Going from an interdepartmental Incident Reporting System to the National Radiation Oncology Incident Learning System (ROILS): Initial Planned Transition

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Overview:

- Background
  - 2010
  - Checklist
  - SBAR
  - Colored Reports
- Why Roils?
  - Culture
  - Learning
  - Safety in Numbers
- Examples
- Conclusions

https://www.astro.org/Clinical-Practice/Patient-Safety/ROILS/Index.aspx
Background:

- 2010 AAPM/ASTRO Safety in Radiation Therapy – A Call to Action
  - Due to many incidences that had made National headlines a renewed emphasis was required.
  - A comprehensive reporting system needed, but many obstacles to overcome:
    - Who reports – Who can Access – Punitive Effects – Elective or Mandatory?
  - This Summit was instrumental in challenging Medical Physicist to re-focus attention on safety and developing a culture centered on Safety in the Clinic.

- We immediately implemented new Checklists in the Department
  - Checklist Manifesto – Dr. A. Gawande
  - Introduced Checklist for Physics, Dosimetry, Therapist (Timeout, Tx Resume)
    - Each of the three checklists has “Do-Confirm” and “Read-Do” checks

**No, no, you’re not thinking; you’re just being logical.** Niels Bohr
Initiated a Color Coded Reporting System (CCRS)

- Green – incident no patient effect: Yellow – incident effects patient
- Provided feedback from each area of the department of how the incident occurred and the effect of the incident.
  - Problem: each area of the department used space to identify someone or another area of the department as the “Fault”.
  - To Subjective and a loss of Objective.
- Reviewed by Director and recommendation reviewed by the PI Committee.
Background:

- Introduced an SBAR reporting system

- Situation – Background – Assessment – Recommendation
  - Gave SBAR to everyone in the Department
  - {Transparency – Incident Learning}
  - Provided continual opportunity to review and re-evaluate the P&P.
  - Was received at times as a “Finger Pointing” mechanism.

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**Treatment Machine: Bolus Typo on Short Sheet**

**Situation:**
A patient was setup for the initial treatment of his boost but the bolus entry was incorrect on the short sheet.

**Background:**
On May 27, 2014 a patient was brought to the EX1 machine to begin the boost for his 1st Check. The Therapist at the machine set the patient as per the Therapist setup sheet. The Therapist at the machine reviewed the Physician Prescription and the short sheet for treatment. Upon review the Therapist noted a discrepancy between the Rx’ed bolus thickness of 1cm and the short sheet entry of 0.8cm. The therapist called Dosimetry and Physics to get more information and resolve the issue. The Physicist went to the console to review the situation. The Physicist determined there was a typo on the short sheet that would not affect the calculation or patient treatment. After a short time the Physicist called Dosimetry to see if the corrections were made. The typo had not been corrected at that time so the Physicist told the Therapist to proceed with the treatment. The treatment was delivered as prescribed and the patient went home.

**Assessment:**
The delivered dose and placement of the field were as prescribed by the Physician. The typo on the short sheet caused confusion but did not require re-planning or recalculating of the prescribed treatment. The Therapist followed the Departmental procedures exactly as instructed and helped to resolve the issue quickly and effectively. The final Physics check did not note the typo on the short sheet.

**REMINDE**
- Physics must continue to be diligent and be certain there is consistency between the Rx and the Short Sheet.
- Therapist should stop and contact Dosimetry and Physics if there is any inconsistency between the Short Sheet and the Rx. As was done in this case.
- Physics will monitor electron boost cases to determine if there is a recurring issue or this was just an oversight by the Physicists doing the final check.
Why Roils:

- Using SBARs and CCRs created an arena of retribution and accusations instead of a Culture of Safety.
- Divisions within the Department grew.
- Recognized the need for an anonymous reporting system that was centered on “What” not “Who”.
- Opportunity to use the “Learning” component of ROILS to provide higher patient safety
- Track “Near Misses” in a consistent manner.
- Desire to have “Reports” to review by a Process Improvement team on a monthly basis.

