2017
YEAR IN REVIEW

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noun /ˈróils/
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.
The American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) launched RO-ILS, a national patient safety initiative on June 19, 2014. RO-ILS is a key milestone in the ASTRO 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 need to capture information nationally 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 initial organizations to be federally-listed as a PSO, 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., which are independent of ASTRO, are entities that provide PSO services and the reporting tool to the radiation oncology practices enrolled in RO-ILS.

EXECUTIVE SUMMARY

- RO-ILS: Radiation Oncology Incident Learning System® continues to steadily grow to cover almost all states.
- RO-ILS facilities include a variety of practice settings representing the diversity of radiation oncology 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 program to ensure ongoing quality improvement and patient safety in radiation oncology.
- In its third year, RO-ILS provided new, expanded benefits such as CME and an accompanying slide deck to quarterly reports in an effort to promote discussion and dissemination within departments.
- The program continues to facilitate the sharing of critical information with the broader radiation oncology community via detailed quarterly reports.
- We have started to see the positive results from revising the data elements and, we are optimistic that RO-ILS will grow even stronger in 2018!

BACKGROUND

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

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PARTICIPATION

Although there is no charge for participation, interested practices must sign a contract with Clarity PSO to receive the protections outlined in the PSQIA. These contracts can cover multiple facilities, depending on practice structure. Over the past three years, 139 practices have executed contracts covering 336 facilities (Figure 1).

Figure 1: Cumulative Number of Contracted Practices and Facilities

“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
Seventy percent of participating practices are comprised of either one or two facilities (Figure 2). On average eight new facilities contract with Clarity PSO each month. An additional 33 contracts covering 68 facilities are currently in the process of executing contracts.

![Figure 2: Contracted Practice Size](image)

Each year, the RO-ILS Year in Review report is published to reflect on growth, lessons learned and new opportunities. This 2017 Year in Review reflects the June 2016 to May 2017 program period, herein simply referred to as “2017” in all figures.

As depicted in Figure 3, private practice/community-based practices compose the majority of executed contracts. There has been a six percent overall increase in the number of participating practices self-declared as private practice or community-based in 2017.

![Figure 3: Practice Setting Distribution by Contract Status at the Practice Level](image)
Contracted RO-ILS practices are spread across almost the entire country (Figure 4). The blue color represents states which have one or more facility currently contracted with RO-ILS. Since the 2016 Year in Review report was published, facilities in Utah, Alaska, Minnesota, Iowa, Kentucky, Mississippi, South Carolina, West Virginia joined RO-ILS. The yellow color represents locations containing only facilities with pending contracts.

Figure 4: Geographic Distribution of RO-ILS Facilities

“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 membership includes radiation oncologists, physicists, dosimetrists, therapists and other patient safety experts. Members of RO-HAC receive an honorarium for their efforts and must sign a contract with Clarity PSO to assure confidentiality before accessing data.

After over a year of careful review and analysis, the RO-ILS data elements were updated in the portal on August 29, 2016. The changes include fewer overall questions, sophisticated branching logic to display only relevant questions and clarification of answer options. The goal of this revision was to promote reliable and complete data collection necessary to accurately inform the radiation oncology community about patient safety while reducing the reporting burden. These modifications were based on participant survey results, RO-HAC input and a comprehensive interrater reliability study. To enable continuous data analysis over time, Clarity PSO mapped old data from the previous questions and answers to the new data elements (labeled as “Prior to Data Element Change” in the graphs). In the long run, we anticipate these new changes will result in more complete data collection and in turn support more rigorous analysis and trending.

Since the origin of RO-ILS, more than 3,330 events have been submitted to the PSO (Figure 5). An average of 122 events were reported each month for the 2016-2017 reporting period, an 11 percent increase in monthly reporting from the 2016 Year in Review. In 2017, RO-HAC grew from eight to twelve members to accommodate additional data analysis on a rapidly growing body of data.

