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QUARTERLY REPORT PATIENT SAFETY WORK PRODUCT

Q2 2017 APRIL 1, 2017 - JUNE 30, 2017

CLARITY PSO, a Division of Clarity Group, Inc. 8725 West Higgins Road • Suite 810 • Chicago, IL 60631 T: 773.864.8280 • F: 773.864.8281 www.claritypso.com

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AGGREGATE REPORT CARD – Q2 2017 April 1, 2017 – June 30, 2017

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METRIC	AGGREGATE CURRENT QUARTER	AGGREGATE HISTORICAL SUM
Reported Events	367	3618
Therapeutic Radiation Incidents Other Safety Incidents Near Miss Unsafe Conditions Operational/Process Improvement	52 37 43 56 179	900 263 1006 877 572
Most Commonly Identified Workflow Step Where Event <i>Occurred</i>	Treatment Delivery Including Imaging: 30% (111/367)	Treatment Planning: 28% (999/3618)
Most Commonly Identified Workflow Step Where Event was <i>Discovered</i>	Treatment Delivery Including Imaging: 38% (140/367)	Treatment Delivery Including Imaging: 28% (1012/3618)
Most Commonly Identified Treatment Technique	3-D: 28% (104/367)	3-D: 23% (840/3618)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents/Other Safety Incidents that Did Not Effect Multiple Patients	≤5% Maximum Dose Deviation to Target: 54% (45/83)	≤5% Maximum Dose Deviation to Target: 67% (503/755)

ANALYSIS & COMMENTARY

INTRODUCTION

This quarterly report contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System[®] during the second quarter 2017. The first section identifies an incident with possible medical impact while this quarter's featured theme delves into process improvement (PI): how to learn the most from events and make sustainable changes within your facility. Each of these sections contain interconnected focus topics that highlight an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS.

HIGH-LEVEL OVERVIEW

At a glance, when comparing data from Q2 2017 to aggregate data from prior quarters (since inception of RO-ILS) there are a number of notable observations. The number of incidents reported over the past several quarter are similar (since Q1 2016), suggesting stable participation and buy-in from RO-ILS participants. However, as the relative stability of quarterly reports in light of increasing number of participants overtime suggests there is ample room for growth and development of a "reporting culture" in radiation oncology.

This quarter the most events occurred (i.e., genesis) in the treatment delivery/imaging process step, however prior analysis of RO-ILS data has shown that the treatment planning process step is where most radiation related incidents occur. We continue to see that most incidents are caught at the treatment delivery/imaging process step by therapists, further highlighting the relative importance of this critical safety barrier in the radiation oncology process. There was an increase in the number of incidents that dealt more with operational/process improvement (i.e., scheduling errors) and a decrease in radiation delivery near-miss events. The number of radiation treatments being delivered with proton therapy is increasing and as expected this quarter we observed an increase in incidents related to proton therapy. Generally, proton therapy is a more complicated radiation process (i.e., compared to IMRT) and careful study/analysis of proton incidents is warranted.

SUMMARY OF INCIDENT WITH POSSIBLE MEDICAL IMPACT

In this quarter (Q2 2017), one incident out of 367 (0.3 percent) events reported to the PSO met the Radiation Oncology Healthcare Advisory Council's (RO-HAC) threshold criteria for possible medical impact. This criterion included therapeutic radiation incidents that had a dose deviation greater than 5 percent and/or OAR(s) that received more than intended and exceeded tolerance levels.

