RO•ILS™

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

QUARTERLY REPORT
PATIENT SAFETY WORK PRODUCT

Q3 2014

JULY 1, 2014 – SEPTEMBER 30, 2014

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AGGREGATE REPORT CARD – Q3 2014

July 1, 2014 – September 30, 2014

Metric	Aggregate Current quarter	Provider Current Qtr	Provider Historical Qtr Avg
Total number of Events Patient Incident Near Miss Unsafe Conditions Not patient related	60 24 25 11 0	81 35 23 22 1	-
Most Commonly Identified Characteristic Event	Desired Procedure Inadvertently Omitted: 20% (12/60) Unanswered/Not Sure: 58% (35/60)	Desired Procedure Inadvertently Omitted: 19% (15/81) Unanswered/Not Sure: 53% (43/81)	-
Most Commonly Identified Workflow Step Where Event Occurred	Treatment Planning 17% (10/60) Unanswered: 70% (42/60)	Treatment Planning 16% (13/81) Unanswered: 65% (53/81)	-
Most Commonly Identified Treatment Technique	3D 23% (14/60) Unanswered: 28% (17/60)	3D 41% (33/81) Unanswered: 32% (26/81)	
Characterization of Dosimetric Severity for Events That Reached the Patient	Desired Procedure Inadvertently Omitted: 29% (7/24) Unanswered: 29% (7/24)	n/a	
Potential Future Toxicity Within Events That Reached the Patient	None or mild: 29% (7/24) Unanswered: 50% (12/24)	None or mild: 43% (15/35) Unanswered: 40% (14/35)	

ANALYSIS & COMMENTARY

ANALYSIS OF PATIENT INCIDENTS

Any analysis is only as good as the data submitted. We would like to highlight several areas where we may improve our data submission. Specifically, we will address event classification.

Of particular interest are events that reached the patient. As seen above, 24 of 60 events from this quarter were designated as "patient incident" meaning that they were an "Incident that reached the patient: A safety event that reached the patient, with or without harm." Other possible classifications include "near miss", "unsafe condition" or "not patient related". It is important to further understand these incidents as they are potentially the most serious.

1.1 Incidents designated with >5% dose deviation

Of the 60 cases submitted this quarter, three incidents were marked as "greater than 5% dose deviation". These were as follows:

- Wrong isocenter. Cause: An incorrect isocenter point selected in the treatment planning system when creating a DRR. Resolution: The error was identified when a cone-beam CT was performed. Patient treated as intended.
- Wrong isocenter. Cause: An incorrect reference scan was selected for cone-beam CT alignment due to a second plan generated. The therapists who were responsible for loading the new reference scan did not see the note do to this. Resolution: When cone-beam CT was performed large rotations were noted so the issue was further investigated and the error was identified. Patient treated as intended.
- Wrong magnification on a lung block for a patient undergoing TBI irradiation. Cause: Magnification marker was misplaced on the patient. Resolution: Large oversized block was noted when patient was set up for treatment. Patient treated as intended.

Please note that all three of these events reached the patient, but all were identified and corrected such that treatment proceeded as intended. There was NO ACTUAL dose deviation in these patients. The clinical sites submitting these incidents recorded "dose deviation" according to what MIGHT have happened had the error not been identified and the treatment proceeded incorrectly.

RECOMMENDATION: When indicating the "dose deviation" of a particular event, evaluate the deviation according to what ACTUALLY occurred and not what MIGHT have occurred.