Figure 5: Cumulative Number of Events Reported to Clarity PSO
During initial reporting on the “Submit Event” page, the provider must classify the event. The original data elements had only three options: incident, near-miss, and unsafe condition. To improve analysis and help RO-HAC triage events, incidents that reached the patient are now separated into two categories, “therapeutic” and “other” (i.e., non-radiation) and an additional “operational/process improvement” category was added for institutions utilizing RO-ILS for multiple purposes. As noted in Figure 6, most of the events in the entire RO-ILS database are “near misses” (29.2 percent) followed by “therapeutic radiation incidents” (25.8 percent). Prior to the data element change, the event classification was generally equally distributed among the three answer options. Since the new data elements were implemented, the most common classification is “operational/process improvement” (33 percent).

Figure 6: Cumulative Event Classification
The reporter must also identify all the applicable treatment technique(s). Prior to the data element change, this question was not required and was included in the secondary, "My Review" section of the portal. Figure 7 represents the treatment technique distribution for the 1,151 events since the data elements were changed. This data element is now required and asked on the primary "Submit Event" section of the portal. Almost half of these events were classified as 3-D, IMRT or VMAT. The majority of events continue to involve external beam. Events categorized as “Other” are typically related to simulation, imaging or administrative problems (i.e., scheduling, check-in).

**Figure 7: Treatment Technique**

- **Not Applicable:** 150 events, 13%
- **kV x-rays (i.e. Orthovoltage and superficial):** 18 events, 2%
- **LDR:** 8 events, 1%
- **HDR:** 20 events, 2%
- **Particles (Protons):** 98 events, 8%
- **Electrons:** 83 events, 7%
- **SRS/SBRT:** 91 events, 8%
- **2-D:** 43 events, 4%
- **3-D:** 316 events, 27%
- **IMRT/VMAT:** 246 events, 21%
- **Not Applicable:** 75 events, 7%

**Figure 7** represents the treatment technique distribution for the 1,151 events since the data elements were changed. This data element is now required and asked on the primary "Submit Event" section of the portal. Almost half of these events were classified as 3-D, IMRT or VMAT. The majority of events continue to involve external beam. Events categorized as “Other” are typically related to simulation, imaging or administrative problems (i.e., scheduling, check-in).
An optional question asks the user to identify whether the event occurred to multiple patients (Figure 8). Previously this question was visible for all events, and was therefore only answered for 47 percent of events. After the data element change, this question is now branched and visible only for those events classified as “therapeutic incidents” or “other safety incidents”. These events have been determined by RO-HAC as the most critical events. Events classified as near-misses or another classification are depicted as “Not Applicable” in the graph. Under the new question structure, this optional question is now answered for 89 percent of applicable events. This indicates that the advanced branching logic has both reduced the reporting burden on the provider and increased data completeness. The majority of incidents (95 percent) reported to the PSO with the new data elements were not a systematic error that affected multiple patients.
As depicted in Figure 9, radiation therapists continue to discover the majority of events. The answered percentage for this optional question increased from 46 to 84 percent with the new data elements even though no significant alterations or branching was applied to this particular question. Overall, 76 percent of events were discovered by either a radiation therapist or physicist.

Figure 9: Cumulative Event Discoverer

Prior to Data Element Change | After Data Element Change

Unanswered: 1407
Radiation Therapist: 991
Physician: 494
Dosimetrist: 171
Other: 139
Physician: 50
Nurse, NP or PA: 37
Administrator: 4
Patient or Patient Representative: 0

“[RO-ILS] helped us by creating a structured way of reporting, analyzing and improving our clinical safety and workflow. It does so by allowing people report any deviation from the normal clinical workflow, whether real or perceived, without any fear of retribution or a negative effect. Having reports also allows us to give a concrete feedback to our employees about the issues reported and how we are addressing them.”

— Tim Nurushev, PhD, DABR, 21st Century Oncology
Quarterly Reports
In total, RO-HAC has issued ten aggregate quarterly reports. All aggregate reports can be found on the RO-ILS website.

Over the past year, RO-HAC identified a clustering of incidents related to miscommunication of the radiation prescription among radiation oncology professionals, especially from the physician to the dosimetrist. This has led to some errors classified as high severity by RO-HAC, many of which reached the patient. Recognizing that the accurate, timely, unambiguous communication of the radiation prescription is a critical part of the radiation planning and delivery process, ASTRO published a white paper to address the issue. “Standardizing dose prescriptions: An ASTRO white paper” (Evans et al., 2016) provides the rationale for standardizing prescriptions, challenges to standardization and the key elements needed for the radiation oncology prescription. To avoid this common error pathway, ASTRO recommends implementing the standard prescription format (Figure 10).

