RO-ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

QUARTERLY REPORT
PATIENT SAFETY WORK PRODUCT

Q4 2015

OCTOBER 1 , 2015 – DECEMBER 31, 2015

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AGGREGATE REPORT CARD – Q4 2015

October 1, 2015 – December 31, 2015

Metric	Aggregate Current Quarter	Aggregate Previous Quarter	Aggregate Historical Sum
Total Number of Events	**251**	**308**	**1295**
Patient Incident	93	102	468
Near Miss	85	133	441
Unsafe Conditions	73	73	386
Most Commonly Identified Characterization of Event	**Not Sure How to Characterize:** 30% (76/251) **Unanswered/Not Sure:** 39% (98/251)	**Not Sure How to Characterize:** 415% (47/308) **Unanswered/Not Sure:** 65% (201/308)	**Desired Procedure Omitted:** 25% (318/1295) **Unanswered/Not Sure:** 37% (473/1295)
Most Commonly Identified Workflow Step Where Event Occurred	**Treatment Planning:** 32% (81/251) **Unanswered:** 20% (50/251)	**Treatment Planning:** 42% (129/308) **Unanswered:** 20% (63/308)	**Treatment Planning:** 31% (402/1295) **Unanswered:** 24% (312/1295)
Most Commonly Identified Treatment Technique	**3D:** 19% (48/251) **Unanswered:** 48% (121/251)	**3D:** **10% (30/308)** **Unanswered:** 70% (216/308)	**3D:** 21% (268/1295) **Unanswered:** 49% (631/1295)
Characterization of Events with Dosimetric Severity for Events that Reached the Patient	**Incorrect Dose to All or Part of Body:** 53% (9/17)	**Incorrect Dose to All or Part of Body:** 39% (11/28)	**Incorrect Dose to All or Part of Body:** 39% (56/145)
Potential Future Toxicity Within Events that Reached the Patient	**None or mild:** 41% (38/93) **Unanswered:** 57% (53/93)	**None or mild:** 38% (39/102) **Unanswered:** 58% (59/102)	**None or mild:** 50% (233/468) **Unanswered:** 45% (211/468)

ANALYSIS AND COMMENTARY

As the Radiation Oncology Healthcare Advisory Council (RO-HAC) reviews submitted incidents, a priority is given to each incident. This priority score ranges from 1-5 and reflects the harm, or potential for harm, as well as the risk of other downstream errors and likelihood that current barriers will prevent the problem. What follows is the event prioritization scale currently in use.

Severity Index	Severity Description	Criteria
1	No potential or real harm	Event does not pose downstream risk in workfl w. Event is not related to patient safety or quality of treatment.
2	Mild potential or real harm	Event may enhance the risk of other downstream errors. Event may cause emotional distress or inconvenience to patient with no clinical impact.
3	Moderate potential or real harm	Event enhances the risk of other critical downstream errors. Temporary pain or discomfort for patient. Deviations from best practices, but with no obvious clinical impact.
4	Severe potential or real harm	Limited barriers to prevention of problem. Event with potential clinical impact that is non-critical.
5	Critical potential or real harm	Extremely limited barriers to prevention of problem. Event with potentially critical clinical impact.

During Quarter 4 2015, a total of 33 out of 251 incidents (13 percent) were scored as 4 or 5 on the priority scale. These include both incidents that reached the patient as well as near misses. Of these high priority incidents, several recurring themes emerged including the risk of emergent or "rushed" cases, the risks of changing the treatment plan during a course of therapy including completing a course of therapy early, missed treatments and prescriptions, and the risk of problems when the physician prescription/intent does not match the care delivered.

1.1 Rushed Cases

Three of this quarter's high index cases included emergent or "rushed" treatment as a clearly documented factor. There is a large body of literature supporting the increased risk that accompanies a compressed timeline for treatment.

Case 1: Incorrectly contoured boost structures

- The treatment team was notified late about the randomization of a patient for a clinical trial. The physician gave instructions to dosimetry regarding how to create/copy boost contours. The radiation plan was reviewed internally and also passed the external protocol review. During treatment, the patient was noted to have an unexpected and early skin reaction. This clinical event led to re-review of the treatment plan, where it was discovered that the boost structures were incorrectly contoured.

Case 2: Incorrect fractions delivered

- In a second case, the treatment team was notified late regarding the dose level randomization of a patient for clinical trial participation. The patient was prescribed 7 boost fractions. The protocol plan was approved and pushed out of dosimetry at 1:30 p.m., reviewed by physics, and the patient was treated at 3:30 p.m. After the single fraction was given, it was discovered that the approved and delivered boost plan was for 14 fractions instead of the prescribed 7 fractions. The plan was modified, and the team delivered the missing dose for that fraction. The subsequent 6 fractions were delivered as intended. The team also noted that this event occurred just as attending physicians were returning from an annual conference meeting and there was a spike in the number of cases needing to start. The following phrases all come from this incident: "spike in plan pushes," "slammed with cases," "cases rushed," "late notification" and "rushed planning."

Case 3: Error in isocenter location

- A patient with two plans/isocenters was scheduled to start concurrent with chemotherapy. Both plans were signed at 6:00 p.m. the day before the scheduled treatment. The day of treatment, physics reviewed and approved all plans and reference images for a 2:00 p.m. treatment. Both kVkV and soft tissue cone beam computed tomography (CBCT) imaging were requested and reference images were approved by physics. Imaging for the first isocenter was performed, the physician reviewed the kVkV images, approved the kVkV images, and instructed the radiation therapists to treat the first site in an effort to expedite this two isocenter patient. The patient was also in pain and the team was concerned about patient movement on the table. Treatment then began for the patient. On further review of the CBCT, the physician determined that there was roughly a 2cm error in isocenter location. The physician phoned the machine and treatment was halted mid-arc. The patient was shifted to the correct location and the treatment was delivered. This resulted in an additional 68MUs (partial arc) delivered to the incorrect location. Subsequently, it was noted that the CBCT reference image was of poor quality. The combination of rush to treat (concurrent chemo, 2 isocenters, patient in pain) combined with a large shift from the isocenter and poor reference CBCT images, led to this patient overdose.

1.2 Changes to the Course of Therapy

Most radiation oncology clinics have well-defined, in depth processes and quality assurance (QA) steps required before treatment begins. It should be noted that any deviation from the originally intended course of treatment increases the risk of error. Examples of deviations include replans, any change in radiation prescription, or finishing a course of therapy early. The following cases illustrate the risk of making changes to a course of treatment without the appropriate safeguards.

