RO-ILS
RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

RO-ILS
noun \ˈrōi(-ə)ls\ Radiation Oncology Incident Learning System; a system to facilitate safer and higher quality care in radiation oncology at no cost to providers or facilities; the only medical specialty society-sponsored radiation oncology incident learning system.

2016
YEAR IN REVIEW
INTRODUCTION

The American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) launched RO-ILS: Radiation Oncology Incident Learning System®, a national patient safety initiative on June 19, 2014.

RO-ILS is a key pillar of ASTRO’s Target Safely campaign, a comprehensive plan to improve safety and quality for radiation oncology. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment.

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) authorizes the creation of Patient Safety Organizations (PSOs) to address the needs identified in the 1999 Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System.* Findings within the IOM’s report highlighted the national need to capture information that would help improve quality and reduce harm to patients.

The Agency for Healthcare Research and Quality (AHRQ) oversees the activities and compliance of federally qualified PSOs. As outlined in the PSQIA, PSOs:

- Share the goal of improving the quality and safety of health care delivery;
- Collect and analyze data to identify and reduce the risks and hazards associated with patient care; and
- Create a secure, non-punitive environment through confidentiality and privilege protections.

ASTRO contracted with Clarity PSO, one of the first federally-listed PSOs, to build the online interface and provide the affiliated patient safety services outlined in the PSQIA. Clarity PSO is a division of Clarity Group Inc., a health care professional liability risk management organization that provides services to a variety of hospitals and specialties. Clarity PSO and Clarity Group Inc., are independent of ASTRO; these entities provide PSO services and the reporting tool to the radiation oncology practices enrolled in RO-ILS.

“Our field can use RO-ILS to learn from our collective practices, where the combined experiences and insights can be pooled and studied, increasing knowledge that we can all apply to improve patient care.”

—Lawrence Marks, MD, FASTRO, University of North Carolina at Chapel Hill
There is no charge for participation, however, interested practices must sign a contract, which can cover multiple facilities, with Clarity PSO to receive the protections outlined in the PSQIA. Over the past two years, 103 practices have executed contracts covering 209 facilities (See Figure 1). On average eight new facilities begin participating in RO-ILS each month. Seventy-nine percent of participating practices are comprised of either one or two facilities. An additional 38 contracts covering 74 facilities are in the process of executing contracts.

FIGURE 1: Cumulative Number of Participating Practices and Facilities

Each year, the RO-ILS Year in Review report is published to reflect on growth, lessons learned and new opportunities. This 2016 Year in Review covers the June 2015 to May 2016 period, herein simply referred to as “2016” in all figures.

As depicted in Figure 2, there was a large increase in the number of private practice or community-based institutions executing contracts since last June (depicted as a green bar).
Additionally, practice setting distribution is calculated according to the number of facilities (See Figure 3). Since last year, there has been a 12 percent increase in the number of participating facilities self-declared as private practice or community-based. In contrast, the percentage of academic/university setting facilities has decreased from 36 to 31 percent and hospital-based facilities has decreased from 17 to 10 percent. The median time to complete contracting for private practices/community-based was two months, where the median time to complete contracting for academic/university practices was five months. This suggests that the contracting process is less streamlined in academic/university settings, leading to a slow rate of adoption in these settings.
RO-ILS participation is widespread and encompasses a majority of the country (See Figure 4). The solid green represents states that have one or more practices currently participating in RO-ILS. Since the 2015 Year in Review report was published, practices in New Mexico, Nebraska, Louisiana and Vermont began participating. The green circles represent states that have practices with pending contracts.

**FIGURE 4: Geographic Distribution of RO-ILS Participants**

“The UCLA Department of Radiation Oncology had an established culture of safety and a long-standing paper-based incident reporting system. … The limitations of a paper-based system… prompted us to consider transitioning to an electronic reporting system, and RO-ILS was an excellent solution.”

— Philip Beron, MD, University of California Los Angeles
DATA

Data analysis is completed by Clarity PSO and the Radiation Oncology Healthcare Advisory Council (RO-HAC), a group of radiation oncology professionals who provide subject-matter expertise on data interpretation, reporting and suggest possible interventions. RO-HAC members include radiation oncologists, physicists, dosimetrists and other patient safety experts. Members of RO-HAC must sign a contract with Clarity PSO to assure confidentiality before accessing data.