Figure 10: Standard Prescription White Paper Key Elements
Key elements and their order specified

<table>
<thead>
<tr>
<th>Treatment Site</th>
<th>Delivery Method</th>
<th>Dose per Fraction</th>
<th>Fraction Number</th>
<th>Total Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formalism pending, some guidance per AAPM Task Group 263</td>
<td>Some formalism presently (If brachytherapy, isotope type should be specified. If external beam, photos, electrons, etc., should be specified at a minimum. Additional information such as energy, technique, etc. may be desirable.)</td>
<td>centiGray (cGy)</td>
<td>Total number of fractions</td>
<td>centiGray (cGy)</td>
</tr>
</tbody>
</table>

The contributing factor of miscommunication is very common in the RO-ILS database and also plays a role when changes are made to the intended treatment, but not appropriately documented in the medical record or communicated downstream to necessary personnel. Standard operating procedures (SOPs) develop consistent protocol and agreed upon expectations for staff, thereby reducing unnecessary variation that can be harmful for patient safety. A frequent action and recommendation in the Quarterly Reports is to develop, update, review, or ensure compliance with a SOP.

In addition to finding trends and making recommendations, RO-ILS is dedicated to promoting quality improvement and safety culture at each facility. The Quarter 4 2016 report provides detailed guidance for implementing effective change within a clinic, including:

- Assuring you have support from administration.
- Clearly defining the problem and change to be made.
- Communicating the change to all staff.
- Involving a range of team members in implementing the change.
- Creating a group and empower champions to lead change.
- Implementing the change using a logical order and defined timelines.
- Reworking your solution (i.e. expect difficulties and resistance).
- Evaluating how effective your change has been.
- Celebrating your success and let staff see and feel real improvement.

Incident learning is not simply collecting and analyzing data but utilizing the information as a catalyst and facilitator behind real change at each facility.
CME
Physicians can now earn continuing medical education (CME) for the RO-ILS Quarterly Reports. The Quarter 3 2016 Report was the first Quarterly Report for which CME is available, and we anticipate providing this new education opportunity for future reports. ASTRO is accredited by the Accreditation Council of Continuing Medical Education (ACCME) to provide CME for physicians and designates this enduring activity for a maximum of 2 AMA PRA Category 1 Credit™. After reading the report, physicians need to pass a five-question assessment and complete the course evaluation. We are exploring expanding continuing education to other members of the treatment team, such as CAMPEP for medical physicists.

PQI Template
RO-ILS 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. 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.

Participant Education
In addition to the aggregate Quarterly Reports, participants receive regular education and support via tools such as webinars run by Clarity PSO and “Tips of the Month”. The “Tips of the Month” (Figure 11) highlight and explain portal features, new RO-ILS benefits, and other safety culture topics. RO-ILS participants have the opportunity to anonymously share knowledge, personal experience and innovation by guest authoring a “Tip of the Month”.

Figure 11: 2016-2017 Tips of the Month

<table>
<thead>
<tr>
<th>Month</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2016</td>
<td>Reporting Unsafe Conditions</td>
</tr>
<tr>
<td>July 2016</td>
<td>New Data Elements</td>
</tr>
<tr>
<td>August 2016</td>
<td>HHS Guidance on Patient Safety Work Product</td>
</tr>
<tr>
<td>September 2016</td>
<td>Document Upload Within the Portal</td>
</tr>
<tr>
<td>October 2016</td>
<td>Standard Prescription White Paper</td>
</tr>
<tr>
<td>November 2016</td>
<td>Debriefing After a Safety Event</td>
</tr>
<tr>
<td>December 2016</td>
<td>Contributing Factors</td>
</tr>
<tr>
<td>January 2017</td>
<td>MIPS Improvement Activity</td>
</tr>
<tr>
<td>February 2017</td>
<td>Report All Safety Events to the PSO</td>
</tr>
<tr>
<td>March 2017</td>
<td>CME Credit Available for Quarterly Reports</td>
</tr>
<tr>
<td>April 2017</td>
<td>Portal Bookmarking and Desktop Shortcuts</td>
</tr>
<tr>
<td>May 2017</td>
<td>Save Between “Reviewer” Tabs</td>
</tr>
</tbody>
</table>
Beginning with the Q3 2016 Report, an accompanying PowerPoint is available to RO-ILS participants for each quarterly report in an effort to promote discussion and dissemination within departments. Participants also receive bi-annual practice-specific reports that include a report card comparing the provider and aggregated historical sums based on RO-ILS data elements as portrayed by the example in Figure 12.

