Corrective Actions

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UC San Diego
February 13th, 2015
Objectives

By the end of this presentation, the listener should gain...

• A **vocabulary** to discussing and thinking about corrective actions,

• An awareness of the **kinds** of corrective actions often used in radiation therapy, and

• A framework for **selecting**, **implementing**, and **monitoring** corrective actions.
Outline

Terminology
Timeframes
Typical Causes
Typical Interventions
Community-wide Corrective Actions
Hands-on Exercise
**Terminology**

Timeframes
Typical Causes
Typical Interventions
Community-wide Corrective Actions
Hands-on Exercise
Terminology

• Unlike root cause analysis and safety culture, the literature for corrective actions and monitoring is far less developed.

• A **corrective action** is a change in process, policy, staff, or equipment to prevent a pathway towards an error.

• The term **intervention** is frequently used instead of “corrective action” in the literature, but can also mean a good catch.
Responses to error can take the form of:

- **Corrective actions** taken to mitigate the harm for this particular patient.
- **Preventive actions** taken to insure that a similar incident will not happen to a patient in the future.
- **Learning activities** taken in response to the incident (e.g., presentation at rounds, etc.).
• Corrective actions make use of error reduction strategies, which are tools to reduce the likelihood of an error.

• One kind of error reduction strategy is the insertion of a safety barrier, which is a process step “whose primary function is to prevent errors or mistakes from occurring or propagating through the radiotherapy workflow.”
Terminology

Timeframes

Typical Causes

Typical Interventions

Community-wide Corrective Actions

Hands-on Exercise
Timeframes for Life Decisions

Suzie Welch popularized an approach to decision making which she called “10-10-10.”

Welch 2010.
A “5-5-5” for Corrective Actions

**Immediately**, one can:
- stop a procedure,
- reassign a staff member,
- discontinue use of a piece of equipment, and so on.

**Within five days**, one can:
- reconfigure software,
- recalibrate equipment,
- retrain staff,
- revise procedures, ...

**Within five months**, one can:
- hire additional staff,
- purchase equipment, ...

**Within five years**, equipment vendors can:
- release improved designs which mitigate known error pathways, ...

Timeframes
Mitigation of Harm to the Patient for Whom an Error has Occurred

Types of deviation from the physician’s intent:

• Too little dose delivered across the treatment site to achieve curative intent.
• Too much dose delivered to sensitive organs.
• Reasons:
  – Inappropriate setup
  – Inappropriate dose delivered
  – Deviation from intended fractionation schedule
Mitigation of Harm to the Patient for Whom an Error has Occurred

Available actions

• Addition or removal of Tx fraction(s)
• Re-planning
• Discontinuation of treatment
• Additional medication or medical intervention
Terminology

Timeframes

**Typical Causes**

Typical Interventions

Community-wide Corrective Actions

Hands-on Exercise
Frequently Cited Causes of Error in RT

- Organizational
  - Communication & Leadership
  - Supervision
  - Staffing
  - Failure to Correct
- Technical
  - Hardware or Software
- Human
  - Recklessness or Negligence
  - Slips and mistakes
  - Exceeding one's Capabilities
- New Equipment
- Environment
- Distraction
Terminology
Timeframes
Typical Causes

Typical Interventions
Community-wide Corrective Actions
Hands-on Exercise
Human Factors Perspective on Corrective Actions

Actions are carried out using devices situated within an environment within which one carries out processes based on the intention of the individual.

Deviations from intended action may occur through a slip or a mistake.
Human Factors Perspective on Corrective Actions

Slips
Execution
Goal
Intention
Action Specification
Evaluation
Perception
Interpretation
Evaluation
Knowledge-based
Goal
Intention
Rule-based
Action Specification

Mistakes
Reduce interruptions
Situated actions
Direct action
Provide Memory aids
Direct perception
Situation awareness
Reduce goal stacks
Decision Support
Train users
Reduce multitasking
Education
Automation
Display design
Visualization
Immediate feedback
Information reduction
Representational aid

Environment
Individual
Process
Devices

ZHANG 2005
Corrective Actions

Typical Interventions

- Safety barrier
- Training
- Other
- Exhortation
- Add QAP or ILS
- External Review
- Enhanced supervision
- Process standardization
Typical Interventions

Safety Barriers

• “Use a check list including ... the expected range of Monitor Units per treatment fraction.”
• “In vivo dosimetry should be promoted.”
• “Radiation therapists who input patient treatment data in the linac computer database should carry out a check as to the accuracy of their input.”
Training

• “Train for the identification of potential serious adverse incidents and how to respond if one occurs.”