In this incident, the patient was scheduled to receive four SBRT fractions to a liver lesion. After the first fraction was delivered, during physician peer review, it was noticed that there were no fiducial markers on the MRI scan that was registered to the planning CT. The MRI was registered to the planning CT using the soft tissue anatomy. The target volume was then delineated on the planning CT, using the MRI scan. Thus, the MRI was misregistered to the planning CT and the target volume location within the liver was inaccurate, which may result in a marginal miss. Further investigation showed that the liver target was visible on the free-breathing planning CT scan. The liver target volume was re-contoured on the free-breathing scan, which was then accurately corregistered (using the fiducials) to the original averaged 4D planning CT. When the two target volumes (prior

MRI based to newly defined free breathing CT) were compared, they overlapped, but were not completely concordant. One fraction was delivered using the incorrectly defined target. The treatment was re-planned using the liver target volume that was delineated on the free-breathing planning CT scan and the appropriate internal target volume (ITV) was used for the remaining 3 fractions. While the event occurred during pre-treatment QA review, it was first discovered during on-treatment QA. Policies, procedures, equipment design, and not following best practices were identified as contributing factors.

FEATURED THEME: PROCESS IMPROVEMENT

Quality improvement and continuous process improvement (PI) have proven to be essential for the quickly evolving field of radiation oncology. The American Board of Radiology (ABR) "defines quality improvement as a systematic approach to the study of healthcare and/or a commitment to continuously improve performance and outcomes in healthcare" (2017). As this definition provides a wide scope for quality improvement, this report's intent is to focus specifically on process improvement. Process improvement, in this report, will focus on how tools such as DMAIC (Define, Measure, Analyze, Improve, Control) can be used to change specific workflows, at the local level, based upon insight gleaned from submitted events.

As described in The Toyota Way Fieldbook, standardized tasks and processes are the foundation for continuous improvement and employee empowerment (Liker 2006). What makes improvement continuous is the ability to adapt today's best practices over time to the next best standard, allowing your processes to be agile. A core principle to getting quality right the first time is to build a culture that supports stopping a process immediately to fix problems and deter further downstream errors. Empowering staff to feel that they are entitled to "stop the line" to ensure safe delivery of a radiation therapy treatment sounds simple, but oftentimes conflicting priorities are felt by staff. The importance of a safety culture must be communicated by leadership as the number one priority, even above finances and staying "on time". Staff need to feel that leadership is invested in the success and the quality of their work and that can be accomplished through maintaining open lines of communication and visibility through routine rounding within your department.

Operationalizing process improvement is much more than learning the tools and talking PI, it is the ability to practice it in every aspect of your daily work. Organizations must be willing to be transparent, reflect on their mistakes and use PI tools to address areas of opportunity. The philosophy of continuous PI is about training and encouraging employees at all levels to seek out problems and proactively prevent them from occurring in the first place. The tools are simply the vehicle to achieve the improvements needed.

PI teams are vital to proactively fixing potential issues as well as retroactively addressing an incident to ensure it does not occur again. There are many philosophies to approaching PI projects. Plan-Do-Study-Act is a common methodology utilized that focuses on incremental improvement over time. This framework focuses on rapid improvement cycles and is generally used for smaller problems that are appropriate for a control trial and error type of experimentation (Jacobson 2016). One common methodology highlighted in this report is DMAIC. DMAIC, unlike PDSA, puts more emphasis on the preparation of a project which make this framework better suited for larger, more complex challenges than PDSA (Jacobson 2016). DMAIC is often used in high-reliability organizations and its projects have a clear end point versus PDSA cycles are based on the premise that they are continuous (Jacobson 2016). A high level version of the DMAIC process steps, along with questions to ask within each phase of the process, is seen in Figure 1 (Rever 2016).

Define	Measure	Analyze	Improve	Control
What is the problem?	What data is available?	What are the root causes of the problem?	Do we have the right solutions?	What do we recommend?
What is the scope?	Is the data accurate?	Have the root causes been verified?	How will we verify the solutions work?	Is there support for our suggestions?
What key metric is important?	How should we stratify the data?	Where should we focus our efforts?	Have the solutions been piloted?	What is our plan to implement?
Who are the stakeholders?	What graphs should we make?	What clues have we uncovered?	Have we reduced variation?	Are results sustainable?

Figure 1. DMAIC tool and process (Rever 2016).

When forming a process improvement team, be sure to include a representative from all areas that are affected by the process being evaluated. While all team members should have an equal voice in the project, the executive sponsor must be someone who has the authority to remove obstacles that may arise throughout the project. Another vital team includes the process owner. Unlike the executive sponsor the process owner is the team leader and is heavily involved in the details and full scope of the project (Liker 2006).