Intelligence is the ability to adapt to change. Stephen Hawking
Process:

- Met with the VP of Patient Safety and Quality – Also need to meet with the Privacy Officer of the Hospital.
  - Will be reviewed by Legal Department at Hospital and contract signed.
- Setup Bi-Weekly Meeting of Leads to review Reports
  - Members: Leads in Therapy, Nursing, Physician, Physics, Administration, Clerical
- Have setup a monthly meeting of the “Process Improvement Committee”
  - Tasked with Review of all ROILS entries and Data points.
  - Establishing the basis for changing of Policies and Procedures based on data trends.
- Provided each Lead in the Department a copy of the “Practice Guide” to review and help develop the reporting scheme.
  - [https://www.astro.org/Clinical-Practice/Patient-Safety/ROILS/Index.aspx](https://www.astro.org/Clinical-Practice/Patient-Safety/ROILS/Index.aspx)
  - Discussed the hierarchy of Data Submission for the Department.
Process:

Flow Chart of Incident Reporting System at AAMC
Process:

- Leads put in the Data to assure accuracy of the report and confirm no patient specific data is included.
  - Except for Age and Gender.
- The Final review of all reports will be done by Physics and Director to strive for consistency in reports.
- Discussed with the Leads the task of “Changing the Culture”
  - Have to go from Retributive to Redeemed:
    - Emphasizing the Patient and the ability for our Department to strive not just survive.
- Began In-House reporting by Physicists and Administration to develop continuity (5 reports completed)
Results:

- To Date we have had 5 Potential ROILS reports:
  - 4 near misses
  - 1 Tx incidence

- Near misses:
  - 2 wrong MR# entered for returning Patients
  - 1 Wrong Rx Tx technique
  - Wrong shift recorded on Setup Sheet
  - Near Misses: 2 Found during Planning Process & 2 during Physics Process

- All Entries had specific info on questions: Q: 1-12 General
- All examples given had approximately 15 entries that were Non-Applicable

Experience is not what happens to you; it's what you do with what happens to you. Aldous Huxley
Results:

12. QUESTION: Title Identifying Event:
13. QUESTION: How was the event discovered?
14. QUESTION: Which of the following best characterizes the event or condition? Select all that apply.

- Desired Procedure Inadverently Omitted
- Wrong Anatomical Treatment Site
- Wrong Dose to All or Part of the Tumor or Normal Tissue
- Wrong Laterality
- Wrong Patient Treated
- Wrong Procedure Done to the Patient
- Wrong Treatment Modality
- Partial Geometric Miss of Target
- Total Geometric Miss of Target
- Mechanical Failure
- Not Sure How to Characterize This Event or Condition
Results:

15. QUESTION: In what workflow step was the event discovered?

16. QUESTION: In what workflow step(s) did the event occur? Select all that apply.
   - Patient Assessment
   - Pre-treatment Review and Verification
   - Imaging for RT Planning
   - Treatment Planning
   - Treatment Delivery
   - On-treatment Quality Management
   - Post-treatment Completion
   - Equipment and Software Quality Management

41. QUESTION: Dosimetric severity scale: FMEA?
   - (100% deviation to <5% no effect) (Risk = Ocurrence*Severity*Probability)

42. QUESTION: What is the clinically observed toxicity?
   - (None to Premature Death)

43. QUESTION: Not all incidents reach the patient. If this incident were to reach the patient, what is the potential future toxicity? (same as Q.42)
Results:

- **52. QUESTION: Contributing factors: (Select all that apply.)**
  - Organizational Management
  - Technical
  - Human behavior involving Staff
  - Patient-focused circumstance
  - External Factors *(beyond facility control)*
  - Procedural Issues

- **1 Tx Incidence:**
  - Rx in ARIA not signed by Physician – Patient Treated for 1SRS Tx
  - Dose and Delivery were in accordance with Rx in IPLAN and ARIA – but Rx not signed in ARIA.
  - Breakdown In Process with Potential serious harm to the patient.
  - Tx Incidence Found on Physics Review post Treatment.

**Breakdown:**

- Q 52: *(Communication/Slip Causing Error/Failure to Execute).*
- Note: MR#: we believe design of ARIA software contributes to issues
Conclusion:

- Reporting through ROILS requires a change in Process
- Big obstacle is getting the Hospital Administration to buy in.
- Many Questions don’t pertain to specific entry being made – need to work out streamlining
- Need to discuss more examples of cases to properly define the reporting for Questions: 14, 23, 40 (near misses), 41, 42-43 (how severe), 52
- Having 2 main people review report adds a considerable amount of effort to their schedules

- Working through the ROILS submission ahead of entering the system is Valuable
- Checkout Keynote Address III from ASTRO: Sidney Dekker
- Change in Culture is a Time Related exercise

Consensus Recommendations for Incident Database Structures in Radiation Oncology

It has become appallingly obvious that our technology has exceeded our humanity.

Albert Einstein