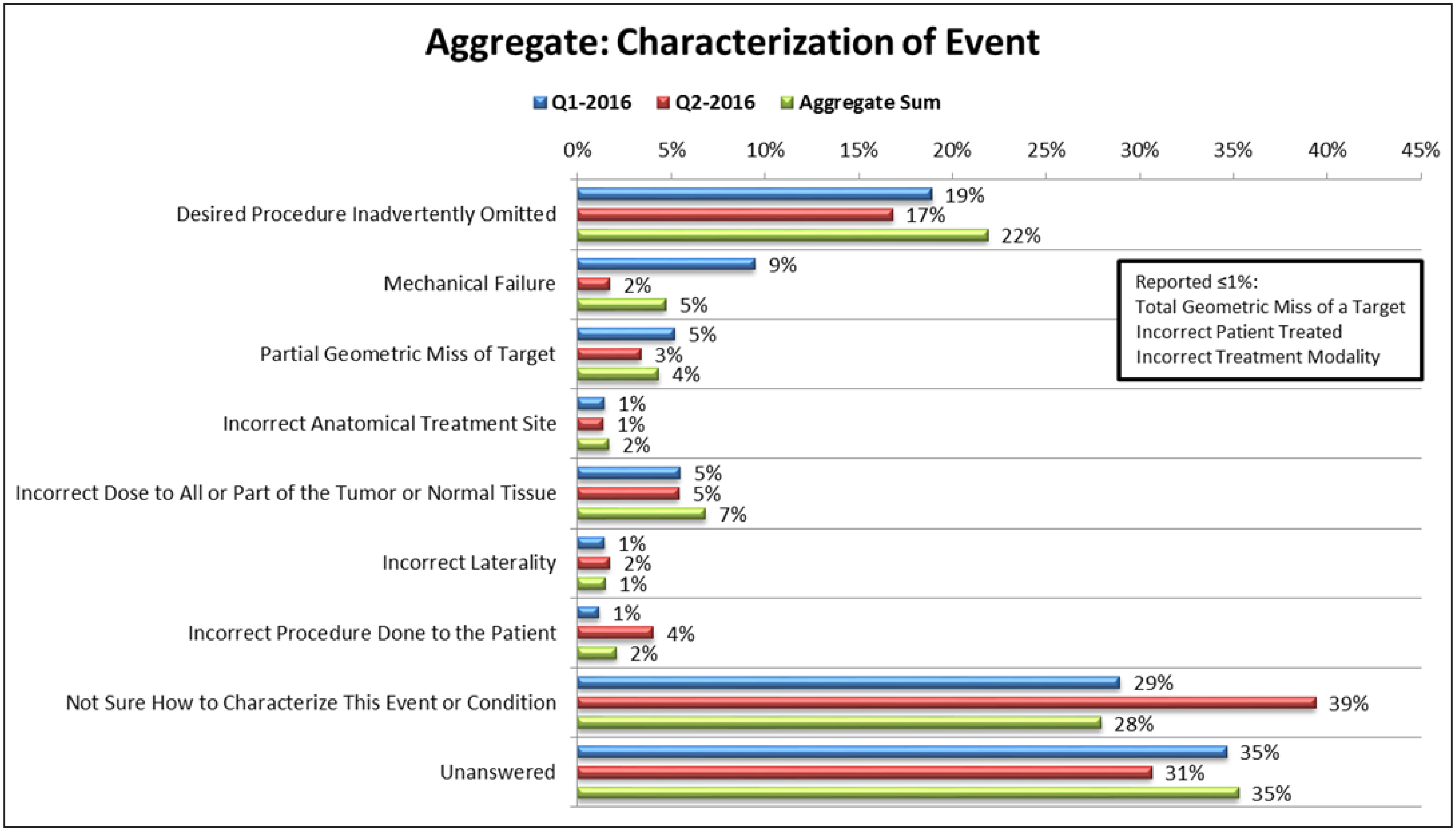
AGGREGATE ANALYSIS GRAPHS



AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued



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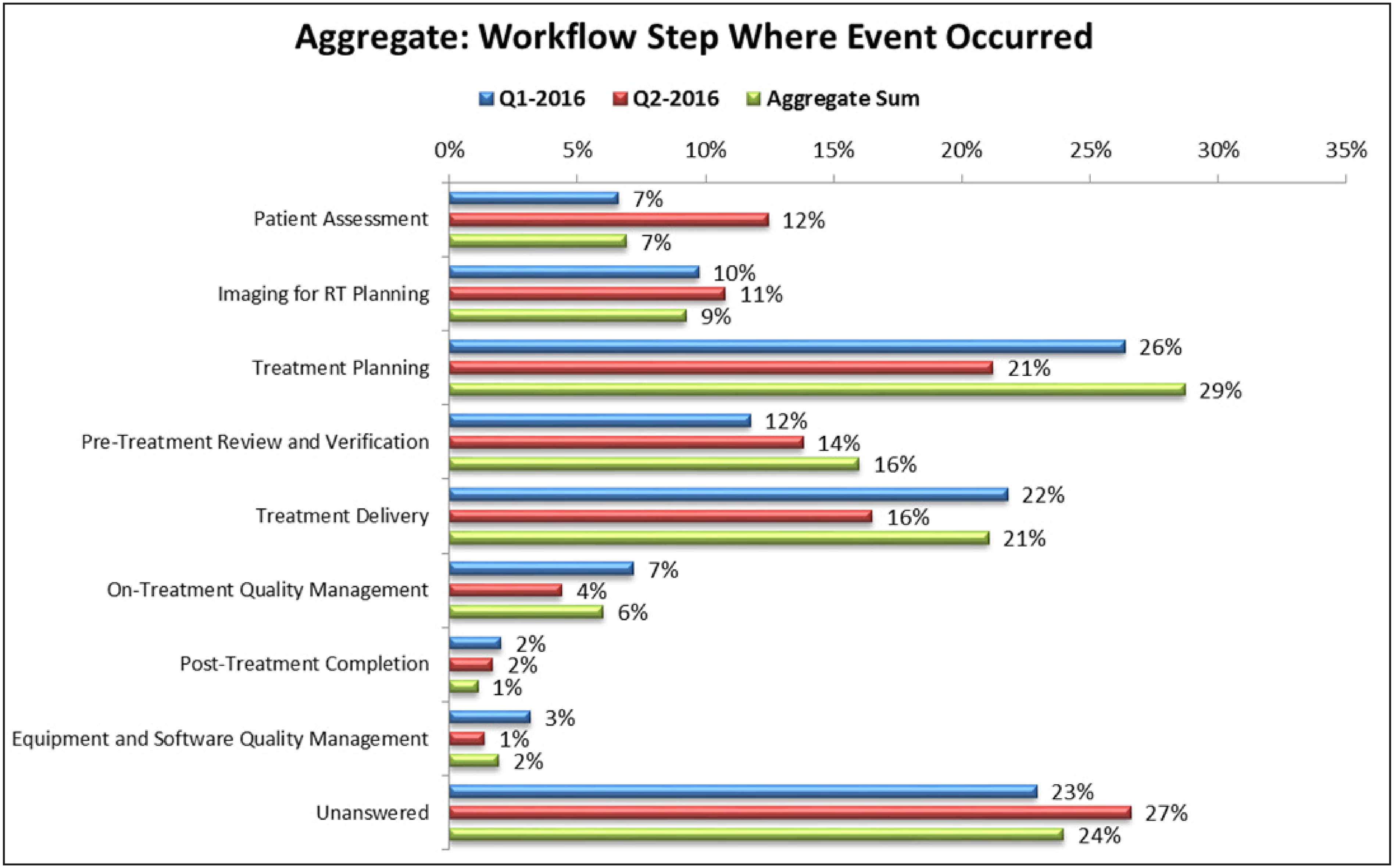