Case 4: Revision of plan without rejecting/discontinuing previous plan

- A patient arrived for his treatment, but no treatment appointment was actually scheduled. The therapists informed dosimetry, who noted that there should be 2 fractions remaining and the final 2 fractions were indeed scheduled. After this discrepancy was resolved, the patient was placed on the table and while alignment imaging was performed, the dosimetrist reviewed the chart more closely and realized the prescription had been changed earlier, but the original plan had not been rejected and discontinued. There had been a revised prescription, but neither the initial prescription nor the original plan had been errored out. A revised plan was created, but had not been approved. Dosimetry informed the therapists, prior to that day's treatment being delivered, and the course was completed as intended.

Case 5: Plan change after start

- A stereotactic body radiation therapy (SBRT) liver patient was planned and the plan was approved. On further review, the treatment team elected to modify/improve the plan, but the initial plan was not rejected. The patient presented for treatment and received the first fraction using the original plan. The therapists noted that there was a new plan while preparing for the second fraction. The old plan was discontinued and the remaining fractions were given as intended using the new plan.

1.3 Missed Treatments and Prescriptions

Case 6: Missed treatment

- A cranial stereotactic radiation therapy/stereotactic radiosurgery (SRT/SRS) patient was sick during the course of therapy and thus missed the final single fraction. No additional treatment was scheduled within the system to deliver that missed fraction. This was not recognized until 5 days (3 treatment days) later during the physics final check. The physician determined that the missed dose was not clinically significant and did not have the patient return for the final fraction of SRT/SRS.

1.4 Physician's Prescription Does Not Match Care Intended/Delivered

A commonly recurring theme is when the physician's radiation prescription does not match the care intended or care delivered. Six of the 33 high priority cases this quarter included this problem as either the incident or central to the incident. Here are two near miss examples.

Case 7: Incorrect planned dose

- The physician prescribed a simultaneous integrated boost (SIB) head and neck plan with 70 gray (Gy), 60 Gy and 56 Gy. The planning dosimetrist missed the lowest dose region (56 Gy, contralateral neck) and planned this region as though it were to receive 60 Gy. The plan was reviewed and approved by the physician. This error was caught during the pretreatment physics check when the physicist noted that the 56 Gy isodose line was missing.

Case 8: Fractions and dose inverted

- A patient presented for his first radiation fraction, was placed on the table, and during time-out it was realized that this was to be fraction 1 of 180 fractions. The prescription was for 180 cGy x 42 fractions = 7,560 cGy. Instead, the plan that was generated, and subsequently approved by the physician and physics was 42 cGy x 180 fractions = 7,560 cGy. As the total dose was correct, the dose-volume histograms (DVHs) and isodose lines were correct but the fraction size was incorrect. The patient had to be taken off the table and replanned.

Note: ASTRO will be publishing a white paper on the elements and format of a standard prescription. This will help create a consistent format for presenting the dose and fraction and thereby reduce the likelihood of this kind of inversion error.

Comments on prescription issues:

Prescriptions and the plans which implement those prescriptions are clearly crucial to the radiotherapy process, and should be given a great deal of attention by individuals, the clinical processes we use, the treatment planning and delivery software, and all the QA processes involved.

Usually the basic normal planning and delivery process is successful at making the prescription, plan and other related information consistent. But errors do occur, and these need to be eliminated by careful checks, avoidance of rushing, and rigorous processes. It is obvious, however, that any event or change which affects this normal flow is much more likely to cause an error, or avoid an important QA check. Though the ways this occurs are many and varied, one way to address those issues is to always have a plan for how to perform the appropriate checks and procedures so if a case does deviate from the normal path, regular QA procedures are still present and patient safety is maintained at the forefront of care.

One way to address changes in prescriptions is to always identify and use a critical first step. As soon as the decision to change a plan is communicated to the planner, the first step is to remove the treatment approval from the current, soon to be old, plan. The details of what exactly to do depends on the electronic medical record (EMR) (or paper system) in use, but the first step is key to prevent further treatment with an old plan.

Finally, one contributing factor attributed to many prescription-related events is the capabilities and user interface in the various planning and treatment management software systems that are used to perform radiotherapy. The prescription task, and maintaining the consistency of all that information throughout the treatment process, are quite complicated, especially when changes, treatment adjustments, machine problems and patient issues affect the treatment delivery and/or schedule. Increasing the sophistication of prescription management by software vendors would contribute to improvements in this critical issue.

2. Overall Characterization of Event Types

There are many ways to review and characterize the events which are submitted to the RO-ILS system. One way is to create general categories of event types, for example, events which involve some issue with the prescription. One such characterization method has been used here, within Figure 1, to illustrate the kinds of events that received high priority scores and which occurred this quarter.

