Quality, Safety, and the Future of Therapy Medical Physics

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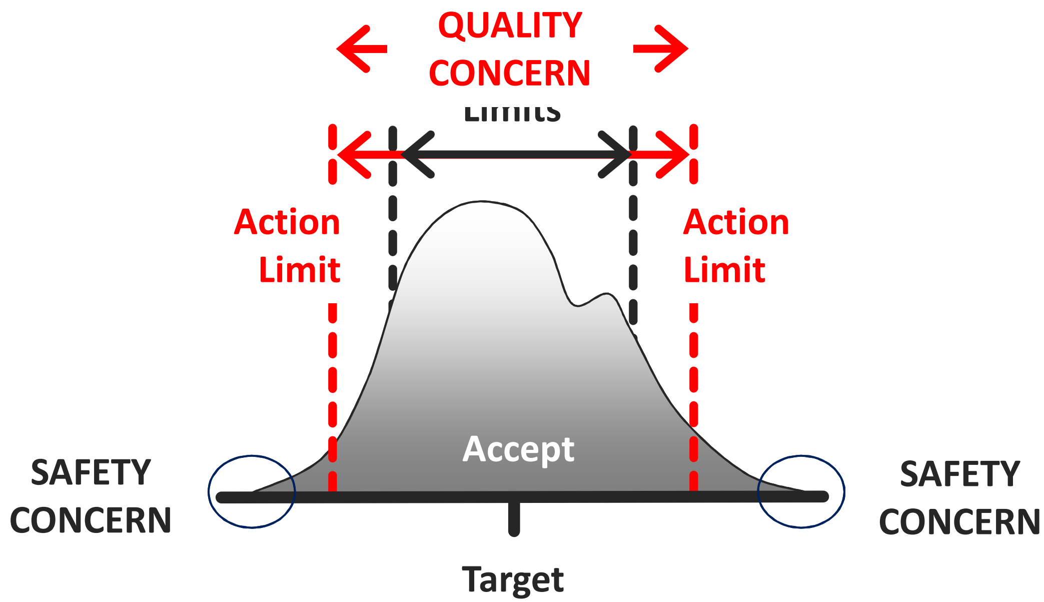
Safety is Event Driven

http://www.nytimes.com/2010/01/24/health/24radiation.html?fta=y

Quality is Data Driven

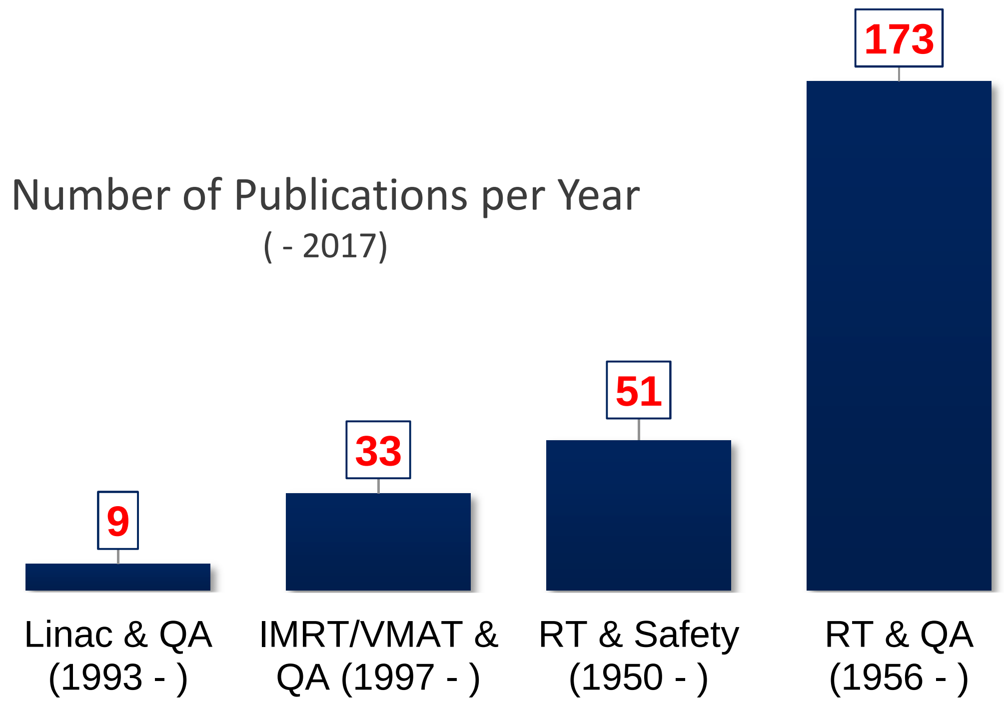


AAPM Task Group Reports

- TG-24 (1984)
  - 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



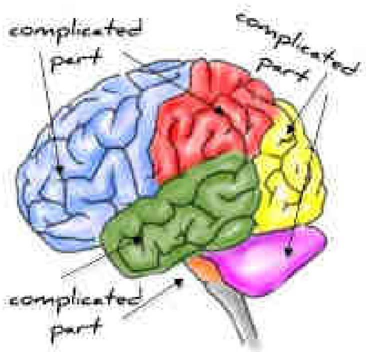
What is “Clinical Medical Physics”?

