Treatment Planning System Commissioning and QA: Incorporating the entire planning process (*E2E Testing*)

Sasa Mutic, Ph.D.

**Conflict of interest statement**

- TreatSafely.org – partner and cofounder
- Radialogica – shareholder, cofounder, and CTO
- Varian - licensing, service, grants, honoraria
- Modus - licensing
- ViewRay – licensing, service, grants, honoraria

**Overview**

- Treatment planning as a part of broader system
- End to End (E2E) testing
- Evidence Based QA\QM
Modern RT - Complexity

- Recent sophistication—large fraction of modern treatment practices developed in the past ten years
- High technical complexity
- Multiple systems (software and hardware)
- Limited to non-existent guidance and regulations
- High pressure
- Increased potential for catastrophic failures

“To error is human. To really foul things up requires a computer.”

Systems Engineering

- The function of systems engineering is to guide the engineering of complex systems
- It is founded on a belief that individual components of an organization are dependent on each other
- It is very much about employing common sense in design of operations
- A set of tools for more effective management of interconnected components

Systems Engineering

- Applicable to systems with the following attributes:
  - Complex
  - Engineered
  - Advanced technology
  - High risk
  - High cost
Systems Engineering

- Systems Design
  - Quality systems
  - Human factors
  - FMEA (TG-100)

- Systems Analysis
  - Modeling and simulation
  - Enterprise management
  - Financial engineering and risk analysis
  - Knowledge discovery

- Systems Control
  - SPC
  - Scheduling

It is difficult for engineers to change human nature and therefore, instead of trying to persuade people not to make errors, we should accept people as we find them and try to remove opportunities for error by changing work situation.

An engineer's view of human error - Trevor Kletz

"We often call this arrangement a "health care system" even though it was never created as a system and has never performed as a system."

National Academy of Engineering and Institute of Medicine, 2005
Organizational Culture

• “Shared values (what is important) and beliefs (how things work) that interact with an organization’s structures and control systems to produce behavioural norms (the way we do things around here).” Uttal, B., Fortune. 17 October 1983.

Error Spectrum

• Publicized – One side of the spectrum, usually large dosimetric errors – NY Times Articles
• Semi-publicized – RPC data
  – Approximately 20% of participating institutions fail the credentialing test at 7% or 4mm*
  – Approximately 30% fail at 5%*
• Unpublicized/unnoted – everyday occurrences
  – “Small” dosimetric errors and geographic misses
  – Suboptimal treatment plans (contouring and dose distributions)
  – Care coordination issues
  – Unnecessary treatment delays

• Pass rate at 7%/4mm – 81.6%
• Pass rate at 5% - 69%
• It indicates that the systems which have less local user input have significantly higher pass rates
  – Tomotherapy – no user input
  – Eclipse – Presumably golden beam data or the benefit of automodeling
What are the obstacles?

• **Publicized** (Catastrophic)
  – Ultimately a technical limitation

• **Semi-publicized** (Semi-catastrophic)
  – Ultimately a cultural limitation

• **Unpublicized/unnoted** – (unknown significance)
  – Technical and cultural limitation

End to End (E2E) Testing

• Designed to identify system dependencies and to ensure that the data integrity is maintained between various system components and (internal and external) systems.

• Two aspects:
  1) A holistic view/test of the overall process and integration
  2) An overall system test rather than testing of multiple individual components (unit tests)

End to End (E2E) Testing

• Where are the ends in RT?
  – For treatment delivery – Simulation orders to delivery record

• Who performs testing?
  – Ideally people responsible for individual tasks

• Is there a need for E2E with closed systems with standard data?
  – True closed systems do not exist. Even if they did exist – user testing still valuable.
End to End (E2E) Testing

• Focus is on system function and not on system capabilities – stressing the system is not the goal
• Demonstration of successful test is important. Do not fail the test and “fix” the problems without repeating the test
• Depending on the novelty of the system, initial failure is expected

Evidence based QM (us as a discipline)

• It is difficult for individual clinics to prioritize their QA/QC/QM activities if the broader field and community is still struggling with what to prioritize
• Prioritization requires data
• Evidence based medicine is everywhere, QA/QC need to embrace the same approach

Example: QA/QC Check Effectiveness

• An analysis of the effectiveness of common QA/QC checks
• IRB between Johns Hopkins University & Washington University
• Both institutions started incident learning systems (ILS) at the same time
• Data:
  o Incident reports: 2007-2011
  o 4,407 reports
  o 292 (7%) “high potential severity”
Common QA/QC Checks

![Graph showing sensitivity (%) with various check points such as Pre-treatment IMRT QA, Online CT: check by physician, SSD check, Online CT: check by therapist, etc.]

Literature search

- pubmed.org search on:
  - (Quality Assurance) AND (Radiation Therapy) AND (IMRT)
    - Results: 463
  - (Chart Checks)
    - Results: 7
  - (Chart Review)
    - Results: 34
- An order of magnitude difference

May 2013 Data

![Graph showing returns with various categories such as Pre-treatment IMRT QA, Online CT: check by therapist, etc.]

Returns
Current IMRT QA Paradigm

“We are pretty good at making sure that we can treat a phantom correctly at ~7:00 pm”

1. Transfer patient plan to a QA phantom
   • Dose recalculated (homogeneous) on phantom – any dose-calculation errors would not be revealed

2. Perform QA prior to treatment
   • Subsequent data changes/corruption may result in systematic errors for all subsequent patients

3. The volume of data impossible to monitor and verify manually
   • Manual checks do reveal data changes/corruptions, but not reliably

4. The process too laborious with questionable benefits
   • A systematic analysis and redesign demonstrates possibility of a much more robust and automated process

Thank you!

“Just checking...”