• “Re-train therapists on patient identification procedures and verification process to ensure treatment plan being used is for the correct patient.”
Typical Interventions

Process Standardization

• “Use the standard convention (name, D.O.B) when identifying a patient.”
• “Standardize treatment techniques so that all involved know exactly what the standard treatment for a given site is.”
Typical Interventions

Enhanced Supervision

• “The existing regulations should be implemented, monitored, and enforced as soon as possible.”

• “Review and revise training records and related documents to ensure that the training status of all individuals is properly recorded and verified and that planning duties are allocated appropriately.”
External Review

• “Participate in intercomparison exercises such as a TLD postal dose quality audit, combined with the establishment of positive procedures for taking actions if a prescribed deviation is found.”

• “Contract an independent consultant to performs structure, function, and safety culture review of the Radiation Oncology group.”
Add a Quality Assurance Program or Incident Learning System

• “Monitor for re-occurrence of the error.”
• “Implement an HDR variance log to track ‘near misses’ associated with HDR treatment planning and delivery, for lessons-learned purposes.”
Typical Interventions

Exhortation

• “Issue a letter informing staff of the incident and stressing their responsibility for verifying the set coordinates and collimator size before each discrete site is irradiated.”

• “Treatment setup staff should more attention to all field parameters.”

• “Reviewed with radiation oncology staff the importance of correct seed type in dose calculation.”
Typical Interventions

Who?
- Physician
- Dosimetrist
- Therapist

Where?
- Pre-Tx review
- Tx planning
- On-Tx QM
- Tx delivery
- Post-Tx completion
Effectiveness

- High level review
- Fault mode eliminated
- Change won’t be forgotten

Cost?

- External action
- Big cost
- Medium cost
- Small time cost
- Zero cost

Typical Interventions

Change may be forgotten

Change won’t be forgotten
• NCRP Report 107 discusses corrective actions for ALARA implementation.
• It recommends weighing the merits of several alternative corrective actions.
Evaluation of Corrective Actions

- Do they address all the deficiencies identified in the causal analysis?
- Are they free of unintended consequences (new problems or error pathways)?
- Are resources available to implement them?
- Can they be implemented on a timely basis?
- Do they apply to other areas in the institution?
PDCA and DMAIC

- Problem solving strategies include PDCA, A3, DMAIC, 8D/PSP, and Kaizen Blitz.
Typical Interventions

Monitoring Implementation for Compliance and Effectiveness

<table>
<thead>
<tr>
<th>Corrective Action</th>
<th>What can be monitored?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety barrier</td>
<td>Consistent use of barrier</td>
</tr>
<tr>
<td>Training</td>
<td>Absence of repeat events</td>
</tr>
<tr>
<td>Process standardization</td>
<td>Compliance with standard</td>
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<tr>
<td>Enhanced supervision</td>
<td>Continued application</td>
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<tr>
<td>External Review</td>
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<td>Procedural change</td>
<td>Compliance with new policy</td>
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Timeframes
Typical Causes
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Community-wide Corrective Actions
Hands-on Exercise
Community-wide Corrective Actions

- Vendor field notices and FDA reports
- Lessons learned from ROSIS, SAFRON, ROILS, ...
  - [http://www.rosis.info/](http://www.rosis.info/)
- MEDPHYS list server, user groups, VHA notices
- Feedback to vendors: IHE-RO, ROSSI, ...
Dose delivery errors: In-vivo dosimetry provides a layer of defense against dose errors.

Patient identification errors: Introduction and adherence to a robust patient identification verification system and by staff being constantly alert to the possibility of patient misidentification.

Data transfer errors: With good quality assurance procedures it is possible to catch most of these mistakes before or at the beginning of the patient’s treatment.

Record and Verify errors: Ensure adequate checks of data entry.
Terminology
Timeframes
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Typical Interventions
Community-wide corrective actions

**Hands-on Exercise**