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CLARITY PSO
A Patient Safety Organization

QUARTERLY REPORT
PATIENT SAFETY WORK PRODUCT

Q3 2015

JULY 1, 2015 – SEPTEMBER 30, 2015

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AGGREGATE REPORT CARD – Q3 2015

July 1, 2015 – September 30, 2015

Metric	Aggregate Current Quarter	Aggregate Previous Quarter	Aggregate Historical Sum
Total Number of Events	**197**	**200**	**852**
Patient Incident	68	83	328
Near Miss	101	73	318
Unsafe Conditions	28	44	205
Not patient related	0	0	1
Most Commonly Identified Characterization of Event	**Not Sure How to Characterize:** 18% (35/197) **Unanswered/Not Sure:** 76% (150/197)	**Desired Procedure Omitted:** 39% (78/200) **Unanswered/Not Sure:** 38% (76/200)	**Desired Procedure Omitted:** 31% (263/852) **Unanswered/Not Sure:** 52% (443/852)
Most Commonly Identified Workflow Step Where Event Occurred	**Treatment Planning:** 39% (76/197) **Unanswered:** 23% (45/197)	**Treatment Planning:** 37% (74/200) **Unanswered:** 13% (26/200)	**Treatment Planning:** 31% (260/852) **Unanswered:** 25% (209/852)
Most Commonly Identified Treatment Technique	**3D:** 14% (27/197) **Unanswered:** 61% (120/197)	**3D:** 22% (44/200) **Unanswered:** 47% (93/200)	**3D:** 25% (216/852) **Unanswered:** 40% (339/852)
Characterization of Events with Dosimetric Severity for Events That Reached the Patient	**Incorrect Dose to All or Part of Body:** 33% (7/21)	**Multiple Characterization:** 34% (11/32)	**Incorrect Dose to All or Part of Body:** 36% (43/120)
Potential Future Toxicity Within Events That Reached the Patient	**None or mild:** 47% (32/68) **Unanswered:** 47% (32/68)	**None or mild:** 64% (53/83) **Unanswered:** 34% (28/83)	**None or mild:** 57% (187/328) **Unanswered:** 36% (119/328)

CASE REVIEWS

The following report includes analysis of incidents with potential medical impact and a review of identified themes. These themes include the importance of reviewing plans, recurring issues related to the correct isocenter for treatment and completing detailed time-outs.

197 events were reported during the third quarter of 2015.

This quarter, three reported events were flagged as "likely to be harmful to the patient". Below, please find case summaries of these submitted events.

CASE 1: INCORRECT VERTEBRAL BODY TREATED

A patient was being treated with a fractionated dose of 4.0 gray (Gy) for 5 fractions for the palliation of bone metastasis in the thoracic-lumbar (T-L) spine. The incorrect vertebral body was treated for 2 of the 5 fractions. Cone-beam computed tomography (CT) was used to perform the alignment. The automatic image alignment algorithm locked onto the incorrect vertebral body, thus resulting in a large shift of the patient. The incident was discovered on the third fraction when the treating radiation therapists noted the discrepancy.

Recommendations:

Over-reliance on modern technologies like cone-beam CT can present problems. Suggestions to counteract these potential problems include the following:

- *Policies and procedures* should be clear regarding the actions to take when large shifts are indicated from image-guided radiation therapy (IGRT) imaging. In this case, the shift was 3 cm and was indicative of a problem. Some centers have adopted policies that require a secondary verification of patient setup when the shifts are larger than a specified amount.

- *Use a cone-beam CT setting that captures a larger extent of anatomy where appropriate.* This may aid in reducing confusion. One vendor supplies a "topogram" to specify the superior-inferior extent of the scan. Another vendor has predefined settings ranging up to 26 cm in this dimension.

- Other centers have begun using *kilovoltage (kV) or megavoltage (MV) planar images to verify alignment* in addition to cone-beam CT. These planar images can show a larger extent of anatomy and reduce the likelihood of aligning to a wrong vertebral body.

CASE 2: CLINICAL TARGET VOLUME (CTV) USED FOR PLANNING INSTEAD OF PLANNING TARGET VOLUME (PTV)

A patient was being treated with 1.8 Gy for 28 fractions for a lung cancer. There was confusion because the physician thought the planner would perform a CTV-to-PTV expansion. Yet, the planner thought that the physician was providing the PTV outline as he normally does. The physician did request that the CTV be expanded in this case, but this communication to the planner was not effective. The problem was discovered after the 10th fraction when the physician ordered a cone-beam CT scan to be fused with the plan. In reviewing this the physician noticed that the coverage was tighter than he expected. The physician discussed this with the patient and was able to modify the plan to meet the intended dosage on subsequent fractions.

Recommendations:

- *A clear and consistent system for labeling of structures* in the planning system may help prevent similar misunderstandings.

- In this facility, the practice of displaying volumes was changed to make similar issues more apparent at the time of plan review. *Colorwashes* are now used which show the CTV/gross tumor volume (GTV) overlaying the PTV, thus the volumes are immediately obvious.

CASE 3: MOUTHPIECE INSERTED INCORRECTLY IN HEAD AND NECK TREATMENT

A patient was being treated with intensity-modulated radiation therapy (IMRT) for a head and neck cancer. The patient had a mouthpiece placed in order to deviate his tongue to the right and thus out of the high dose region. On the 23rd fraction, the patient asked the therapist if the mouthpiece was in the correct position. The therapist discovered that the patient had been inserting it incorrectly, thus moving his tongue to the left instead of the right.

Recommendations:

A contributing factor in this error is miscommunication about patient setup. There are several means to improve this communication:

- *Use a designated area in the electronic chart* to communicate information about the patient setup. All staff should know about this area and a sign off procedure should be established.

- *Improve the hand-off of communication* between treatment teams. This might include a huddle between the therapists involved in the simulation and the therapists performing treatment. This huddle would include a review of patient setup information. Another means of improving hand-off and transparency could include the use of checklists. A checklist item might include information about patient setup.