- Radiation safety and shielding design
- Helping at the machines – SRS, SBRT, gating, faults, etc.
- Ad hoc patient interactions – answering questions, etc.
- Accep[illegible]
- 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

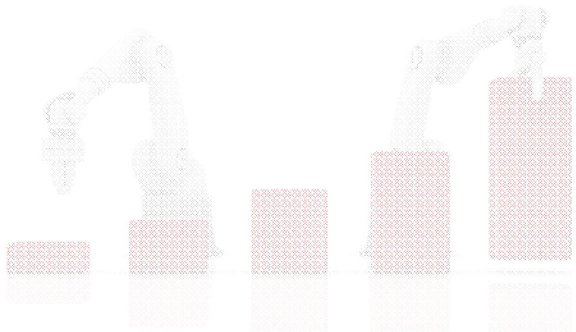
Ideas Requiring and Enabling Change

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

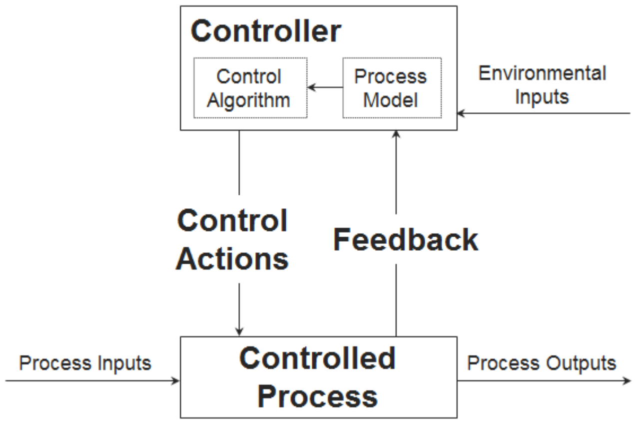
- The Report of the Task Group 100 of the AAPM
  - Applications of Risk Analysis Methods to RT Quality Management
- Key Components of TG-100
  - Quality management
  - Process mapping
  - Failure Modes and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTA)