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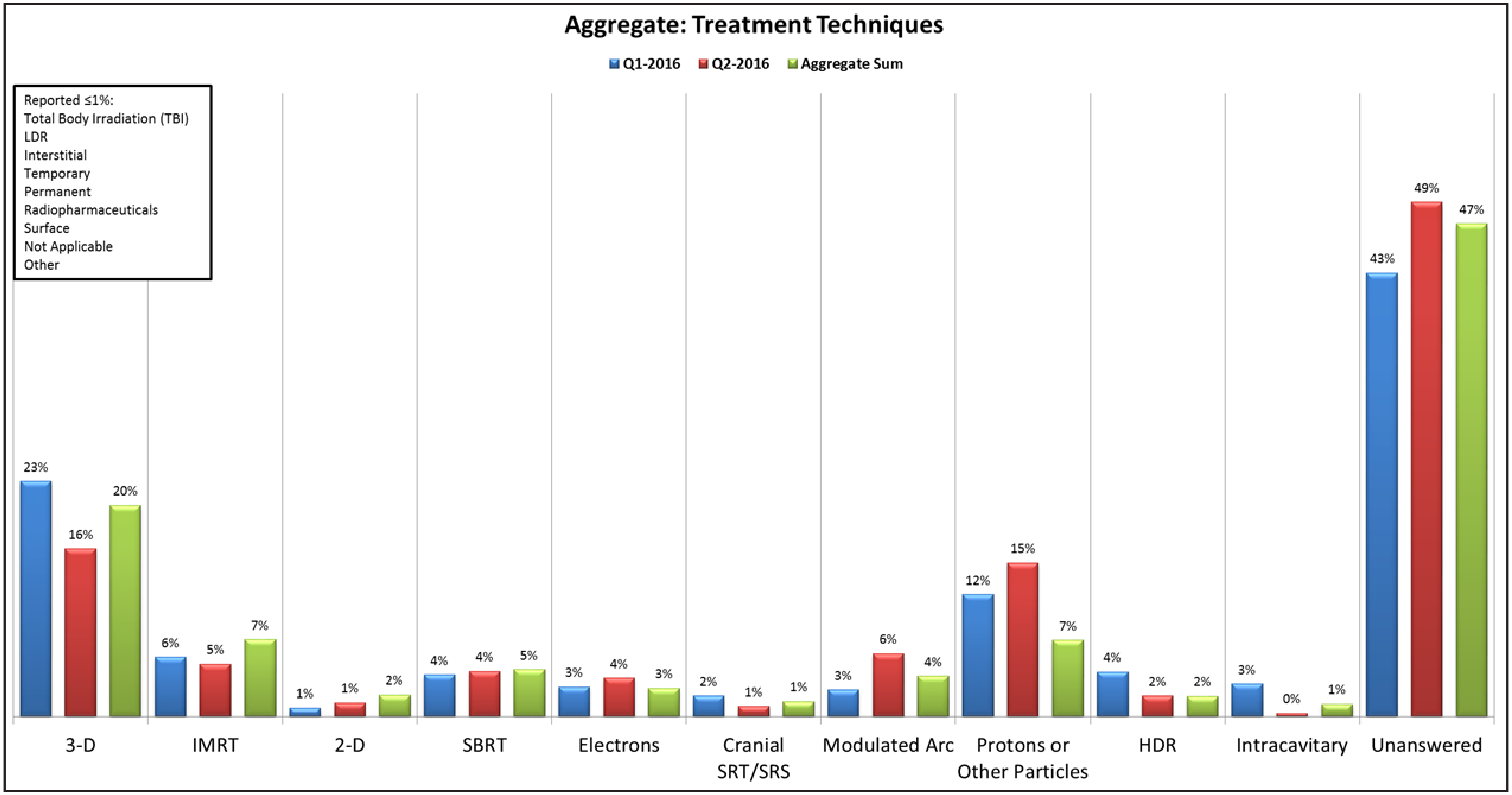
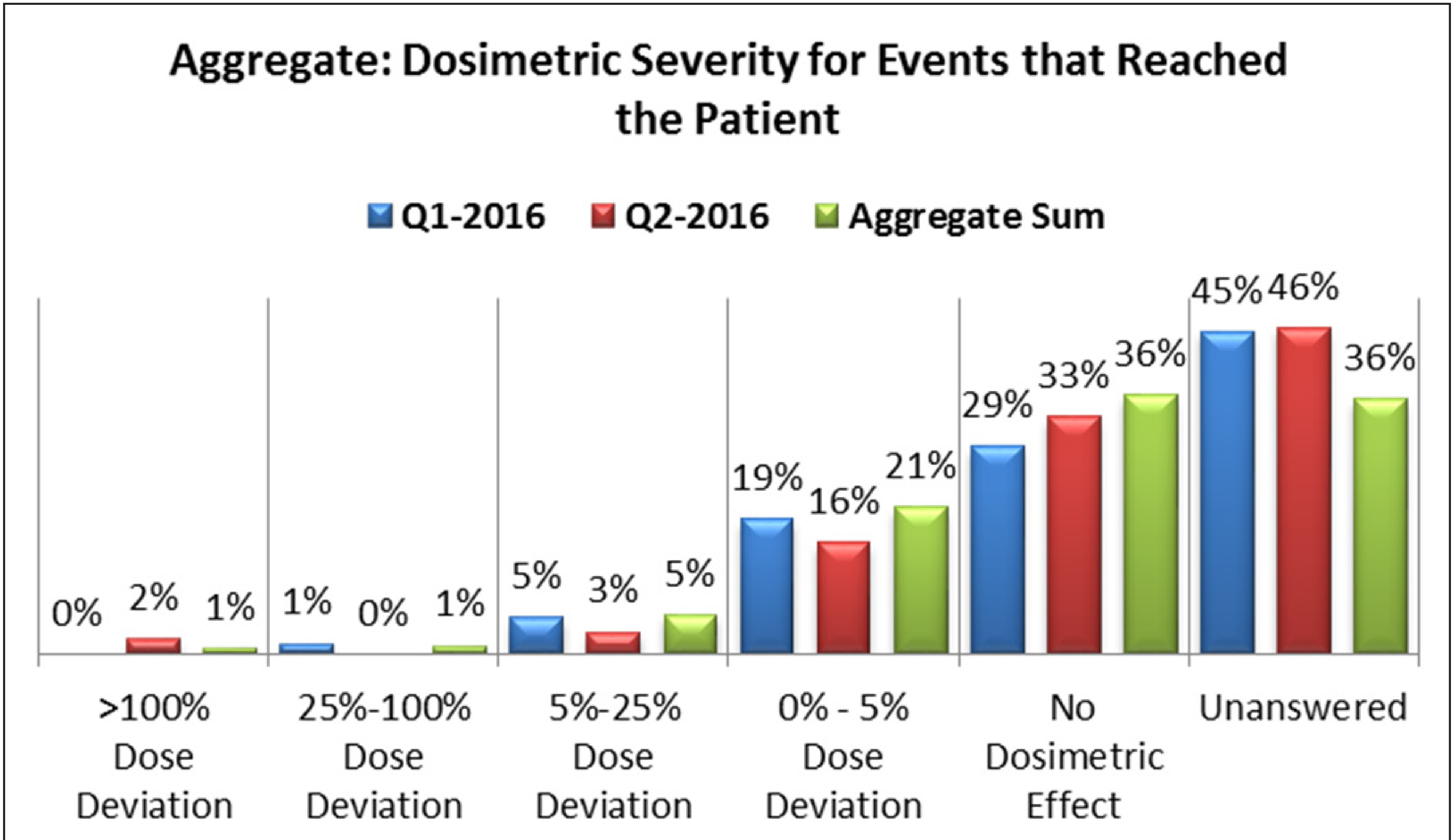
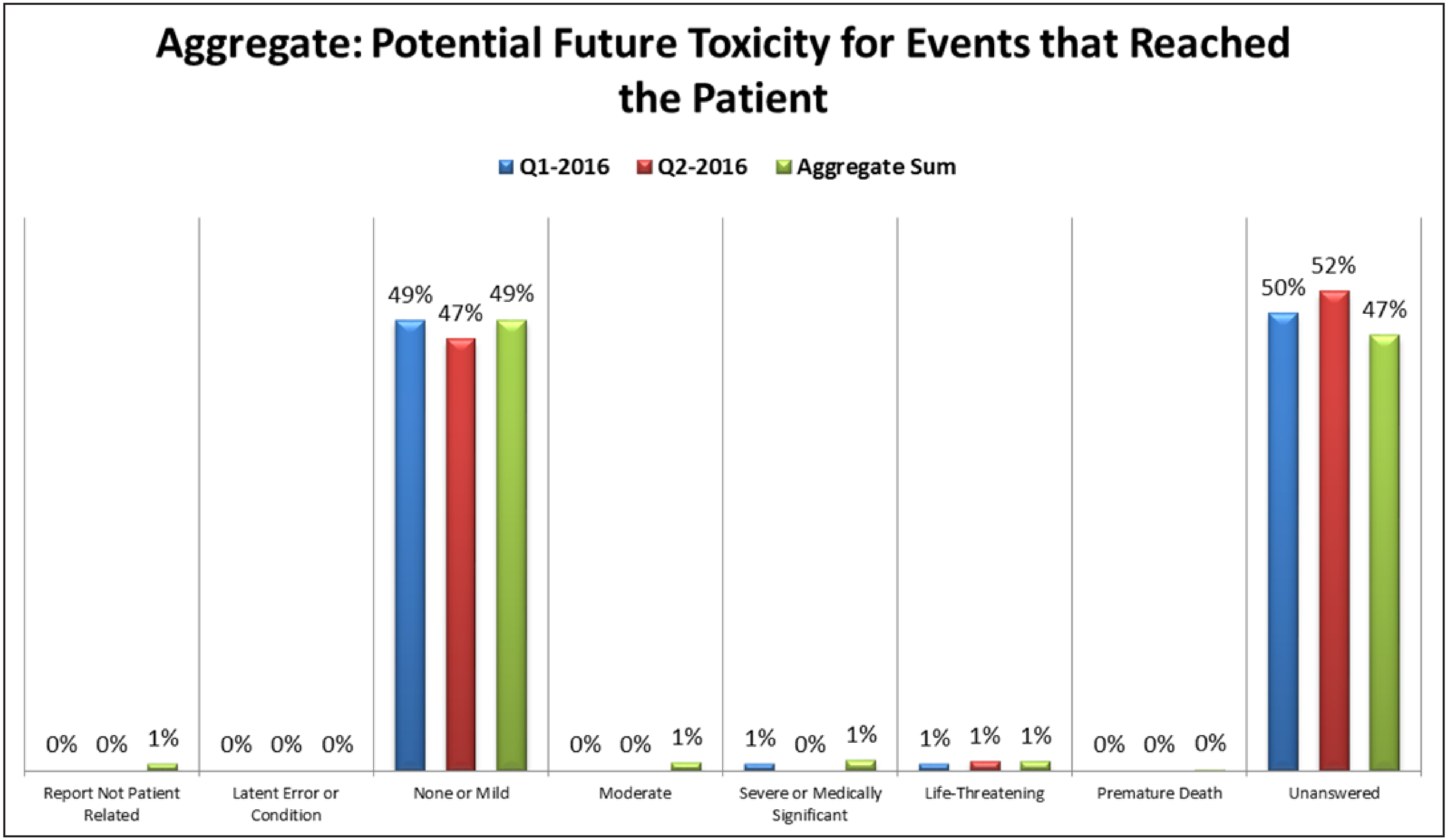
AGGREGATE ANALYSIS GRAPHS | continued

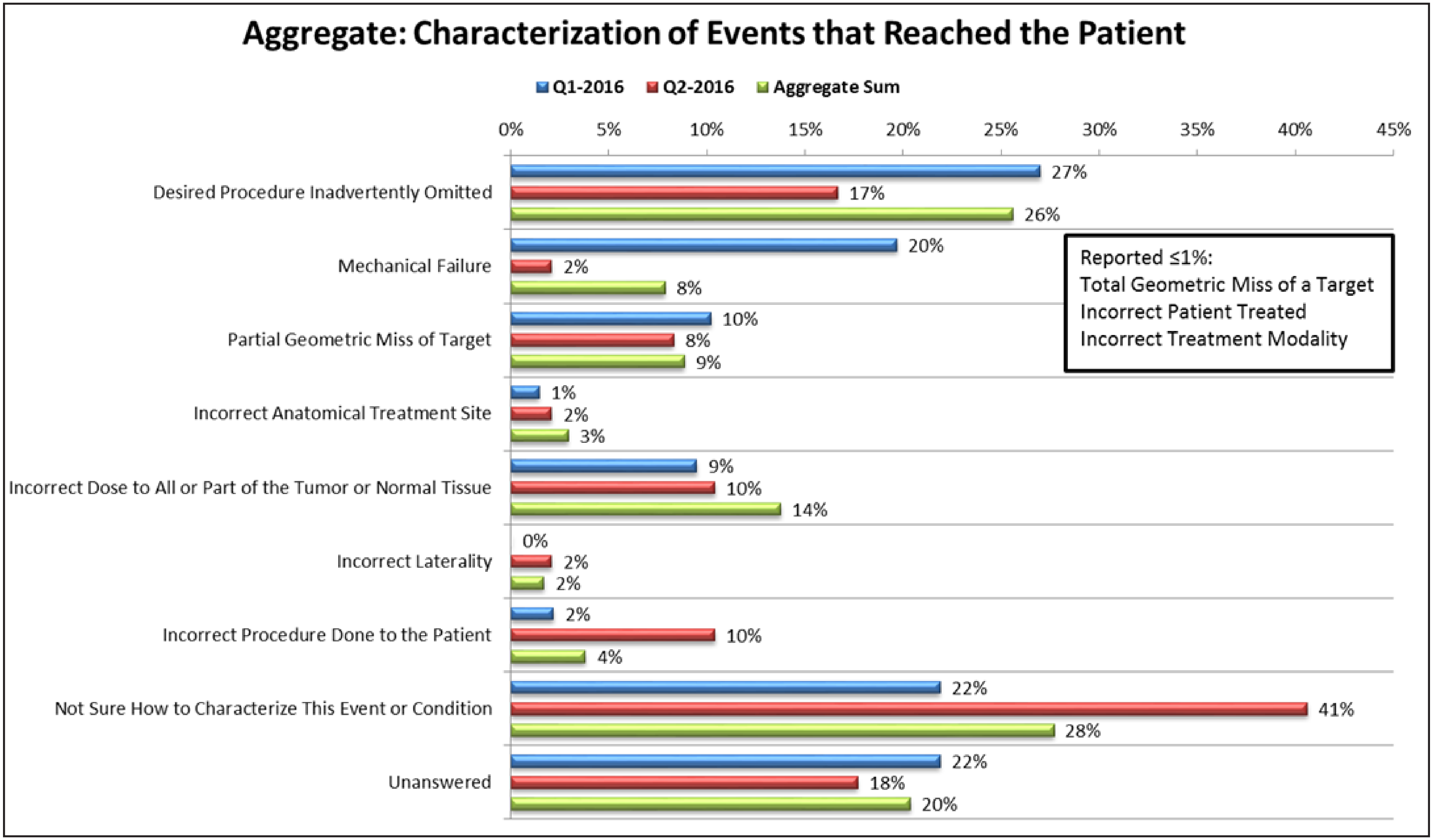


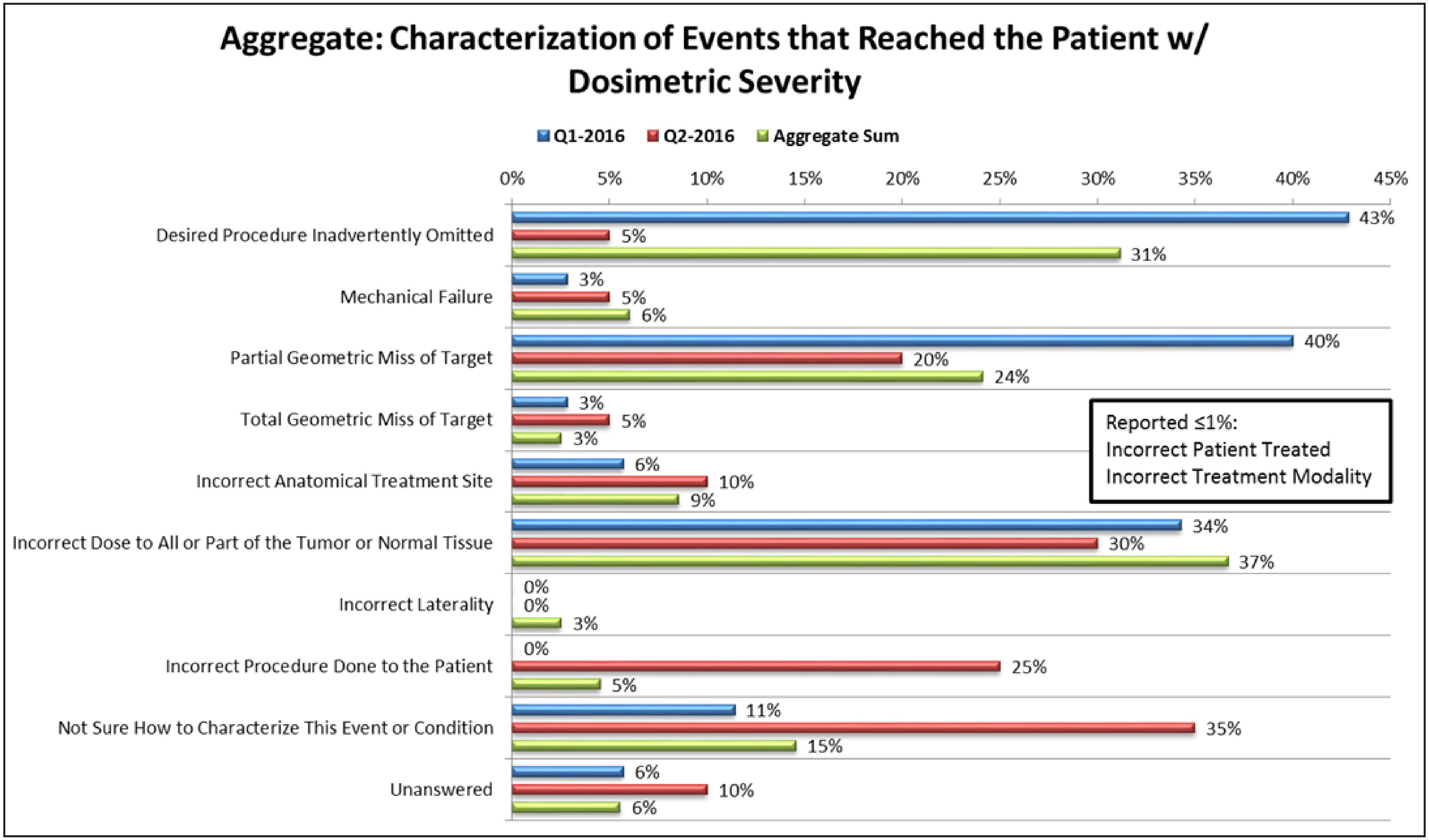