- *Photographs* are an excellent way to communicate information. In some oncology information systems, patient setup photos can be attached or associated with the prescription or other aspects of the treatment course to further ensure that they are reviewed.

ANALYSIS AND COMMENTARY

The following are featured themes that appear in multiple events both within this quarter and in previous quarters.

FEATURED THEME #1: THE IMPORTANCE OF REVIEW

This quarter, in numerous events, the review of plans played a key role in preventing errors from impacting patients. Plan review comes in many forms: review of a treatment plan by a physician prior to release, peer review of contours and/or treatment plans by other physicians, and review of plans by a physicist and therapist either prior to treatment of the patient, or weekly.

Below, please find a summary of several of this quarter's submitted events, which have been identified and caught through review:

Prescription errors: A common form of prescription error is a dose prescription in the treatment plan that does not match the prescription that the physician intended.

- One case included a physician sending an email to the planners with a typo (20 Gy in 10 fractions instead of 20 Gy in 5 fractions). Since this was a palliative case some of the normal checks were not in place. In this case, it was actually the patient who identified the problem. She told the therapist after her first treatment that she thought she should only be getting 5 treatments instead of 10.

- In another case, a patient's plan was transferred between treatment units due to a scheduling conflict. In the transfer process, a typo was made in the planning system (30 Gy in 20 fractions instead of 30 Gy in 15 fractions). This was not identified in the physics review, but was caught by the therapist in a pre-treatment plan review.

- Another case included a patient who was re-planned after the seventh of 25 fractions. However, the prescription was not changed to accurately reflect this re-plan. Instead of indicating that the first 7 fractions of the old plan were to be followed by the 18 fractions of the new plan, the prescription indicated that the 25 fractions of the old plan were to be followed by the 18 fractions of the new plan. This was identified by a therapist during weekly chart review.

- Mismatches can often be caught in physics plan reviews. Such as seen in many cases similar to this: a plan was performed for 1.8 Gy for 28 fractions while the intended prescription was 2.67 Gy for 15 fractions. Mismatches similar to this one were identified during the physics plan review.

Treatment planning calculation errors:

- Incorrect MU calculation. One error involved an incorrect monitor unit (MU) calculation, computed for the incorrect setup. The case involved an emergent treatment on the weekend using a posterior-anterior (PA) field to the lumbar (L) spine (4.0 Gy). The therapist calculated the MU for a source-axis distance (SAD) setup (i.e., depth of 7 cm, source-surface distance or SSD of 93 cm). A physicist reviewed the calculation and questioned whether a palliative PA spine field would be setup to 100 SAD (the more typical setup in this clinic is 100 SSD). The therapist doubled checked the setup and noted the error. A contributing factor noted is that the software used defaults to a 100 SAD setup.

- Plan performed on a free-breathing CT scan instead of the intended deep-inspiration breath-hold scan. Similar to a Q1 2015 event, an event this quarter also involved a plan performed on an incorrect scan. A breast cancer patient was scanned twice, once under free-breathing conditions and once with breath-hold. Since there was no documentation in the chart as to breath-hold, the planner assumed this was a free-breathing treatment and planned accordingly. Only when the physician was discussing the advantages of breath-hold with the therapists was it noted that the plan was actually performed on a free-breathing scan. In this facility, naming conventions are now utilized to note clearly when a plan incorporates breath-hold.

- Incorrect density used in an override. In the planning of a sarcoma patient with a hip implant, the incorrect density override was applied to the data set. This was discovered after 2 fractions when a re-plan was done due to the inability of the patient to lie still.

Contouring errors: These errors are often more challenging to identify since they are often only apparent in physician review or in review by an experienced planner or physicist.

- A stereotactic body radiation therapy (SBRT) treatment of a L4 lesion was being performed. The cord was only contoured to the bottom of L3, but the cauda equine was not contoured below that. The physicist planner identified the issue by comparing it to previous plans.

Previous radiation therapy not included or considered in the treatment plan:

- In this case, at the completion of a SBRT plan, doses from the patient's previous treatment were added to review the cumulative dose. It was discovered that the total dose was above tolerance for a critical structure. The treatment plan was rerun to account for the composite of total doses.

- In another case, a sequential three-course treatment was planned for a head and neck cancer patient. While planning the second course, the dose from the first course was not included or evaluated on a composite plan. The plan went to treatment. While planning the third course of treatment, the error was identified. It was noted, that the cord would have received 70 Gy.

While the above are a list of some of the most critical error scenarios reported this quarter, it is not an exhaustive list. Other error scenarios relevant to plan review include labeling errors in treatment sites or fields. Though labeling errors such as this may seem minor, they have the potential to contribute to more serious errors.

Note that the ASTRO peer review white paper (Marks et al, 2013; listed below) mentions re-treatment in several contexts. One question to be asked: "Is there overlap with a previously-irradiated field?" (Noted under "Therapist-focused tasks"; see Section 3.5). Re-treatment cases are also identified as one of the situations where peer review is anticipated to be most useful (Table 2 in the paper).

Recommendations on the review of plans: While the topic of plan review is evolving, there are several reports which describe recommendations and processes around plan review from various perspectives. These include the following:

- Zeitman A, Palta J, Steinberg M. Safety is No Accident: A Framework for Quality Radiation Oncology and Care: ASTRO; 2012. www.astro.org/safetyisnoaccident
- Marks L, Adams R, Pawlicki T, Blumberg A, Hoopes D, Brundage M, & Fraass B. Enhancing the Role of Case-Oriented Peer Review to Improve Quality and Safety in Radiation Oncology, ASTRO White Paper, Practical Radiation Oncology, 2013; Vol. 3(3), 149-156 www.astro.org/peerreviewpaper
- AAPM Task Group 103 report on general principles of peer review https://www.aapm.org/pubs/reports/RPT_103.pdf
- Eatmon, Stephanie, Error Prevention in Radiation Therapy, ASRT "Essential Education" Supplement, CE directed Reading, Radiation Therapist, 2012, 21(1), 59-74
- ASRT Radiation Therapy Clinical Performance Standards: http://www.asrt.org/docs/default-source/practice-standards-published/ps_rt.pdf?sfvrsn=2
- AAPM Medical Physics Practice Guidelines #4: Fong de Los Santos, L et al., Medical Physics Practice Guideline 4.2: Development, implementation, use and maintenance of safety checklists, J Appl Clin Med Phys, 2015; 16(3), 37-59