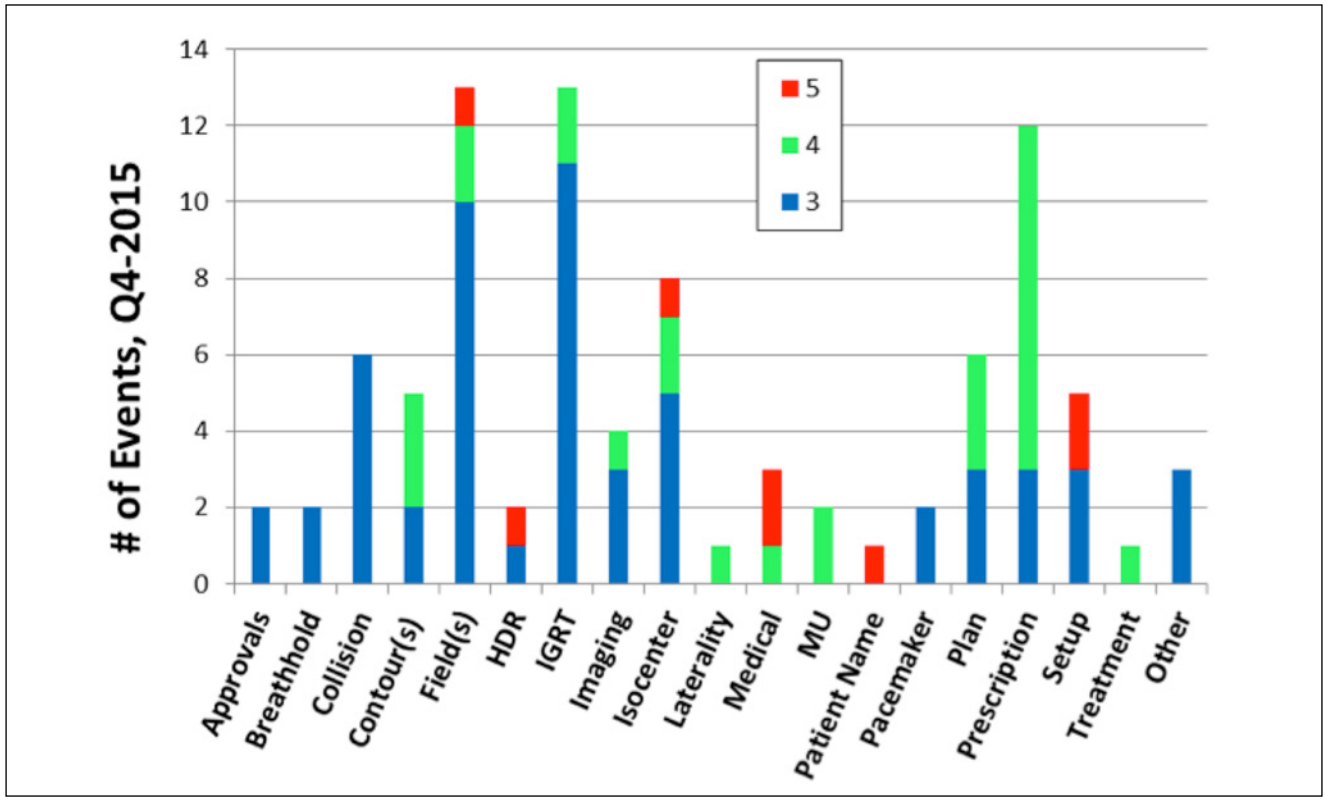


Fig 1. Events for Q4 2015, characterized by type of issue. Only events with a priority score of 3, 4 or 5 included.

Several points are dramatically shown here. The categories with larger numbers of errors, of course, are areas which should be evaluated in detail.

- As mentioned above, prescription errors are particularly important, though many different types of prescription related events are included in this category. More interesting is that many of the prescription errors are ranked as reasonably severe issues that must be addressed.

- Another significant category, as mentioned in earlier reports, is associated with patient setup, isocenter placements, and the image guided radiation therapy (IGRT) process used to verify or set patient positioning. Combining those 3 related categories resulted in 26 errors, nearly 30 percent of the events ranked 3-5. As these events all impact getting the patient in the right place for treatment, it is crucial to work to improve these processes, so the radiation is delivered to the correct locations within the patient.

- Contouring, and names of contours, are also important. Although there were only 5 events in this category, 3 were scored high, typically because the naming of a target-related contour misled people in the planning or delivery process, so they had the potential to affect the dose the patient was treated with. Clearly both accuracy of contouring (targets in particular), and correct and clear naming of structures in the planning process are important issues.

- Another issue of concern are collisions. Though some of these errors are limited collisions between machine hardware (though potentially a significant problem), others are related to the potential for machine to patient collisions. As the old method of therapists positioning the machine for each field while standing in the treatment room has been decreasing, the importance of making sure that complex arc and non-coplanar treatment fields will safely clear the patient has increased. Clearly more work and attention is needed in this area.

- One more issue involves the uncommon, but still critical, events which directly affect the patient. Three events involve radiation-related procedures, though not directly related to the radiation. One was severe bleeding during the course of a high dose rate (HDR) procedure, while a second involved power problems/downtime during an anesthetized proton therapy procedure. Both involved trips to the ER. A third involved significant miscommunication during preparatory communication and/or an implant surgical procedure in which one of the surgeons refused to do their part of the procedure. These unlikely events, outside the typical procedures faced routinely in the clinic, highlight the need for careful preparation and communication with all parties involved in these procedures, in planning for potential problems, and in a system which is able to respond quickly and appropriately to an emergency situation.

Concluding Recommendations

There are many reasons why the physician prescription may not match the care delivered. There will always be changes made to certain radiation treatment plans and courses. We all know that medical emergencies and other legitimate reasons to expedite treatment are not uncommon. Each incident is different. In general, we may consider two basic strategies for such problems.

1. Minimize the risk by eliminating the possible risk factor (e.g., elect to not treat a "rushed" case emergently if not truly needed; develop a “no-fly” or similar strategy)

2. Accept the risk, but engineer specific safeguards to mitigate that risk (e.g., the "rushed" case truly is emergent, and will be treated today, but inside a well-designed and well-defined system that acknowledges and accounts for these special situations).

We emphasize that when considering solutions, a key component of robust quality assurance is to focus efforts on the most productive classes of interventions. The Institute for Safe Medication Practices (ISMP Medication Safety Alert 1999, June 2) describes the following hierarchy of effectiveness.

