Optimizing Efficiency and Safety of Radiation Therapy Process: Root Cause Analysis and Process Change

Jonghwa Chang, Ph.D. 1, 2
1 Department of Radiation Medicine, Northwell Health
2 Hofstra Northwell School of Medicine at Hofstra University

Conflict of Interest Disclosure
• I have no conflict of interest to disclosure.

Outline
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2. Quality improvement tools
3. Event reporting
4. Lean six-sigma approach for system change
5. Summary

Introduction

Department of Radiation Medicine, Northwell Health
• Seven locations
• 2800 consults per year
• 2100 Tx with external beam radiotherapy
• 250 patients per day
• 9 medical linear accelerators
• 6 New TrueBeams
• HDR, PSI, IVBT, Gamma Knife, Zeiss, Tomotherapy, Cyberknife
• Physics Members: 19 physicists, 10 dosimetrists, 4 IT specialists

Radiotherapy Work Flow
Simulation → Contouring → Planning → Physics secondary check → Treatment/Plan Execution
Radiotherapy Process is a Production Line

- Linear in nature
- A few feed-back loops
- Require different expertise for each step:
  - Radiation oncologist
  - Medical Physicist
  - Radiation therapist
  - Nurse
- Both efficiency and safety are crucial to the success of a radiotherapy department.

Hospitals with better HSOPS scores tend to have lower rates of PSIs.

- PSI: Patient Safety Indicators, rate of adverse events
- HSOPS: Hospital Survey on Patient Safety Culture; a survey for measuring staff perceptions of patient safety


Good practices that can improve quality

<table>
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<th>HSOPS Variable</th>
<th>Correlated With PS Composite</th>
<th>Standardized Regression Coefficient</th>
<th>Unstandardized Regression Coefficient</th>
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<tr>
<td>Correlated with patient safety culture</td>
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<td>3.15</td>
<td></td>
</tr>
<tr>
<td>Radiation oncologist</td>
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<td>Medical staff</td>
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<tr>
<td>Radiation therapist</td>
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<td>Nurse</td>
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</tbody>
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- RCA: root cause analysis
- FMEA: failure mode and effects analysis
- Lean six sigma

RCA (root cause analysis)

- A reactive process taking place after the harm has been done.
- Deals with actual failures
- Seeks to know the causal set of each of all possible effects.
- Looks backwards
- Commonly used in medicine

FMEA (failure mode and effects analysis)

- A proactive process aimed at predicting the adverse outcomes of various human and machine failures, and system states
- Deals with hypothetic failures
- Seeks to know the effects of each of all possible causal sets.
- Looks forward in time
- Less commonly used in medicine but are catching up
 AAPM 2018: Root Cause Analysis and Process Change

Solution: a lean process

Quality improvement tools used at Northwell Health

- How problems are identified:
  - Reported events from internal or RO-ILS
  - Actual incidents
  - Suggestions from periodic QA meetings
- How problems are analyzed:
  - Primarily relying on RCA
  - Sometimes use FMEA
  - Lean six sigma for process change

Combined RCA with event reporting

Northwell Aspects of Care (AoC) System

- Internal Reporting System
  - Developed at Northwell
  - In use for over 7 years (until September 2017)
  - Over 8000 reports
  - Has led to many initiatives
- Reporting
  - All staff reports (can do anonymously)
  - Reports reviewed by Quality Management team
  - Reports summarized at monthly QM meetings

Combine RCA and event reporting to improve quality

- Reporter was required to perform certain degrees of RCA analysis
- Advantages:
  - Reporter has the first hand information about root cause of the event
  - Very fine granularity making it easy for later analysis of the event
- Disadvantages:
  - Not easy to complete all required fields, particularly for the RCA parts
  - Takes quite some time (>10 minutes) for each report

RO-ILS: Radiation Oncology-_incident learning System

- National Reporting System
  - Developed and sponsored by ASTRO/AAPM
  - Operated through a Patient Safety Organization
  - Has national committee presence for overseeing
- Analyses and Feedback
  - Institutions can use for internal reporting
  - Can submit events that may be of value nationally
  - A separate committee RO-HAC reviews
  - Quarterly reports generated
Northwell switched from internal reporting system to RO-ILS in September 2017

- The switch was gradual: both reporting systems co-existed for a few months
- Staff was fully trained before the switching
- Why switching: be able to report to and learn from the national ILS data base.

The RO-ILS system lacks the granularity provided by the in-house system

How to learn from the data in ILS system?