FEATURE THEME #2: INCORRECT ISOCENTER

As with previous quarters, events with incorrect isocenters continue to be reported. There were at least ten such reports this quarter. Although these events are largely near-miss events (identified prior to treatment), they reveal an error pathway that can cause serious harm to patients. Causes for these near miss events include:

- An incorrect reference point imported into or selected in the planning system.
- An isocenter that is not the same for all beams.
- Incorrect shifts communicated to the treatment team.
- Incorrect shifts marked on the patient or the immobilization device.
- Incorrect isocenter associated with a change to a new system. In one case, a new laser system was acquired in the CT simulator. As part of this there was a change to the procedure whereby the shifts are applied at the time of simulation. There were miscommunications and misunderstandings around this which resulted in an incorrect identification of the isocenter.

FEATURED THEME #3: TIME-OUTS

Problems with time-outs appear in numerous reports. One case reported that a patient undergoing treatment for left breast cancer was to be re-simulated for an electron boost to be started after 22 fractions. The patient was sent to the CT simulator for scanning. In this facility, it is standard practice to re-scan the patient any time the setup is changed. In this case, the physician wanted the patient to lie flat to achieve an en face beam so the patient was re-scanned. At the time of simulation, the right breast was wired and scanned instead of the left breast as intended. The error was noted at the time of treatment planning during the plan check-in process. As part of this process, photos of the patient setup are reviewed by a staff member not involved in simulation. The photos are also associated with the prescription in the oncology information system (OIS). During this process, the staff noticed that the wire was on the incorrect side of the patient, even though they knew they had the correct patient because the patient's face was in the correlating image.

For this facility, this event underscored gaps that were present in the time-out performed at simulation. The time-out policy consists of verifying the patient's name, disease, and treatment site. This is followed by completing a "quality checklist" in the OIS. This process was clearly not working reliably since the patient was scanned incorrectly. Part of the issue lies with the difficulty in performing a thorough time-out on a patient who is very familiar to the staff after more than four weeks of treatment. Any time there is a change in the treatment or treatment plan, however, there is a need for heightened awareness. This case was used as a learning example for the CT simulation therapy staff and an education module was developed around this.

More information on time-outs can be found in the following references:

- Zeitman, A., Palta, J., and Steinberg, M. Safety is No Accident: A Framework for Quality Radiation Oncology and Care: ASTRO; 2012. www.astro.org/safetyisnoaccident
    - *Quotes: "Ensure patient-specific procedure time-out", and "In addition, two radiation therapists should always be available in the event of emergencies and as a "second set of eyes" to verify information during time-outs for procedures"*

- Eatmon, Stephanie. Error Prevention in Radiation Therapy, ASRT "Essential Education" Supplement, CE directed Reading, Radiation Therapist, 2012, 21(1), 59-74.
    - *Quote: "A time-out stops the treatment process so that any questions can be answered to the satisfaction of the individual calling the time-out. Regardless of how it may affect the treatment schedule, all members of the team should respect a time-out and take it seriously."*

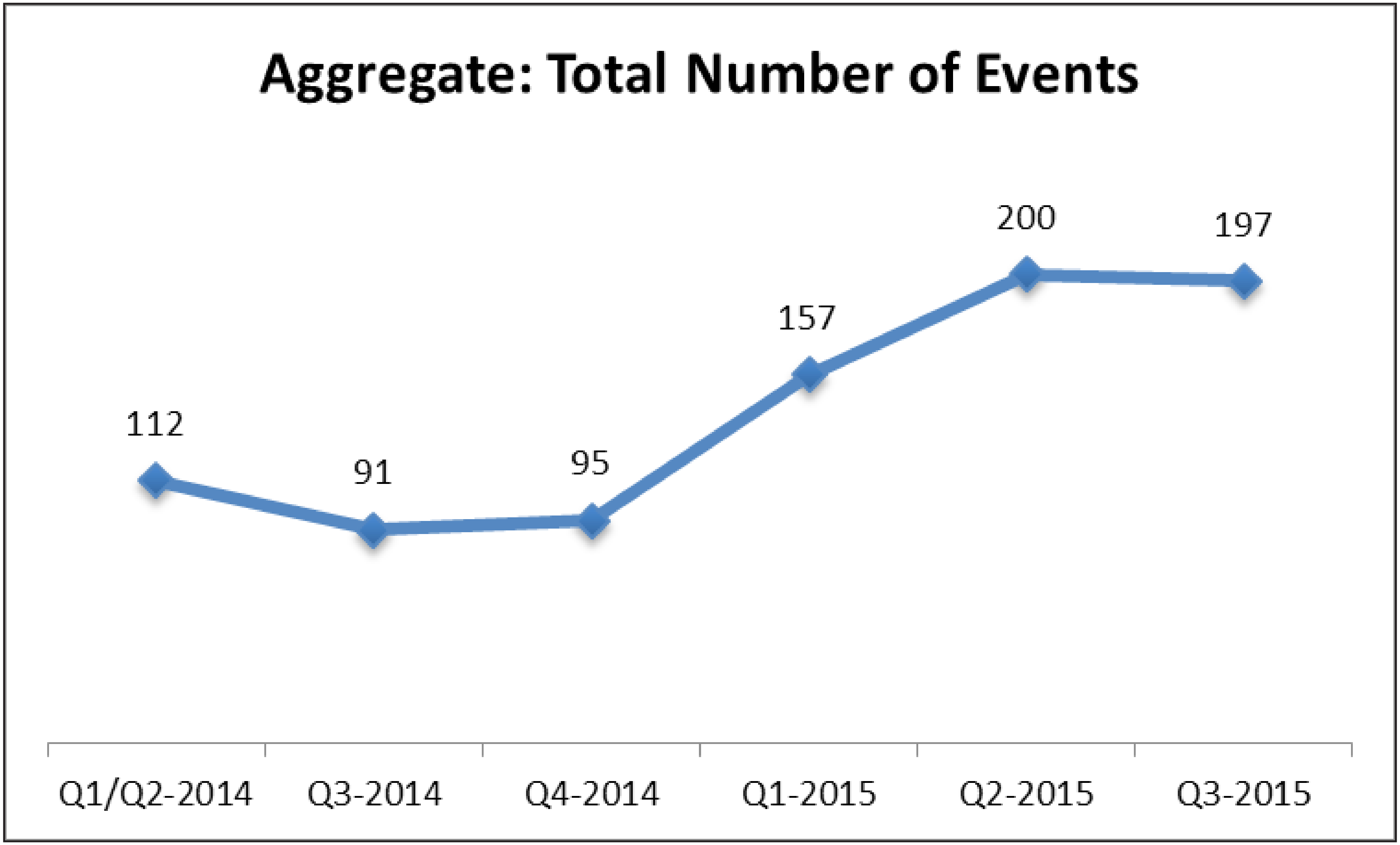
- ASRT Radiation Therapy Clinical Performance Standards http://www.asrt.org/docs/default-source/practice-standards-published/ps_rt.pdf?sfvrsn=2
    - *Quotes: "The radiation therapist…..performs procedural timeout." and "Documents procedural timeout."*