1.2 Incidents with possible medical impact

There was one case this quarter labelled as "severe or medically significant." Upon further inspection this event included the following:

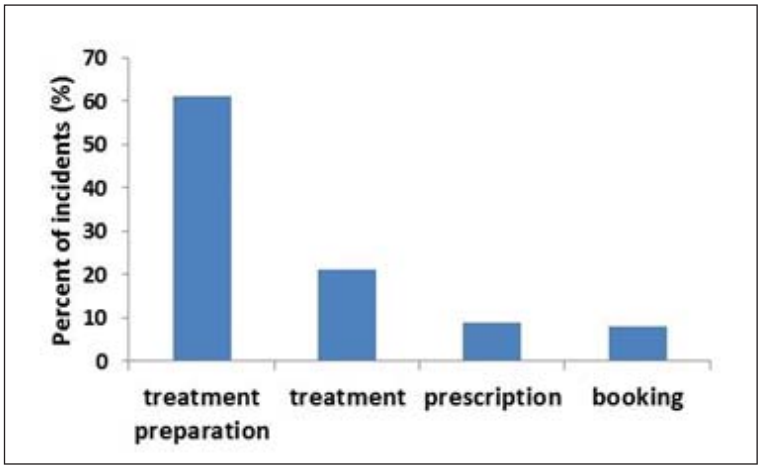
- A patient with metastatic synovial sarcoma was receiving treatment to the L3 spine for symptomatic nerve root compression. The patient's progressive pain was poorly managed, however, and referral to the available pain service was warranted and may have been beneficial. Within this clinic and education program was undertaken for providers around this topic.

This case highlights the opportunity we have to improve patient care outside the specific arena of radiation delivery. Pain control is an important component of radiation oncology practice and the submitting institution should be commended for addressing this as an opportunity for improvement.

ANALYSIS OF RECURRING THEMES

2.1 Events occurring within treatment planning

In first three quarters of data collection, the workflow step of treatment planning was identified as the most common point at which errors occur. This can be seen in the above in the report card where the most commonly identified workflow step is treatment planning (17% of events). (However, it should be noted that in the data from quarter 3 users did not supply information about workflow step in 42 of the 60 events). The treatment planning process has been identified as a risk point in several previous institutional studies. The graph depicted was created from data extracted from one such study, found within the article listed below.



Clark, B.G., Brown, R. J., Ploquin, J., & Dunscombe, P. (2013). Patient safety improvements in radiation treatment through 5 years of incident learning. *Practical Radiation Oncology*, 3(3), 157-163. http://dx.doi.org/10.1016/j.prro.2012.08.001

Although, the data are insufficient to draw conclusions about what might drive these errors in treatment planning, a few themes began to emerge as we reviewed submitted cases:

- **Communication.** This is a recurring issue and appears to be a significant driver of error. In one case, cone-beam CTs were not performed due to a misunderstanding about the treatment intent of the physician. In another case, the attending changed the energy of an electron treatment but did not fully communicate this to the technical staff.
- **Changes to plan.** Changing a patient's treatment once under way appears to be a risk-prone process. An example is a block change made by the attending but then not being fully executed by the technical staff.
- **Training and education.** A number of reports centered on slips made involving students/trainees not remedied by staff. Examples include an incorrect eye block on a whole brain case or an incorrect isocenter shift made in treatment planning.

CASE REVIEWS

Case reviews offer an opportunity to learn about patient safety through sharing of actual events. Below are two events reported to the RO-ILS and were identified as opportunities for reflection and learning.

CASE REVIEW 1

- Two patients with similar disease/dose/fractionation were treated out of order and the incorrect plan (i.e. other patient's plan) was treated on the first patient. The pretreatment "time-out" process used to verify correct patient, site and procedure did not prevent this incident. Two other cases this quarter included the incorrect extremity imaged or planned for treatment, but these incidents were identified and corrected before radiotherapy began.
    - These incidents highlight the importance of performing a robust pre-procedure verification and "time-out" process before every simulation and every fraction.
    - According to the ASRT Radiation Therapy Clinical Performance Standards (***http://media.asrt.org/pdf/governance/practicestandards/ps_rt.pdf***): *"The radiation therapist…..performs procedural timeout." and "Documents procedural timeout."*
    - Such incidents share commonalities with wrong site surgery cases
    - The Joint Commission TJC) includes the use of a "time-out" immediately prior to surgeries and "other invasive procedures that expose patients to harm."
    - Every radiotherapy clinic should implement a formal time-out process. TJC Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery is available as a resource at ***http://www.jointcommission.org/standards_information/up.aspx***.