DEFINE

The first steps to starting a project are to define the problem (scope), the goal, and gap between the current and goal state. While developing the project charter and mapping out the process, the team should determine what metric(s) will be utilized to identify when the problem has been solved.

MEASURE

The next step is to start measuring the data. The significant process inputs and performance standards should be identified. The baseline performance data should be gathered and a data collection plan generated. It is important to make sure that the selected data accurately reflects the problem and is telling the story of the problem.

ANALYZE

The third phase is to begin analyzing the data. Is there any low-hanging fruit that the team can correct to establish some quick wins and credibility? The root causes of the problem are identified in this step of the project and prioritized by their potential impact for change.

IMPROVE

The improve phase then turns the analysis into action. Implementation of solutions occurs here and tolerances for new processes are established. Occasionally, unintended consequences of your improvements will begin to surface. As a team, you will need to determine whether to address the consequences now or address them at a later time.

CONTROL

After you have had enough time to allow your improvements to be implemented and measured for success (usually at least 3 months), you are ready to enter into the control phase. Control phase is the most important phase in the DMAIC process as this is where the new processes become "muscle memory". The careful monitoring of process controls is vital to ensure the improvements become institutionalized and sustained. A control plan is essential for the process owners to follow as well as a response plan for when the process falls out of "control".

The following Figure 2, adapted from Rao (2010) and iSixSigma[®] (n.d.), provides an overview of the Six Sigma DMAIC improvement process and each phases' components (objectives, activities, tools, and deliverables).

OBJECTIVE	ACTIVITIES	TOOLS	DELIVERABLES
 Phase 1: Define Opportunities Validate opportunity and charter Create definitions Organize group to be an effective team 	 Create project charter Process map Identify quick wins and milestones Determine critical to process (CTP) and critical to quality (CTQ) variables Foster teamwork Identify key stakeholders 	 Project charter Action plan Sigma goal and gap Process flowchart SIPOC diagram Stakeholder analysis 	 Project charter Project plan Process maps Quick win opportunities and milestones Creation of CTP and CTQ variables
 Phase 2: Measure Performance Identify critical measures Create measurement plan Establish sigma baseline performance 	 Determine input, process, and output indicators Create measurement plan and operational definitions Validate measurement plan Evaluate baseline performance Process control and capability 	 Process flowchart Check sheets Gap analysis Benchmarking 	 Input, process, and output indicators Operational definitions Measurement plan Cause and effect diagram Baseline performance
 Phase 3: Analyze Opportunity Identify root causes and failure modes Determine causes of variation 	 Identify and validate root causes Use statistical tools Identify variation sources Determine value/non-value added process steps 	 SOV studies Fishbone diagram Regression analysis Run chart, histogram, scatter plot, etc. 	 Results of data analysis Root causes Possible solutions
 Phase 4: Improve Performance Identify, evaluate, choose correct improvement solution(s) Choose change management approach 	 Design of experiments (screening/RSM) Generate solutions Evaluate and select solution(s) Communicate solution(s) Implementation plan 	 Gantt chart New process map Mistake proofing Brainstorming FMEA 	 Solution(s) to implement Implementation plan Solution(s)' impacts and benefits
 Phase 5: Control Performance Implement solution(s) Plan to maintain improvement Identify replication and standardization opportunities Finalize project 	 Implement solution(s) Verify results, benefits, savings Integrate and manage solution(s) in workflow Develop standards and procedures Team closure activities 	 Control chart Sigma goal and gap analysis Project work plan Cost savings 	 Process control plan to maintain improvement Solution(s) results Opportunities for replication and standardization

Figure 2. Six Sigma DMAIC improvement process. Adapted from Rao (2010) and iSixSigma® (n.d.).

PROCESS IMPROVEMENT TOOLS:

The following includes several process improvement tools that have the potential to make a large impact in the field of Radiation Oncology. While there are many process improvement tools available, this report will only highlight a few.