Since the origin of RO-ILS, a total of 1,750 events have been submitted to the PSO (See Figure 5). An average of 102 events were reported each month for the 2015-2016 reporting period. The number of reported events more than doubled (2.7 fold increase) this year compared to the 1.8 fold increase in participating facilities, demonstrating high engagement of enrolled RO-ILS participants.

FIGURE 5: Cumulative Number of Events Reported to Clarity PSO
During initial reporting, the provider must classify the event. As noted in Figure 6, more “Incidents that reached the patient with or without harm” (36.3 percent) were entered compared to “near misses” (33.8 percent) and “unsafe conditions” (29.8 percent). In comparison to the 2015 report, there were slightly fewer incidents that reached the patient (a 4 percent drop) and more near misses (a 4 percent increase) reported this year. We hypothesize that this shift may be the result of RO-ILS educational efforts and added awareness which allowed more safety events to be caught before reaching the patient. RO-HAC analysis thus far indicates that the vast majority of the incidents are of minor or no clinical consequence.

The reporter must also identify the event type (See Figure 7). The vast majority of events continue to involve external beam. Issues categorized as “Other” are typically administrative problems (i.e., scheduling, check-in) or process-related (i.e., chart documentation, communication, etc.). As part of the follow-up analysis, users are asked to identify all of the treatment technique(s) related to the event (See Figure 8). Of the over 850 external beam events for which this question was answered, most events (42 percent) were related to 3-D radiotherapy, followed by intensity-modulated radiation therapy (IMRT) (16 percent) and protons/particles (12 percent). The high percentage of 3-D events compared to IMRT is surprising considering the complexity of IMRT. The added IMRT quality assurance (QA) procedures may be a factor in reducing errors with this treatment modality.
An optional question asks the user to identify whether the event occurred for other patients (See Figure 9). Of the overall answered events, in the majority of cases (70 percent), the event affected only one individual.

**FIGURE 9: Did this Event or Condition Occur for Other Patients?**
As depicted in Figure 10, radiation therapists continue to discover the majority of events. Of the answered responses, 76 percent of events were discovered by either a radiation therapist or physicist.

**FIGURE 10: Who Discovered the Event?**

A large percentage of users did not answer these two optional questions. As you will read below, we are revising the data elements to reduce the burden of data entry and thereby hope to have more complete, structured data to inform our safety activities.

“To really take safety seriously requires more than vigilance, it requires us to be proactive. RO-ILS not only gives us the ability to track our own deficiencies but also to learn from hundreds of other departments, with the hope that we can identify future problems before they become errors.”

— Jay Burmeister, PhD, Karmanos Cancer Center
Quarterly Reports
In total, RO-HAC has issued six quarterly aggregate reports based on extracted data, analyzed trends and themes and present case studies. All aggregate reports can be found on the RO-ILS website. Common themes found throughout the reports are listed below.

Positive Findings:
- **QA Processes.** Overall, the reports have found that many quality assurance processes already in place are effective in catching near misses.
- **Review of plans.** The review of plans by physicians, physicists and therapists plays a key role in preventing errors from impacting patients.

Areas for Improvement:
- **Communication.** Various forms of communication including hand-offs, verbal requests and incorrect manual data entry are a recurring issue and appear to be a significant driver of error.
- **Training and education.** A number of reports centered on missteps made involving students/trainees not remedied by staff.
- **Policies and procedures.** Events are related to failure to follow these guidelines, rather than the lack of appropriate policies or procedures. This reality suggests a need for further emphasis on staff training with a review of policies and competencies.
- **Incorrect isocenter.** Events with incorrect isocenter are largely near-miss events (identified prior to treatment). They reveal an error pathway that can cause serious harm to patients.
- **Inaccurate, incorrect or incomplete treatment prescription.** This is a common error pathway that occurs in many forms, such as a miscommunication from the physician to the planner or the failure to execute a plan as intended. ASTRO’s upcoming White Paper on Standardizing Dose Prescriptions will create a consistent format and thereby reduce the likelihood of some prescription errors.
- **Contouring.** Both accuracy of contouring (targets in particular), and correct and clear naming of structures in the planning process are important issues.

Risk-prone Processes:
- **Changes to plan.** Any deviation from the originally intended course of treatment increases the risk of error and requires heightened awareness. Examples of deviations include re-plans, change in radiation prescription or finishing a course of therapy early.
- **Rushing processes.** Emergent or “rushed” treatment is a clearly documented factor of many incidents. There is a large body of literature supporting the increased risk that accompanies a compressed timeline for treatment.