CASE REVIEW 2

- In this case the treatment plan was not executed as intended. The physician intended to treat with a "dose painting" IMRT plan (i.e. delivering a high dose region to one PTV region and, concurrently, a lower dose to another PTV region). This was specified in the prescription notes. During planning, however, the low dose PTV was not included. The entire treatment volume was planned to the same dose. This was discovered during a physics weekly check after 3 fractions were treated.
- This case underscores the importance of good communication and also the value of quality checks such as physics plan and chart review and physician review/plan approval and peer review. It is not clear from the case description provided which of these quality control checks was performed and in what order. We highlight the following standards:
    - For medical physics plan and chart review:
        - ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy (***http://www.acr.org/~/media/ACR/Documents/PGTS/standards/ROPhysicsExtBeamTherapy.pdf***) notes: "The medical physicist must review all dose distributions. The physics review must include a review of the dose prescription and the patient's treatment record to ensure that the graphical dose distribution is consistent with the dose prescription and the treatment record."

- For physician review/plan approval:
  - ACR Practice Guideline for Radiation Oncology - Revised 2009 (*http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/Radiation-Oncology*) note that: "It is essential that all treatment parameters be described in detail and orders be signed by the responsible radiation oncologist."
  - In addition, the 2014 ACR-ASTRO Practice Parameters for Radiation Oncology stipulates that "The prescription, treatment plan and dose calculation must be signed and dated by the radiation oncologist prior to the initiation of radiation therapy." (*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Radiation_Oncology.pdf*)

The case also highlights the central role of computer systems as a communication medium. Though the required information was present in the EMR (i.e. prescription note from the physician), this information was not readily displayed to the person performing planning. Improved interfaces may prevent such miscommunications.

