Quality, Safety, and the Future of Therapy
Medical Physics

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Safety is Event Driven


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Rocky Mountain AAPM Chapter | May 2017
Quality is Data Driven

- Target
- Accept
- Action Limit
- Safety Concern
- Quality Concern
- Limits

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AAPM Task Group Reports

  - Physical Aspects of Quality Assurance in Radiation Therapy
- TG-28 (1987)
  - Radiotherapy Portal Imaging Quality
- TG-35 (1993)
  - Medical Accelerator Safety Considerations
- TG 40 (1994)
  - Comprehensive QA for Radiation Oncology
- TG 142 (2009)
  - Quality assurance of medical accelerators

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management (2016)
Quality and Safety Work

Number of Publications per Year
(- 2017)

- Linac & QA (1993 - )
- IMRT/VMAT & QA (1997 - )
- RT & Safety (1950 - )
- RT & QA (1956 - )

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What is “Clinical Medical Physics”?

- Radiation safety and shielding design
- Helping at the machines – SRS, SBRT, gating, faults, etc.
- Ad hoc patient interactions – answering questions, etc.
- Acceptance, commissioning, calibration, acceptance testing
- Checking things vs innovation
  - Machine QA, Second checks, Weekly checks, patient-specific QA
  - Linacs, 3D planning, IMRT, Gating, IGRT, Protons, MR-IGRT, etc.

Time for a change
Ideas Requiring and Enabling Change

Complexity

Complicated

Automation
Complicated is Not Complex

- Complex entities have special components
  - Diverse, interdependent, connected, adapting

- Characteristics of complex systems
  - Emergent properties
  - Novel functions
  - Robust
  - Unpredictable
  - Large events

Radiotherapy and Imaging
- Complex socio-technical system
- Understanding accidents is not just a failure of equipment or process step
Accident Causality Models

- **Reliability Engineering**
  - Based on probability of success
- **Accidents seen as...**
  - Combination of unsafe acts and latent hazard conditions within the system which follow a linear path
- **Analysis tools**
  - Process maps and FMEA

- **Systems Engineering**
  - Based on component interaction
- **Accidents seen as...**
  - Combinations of mutually interacting variables which occur in real world environments
- **Analysis tools**
  - Control loops and STPA
AAPM TG-100

• The Report of the Task Group 100 of the AAPM
  • Applications of Risk Analysis Methods to RT Quality Management

• Key Components of TG-100
  • Quality management
  • Process mapping
  • Failure Modes and Effects Analysis (FMEA)
  • Fault Tree Analysis (FTA)
Another Approach to Safety Assessment

- **Systems-Theoretic Process Analysis (STPA)**
  - Process is described by a number of control loops
  - Results in a hierarchical understanding of process operation

Inductive vs Deductive

Forward search → (e.g., FMEA) → Final States

Initiating Events (e.g., failures modes)

A → W non-hazard

B → X Hazard

C → Y non-hazard

D → Z non-hazard


Backward search ← (e.g., FTA, STPA) ← Final States

Initiating Events (e.g., causal scenarios)

A ← X Hazard

B ← C

C ← D

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Systems Understanding of Safety

- Safety is an emergent property of a system
  - Not a component of the system
  - Hardware, software, or process can’t be deemed as ‘safe’

- Most errors reflect predictable human failings in the context of poorly designed systems
Ideas Requiring and Enabling Change
Automation

Real World Process

Inputs → Outputs

Model of the World
(from sample of real world)

Predict Process Outputs

Improve Model

Courtesy of Kevin Moore, PhD
Automated Planning

- Fundamentally flawed and dangerous
- Poorly optimized and/or wrong clinical trade-offs
- Good OAR dose sparing and target coverage
- Excellent conversion of clinical goals into optimization objectives and priorities
- Best possible dose distribution for the given technique (e.g. VMAT)