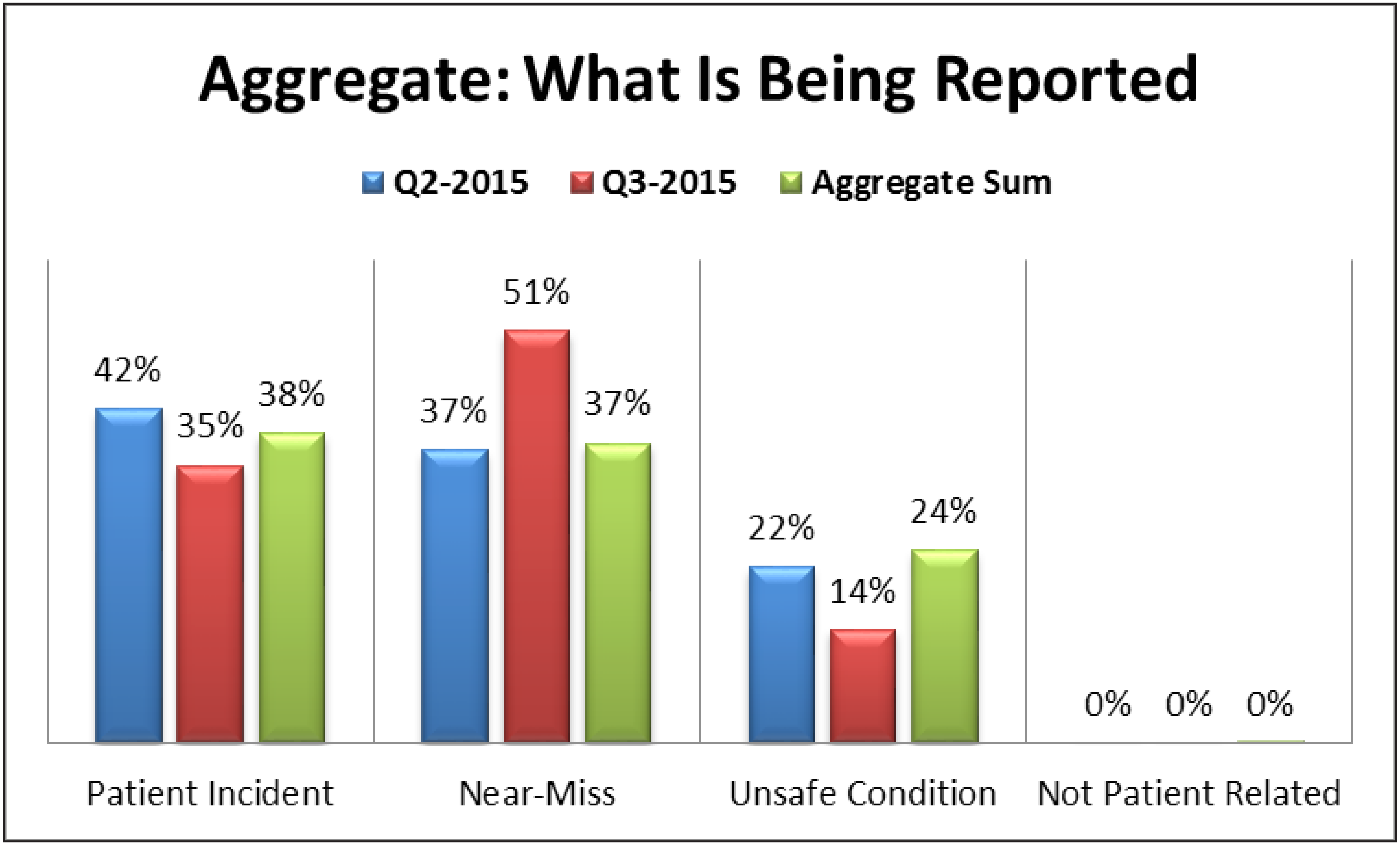
SUGGESTED BEST PRACTICES:

The following suggested best practices were made by participants at the RO-ILS User Group Meeting, October 17, 2015, at the ASTRO 2015 Annual Meeting. We will continue to provide suggested best practices in future Quarterly Reports and/or Tips of the Month.

- As new employees are hired, provide training and education about the safety culture within the facility, and expectations regarding reporting.
- Hold monthly or quarterly review meetings to look at trends, and identify how to improve.
- Institute a "Good Catch" program that includes staff recognition.