SUGGESTIONS

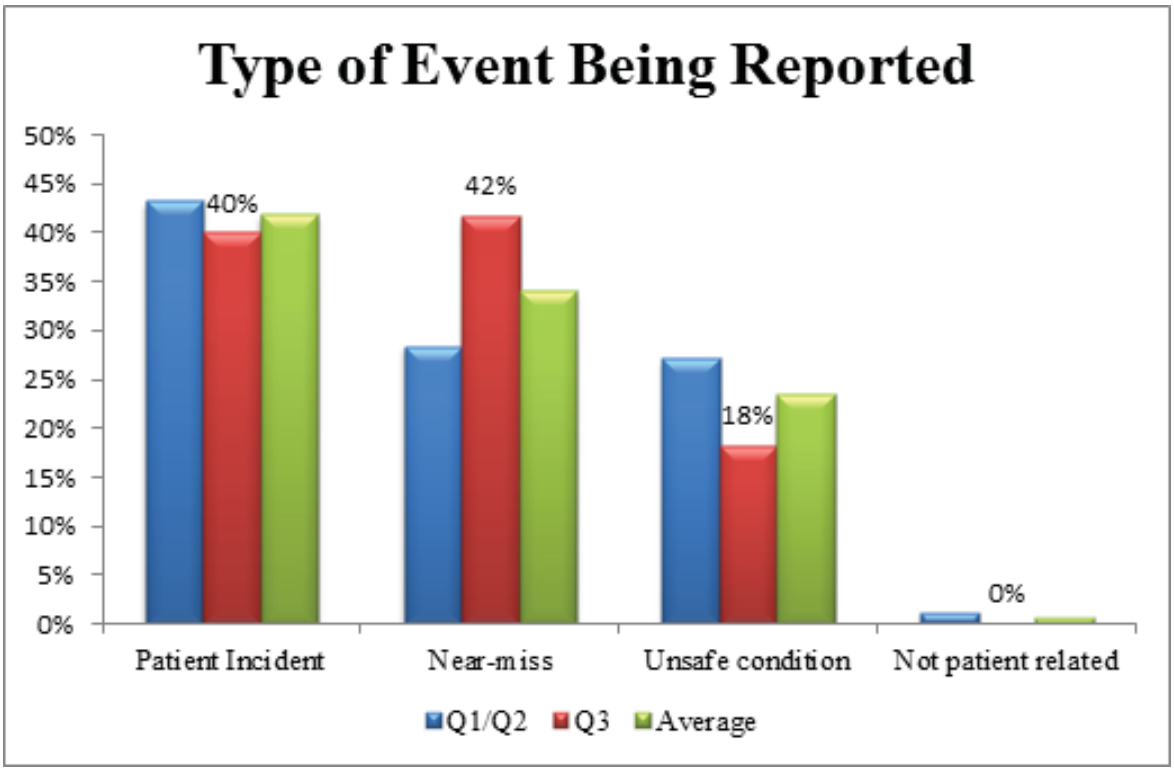
SUGGESTIONS FOR IMPROVING THE USE OF THE RO-ILS SYSTEM

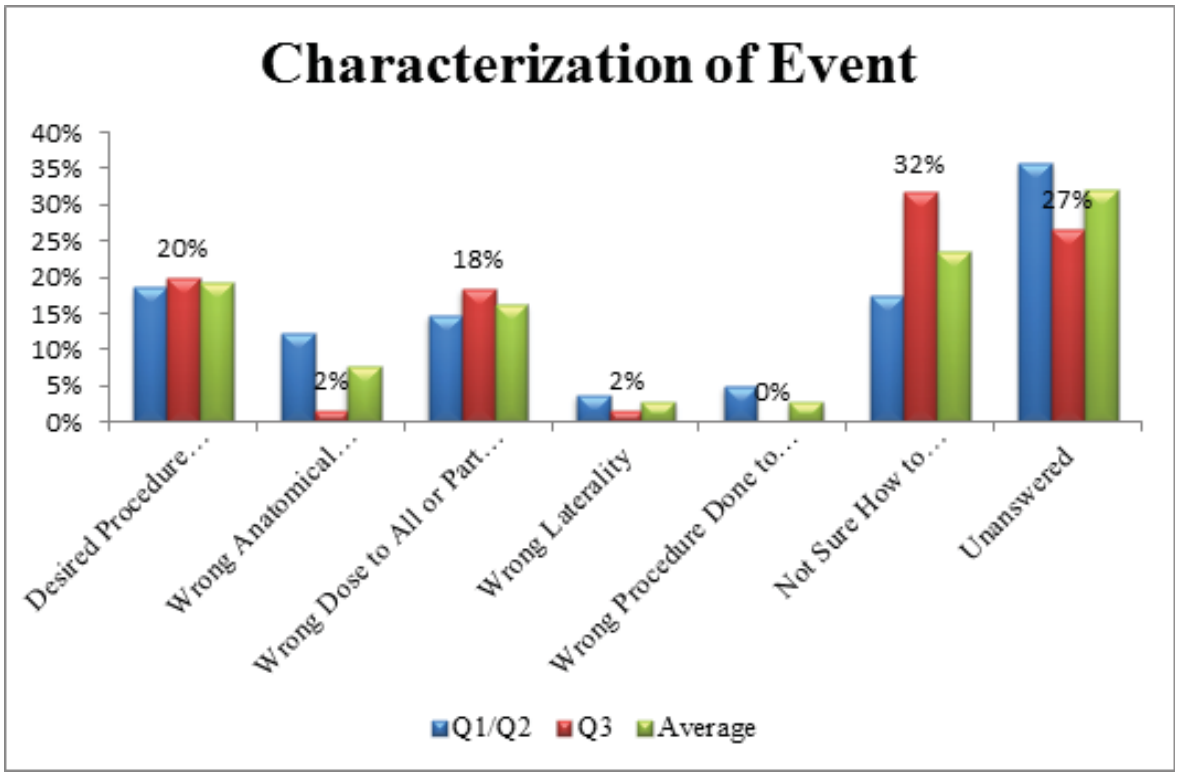
The RO-ILS data from Quarter 3 indicates that there is inconsistency in certain aspects of how the system is used. Above all, more data is needed to enable a thorough and valid analysis of characteristics and trends in this data. Here are some tips and suggestions from the user's perspective:

- Complete as much of the "My Review" section as possible. We note that as of September 2014, this section has been reformatted to facilitate robust data entry and analysis of events. To date, missing data is the biggest shortcoming in the RO-ILS. For example, over half of all reports do not include information on workflow step or event characterization.