Another Approach to Safety Assessment

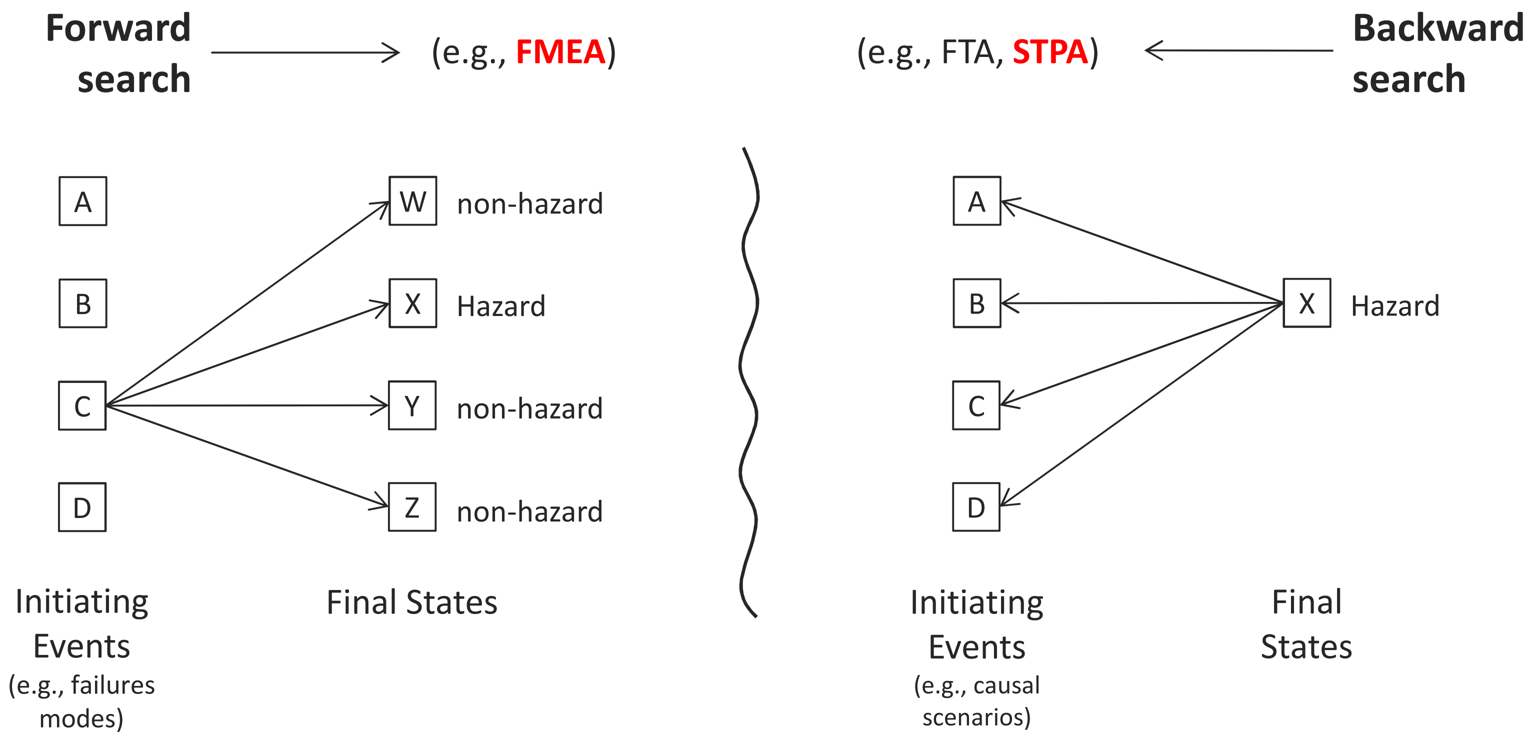
- Systems–Theoretic Process Analysis (STPA)
  - Process is described by a number of control loops
  - Results in a hierarchical understanding of process operation

Leveson. Safety Science, 2004.

Pawlicki *et al*. Med Phys, 2016.



Inductive vs Deductive



Pawlicki *et al*. Med Phys, 2016.