Aggregate: Dosimetric Severity for Events that Reached the Patient
Q1-2016
Q2-2016
Aggregate Sum
0%
2%
1%
1%
0%
1%
5%
3%
5%
19%
16%
21%
29%
33%
36%
45%
46%
36%
>100% Dose Deviation
25%-100% Dose Deviation
5%-25% Dose Deviation
0% - 5% Dose Deviation
No Dosimetric Effect
Unanswered


Aggregate: Potential Future Toxicity for Events that Reached the Patient
Q1-2016
Q2-2016
Aggregate Sum
0%
0%
1%
0%
0%
0%
49%
47%
49%
0%
0%
1%
1%
0%
1%
1%
1%
1%
0%
0%
0%
50%
52%
47%
Report Not Patient Related
Latent Error or Condition
None or Mild
Moderate
Severe or Medically Significant
Life-Threatening
Premature Death
Unanswered

AGGREGATE ANALYSIS GRAPHS | continued




Aggregate: Characterization of Events that Reached the Patient w/ Dosimetric Severity
Q1-2016
Q2-2016
Aggregate Sum
0%
5%
10%
15%
20%
25%
30%
35%
40%
45%
Desired Procedure Inadvertently Omitted
43%
5%
31%
Mechanical Failure
3%
5%
6%
Partial Geometric Miss of Target
40%
20%
24%
Total Geometric Miss of Target
3%
5%
3%
Incorrect Anatomical Treatment Site
6%
10%
9%
Incorrect Dose to All or Part of the Tumor or Normal Tissue
34%
30%
37%
Incorrect Laterality
0%
0%
3%
Incorrect Procedure Done to the Patient
0%
25%
5%
Not Sure How to Characterize This Event or Condition
11%
35%
15%
Unanswered
6%
10%
6%
Reported ≤1%:
Incorrect Patient Treated
Incorrect Treatment Modality