- Weekly QA meeting to go over the reported events.
- Most reported events are minor. Need to identify major events (e.g., near miss...)
- Root cause analysis performed at the department QA meeting and individual group (e.g., physics, MD, ...) meeting.
- Process changed if deemed necessary.

Lean six-sigma approach for system change

Three enemies of Lean: Muda (waste), Muri (overburden) and Mura (unevenness)

Chairman’s Support is critical

**Process map is key to the success of all QA projects**

Example: There were a couple of event reports that GE patients stayed very long (> 6 hours) for the treatment. The department decided to perform a RCA and revise the process so that the treatment time can be shortened. The following is the process map for GE SRS procedure before change.

**Lean model can better handle the Mura (fluctuation) in RT patient load**

- Mura increases the possibility for Muri (overburden) and therefore Muda (waste).
- Our solution: Each physics/dosimetry member can plan/treat every site
- Advantage:
  - Avoid the formation of physician-planner pairs
  - Promote team work
  - Smooth and standardized output
- Problem: difficult cases not done by best members
- Solution:
  - A go-to guy for each site
  - Periodic peer review

**Standardization can reduce Muri (overburden)**

- Northwell has standardized:
  - Directives
  - Plan constraints
  - Plan producing process
  - Incident reporting and processing
- This standardization is implemented across all 7 sites:
  - One EMR system: Mosaiq
  - One treatment planning system
  - All sites participate daily Smart Round remotely
  - All external beam cases are reviewed

**No-fly policy to make sure that everyone can do his/her job with sufficient time**

- Peer review before treatment planning (Smart Round)
- To avoid rushed process, treatment not scheduled until the plan is reviewed and approved.
- No fly: treatment not start unless everything is ready the day before (barring urgent cases)

**The planner and MD are required to avoid incremental improvements of IMRT/VMAT plans**

- Incremental improvements degrades the efficiency and quality because:
  - It creates wastes: takes longer to optimize than consider all constraints from the beginning
  - Easy to make mistakes when changing the constraints on the fly
  - Less time for plan check
- Northwell Policy: If the constraints specified in the directives are met, the MD cannot ask the planner to make incremental changes of the plan unless the request is reviewed and approved by the Smart Round.
To reduce Mura (unevenness), an in-house white board is used to control the flow and distribution of work.

The white board data are queried monthly to measure the operational efficiency for high risk tasks.

MUDA or waste deviates from optimal allocation of resources
- The 8 (or 7) wastes of Lean
  1. Defects,
  2. Overproduction,
  3. Wasting,
  4. Non-used Talent,
  5. Transport,
  6. Inventories,
  7. Motion and
  8. Excess (or over) processing.

The project
- Team: 3 radiation therapists, 2 chief therapists, 2 radiation oncologists (1 was the department chairman), a medical physicist, and an administrator.
- The department chairman ensured that the team members were provided with sufficient and uninterrupted time to engage in the project.
- Goal: to reduce the overall time for completing tasks undertaken during the treatment slots by reducing wasteful steps and streamlining the workflow.
- Metric: the average time for completion of all tasks in the slots.
- Measurements extracted from Mosaiq.

Kaizen project at Northwell to eliminate waste

4 sequential and uninterrupted stages
- Process mapping: >90 tasks by 2 treating therapists
- Identification of issues associated with each of the steps that potentially affected efficiency and safety. Classified according to TIMWOOD tools.
- Cost effective analysis: potential benefits and level of effort estimated to address recast by consensus into a 2x2 benefit matrix.
- Implementing issues with high potential benefit and low corrective effort
  - Presentation and review at a monthly QM meeting
  - A 2-month pilot study of the initiatives on one machine.
  - Full implementation
Figure 1 Workflow in the treatment slot. One therapist (driver) primarily interfaces with the devices, the other (runner) with the patient. Tasks in italic type are jointly performed.

Figure 2 Benefits versus effort matrix illustrating sample proposed solutions.

Figure 3 Average treatment time per slot for TrueBeam linear accelerators in 3 sequential phases: pre-Kaizen (10 months), transitional (first 3 months of Kaizen), and follow-up (6 months).

Conclusions
- Changes must be made for quality-based medicine.
  - Time- and resource constraints are manageable.
  - Lower incident rate is associated with higher staff perception of patient safety.
- Take advantages of quality improvement tools: RCA, FMEA, ILS...
- Six-sigma lean process can be implemented:
  - Support from the Department, particularly the chairman, is critical.
  - Process map: cannot start without one
  - Avoid fluctuations, overburdens, and wastes
  - Standardization, no workarounds
  - Continuous improvement

Thank You!