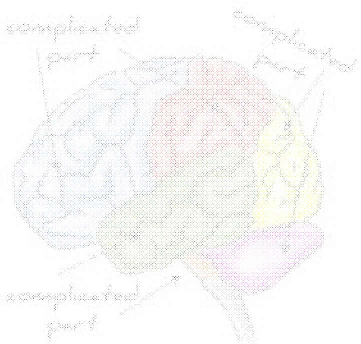
Systems Understanding of Safety

- Safety is a 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

Complexity

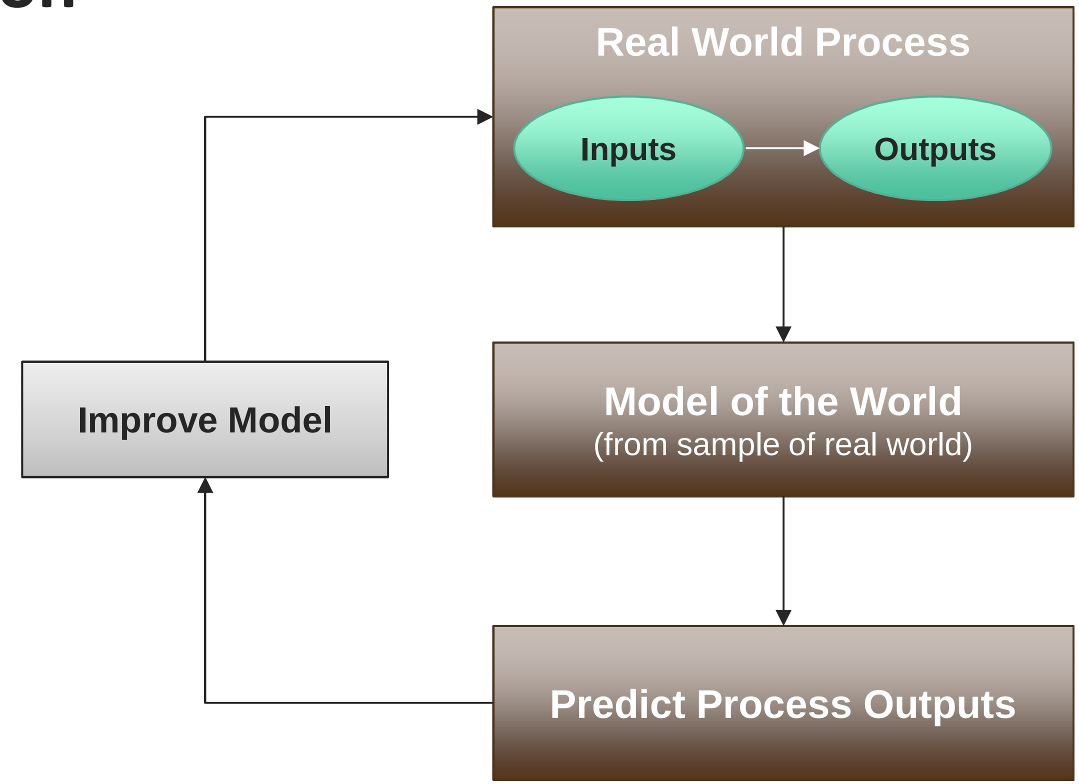


Complicated

Automation

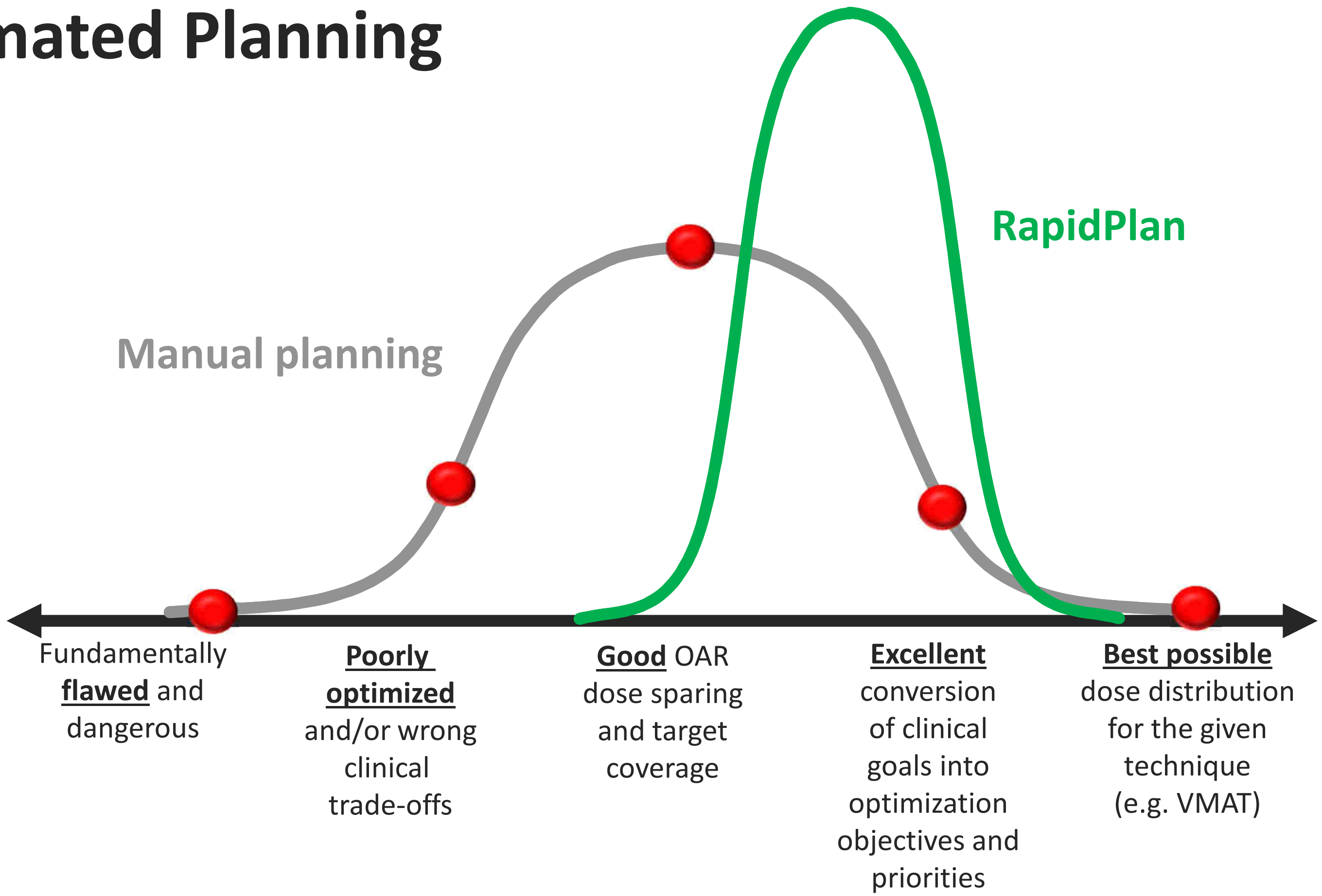
Courtesy of Kevin Moore, PhD

Automation



Courtesy of Kevin Moore, PhD

Automated Planning



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

Courtesy of Kevin Moore, PhD

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

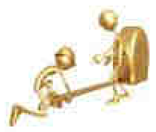
- Initial push back
  - Job security, competing with a computer
- Now embrace as a tool to speed up their work
  - Saves them about 40% of their time per case
- Better communication with physicians
  - RapidPlan gives them credibility
- Ultra-fast ramp up for new dosimetrists