One way to ensure safe practices is through the use of visual controls whenever possible. Using visual controls in Radiation Oncology can be as simple as therapists placing flash cards on the control console to indicate that the patient is to be imaged that day or that a physician is required to be present for treatment that day. This control makes it easy for the treating therapist as well as the second check therapist to glance over and see what is needed for the day with that patient. Another visual control can be picture SOP's (standard operating procedures) in the treatment room that remind staff to follow standard work. Visual whiteboards for plans in the planning process will quickly give an instant snapshot as to the progress of the work. Patients can even benefit from visual controls in the waiting rooms that indicate the status of their treatment machines; on-time, delayed and times of current delays.

The airline industry has long mastered the use of **checklists** to simplify extremely complex tasks and situations. Healthcare was soon to follow with checklists of their own, initially reserved for OR suites which created safe surgery checklists. Checklists are now routinely used in Radiation Oncology for timeouts, machine QA, weekly chart checks, pre-treatment QA checklists and more. The purpose of the checklists is to ensure that all tasks are completed in a systematic manner for every case, thus creating standard work processes in the meantime.

After identifying the best practice for a process, create **standard operating procedures**. These documents should be reviewed regularly and improved as the best practice changes. A standard work document sets clear expectations for staff and allows managers the ability to quickly recognize when the correct sequence is not being followed. A standard work document also allows for more efficiency within the clinic because it cuts down on process variation.

Idea boards are starting to be used more frequently in healthcare settings to allow the process owners to suggest improvement opportunities. This single tool can begin to move the needle on culture change in a department because it gives all staff members a voice in creating change. The visibility of the boards show staff that leadership values their suggestions and is invested in making improvements to their work environment. Figures 3 and 4 show examples of idea boards (Graban 2011).

Visual Idea Board	Basic Idea Card
	Problem Implementation Steps

Figures 3 and 4. Examples of an idea board and idea card (Graban 2011).

Using quick **team huddles**, as opposed to the standard one-hour meeting, speeds up the work of improvement teams. Huddles enable teams to have frequent but short briefings so that they can stay informed, review work, make plans and move ahead rapidly. Benefits of huddles include:

- Allowing for increased participation and engagement of frontline staff and bedside caregivers, who often find it impossible to get away for the conventional hour-long improvement team meetings
- Keeping momentum going, as teams are able to meet more frequently.

Routinely reviewing your facilities' existing processes, creating best practices and training staff to those changes will help to streamline workflow, reduce waste, best utilize available resources and adapt quickly to changes in the field. Based on the events that were analyzed for this quarter, a number of incidents could have benefited from utilizing PI tools to develop policies or to update current policies, standardize workflows for staff, set expectations and potentially decrease errors. Two such incidents have been highlighted below.

CASE 1: WRONG VERTEBRAL BODY TREATED USING A STEREOTACTIC LOCALIZATION SYSTEM THEN CBCT IMAGING FOR IMRT

One fraction out of 45 total fractions was treated to the wrong vertebrae. The patient was aligned in the room and the stereotactic localization system initial fusion requested a 2.5 cm superior/inferior (sup/inf.) shift which was performed by the therapists. A CBCT was then performed and a -0.4 cm correction was made before treating the patient. Total offset from the correct isocenter for the treatment was 2.1 cm. The error was discovered by the physician in offline review when it was noted that the wrong vertebrae had been localized by the stereotactic localization system and was not detected by the treating therapists. A root cause analysis was performed and there were many factors that contributed to this error, they are listed on the next page.

Contributing factors in this case included:

• Procedural Issues

It is noted that a 3-point set-up was used at simulation rather than the infrared markers used for the stereotactic localization system for this case, which necessitated shifts to be made daily before imaging (shifts not performed on the day of the error led to the stereotactic localization system registering the wrong vertebrae for alignment). Using the stereotactic localization system for fractionated spine alignment is outside of the normal workflow for this center. Also, the vac-loc bag was not indexed due to potential collision issues with the set-up (an indexed bag may have alerted the therapists to the large shift outside of their normal table tolerances).