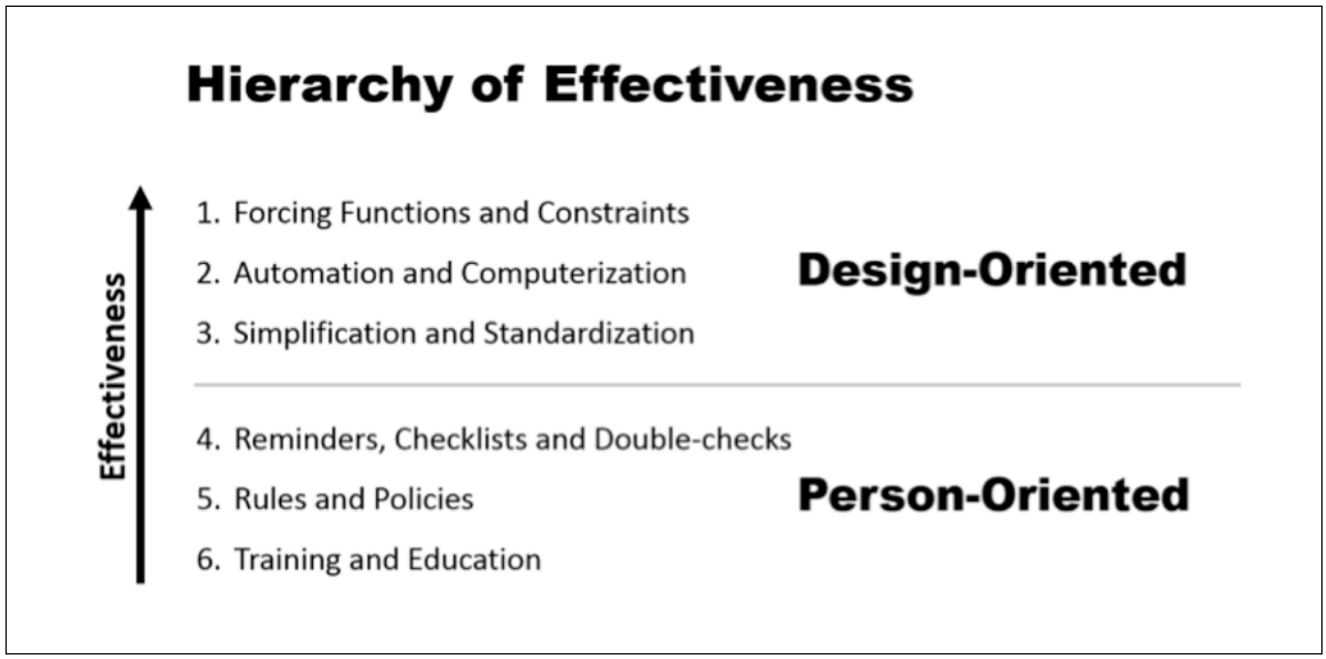


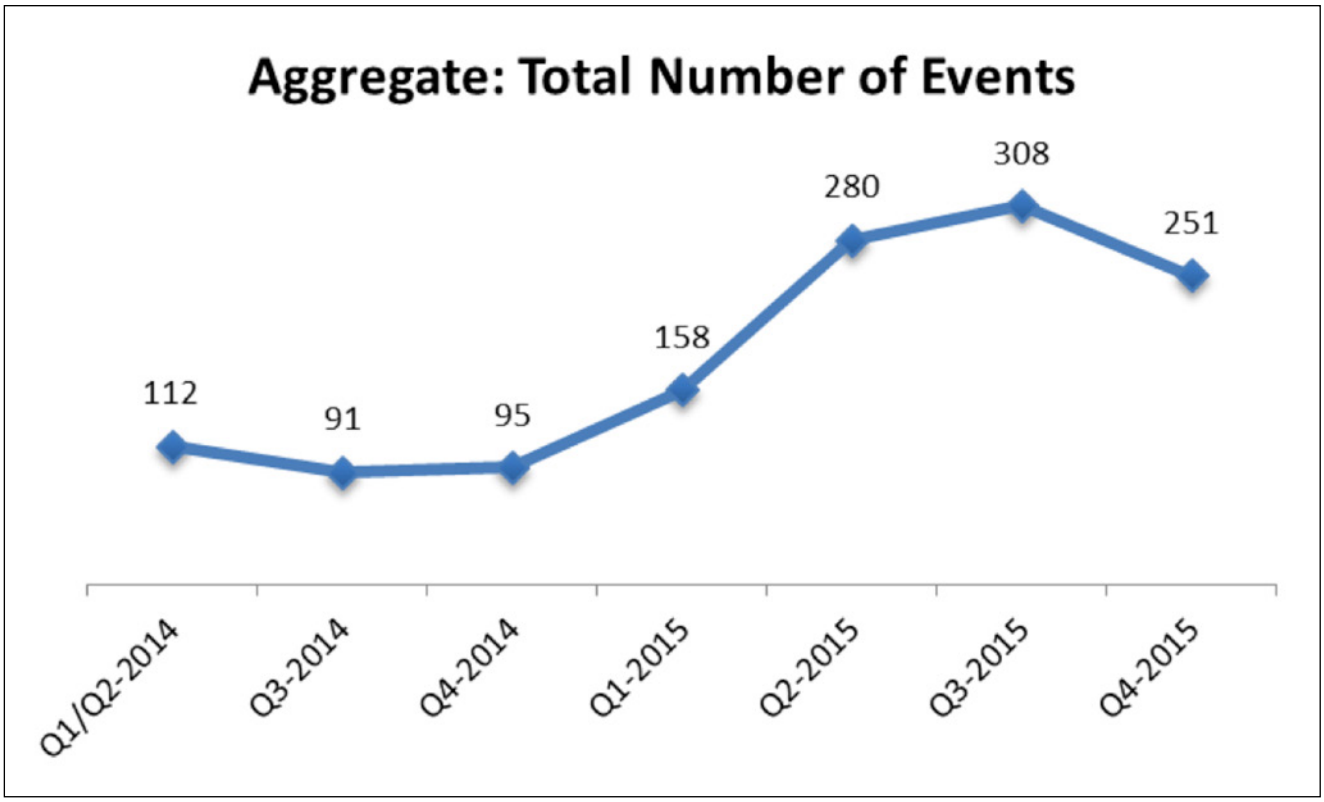
Fig 2. Hierarchy of Effectiveness. Based on a bulletin from the Institute for Safe Medication Practices Medication Error Prevention “Toolbox” ISMP Medication Safety Alert 1999 (June 2)