Data Elements
In mid-2015, we began reviewing the data elements to promote reliable and complete data collection necessary to accurately inform the radiation oncology community about patient safety.

The proposed changes to the data elements were based on user experience, expert opinion and two inter-rater reliability (IRR) studies. In July 2015, 66 RO-ILS participants completed a user survey in which they were asked if each data element was clear, the answer options adequate and information helpful for internal analysis. Results from the first IRR study on the
current data elements acted as a basis from which to benchmark the proposed new data elements. After multiple rounds of review by ASTRO committees, the RO-ILS Steering Group and the RO-HAC, the revised data elements were agreed to and finalized. The revised data elements will be introduced into the RO-ILS portal this summer.

Based on the above analysis and study, the changes to the RO-ILS data elements include:
• Removal of inconsistent and non-critical data elements, resulting in fewer overall questions.
• Development of new sophisticated branching logic to display only relevant questions and reduce the total number of questions, especially for events that did not reach the patient.
• Requiring that certain targeted questions be answered by the user in order to facilitate thorough and complete analysis.
• Additional clarification on answer options.

Appendix A provides a list of the significantly revised and new data elements along with the rationale for the changes.

The full list of new data elements and associated educational material will be shared with participants prior to the new elements going live. When the data elements are live, the RO-ILS Participation Guide with the new data elements will be posted on the RO-ILS webpage. We anticipate these new changes will result in more complete data collection and in turn support more rigorous analysis and trending.

**PROGRAM**

**Education**
In addition to the Quarterly Reports, participants receive regular education and support such as webinars run by Clarity PSO. Participants also receive bi-annual practice-specific reports. Lastly, in May 2015, RO-ILS began sending its participants regular “Tips of the Month” (See Table 1). These tips highlight and explain the protections and benefits afforded by the PSQIA, user experience and innovation and other safety culture topics.

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**PQI Template**

RO-ILS also includes a Practice Quality Improvement (PQI) template as a free companion to the portal. The RO-ILS PQI template is qualified for physicians and physicists by the American Board of Radiology (ABR) in meeting the criteria for practice quality improvement, toward the purpose of fulfilling requirements in the ABR Maintenance of Certification Program. One hundred thirty-two individuals downloaded the RO-ILS PQI template since last June. As a PQI project, radiation oncology practices participating in RO-ILS will complete two consecutive cycles of the four-part Plan-Do-Study-Act (PDSA) process for quality improvement using the RO-ILS online portal to submit and internally track events.

**MACRA**

On May 9, 2016, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule for the Quality Payment Program as described in the Medicare and CHIP Reauthorization Act (MACRA) of 2015. The proposed rule includes specific criteria for the establishment of the Merit-based Incentive Payment System (MIPS) for eligible clinicians or groups under the Physician Fee Schedule. Annual MIPS payment adjustments will be determined by performance in four categories: quality, advancing care information, clinical practice improvement activities (CPIA) and cost. Participation in an AHRQ listed PSO is one of the proposed options for the CPIA category. It is ASTRO’s opinion that RO-ILS participation will satisfy this activity and contribute to a provider’s CPIA score. A full summary of the proposed rule can be found on the ASTRO website. ASTRO is pleased to offer this safety and quality improvement program that will now meet quality requirements and positively impact Medicare payment.

**Support**

ASTRO is committed to providing this exceptional program to the radiation oncology community free of charge. To support the financial burden, we are seeking support from the vendor community and related associations. Please contact ASTRO’s corporate relations department (corporaterelations@astro.org) to discuss industry support opportunities. Associations can contact RO-ILS (roils@astro.org) to learn more about how to get involved.

“Using RO-ILS in addition to our internal incident reporting system adds value; by pooling incident reports from many clinics we will finally have meaningful statistics to help guide our error prevention efforts.”

— Sonja Dieterich, PhD, UC Davis Cancer Center
SUMMARY

RO-ILS participation almost doubled this year to include an even wider geographic area and variety of practice settings representing the diversity of radiation therapy providers. The specialty-specific data gathered via the RO-ILS portal and analyzed by the RO-HAC has provided valuable data to inform the safe delivery of radiation therapy. RO-ILS will continue leveraging lessons learned from the initial year to ensure ongoing quality improvement and patient safety in radiation oncology. In its second year, RO-ILS provided new, expanded benefits to RO-ILS participants and facilitated the sharing of critical information with the broader radiation oncology community via detailed quarterly reports. Significant effort and thought went into revising the current data elements to promote more reliable data collection, and we are optimistic that RO-ILS will grow even stronger in 2017! For more information on RO-ILS visit www.astro.org/roils.