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
  - Pawlicki *et al*. Med Phys, 2016.
- 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

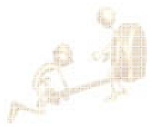
TPS vs Measurement = 2.715%

Maybe I should do another experiment?

If only I had more time!

Quality and Safety

Event View



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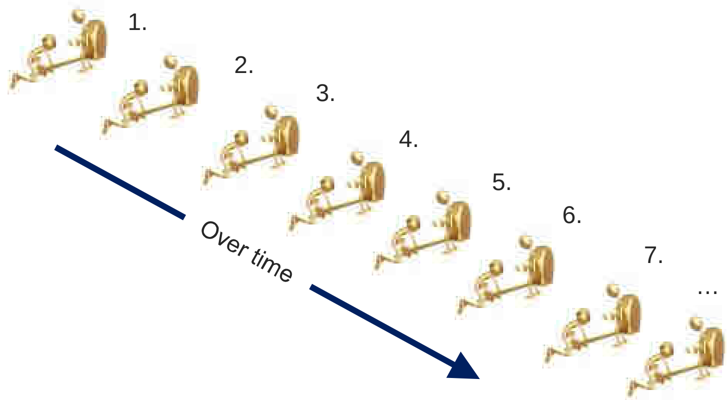
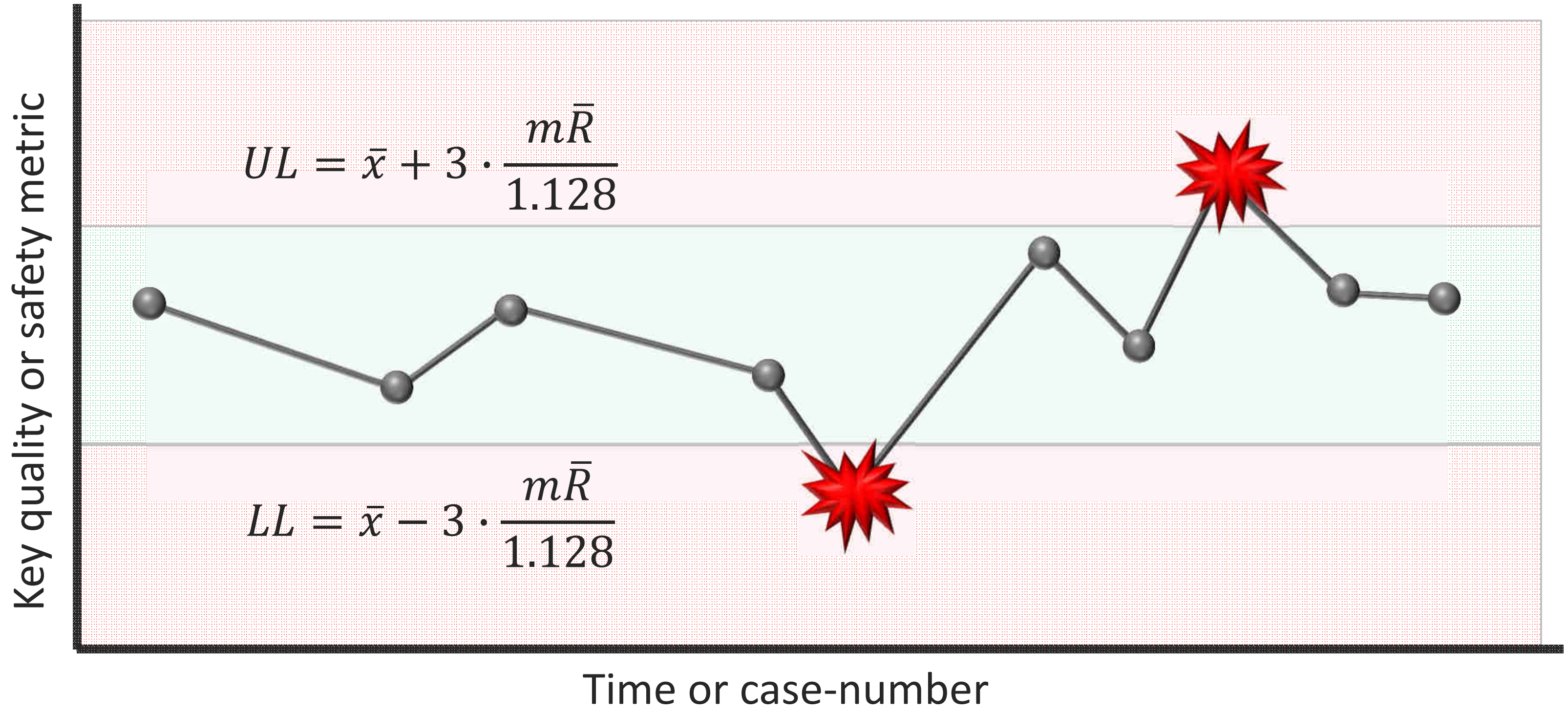
Process View