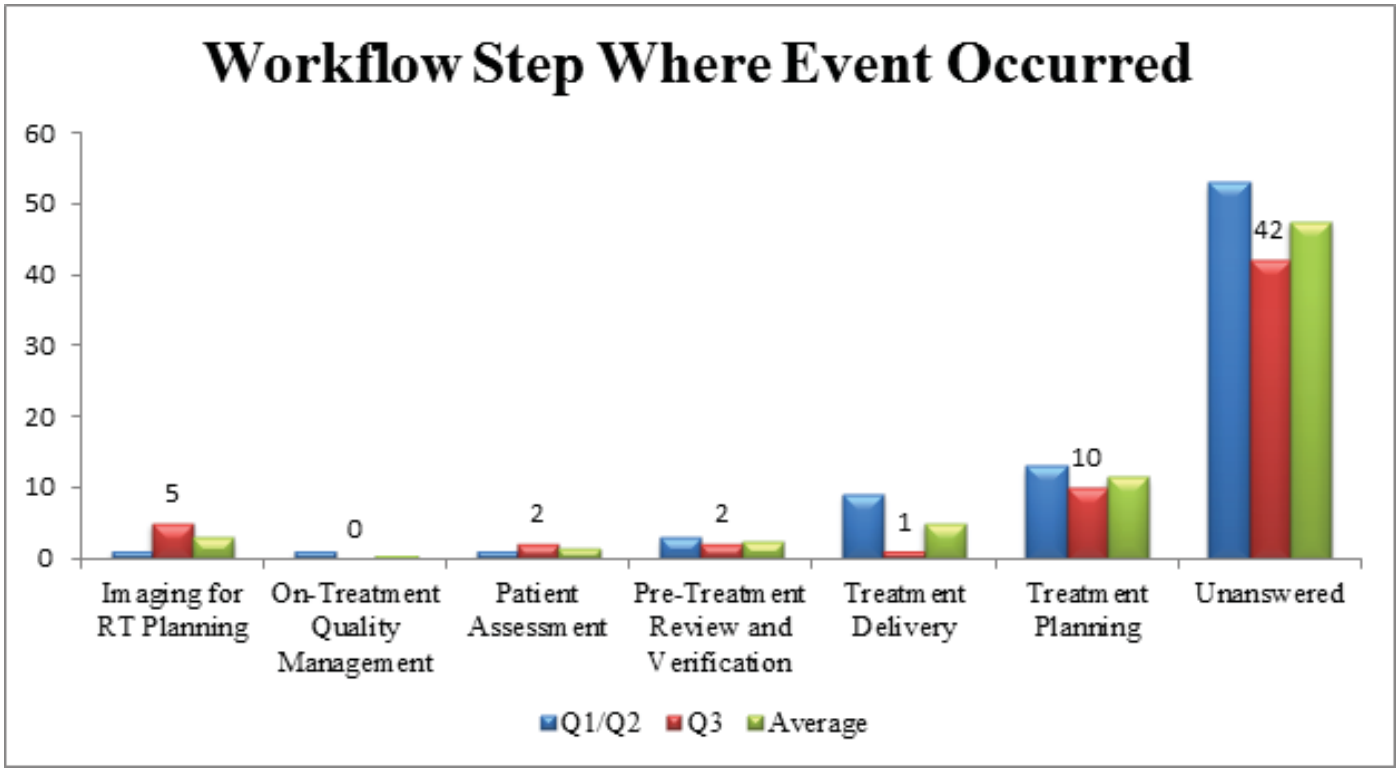
- When reporting incidents which reached the patient it is most useful to identify the ACTUAL dose deviation in the report instead of the POTENTIAL dose deviation which might have occurred had the error not been identified.