At this facility, CBCT registration after the stereotactic localization system is used for verification only. In this case, CBCT was used for alignment but the incorrect vertebrae had already been localized. Further alignment of the incorrect vertebrae was then performed. The limited field of view did not allow the therapists to fully recognize the discrepancy in the setup by comparing adjacent anatomic structures. When the treating therapist (who had not been trained on the stereotactic localization system) was uncertain of the setup, he/she defaulted to the judgement of the stereotactic localization system trained therapist which limited the "second-check".

Technical

The shifts from the three-point setup were not performed prior to the stereotactic localization system registration, this led to mis-registration of the adjacent vertebrae as the target. The large shift (2.5 cm) did not cause therapists concern even though department policy is to page a resident for shifts larger than 2.0 cm. In this case, the resident was not paged to confirm the shift. The use of the robotic couch routinely gives large shifts which may have led to alarm fatigue from the therapists.

• Human Behavior Involving Staff

The therapist running the treatment machine was filling in that day and had not been trained on the stereotactic localization. An untrained therapist is incapable of being a reliable "second check" on the treatment machine. The therapist who was untrained did not act on her instinct that something seemed "off" and realign the patient. Training may have helped the therapist feel like his/her opinion was sufficient reason to "pause" to assure proper alignment.

• Policies and Procedures

This error could potentially have been prevented if the policy to call the resident to the machine for any shift greater than 2 cm had been followed. Also, the policy of using CBCT for verification only was not followed and although this did not negatively affect the treatment, it does indicate a culture of complacency.

• Leadership and Culture

In this case, the therapist untrained in the stereotactic localization system did not feel empowered to speak up even when he/she felt something may be wrong. Also, the root cause analysis provided mentions that the therapists felt pressure to get patients aligned and treated in order to stay "on time". These pressures are not conducive to a "safety first" culture and may lead to confusion amongst staff as to the true priorities within their facility.

Actions and Recommendations:

• Standardize CT simulation setups

This is important when the stereotactic localization system is to be used for treatment. If special markers are to be used for these cases, then create a workflow for CT simulation therapists to easily access that information prior to marking the patient. A procedure to communicate use of the stereotactic localization system to dosimetry/treating therapist should also be established and reviewed with the staff.

• Competencies

These should be developed and placed in employee records for training on new equipment. Untrained therapists should not be eligible to be considered a second therapist on equipment they have yet to be trained on. Establish a training schedule for staff when new technology is implemented in your clinic. Ensure the training is complete and knowledge is retained through the use of competencies checked off by "superusers" on your staff.

Policies

For policies regarding calling a physicist/physician for shifts larger than desired, require staff therapists to enter a note into the chart when someone has been called back to review a large shift. On weekly chart check, if there are shifts above the desired tolerances, verify that a note is in the chart. Review shift tolerance policies regularly with staff and make sure to immediately address cases when the policy is not followed with the involved staff members.

• Put Safety First

Regularly round and talk to your staff about putting safety first. Make your staff know that safety is your number one priority and that any staff member has the power to stop a process when they feel that something may not be correct. Establish standard pathways to escalate issues so that staff members can quickly contact whomever is needed to rectify the situation.

CASE 2: TREATMENT FIELD TREATED TWICE IN ONE DAY

A new patient was scheduled for day one of treatment. Upon completion of treatment, the therapist received a message saying "Session Complete" and they selected "Yes". They then received a notification that the patient would receive an "underdose" for the day. The patient was still in the room dressing, therefore, the therapists asked him to wait. The therapists called the dosimetrist and between them, they could not find a recording of the field being treated on any of their computers. The only indication of the field having been treated was that the daily dose in the record and verify system was written in black as 180cGy whereas it would usually be in red if they had not delivered all of the dose. The dosimetrist decided to add another field B2 for the therapists to treat, which they did. The therapists called physics afterward to discuss what happened. Physics contacted the vendor for the record and verify systems, confirmed that the patient was treated twice to the B2 field.