AGGREGATE ANALYSIS GRAPHS

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Q3-2015
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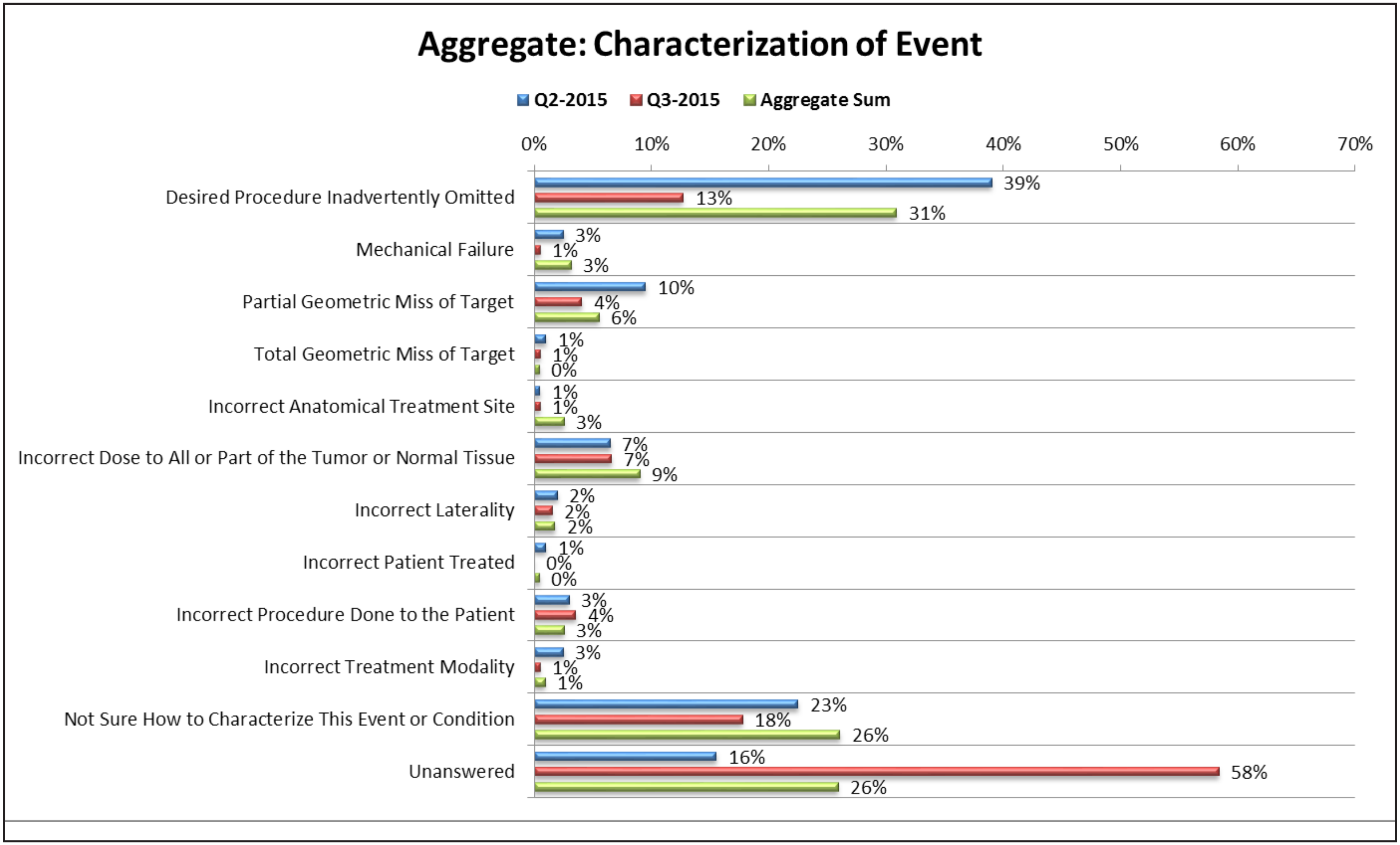