Are people and equipment doing it right?

How is the process performing?

Statistics-Based Decision Strategy

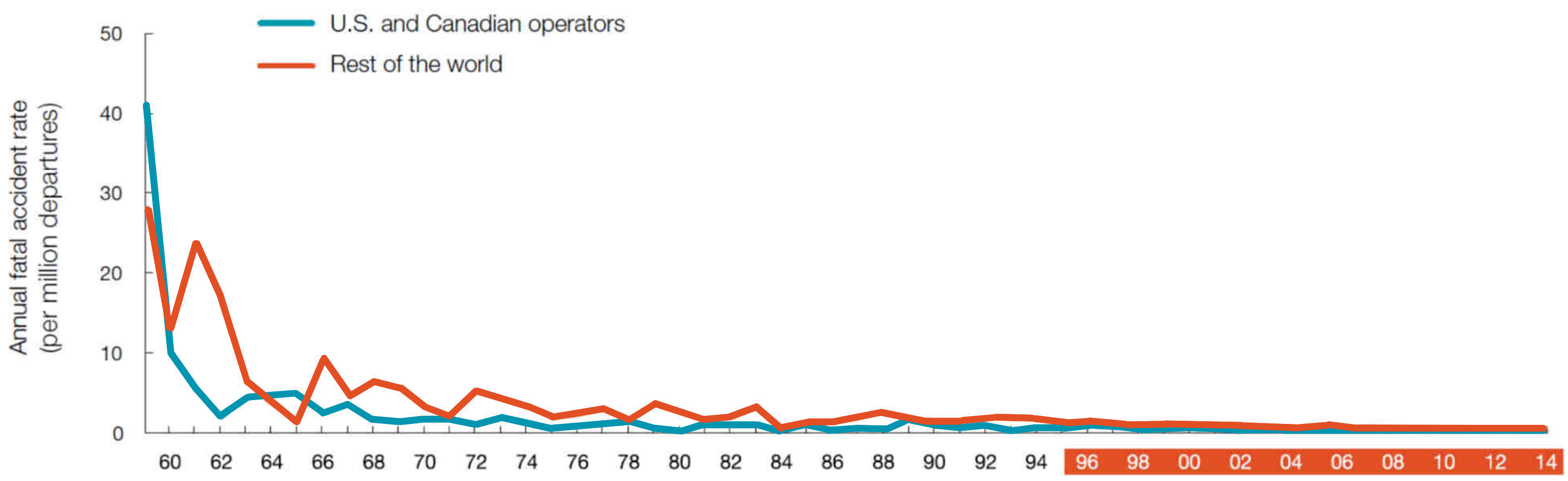


A Way Forward: Continuous QA

- 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

Fatal Accidents | Worldwide Commercial Jet Fleet | 1959 through 2014



http://www.boeing.com/resources/boeingdotcom/company/about_bca/pdf/statsum.pdf

What is our clinical future?

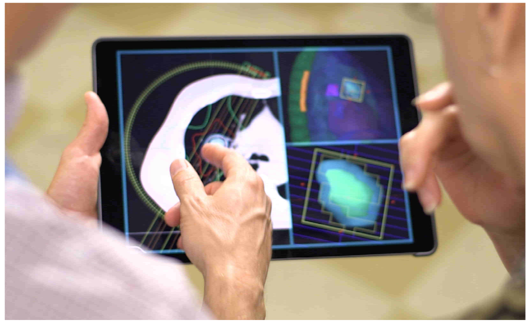
- Modified QA to maximize impact while minimizing effort
- Automated planning, plan and process checks

- How can we utilize our expertise to have a firsthand impact on patient care?