Manual planning

RapidPlan

Courtesy of Kevin Moore, PhD
UCSD RapidPlan Approach

• Setting up auto-planning routines (Phase 0)
  • Modelling

• Planner first, then RapidPlan (Phase 1)
  • Blinded study

• RapidPlan first, then planner (Phase 2)
  • Plan refinement

• RapidPlan only unless constraints violated
  • Planning as a Service
UCSD RapidPlan Results

- **Phase 0** – Modeling/Validation (~500 prior pts)
- **Phase 1** – Blinded study (~300 pts)
  - HN, lung SBRT, and SRS beat manual planning 65-80% of the time
  - Prostate and liver SBRT are approximately equal
  - GYN and prostatic fossa wins 35-40% of the time
- **Phase 2** – RapidPlan then manual refinement (~250 pts)
  - Documenting plan improvements (if any) as we go
Dosimetrist Perceptions

• Initial push back
  • Job security, competing with a computer

• Now embrace as a tool to speed up their work
  • Saves them about 40% of their time per case

• Better communication with physicians
  • RapidPlan gives them credibility

• Ultra-fast ramp up for new dosimetrists
Automated Acceptance, Commissioning, & QA

• Better use of existing technology, e.g., EPID
  • Yaddanapudi et al. Med Phys, 2017 (accepted).

• Universal software, e.g., MPC
  • Clivio et al. Radiat Oncol, 2015.

• Systems-based safety assessment, e.g., STPA

• Process-based data analysis, e.g., SPC
  • Pawlicki et al. Seminars in Rad Onc, 2012.
Current Approach to Quality (and Safety)

Event View

Did it get done right?
Each case is a go/no-go decision.
Leads to This Type of Thinking

Physics Experiment

Commissioning Procedure

TPS vs Measurement = 2.715%

Maybe I should do another experiment?
If only I had more time!
Quality and Safety

Event View

Did it get done right?
Each case is a go/no-go decision.

Process View

Are people and equipment doing it right?
How is the process performing?
Statistics-Based Decision Strategy

Key quality or safety metric

\[ UL = \bar{x} + 3 \cdot \frac{m\bar{R}}{1.128} \]

\[ LL = \bar{x} - 3 \cdot \frac{m\bar{R}}{1.128} \]
A Way Forward: Continuous QA

• Largely automated daily linac QA only
  • No monthly or annual linac QA

• New approach: plan/weekly–checks, patient-specific QA
  • Take a patient view and leverage existing data

• Learn and adapt
  • Better response to process changes, near-misses, and incidents
U.S. and Canadian Operators Accident Rates by Year

What is our clinical future?

- Modified QA to maximize impact while minimizing effort
- Automated planning, plan and process checks

- How can we utilize our expertise to have a firsthand impact on patient care?
Physics Direct Patient Care Initiative

- Establish an independent relationship with patients
- Take ownership of technical aspects related to treatment
- Designed interactions with patients
Patient Interactions

Physician
Consult → OTV → Follow up

Physicist
CT Sim Consult → First Tx → OTV → Last Tx
Resident (and Faculty) Training

Year 1
- Patient Communication Course
- In-House Training
- Observation
- Standardize Patient

Year 2
- Lead with observation
- Solo
- On-going Competency Assessment
Randomized Clinical Trial
PDPC vs Conventional

Primary Endpoint
• Patient anxiety & satisfaction
• Questionnaire
  • 3 time points during RT course

Secondary Endpoint
• Physician efficiency
• Monitor physician workload
  • Weekly on-treatment visit duration
Our Clinic of the Future

Dosimetrist
Physician
Therapist
Administrator

Dosimetrist
Physicist
Nurse

Patient

RO-ILS
RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM
Sponsored by ASTRON, an AAPM Project
Summary

• Understand and address complexity
  • Enforce system controls, not just ‘checking things’

• Automation and process-based data analysis
  • Planning, QA, and workflow

• Physicists become part of the direct patient care team
  • Use our unique perspective to improve radiotherapy