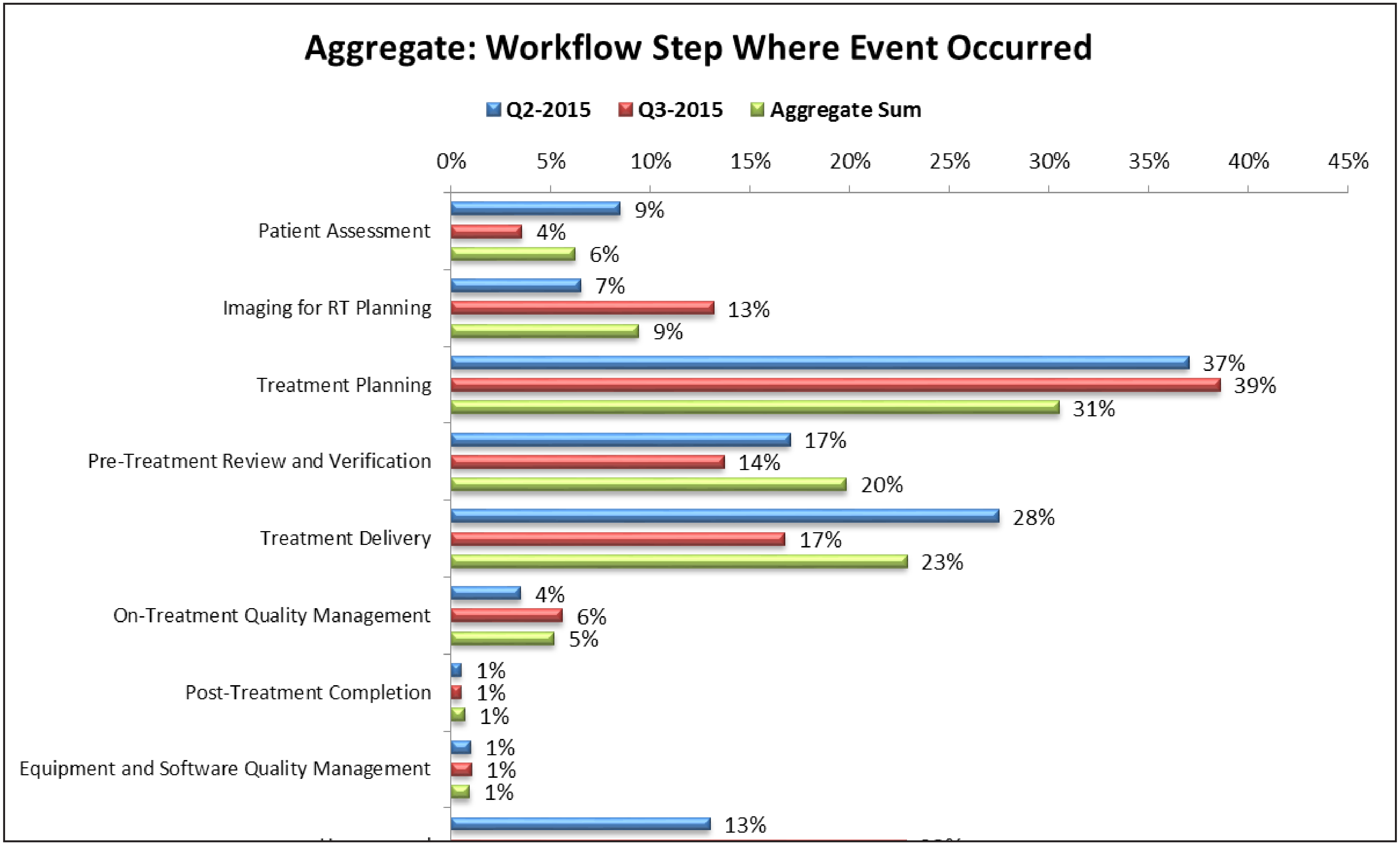
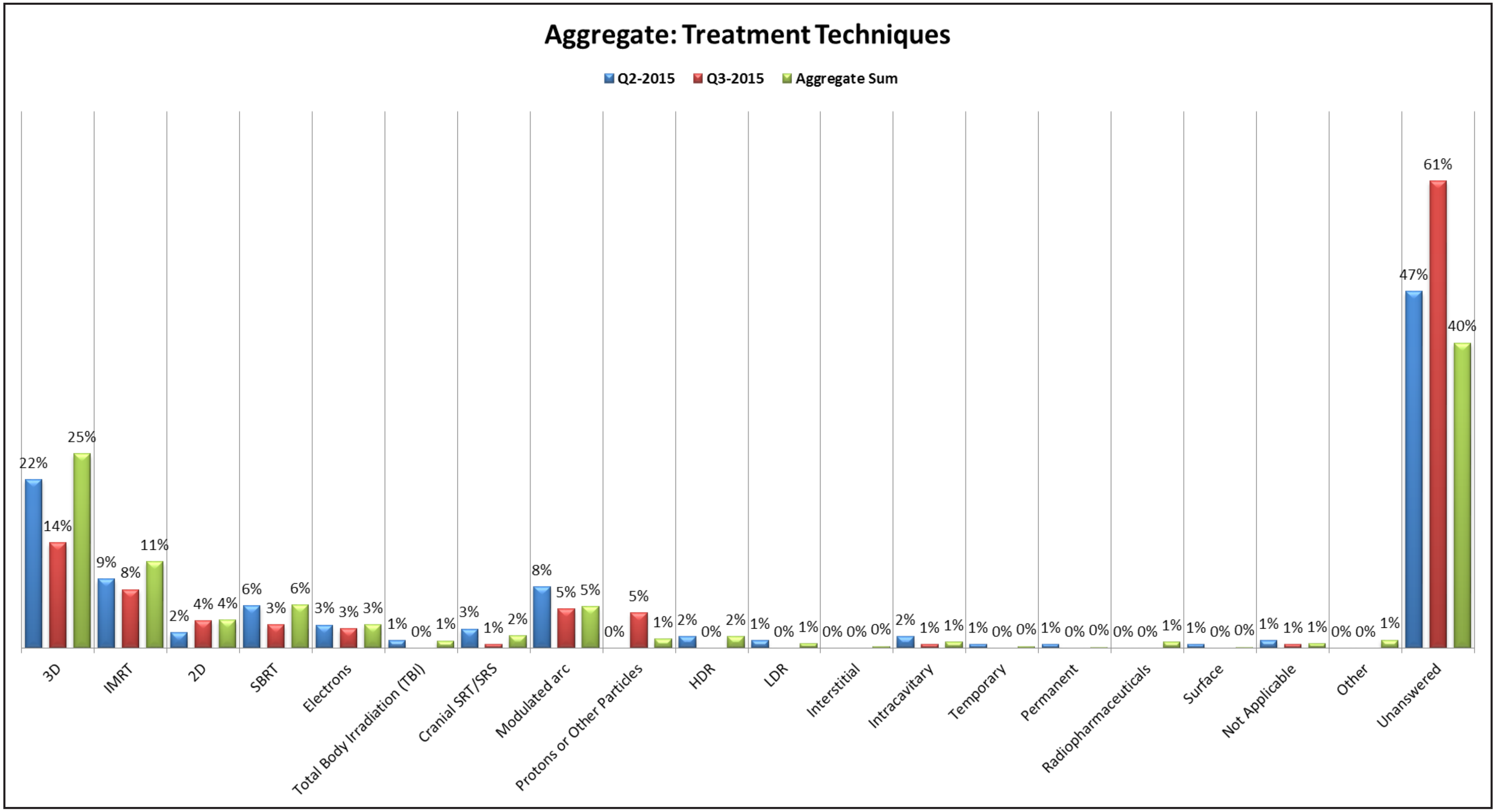
35%
38%
37%
51%
37%
22%
14%
24%
0%
0%
0%
Patient Incident
Near-Miss
Unsafe Condition
Not Patient Related