**Figure 12: Sample Practice-specific Report Card**

<table>
<thead>
<tr>
<th>METRIC</th>
<th>PROVIDER HISTORICAL SUM</th>
<th>AGGREGATE HISTORICAL SUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Events</td>
<td>150</td>
<td>2681</td>
</tr>
<tr>
<td>Therapeutic Radiation Incidents</td>
<td>39</td>
<td>733</td>
</tr>
<tr>
<td>Other Safety Incidents</td>
<td>7</td>
<td>167</td>
</tr>
<tr>
<td>Near Miss</td>
<td>89</td>
<td>836</td>
</tr>
<tr>
<td>Unsafe Conditions</td>
<td>12</td>
<td>744</td>
</tr>
<tr>
<td>Operational/Process Improvement</td>
<td>3</td>
<td>201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Most Commonly Identified Workflow Step Where Event Occurred</th>
<th>Treatment Delivery Including Imaging: 47% (71/150)</th>
<th>Treatment Planning: 28% (756/2681)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most Commonly Identified Workflow Step Where Event was Discovered</td>
<td>On-Treatment QA: 32% (48/150)</td>
<td>Treatment Delivery Including Imaging: 26% (709/2681)</td>
</tr>
<tr>
<td>Most Commonly Identified Treatment Technique</td>
<td>3-D: 41% (61/150)</td>
<td>3-D: 21% (565/2681)</td>
</tr>
<tr>
<td>Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents/Other Safety Incidents that Did Not Effect Multiple Patients</td>
<td>≤5% Maximum Dose Deviation to Target: 87% (34/39)</td>
<td>≤5% Maximum Dose Deviation to Target: 69% (352/512)</td>
</tr>
</tbody>
</table>
MIPS
On November 4, 2016, the Centers for Medicare and Medicaid Services (CMS) published the final rule for the Quality Payment Program as described in the Medicare and CHIP Reauthorization Act (MACRA) of 2015. The final 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. During the transition year, 2019 MIPS payment adjustments will be determined by performance during 2017 in three performance categories: Quality, Advancing Care Information and Improvement Activities (IA). The Improvement Activities performance category is worth 15 percent of the overall composite performance score. Additionally, all activities must be completed for a minimum of 90 consecutive days.

“Participation in an AHRQ listed PSO” is one of the approved improvement activities. While only attestation of activity completion is necessary for 2017 reporting, appropriate documentation is recommended in the event of an audit. For this particular activity, CMS suggests “documentation from an AHRQ-listed patient safety organization (PSO) confirming the eligible clinician or group’s participation with the PSO.” Therefore, upon request, Clarity PSO will send a Letter of Participation stating participation in RO-ILS during the reporting period. Please email radoncsupport@claritygrp.com to request a RO-ILS Letter of Participation. Letters will be sent in early 2018 to coincide with reporting deadlines.

Additionally, a second improvement activity could be met with the RO-ILS PQI template. “Participation in MOC Part IV” is described as, “Improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.” CMS suggested documentation includes “1) Participation in Maintenance of Certification from ABMS Member Board - Documentation of participation in MOC Part IV from an ABMS member board including participation in a local, regional or national outcomes registry or quality assessment program; and 2) Monthly Activities to Assess Performance - Documented performance of monthly activities across practice to assess performance in practice by reviewing outcomes, addressing areas of improvement, and evaluating the results.”

During the 2017 transition year, reporting one improvement activity is sufficient to avoid a negative 4 percent payment adjustment in 2019. ASTRO is pleased to offer this safety and quality improvement program that will now meet quality requirements and positively impact Medicare payment. Find more details about the MIPS program on the ASTRO website and send any MIPS questions to mips@astro.org.

“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
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.
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.

www.astro.org/ROILS