Error Management and Patient Safety in Radiation Therapy: Fault Tree Analysis

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Administrative Stuff

Learning objectives:

■ To understand fault trees.
■ To understand how to use fault tree analysis to design quality management.

Conflicts of Interest: The author has none.
Proactive Steps to Address Hazards: Initial Design

Design the procedure with the system in mind:

- To facilitate communications
- To minimize energy (e.g., minimize distances to move, have ready access to materials)
- Provide all environmental support (e.g., lighting, sound control)
SEIPS Model Work system
(Balance Theory; Smith and Carayon, 1989; Carayon and Smith, 2000)
Slide from Pascale Carayon
Proactive Steps to Address Hazards: Analysis and Actions

- After initial design of a procedure (or looking at a procedure in place), assess the risks.
- For the high risks, try to redesign them out.
- When not possible, develop interventions.
What to Do?

1. Understand the process
2. Assess the hazards (e.g., FMEA)
3. Establish the failure propagation patterns (e.g., Fault tree analysis - FTA)
4. Address the hazards
5. Test and evaluate
2. Assess the Risk

Eric just discussed this.
3. Establish the Failure Propagation Pattern

- This is the fault tree analysis.

- For the fault tree
  - Begin at the failure
  - Ask what are all the possible causes
  - Relate the causes through logical gates
  - For each cause, ask what would be the cause
  - Repeat as needed
Example: Calculation Fault Tree

Error in Calculation

- Error in Input Data
- Error in Data Entry
- Error in Calculation Algorithm
- Error in Prescription
Example: Calculation Fault Tree with QM

- Error in Calculation
  - Error in Input Data
  - Error in QC
- Error in QA
  - Error in Prescription
  - Error in QC
  - Error in PT Calculation
    - Error in Data Entry
    - Error in QC
    - Error in Calculation Algorithm
    - Error in QC
Process Tree for Prostate Implants with Loaded Needles

1 Gathering materials
- MP brings planning images to procedure room
- MP brings plan to procedure room identifying needle location and depth
- MP brings needles to procedure room

2 Prepare patient
- Scrub patient
- Anesthetize patient
- Move patient to table
- Bring patient into procedure room
- Identify patient

3 Position US probe
- Prepare and insert US probe
- RO rotates probe and mounting bracket to match previous images
- RO checks images along whole superior-inferior range

4 Insertion of needles and sources
- MP finds needle in package or container
- MP hands needle to RO
- MP brings planning images to procedure room
- RO pushes needle until tip shows at desired depth
- RO inserts needle into indicated hole in template
- RO selects next needle

5 Review implant
- RO scans through images looking for gaps
- RO adds extra sources if needed and available

Successful treatment

1, 4, 6, 7
2, 5
3, 9, 19
4, 10, 11
8, 16, 17, 18
9, 11, 12, 13
10, 19
14, 25
15, 20
22, 23
1, 6, 7, 18, 20
2, 5
3, 4
8
9, 11, 12, 13
14, 15, 16, 17
One Step of the Process Tree

4 Insertion of needles and sources

- RO selects next needle
- RO holds stylet and removes needle
- RO pushes needle until tip shows at desired depth
- RO inserts needle into indicated hole in template
- MP hands needle to RO
- MP finds needle in package or container
- RO determines starting needle
Fault Tree for Prostate Implants with Loaded Needles

Again, don’t worry about reading it, this is for scale.
4. So What?

- Start with the branches of the fault tree that corresponds to the branches of the process tree with the greatest hazard, either PRN or severity.
- Might as well start with the top of the branch, even though that is completely arbitrary.
- Consider the possible interventions.
Possible Interventions

- First correct any environmental problems – that usually is a relatively inexpensive but effective operation.

- Then consider the key core components identified by TG 100
  - Training
  - Communication
  - Standardized policies and procedures

- Make sure resources are allocated as needed (i.e., staffing and equipment.)
Fault Tree with Interventions

Again, don’t worry about reading it, this is for scale.
Taken care of by the generally complete training, establishing clear communication modalities (possibly forms) and establishing protocols, policies and procedures.

- Systemic corrections
- Quality assurance
- Quality control
- Managerial changes
- Procedural changes
Quality Management

Quality Control – Activities that force specific quality on a process. Often operates on inputs.

Quality Assurance – Activities that demonstrate the level of quality of a process. Often checks outputs.
One Example

- Human error: Omission – Time-out not performed
- Training – patient identified incorrectly
- QC failure: Time-out form

Patient misidentified

Systemic corrections
Quality assurance
Quality control
Managerial changes
Procedural changes
Another Example

MP fails to hand the correct needle to RO

Human Failure: Inattention/Poor performance

Confusion between packages

Poor demarcation of needles

MP drops needle

Failure of call and response

Poor room layout

Human failure: MP slips

Systemic corrections

Quality assurance

Quality control

Managerial changes

Procedural changes

Quality assurance

Quality control

Managerial changes

Procedural changes
Another Example

RO fails to align images along the range

Or

Training failure

Human Failure: Inattention/Poor performance

US images inadequate

US QA failure

AND

Systemic corrections

Quality assurance

Quality control

Managerial changes

Procedural changes

Quality assurance

Quality control

Managerial changes

Procedural changes
No Preventing Human Error

- QC failure: Prostate image time out
- RO fails to align images along the range
- Human Failure: Inattention/Poor performance
- Training failure
- US images inadequate
- US QA failure

Add some QC downstream
Commissioning

Key item for commisioning

Key item for facility managerial changes

Taken care of by the generally complete training, establishing clear communication modalities (possibly forms) and establishing protocols, policies and procedures

Taken from TG 100
Levels of QM

- Commissioning
- Periodic Testing
- Per patient
Good Beginnings

- Acceptance Testing is making sure the procedure works as specified.
  - Usually applied to hardware and software.
  - Also applies to walking through new procedures.
- Commissioning gets a procedure started
  - Gathers all the data needed.
  - Gives confidence that systems work as expected.
  - Finds when the system fails.
- Essential to any procedure.
What to Do?

1. Understand the process
2. Assess the hazards (e.g., FMEA)
3. Establish the failure propagation patterns (e.g., FTA)
4. Address the hazards
5. Test and evaluate – Quality Improvement: a different presentation
Conclusions

Fault tree analysis facilitates quality planning:

- Redesigning to eliminate hazards.
- Adjusting resources.
- Ensuring the key core components.
- Performing comprehensive commissioning.
- Establishing quality management.