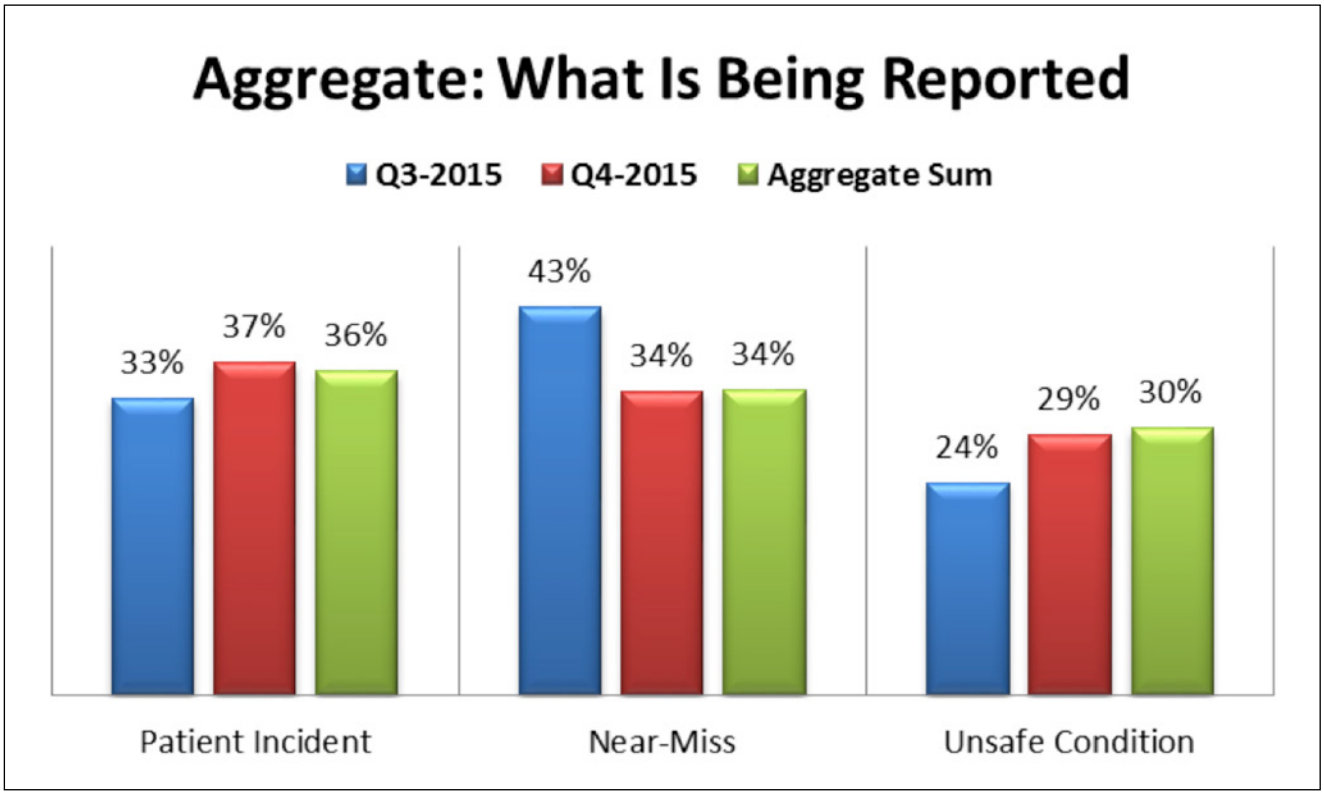
Each time a team sits down to discuss possible solutions to problems they have identified, they should consider where their solution falls on the above hierarchy (Figure 2) and question whether there is a more highly effective, viable solution that can be instituted. It is easy to see a problem, and then designate more training as a solution. Yet, a better, more effective way may be to standardize a method or template, simplify a process, or find a way to automate or use a forcing function.

We must remember that while it is easy to mandate additional training, increase education, write new rules, revise policies, set-up checklists, give reminders, and perform additional double-checks, the best solutions are design-oriented. Note that while certain forcing functions and constraints may require hardware/software solutions (including development by vendors), simplification and standardization are tools that any clinic can implement.

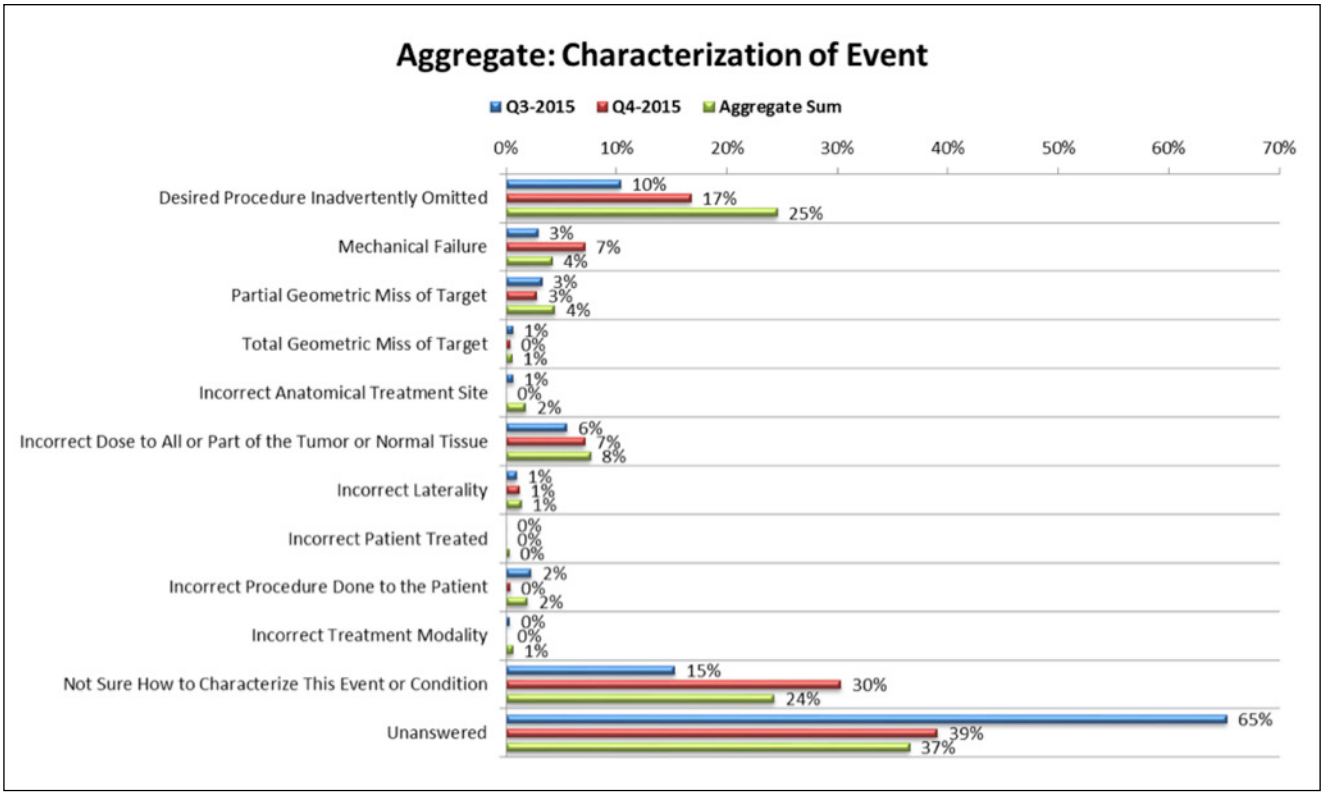
For example, the use of templates (commonly built in as options to many treatment planning systems) constitutes a type of simplification and standardization that can be an effective strategy against many radiation prescription issues such as those described in section 1.4, cases 7-8. Each clinic should analyze its own workflow and design processes to minimize risk.

