Root Cause Analysis for Radiation Oncology

Steven Sutlief, PhD
Department of Veterans Affairs

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• 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:

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Origin</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety-based</td>
<td>Accident analysis</td>
<td>Occupational Safety and Health.</td>
</tr>
<tr>
<td>Production-based</td>
<td>Quality control</td>
<td>Industrial Manufacturing.</td>
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<td>Process-based</td>
<td>Production-based</td>
<td>Business processes.</td>
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<td></td>
<td>RCA</td>
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<tr>
<td>Failure-based</td>
<td>Failure analysis</td>
<td>Engineering and Maintenance.</td>
</tr>
<tr>
<td>Systems-based</td>
<td>Amalgamation of the preceding schools</td>
<td></td>
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</table>
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.
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

Adapted from Normal Accidents, Charles Perrow, p97

7/21/2010

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Interaction/Coupling for Rad Onc

- **Tight**
  - Linear: Patient Simulation
  - Complex: Stereotactic Radiosurgery Plan and Treat
  - Monthly Linac Quality Assurance
  - Rad Onc Data communications maintenance

- **Loose**
  - Linear: Daily Linac Quality Assurance
  - Complex: Rad Onc Patient Admission and Discharge.
  - Annual Linac Quality Assurance
  - IMRT Treatment planning and assessment

- **Complex**
  - Linear: Patient plan hand off to the therapists
  - Monthly Linac Quality Assurance
  - Annual Linac Quality Assurance
  - IMRT Treatment planning and assessment

- **Loose**
  - Complex: Rad Onc Data communications maintenance
  - Rad Onc Patient Admission and Discharge.
  - Annual Linac Quality Assurance
  - IMRT Treatment planning and assessment

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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?
Radiation Therapy Example

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

Patient undergoes radiotherapy

One day the therapists switch the beam order to facilitate filming

Second field is erroneously delivered at location of first field

Patient receives excess radiation at the location of the first field
Radiation Therapy Example

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

Patient undergoes radiotherapy

One day the therapists switch the beam order

Second field is erroneously treated at location of first field

Patient receives excess radiation at the location of the first field

• **Question:** Why was switching field order done?
  • **Answer:** Reordering the fields simplified filming of the field portals.

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

- Patient undergoes radiotherapy
- Therapists realize portal imaging would be faster if fields reordered
- One day the therapists switch the beam order
- Physicist distracts therapist with a question during patient setup
- Patient receives excess radiation at the location of the first field
- Subsequent tx modified to account for excess dose
- No 2nd therapist available to double check field setup
- Second field is erroneously treated at location of first field
Radiation Therapy Example

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)
Radiation Therapy Example

Cause/Effect Diagramming

• Brainstorming:
  - Patient receives excess radiation (Problem Statement)

• Causal chain:
  - Distracted Therapist doesn’t fix setup (Action)
  - Interruption by physicist (Condition)
  - No 2nd therapist to verify fields (Condition)
  - Rush to get back on schedule (Condition)
  - Lack of other staff to ask
  - 2nd therapist pulled elsewhere
Radiation Therapy Example

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 pre-existing duty to act.
Radiation Therapy Example

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.
Radiation Therapy Example

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

• Patient Safety: Achieving a New Standard for Care, Institute of Medicine, 2004.
References (continued)

- To Err is Human, Institute of Medicine, 1999.
- Crossing the Quality Chasm, Institute of Medicine, 2001.


• 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)