The mission of RO-ILS® is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment.
To improve analysis and help triage events, incidents are now separated into two categories, Therapeutic vs. Other (non-radiation). An additional "Process Improvement" category was added for institutions utilizing RO-ILS for multiple purposes.

**Event Classification:**
- Therapeutic Radiation Incident: Radiation dose delivered not as intended, with or without harm
- Other Safety Incident: Event that reached the patient, not involving radiation dose, with or without harm (examples: collision, fall, etc.)
- Near-miss: A safety event that did not reach the patient
- Unsafe condition: Any condition that increases the probability of a safety event
- Operational/Process Improvement: non-safety event

For the two workflow related questions, the answer options were revised to be more in line with common radiation therapy terms, specify steps in the process and include examples. Additionally, a new answer option of "Outside the RT Workflow or Other" allows for more flexibility.

*In what workflow step was the event first discovered?*
- Before Simulation
- Pre-planning Imaging and Simulation
- Treatment Planning
- Pre-treatment QA Review (e.g., Physics Plan Check)
- Treatment Delivery including imaging (e.g., at the machine)
- On-treatment QA (e.g., weekly check, physician OTV)
- After Treatment Course is Finished
- Equipment and Software QA
- Outside the Radiation Therapy Workflow or Other

*In what workflow step(s) did the event occur? (Select all that apply)*
- Before Simulation
- Pre-planning Imaging and Simulation
- Treatment Planning
- Pre-treatment QA Review (e.g., Physics Plan Check)
- Treatment Delivery including imaging (e.g., at the machine)
- On-treatment QA (e.g., weekly check, physician OTV)
- After Treatment Course is Finished
- Equipment and Software QA
- Outside the Radiation Therapy Workflow or Other

This question was revised to specify the target and organs at risk (OAR(s)). Additionally, this question will now only apply for events classified as "Therapeutic Radiation Incidents" related to one patient.

What was the dose deviation for the course of treatment between the planned total prescription and the delivered dose? (Select all that apply)
- ≤5% maximum dose deviation to target
- >5% but ≤25% maximum dose deviation to target
- >25% but ≤100% maximum dose deviation to target
- >100% maximum dose deviation to target
- OAR(s) received more than intended but within tolerance levels
- OAR(s) received more than intended and exceeded tolerance levels

The current list of contributing factors was not specific enough to benefit analysis efforts therefore, answer options were modified to better reflect clinical practice.

**Contributing factors: (Select all that apply)**
[Significantly refined answer options]
Table 3: New Data Elements

If an event has been or will be reported outside of RO-ILS and the institution, the following question will appear. This new data element will be extremely helpful for identifying and triaging events which meet a higher threshold for external reporting.

*To whom was the event reported? (Select all that apply)

- FDA
- NRC
- State
- Vendor/Manufacturer
- Other

This new question identifies if equipment was involved in the event. If the user selects “Yes” to this question, they will receive the six follow-up questions asking for equipment information.

*Was this event equipment related?

- Yes
- No

The inter-rater reliability study found that the questions asking about specific patient harm were not particularly reliable, therefore this new question will help with event triage and gauge event impact.

*In terms of risk to patient safety, how significant was this event?

- Mild
- Moderate
- Severe

This new question allows users to brainstorm what could be done differently to prevent similar events. These suggestions will support the development of quarterly reports and will be shared with the radiation oncology community when appropriate.

What might prevent future events like this?

[Free Response]

This was added to provide users space to collect any internal information relevant to the event, such as #hashtags described in the December 2015 Tip of the Month.

You may use this space for your internal use (i.e., internal tags)

[Free Response]
ABOUT ASTRO
American Society for Radiation Oncology (ASTRO) is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy.

ABOUT AAPM
The American Association of Physicists in Medicine (AAPM) represents 8,000 medical physicists who assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. This is accomplished through their efforts in providing clinical services and consultation, research and development, and teaching. Medical physicists' role in radiation oncology is to assure that the equipment is calibrated and operating correctly and that the patient receives safe and effective treatment as prescribed by the radiation oncologists.