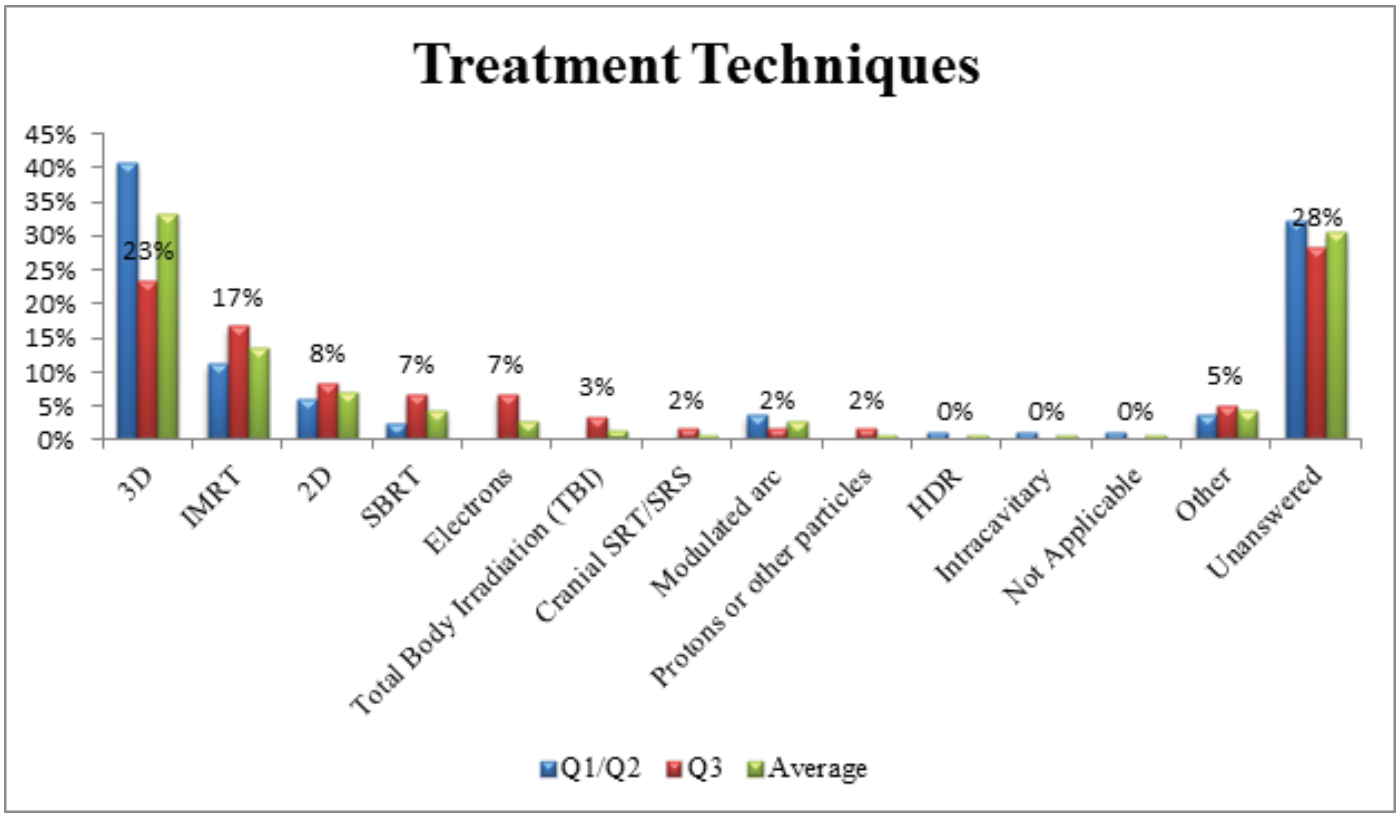
AGGREGATE ANALYSIS GRAPHS





AGGREGATE ANALYSIS GRAPHS | Continued





AGGREGATE ANALYSIS GRAPHS | Continued