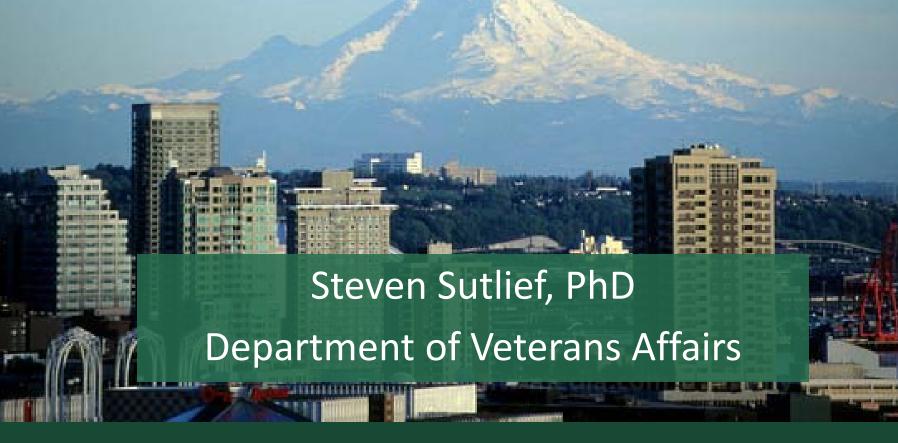
Root Cause Analysis for Radiation Oncology





Acknowledgements

 I want to express my thanks to Ed Leidholdt, Jr., Carl Bergsagel, the VA Radiation Oncology Field Advisory Group, and my fellow members of the AAPM Working Group for the Prevention of Medical Errors for insightful discussion of error prevention.

- Conflict of Interest: None.
- Mention of commercial products does not constitute endorsement of those products.

Objectives

- Understanding RCA outside/within healthcare
- Determining appropriate uses for RCA
- Knowing tools for performing RCA
- Assessing role of RCA in error prevention

What is Root Cause Analysis?

Introduction: Keys Parts of RCA

- Start with a problem whose causes may not be obvious.
- Get the right people on the analysis team.
- Visit the site, collect data, interview participants
- Create an event sequence diagram.
- Identify causes and effects, then keep asking why ("5 times") to find what is under each cause.
- Formally report recommendations and track the efficacy of the corrective actions.

Root Cause Analysis Outside and Inside Healthcare

Understanding RCA outside Healthcare

RCA started in engineering (1960s) and was exported to many disciplines:

Methodology	Origin	Application	
Safety-based	Accident analysis	Occupational Safety and Health.	
Production-based	Quality control	Industrial Manufacturing.	
Process-based	Production-based RCA	Business processes.	
Failure-based	Failure analysis	Engineering and Maintenance.	
Systems-based	Amalgamation of the preceding schools		

Understanding RCA within Healthcare

- The Joint Commission established a requirement for RCA in its 1999 sentinel event standards.
- The Department of Veterans Affairs National Center for Patient Safety was established in 1999.
- Institute of Medicine issued "To Err is Human" in 1999, followed by multiple reports on error reduction, including "Patient Safety" in 2004.
- (Charles Perrow published "Normal Accidents: Living with High-Risk Technologies" in 1999.)

VHA Event Dissemination

- The VA National Health Physics Program has provided newsletters describing misadministrations.
- The VA's reporting requirement for radiotherapy medical events included an RCA process which produced a set of "lessons learned" to be shared in the newsletters along with an anonymized description of the event.



National Health Physics Program Radiation Oncology Newsletter

2006

Treatment of a Patient with the Wrong Fields

An event occurred at a VA Radiation Oncology Service in which a patient was

Understanding RCA within Healthcare

- The Joint Commission encourages, but does not require, self-reporting of sentinel events.
- If the Joint Commission becomes aware of a sentinel event, the accredited organization is expected to "prepare a thorough and credible root cause analysis and action plan."
- Sentinel event is defined on one of the later slides.

When to Perform RCA?

When Mandated
Or
When Warranted by Interaction/Coupling

When to Perform RCA?

When required to by an oversight agency:

- US Nuclear Regulatory Commission
- The Joint Commission

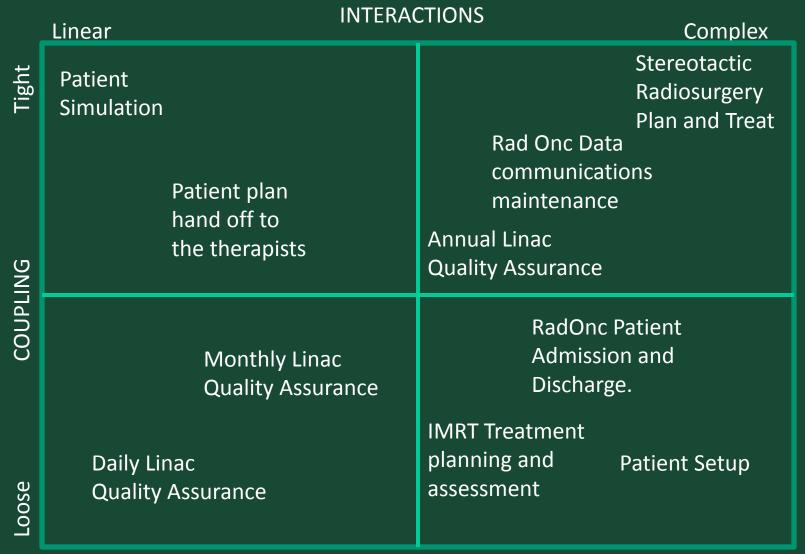
When required by Medical Center policy.