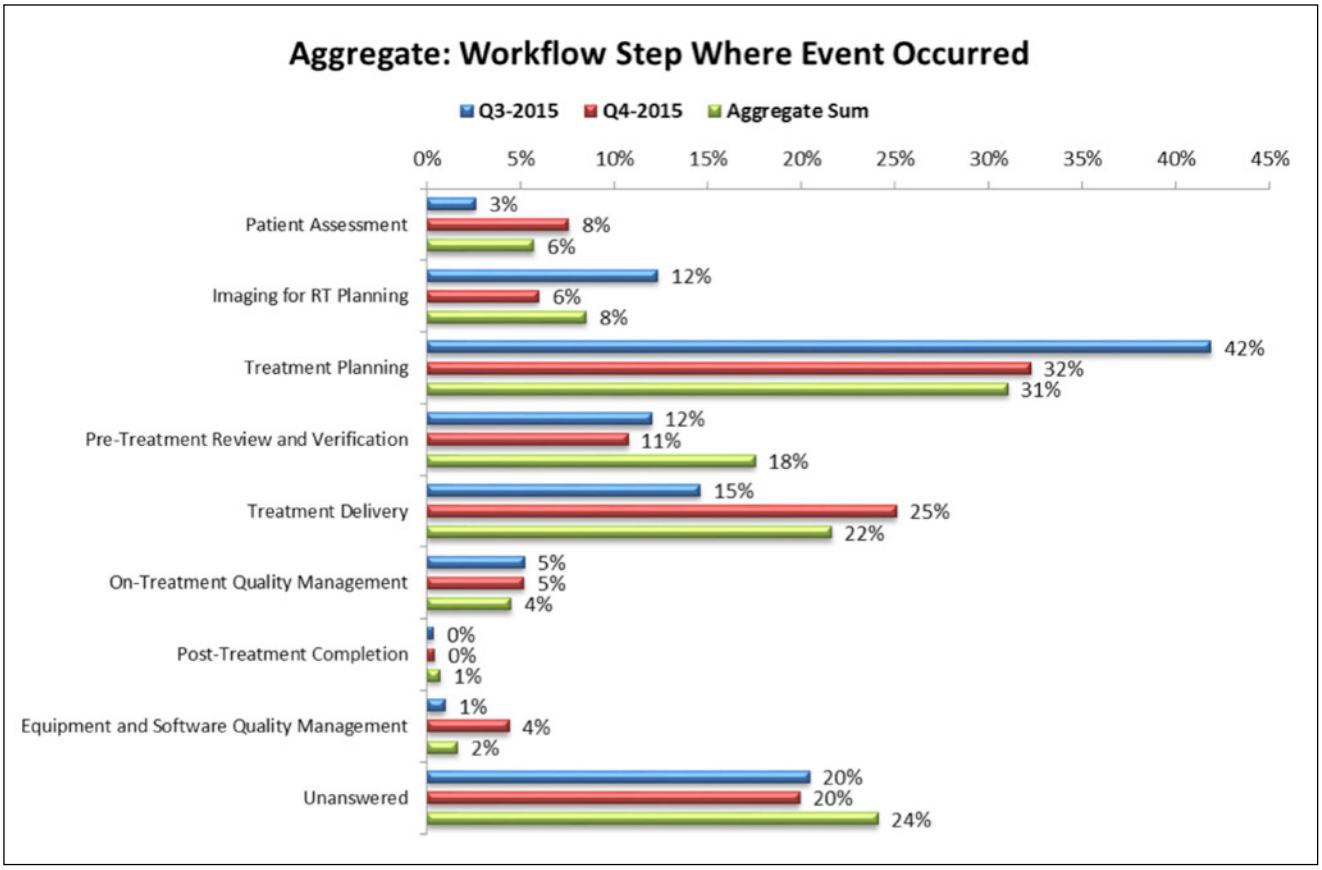
AGGREGATE ANALYSIS GRAPHS





AGGREGATE ANALYSIS GRAPHS | Continued





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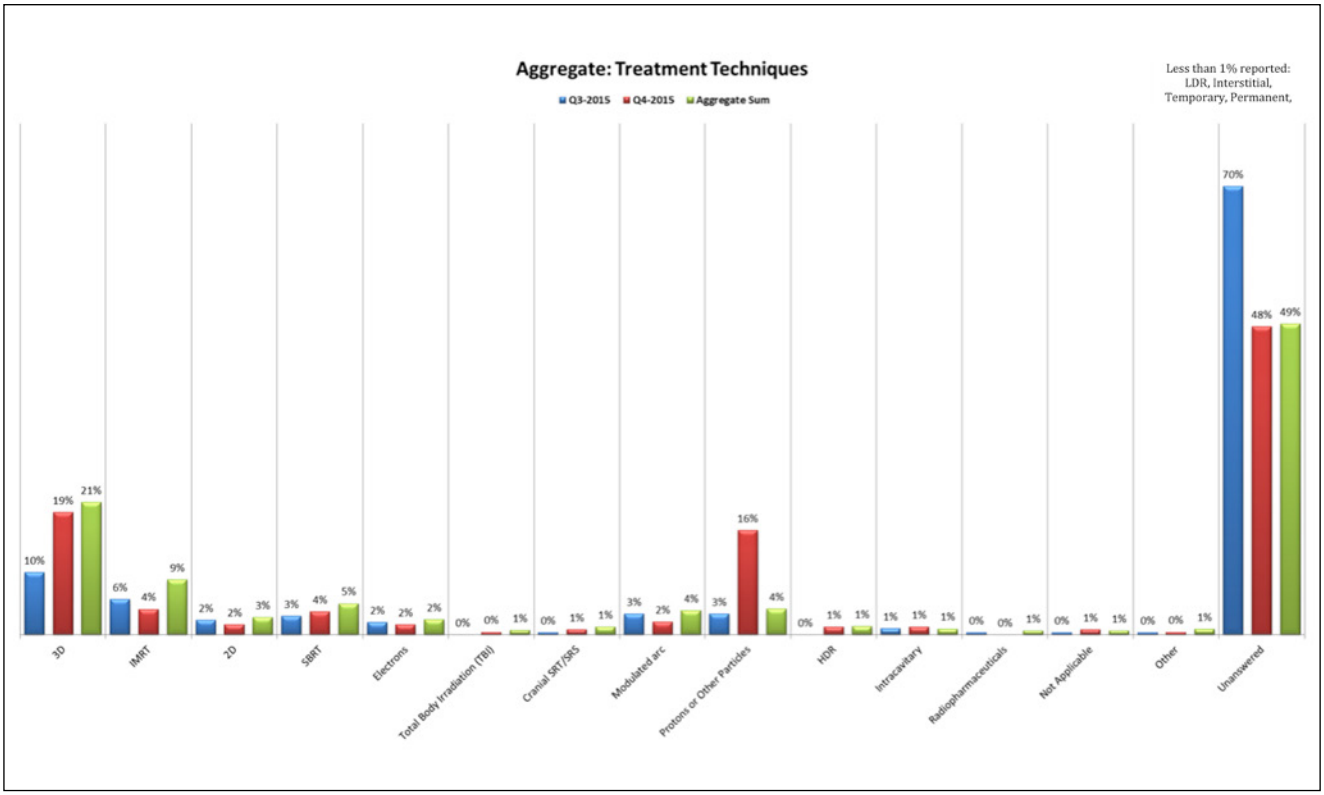