Contributing factors in this case included:

• Training

This case demonstrates how important it is to use safety tools to make staff stop and think about the actions they are performing or being asked to perform to deliver a safe treatment. Considering this was day one of treatment and all the parameters should have been checked, the therapist would know they delivered both treatment fields. Educating the staff on how to appropriately handle issues that arise while treating patients and how to escalate these issues up the proper chain of command can be very beneficial. The therapist and dosimetrist should have "paused" and investigated further or consulted with the physicists/physician before creating a new field to treat.

• Technical

Due to this issue, it would be worth consulting with the IT department to ensure all equipment and networks are working properly. Ensuring errors that occur are being reported to the vendors is a good practice as well. Keeping a log to track communication errors can be used for PI agenda items.

• Policy and Procedures

It appears that no policy on communication failures between the linear accelerator and record and verify systems exist, so this would be a good opportunity to develop one.

• Leadership and Culture

Making sure staff feel comfortable and empowered to report issues is crucial to maintaining a culture of safety. Setting the tone in the department that if staff members are uncertain about an issue, it is okay to pause before proceeding, and escalating the issue through the proper channels if appropriate.

Actions and Recommendations:

• Establish SOPs

Establish a policy for verifying daily treatment doses in the record and verify system before entering the room to get the patient off of the table. Ideally, two therapists would be involved in this double check of treatment accuracy. This procedure should be followed as part of the therapists' normal routine when treating all patients. The standard workflow for each staff member needs to be defined in order to streamline processes and evaluate performance. Assure staff is properly trained to these standards and are held accountable when they stray from the defined workflow. Although we do not condone a punitive work environment, there does need to be accountability for intentional disregard of procedures set in place.

• Create Escalation Plans

A cross-functional PI team should come together and develop an escalation plan for when and how to involve the right team members in situations that are outside of the normal treatment workflow. This plan should be easily accessible at the treatment machines as a resource for all staff members. In this case, the escalation should have been to contact physics when there was a discrepancy with treatment delivery.

• Discuss record and verify issues with vendors real-time

In this case, had the vendor been contacted real-time the second arc would not have been delivered. It is always better to be safe than sorry. Train your staff to "pause" when a situation arises that needs to be clarified. The vendor and physics staff could have walked through the case before putting the patient back on the table, adding an errant treatment field and realizing the mistake before it was too late to correct. Training staff to correctly verify doses in the record and verify system needs to be done on a regular basis.

Good Teamwork

Good teamwork is essential to delivering a safe treatment. Teamwork training in fields such as aviation has been successful in reducing failures related to poor communication, cross-monitoring or peer coaching (observing others' behaviors to reduce risk of failure and share workload) (Helmreich 1998). As these cases show, it is vital to peer coach across team members on behalf of the patient to avoid patient harm. Teamwork is not a specific fix for any one type of error, but it should be viewed as one type of adaptable human factor intervention with a set of teachable skills and behaviors capable of optimizing safety, which is a good indicator of a high-reliability organization. Teamwork training requires a change of safety culture, which can be difficult. Leadership must be fully committed to the process before implementing teamwork training for all staff. Resistance to behavioral change is likely to be encountered, and it will be necessary to demonstrate the clinical relevance of this training (Grabowski 1997).

Continuous Process Improvement

Having monthly meetings to address any new procedures or to make changes to current practices is a good way to make sure staff is staying up to date on the departmental policy and procedures. Also, regular discussion of good catches within your department is a good way to get feedback from the process owners on what could be done differently to prevent an error from occurring. Empower your team to begin looking for variation in practice, potential for errors and waste in their workflows, then commit to working systematically to improve those processes and create new best practices. The culture will change when leadership allows all staff members to have a voice and "stop the line" when they see something outside of the normal workflow.

RESOURCES

Institute for Healthcare Improvement: Huddles

11 Tenets of a Safety Culture

Safety Is No Accident

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AGGREGATE ANALYSIS GRAPHS

