- When deemed worth the time and effort to perform more than a superficial analysis:
- Taxonomies are being developed to assist in how we capture events and categorize them.

Interaction/Coupling Diagram

	Linear		CTIONS	Complex	
Tight	Dams	Power Grids	Nι	uclear plant	
			Aircraft		
	Rail Transpor	t	Space miss	sions	
JNG					
COUPLING	Assembly-line p	roduction			
			Military Adventures Mining		
4)	Most	Manufacturing		& D Firms	
Loose					

Interaction/Coupling for Rad Onc



Chronic vs Sporadic Events

- Sporadic problem: "a sudden adverse change in the status quo, requiring remedy through restoring the status quo."
 - Example: Patient receives multiple fractions before staff discover the iso-shift was incorrect.
- Chronic problem: "a long-standing adverse situation, requiring remedy through changing the status quo."
 - Example: Physician routinely fails to review portal imaging before first treatment fraction, leading to occasional delays in treatment.

How does one perform RCA?

Simple Framework for RCA

- Chronological sequence
 - Diagram the flow of events leading up to the incident (including the three "whys")
- Cause and Effect Diagramming
 - Identify the conditions that resulted in the adverse event or close call
- Causal Statements
 - Develop root cause and contributing factor statements, actions, and outcomes

The Three Whys

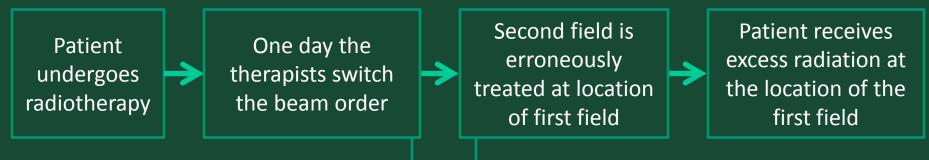
When distilling the event narrative into an event flow diagram, it is useful to ask the three whys:

- What happened?
- Why did it happen?
- What are you going to do about it?

• Initial event flow diagramming: use the event narrative to construct the discrete events in chronological order.



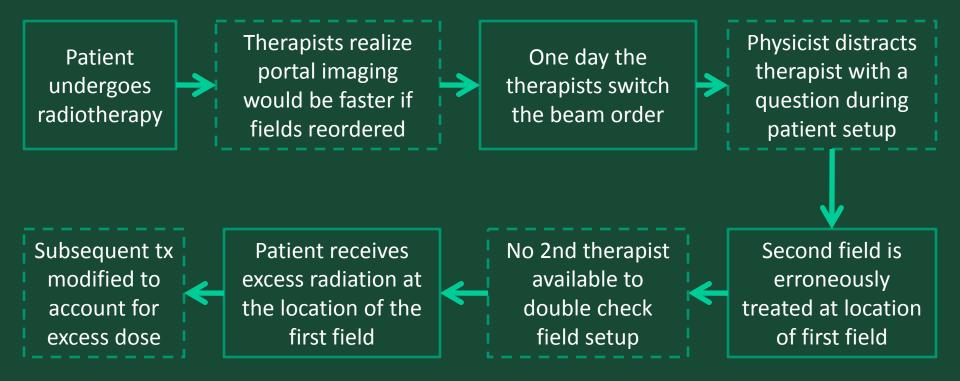
Intermediate event flow diagramming: ask
 why each event occurred until there are either
 no more questions or no more answers.



- •Question: Why wasn't normal setup followed?
- •Answer: The physicist interrupted the therapist with a question.
- •Question: Why wasn't the field position verified?
- •Answer: No second therapist was available.

•Answer: Reordering the fields simplified filming of the field portals.

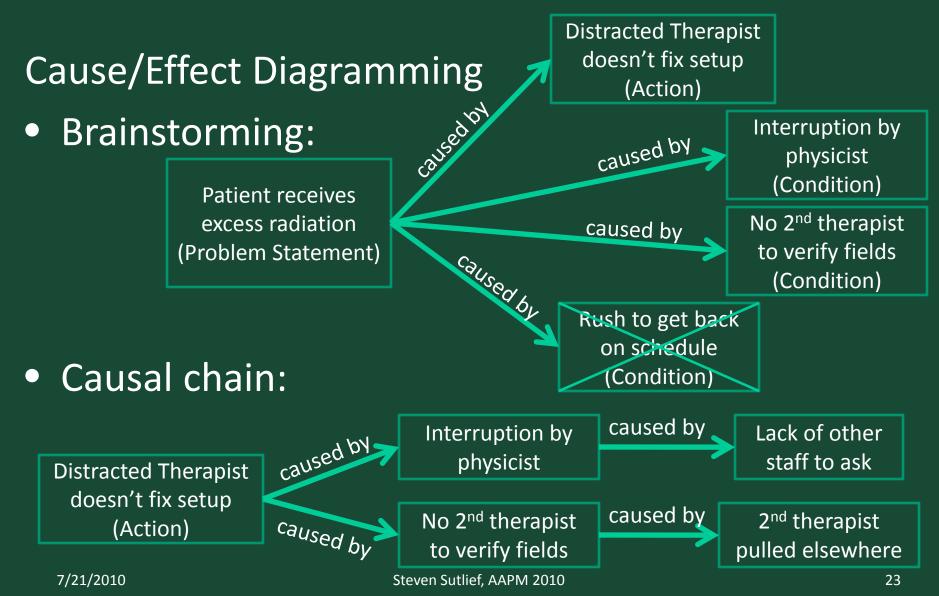
• Final event flow diagramming: done after answering "why" questions, interviews, and reference review.