Courtesy of Todd Atwood, PhD

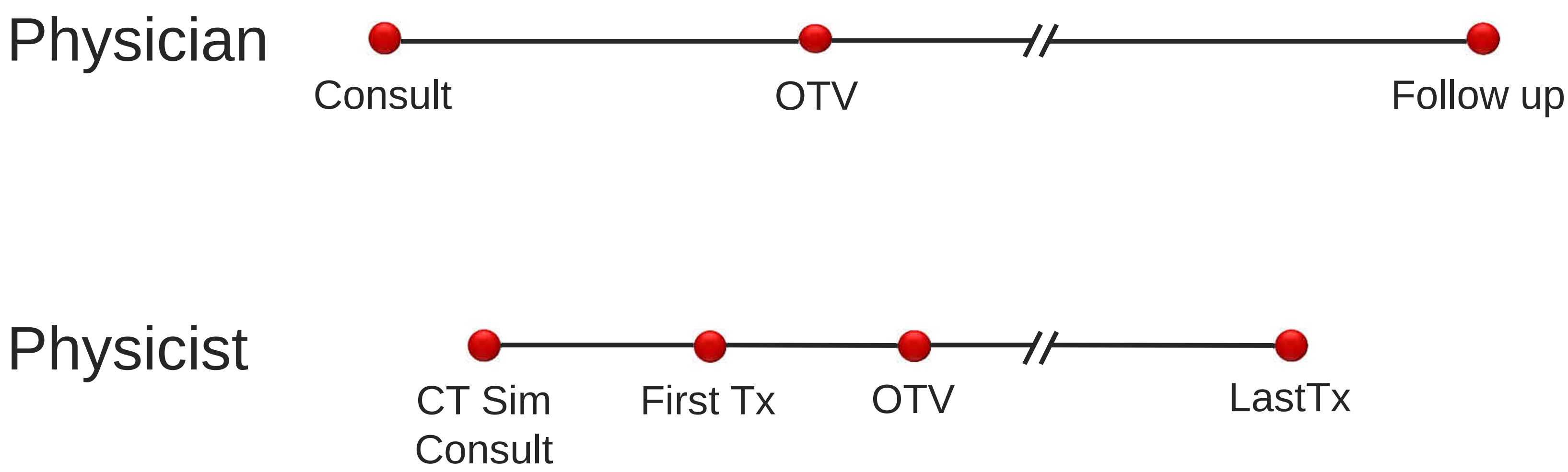
Physics Direct Patient Care Initiative

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



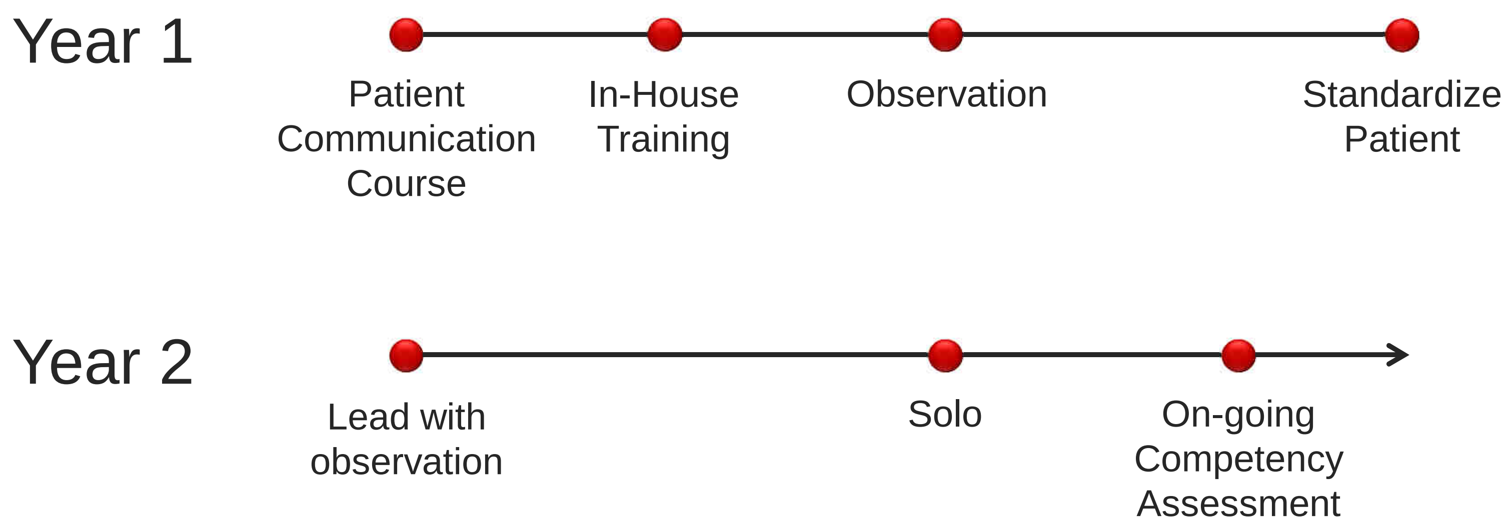
Courtesy of Todd Atwood, PhD

Patient Interactions