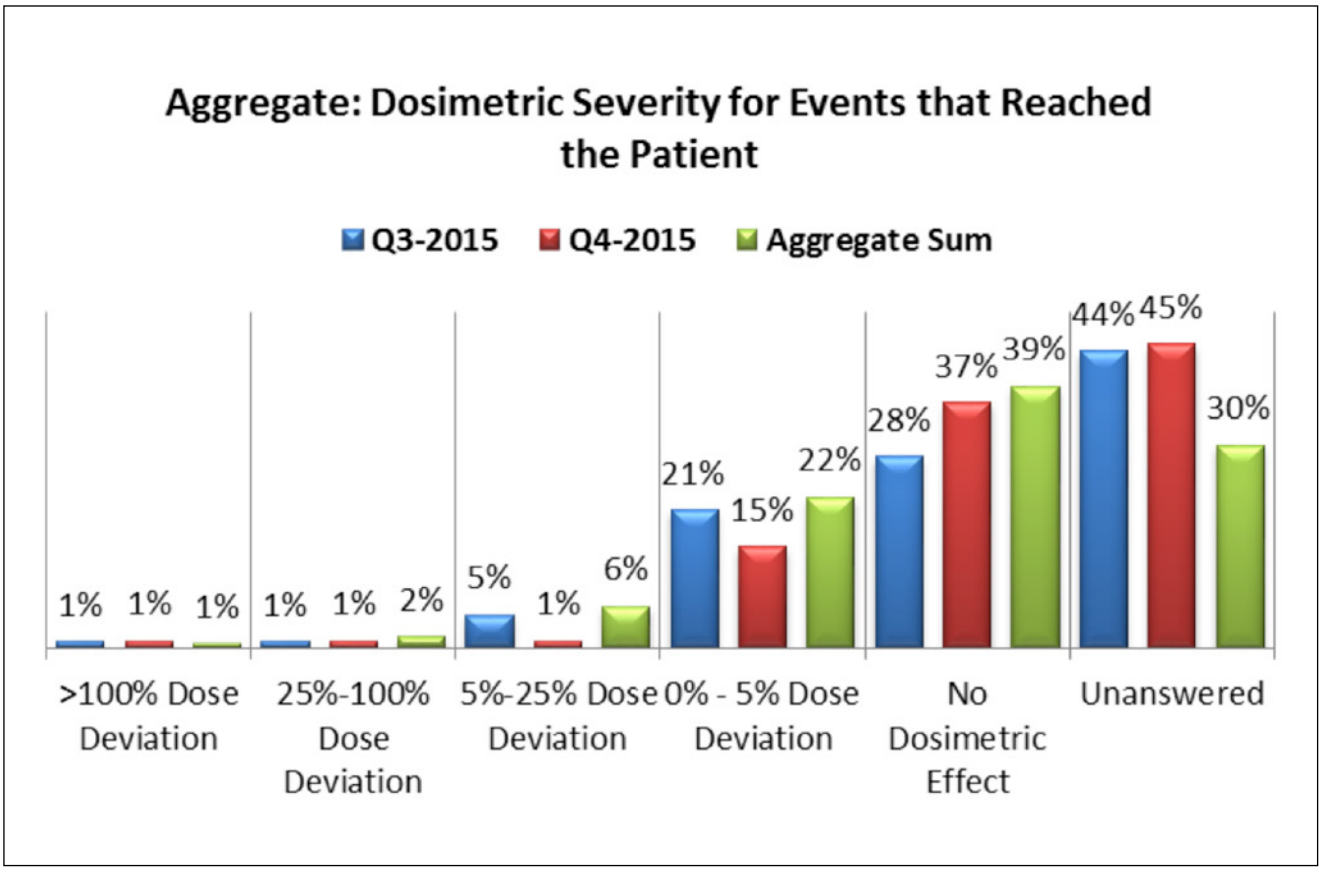

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