Cause and Effect Diagramming:

- Review the event flow diagram and clarify the problem statement.
- Brainstorm a list of causes and choose the most important.
- Complete the causal chain.
- Conclude the investigation by developing root cause and contributing factors statements.

Patient receives excess radiation (Problem Statement)



Root Cause/Contributing factor statements ---

The Five Rules of Causation:

- Clearly show the cause and effect relationship.
- Use specific descriptors, not vague words.
- Identify preceding causes, not human error.
- Identify preceding causes of procedure violations.
- Failure to act is only casual when there is a preexisting duty to act.

Root Cause/Contributing factor statements:

- Therapist was distracted by other staff.
- Complex field arrangement.
- Therapists didn't perform independent checks.
- Root: procedures did not prohibit reversing field order or require independent field checks.

Actions:

- Two therapists will identify each field prior to delivery.
- The field order of complex field arrangements will not be reversed for convenience.
- Staff training for revised policies.

Outcome measures:

Tracking of future setup errors.

RCA Implementation



Post-it® Notes

Presentation Board

Software

Useful tools

- The Joint Commission's "Framework for Conducting a Root Cause Analysis and Action Plan" is an excellent six-page Word document that leads you through the steps of RCA.
- The VA National Center for Patient Safety
 "Root Cause Analysis Tools" flip book is an
 excellent tool for performing RCA as described
 in this talk.

Other Tools (Commercial)

- PROACT®: Methodology and software for performing RCA, FMEA, and Opportunity Analysis. Reliability Center Inc.
- REASON®: Training and software for performing RCA. Decision Systems, Inc.
- TapRooT®: Training and software for the incident investigation process including RCA.
 System Improvements, Inc.
- Others...

Available Reports Containing RCA

- The Radiation Therapy Incident at the Centre Hospitalier Jean Monet, Epinal, France
- Report into unintended overexposure of Lisa Norris at Beatson, Glasgow
- Treatment mistakenly delivered without wedge for 14 of 15 treatment fractions
- Error in transfer of treatment plan from R&V to linac,
 MLC fully open for three treatment fractions
- Error in commissioning orthovoltage machine, 620 patients treated, no independent check References are given in the slide-notes.

(References are given in the slide-notes.)

More Reports Containing RCA

IAEA reports:

- Accidental Overexposure of Radiotherapy Patients in Bialystok
- Investigation of an Accidental Overexposure of Patients in Panama
- Accidental Overexposure of Radiotherapy Patients in San Jose, Costa Rica

Conclusions

- Root Cause Analysis may be prompted by an outside agency, the medical center, or internal to the department.
- One methodology for RCA consists of:
 - Flow diagramming
 - Cause and effect diagramming
 - Causal statements, and
 - Actions and outcomes
- Everyone has their own formalism for RCA. Pick one.

References

- Error Reduction in Health Care, Patrice L.
 Spath, Ed., 2000.
- Patient Safety: Achieving a New Standard for Care, Institute of Medicine, 2004.
- Patient Safety: The PROACT Root Cause
 Analysis Approach, Robert J. Latino, 2009.
- Understanding Patient Safety, Robert M.
 Wachter, 2008.

References (continued)

- Normal Accidents: Living with High-Risk Technologies, Charles Perrow, 1999.
- To Err is Human, Institute of Medicine, 1999.
- Crossing the Quality Chasm, Institute of Medicine, 2001.
- TJC, Sentinel Event Policy and Procedures,
 2004, available on the Web.

References (continued)

- Techniques for Root Cause Analysis, Patricia M. Williams, Proc (Bayl Univ Med Cent). 2001 April; 14(2): 154–157.
- Holmberg O, McClean B. Preventing treatment errors in radiotherapy by identifying and evaluating near misses and actual incidents. J Rad Ther Practice 3:13-25 (2002)
- ICRP Publication 86: Prevention of Accidents to Patients Undergoing Radiation Therapy

References (end)

- IAEA Prevention of Accidental Exposure in Radiotherapy (slides)
- IAEA Accident Prevention (html)
- IAEA Lessons Learned from Accidental Exposures in Radiotherapy, IAEA Safety Reports Series No. 17, IAEA, Vienna (2000)