AGGREGATE ANALYSIS GRAPHS | continued



AGGREGATE ANALYSIS GRAPHS | continued




Aggregate: Treatment Techniques
Q2-2015
Q3-2015
Aggregate Sum
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11%
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6%
3%
6%
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3%
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47%
61%
40%
3D
IMRT
2D
SBRT
Electrons
Total Body Irradiation (TBI)
Cranial SRT/SRS
Modulated arc
Protons or Other Particles
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LDR
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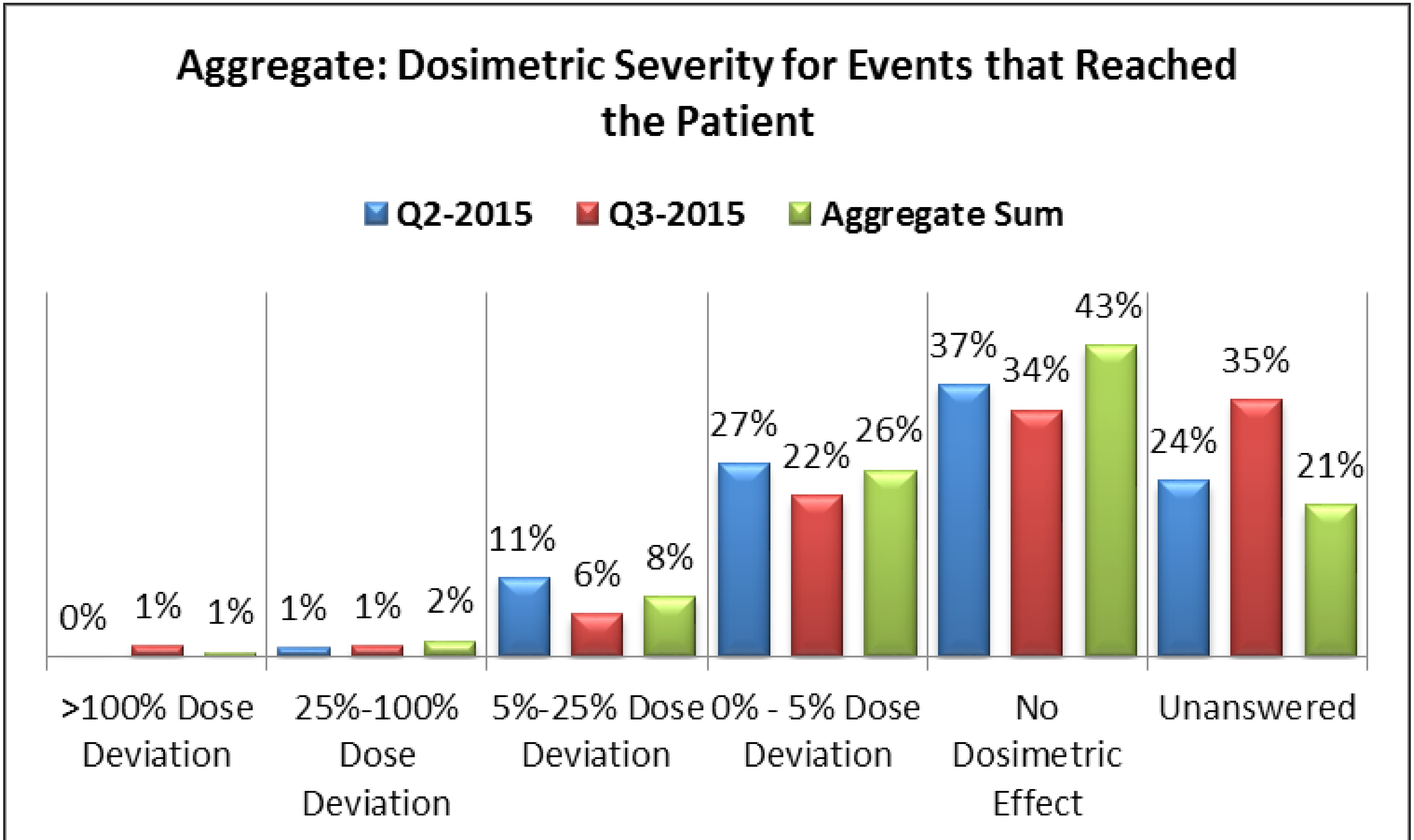
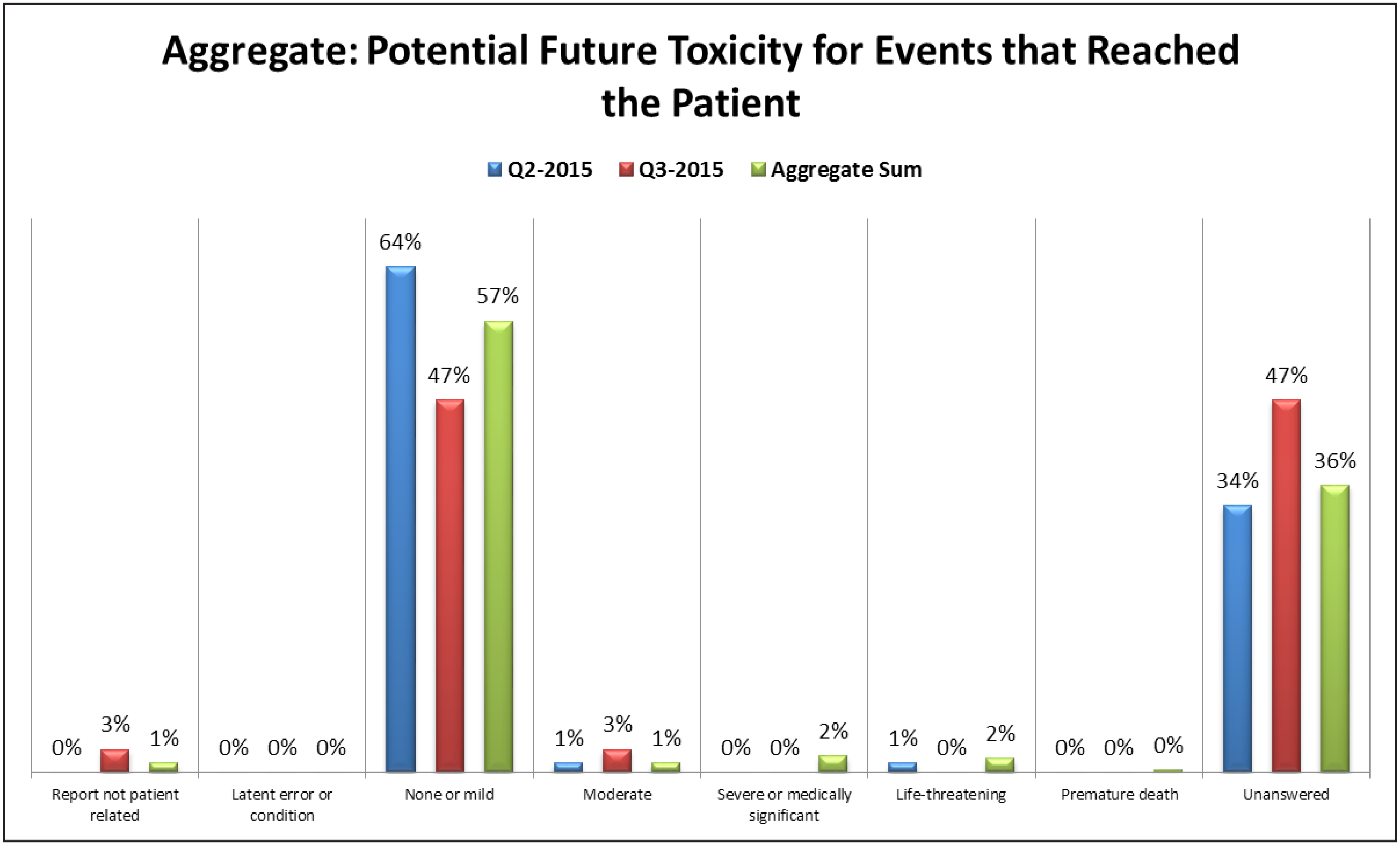
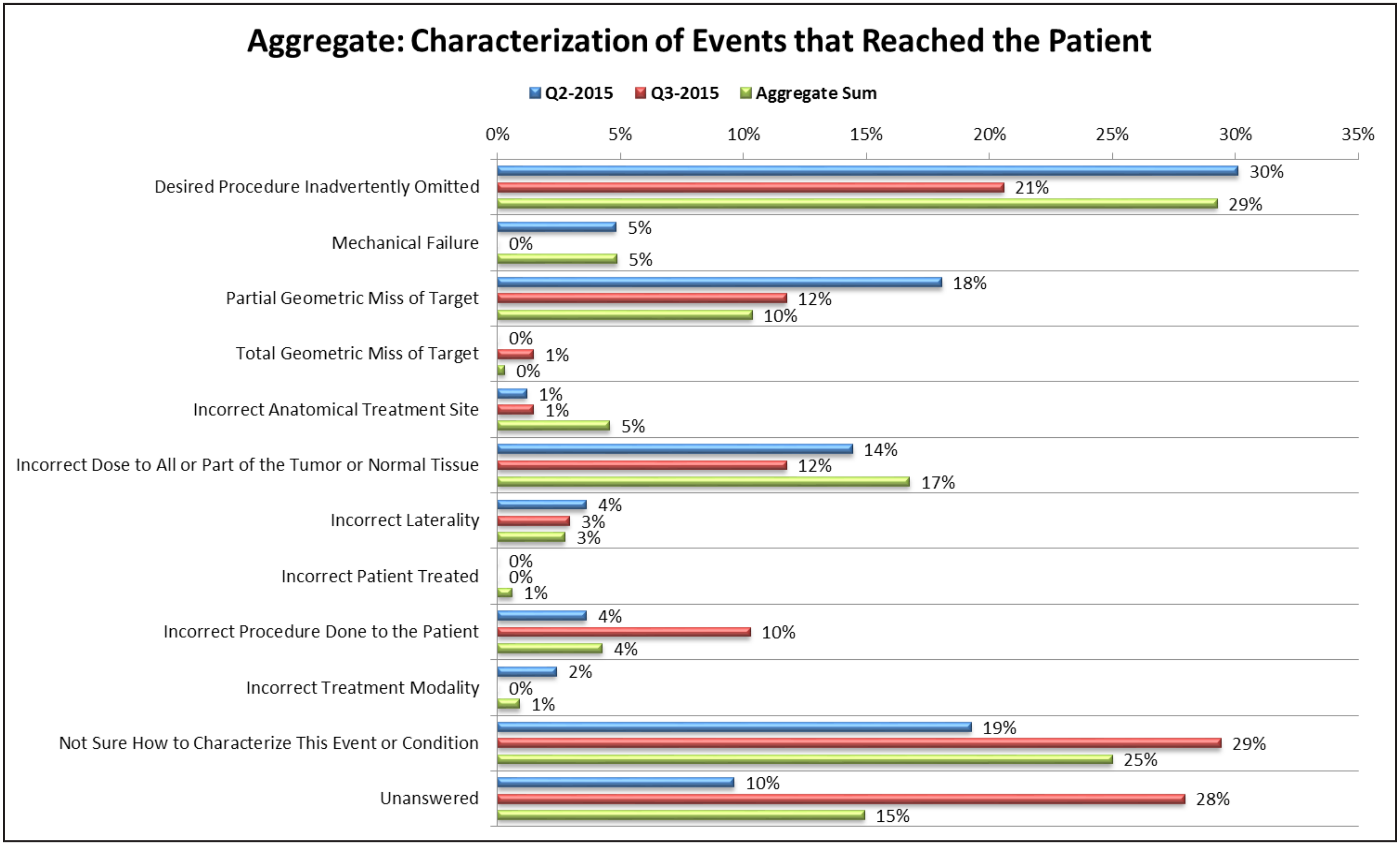
Temporary
Permanent
Radiopharmaceuticals
Surface
Not Applicable
Other
Unanswered

AGGREGATE ANALYSIS GRAPHS | continued




Aggregate: Potential Future Toxicity for Events that Reached the Patient
Q2-2015
Q3-2015
Aggregate Sum
0%
3%
1%
0%
0%
0%
64%
47%
57%
1%
3%
1%
0%
0%
2%
1%
0%
2%
0%
0%
0%
34%
47%
36%
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 ANALYSIS GRAPHS | continued