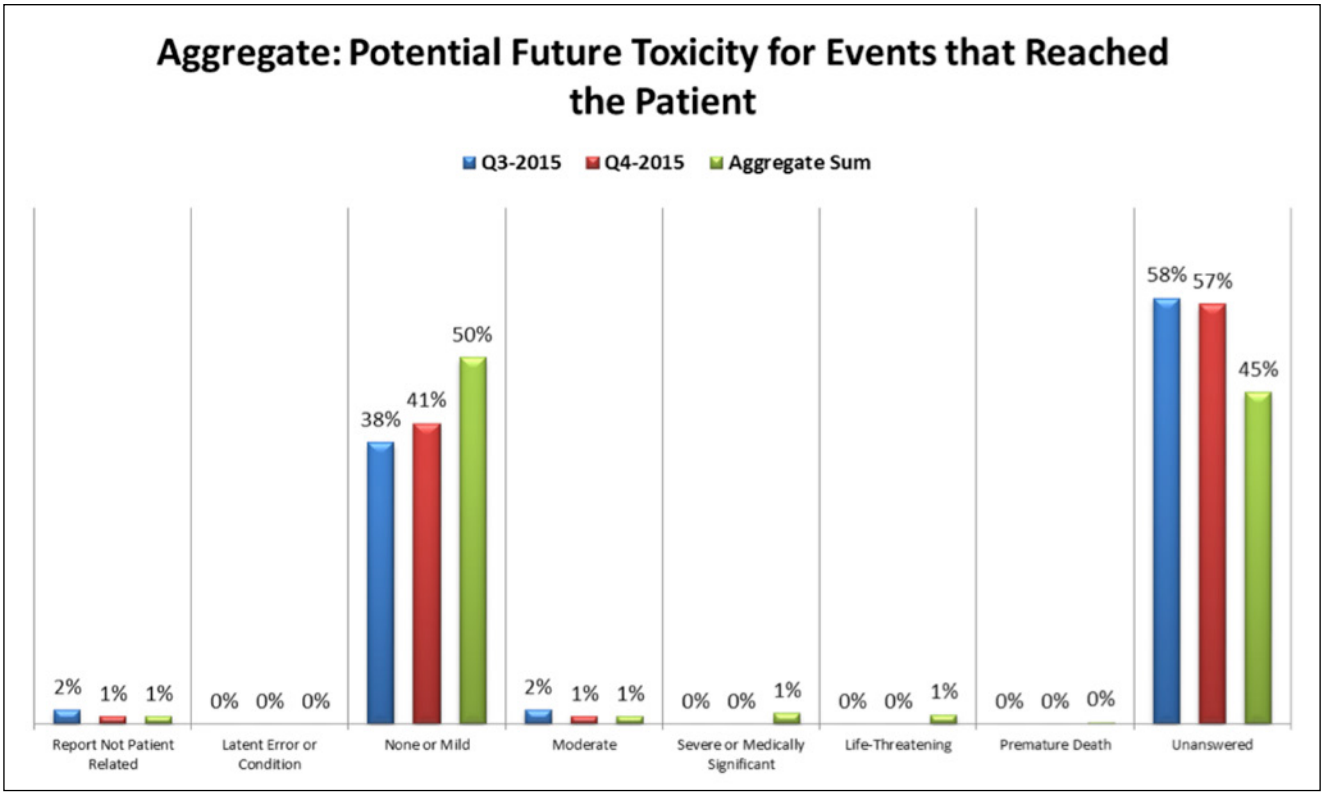

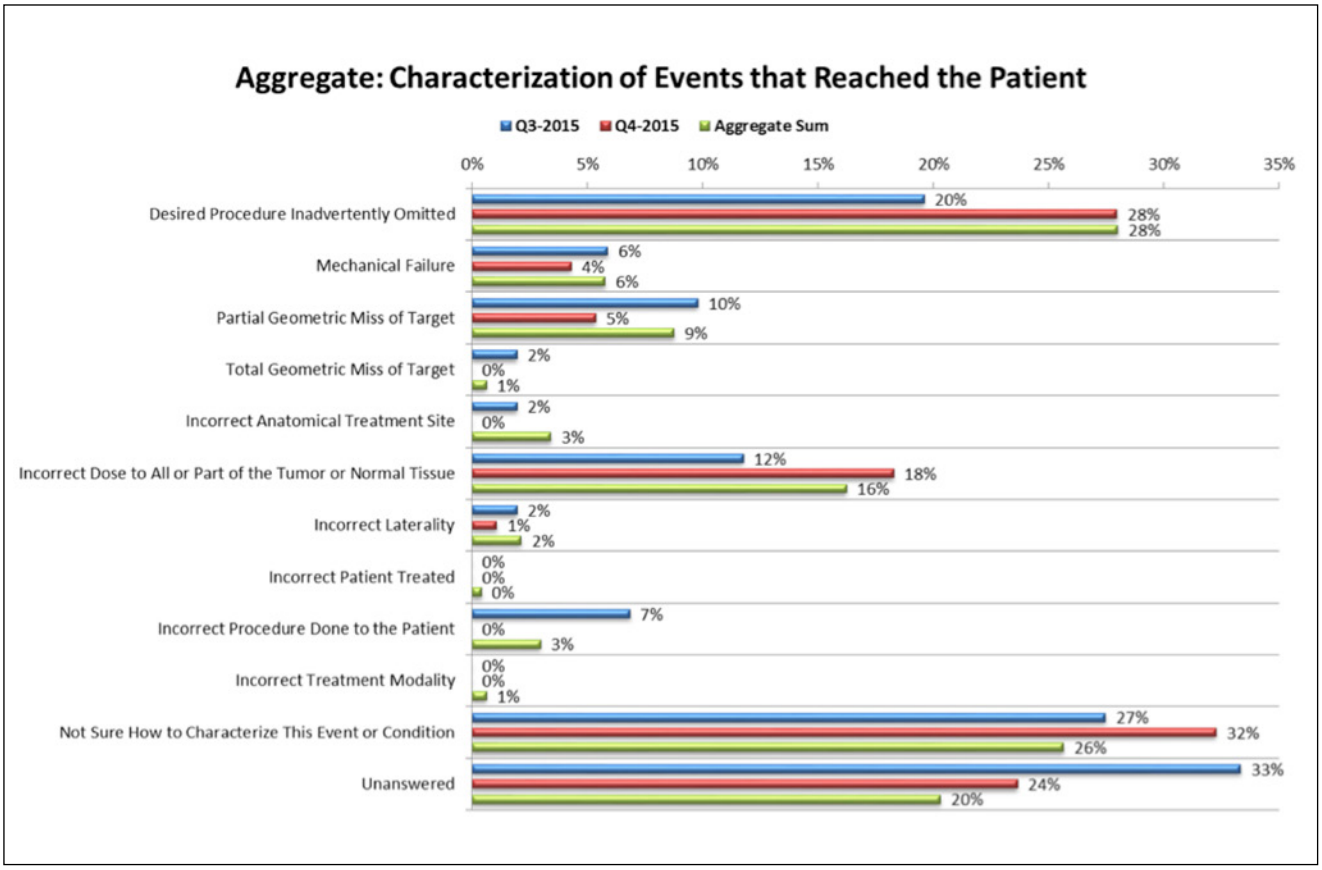

AGGREGATE ANALYSIS GRAPHS | Continued