Courtesy of Derek Brown, PhD

Resident (and Faculty) Training



Randomized Clinical Trial

PDPC vs Conventional

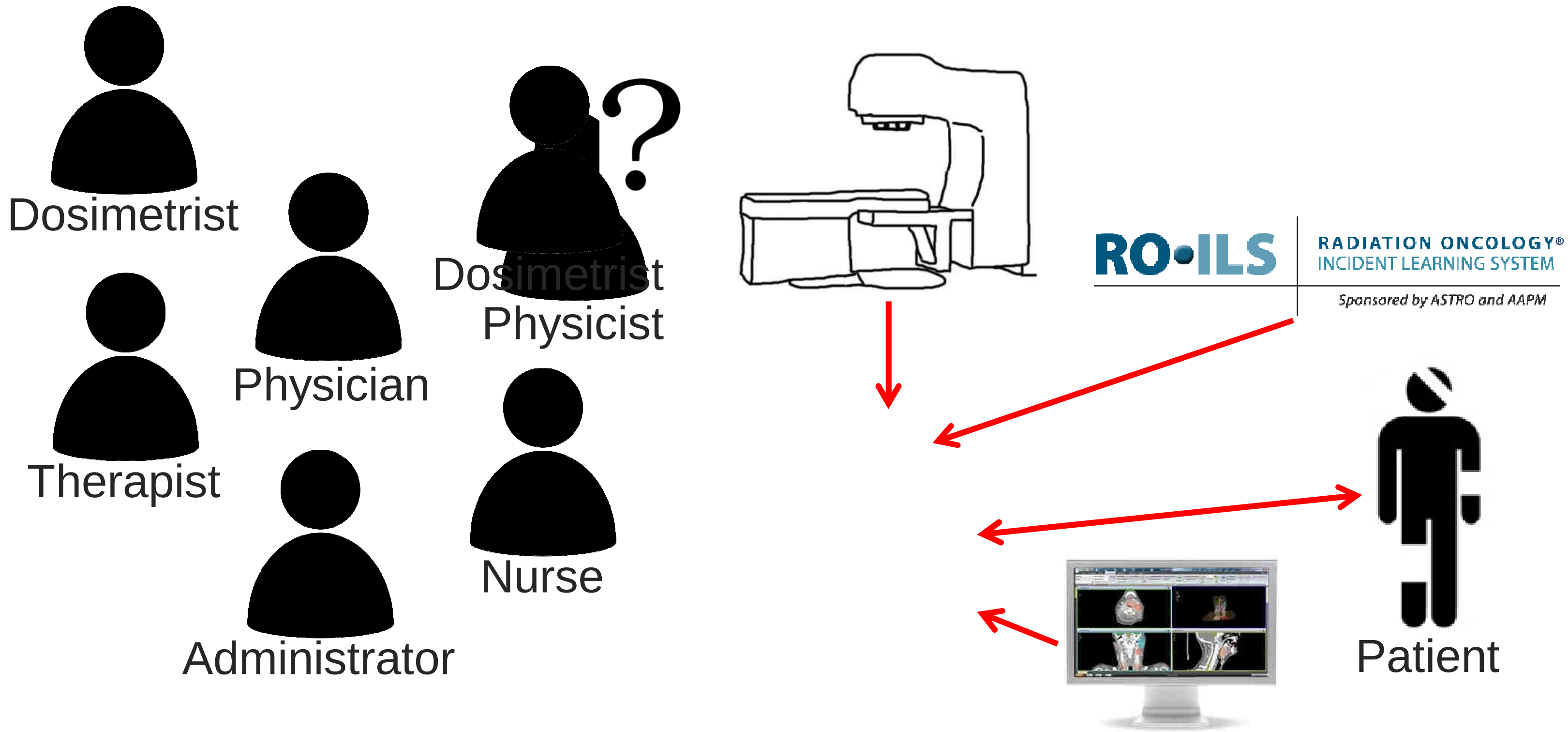
Primary Endpoint

- 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



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