Beyond FMEA: Future and Summary

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Outline

• Failure Effects and Modes Analysis: What it does and does not do
• Complementary QA and QM process design tools for improving RT Quality
  - Fault Tree Analysis (FTA)
  - Root cause analysis (RCA)
  - Event taxonomies
  - Sensitivity analyses
• Recommended next steps
  - Guidance groups
  - Individual clinics
Classification of QA Tools

• Binary events: An error occurs or not
  ➢ Prospective: improve delivery system design
    ✓ FMEA
    ✓ Fault Tree Analysis (FTA)
  ➢ Retrospective/Reactive: Develop corrective action following an error occurrence
    ✓ Root Cause Analysis (RCA)
    ✓ Error taxonomies

• Continuous variable outcomes: calibrations, etc.
  ➢ Prospective: Sensitivity analysis
  ➢ Retrospective: process control
Examples: Highest Risk IMRT Steps

- Steps with highest RPN ratings
  - Pre-Tx Bio-images misinterpreted: CTV error
    - RPN = O₧SₓD = 6.5 x 7.4 x 8 = 388
  - >3*σ CTV/OAR delineation errors
    - RPN = O₧SₓD = 5.4 x 7.4 x 7.9 = 366
  - Linac dose delivery errors (D/MU, etc.)
    - RPN = O₧SₓD = 5.4 x 8.2 x 7.2 = 353
  - MD prescription ignores previous Tx
    - RPN = O₧SₓD = 5.3 x 8.6 x 7.3 = 333

FMEA Contributions

- Prospective process design/evaluation tool
  - Identify high risk process steps in absence of QA program
- Emphasizes procedure design, information flow, and staff interactions
  - Therapists, physicists, physicians cooperatively making flow chart and FMEA has benefits
    - Good corrective to “device-centric” physicist bias
    - Everyone has to think outside their domain
    - Process flow charting itself helps identify bottlenecks, problems
- Semi-quantitative ranking helps prioritize QA resources
**FMEA Limitations**

- **Methodological Limitations**
  - OSP assignments are subjective, dependent on team’s experiences
    - TG-100 FMEA: Largely limited to physicist input
    - documents beliefs, not actual risks
    - Propagation of errors from one step to another not modeled
- No guidance on managing identified hazards
- Prospective tool: not intended for analyzing events and identifying corrective actions

**Fault Tree Analysis**

- Models error propagation across subprocesses and steps including QC/QA checks
- Decide which process steps need QA/QC checks to mitigate high risk errors identified by FMEA
- Requires error pathway knowledge and associated probabilities

- System failure postulated: all possible causal paths followed backward to potential antecedent errors
  - OR gate: Any antecedent error occurs ⇒ Error propagates
  - AND gate: All antecedent errors occur ⇒ Error propagates
Fault Tree Analysis: External Beam Treatment Planning

- FTA can reveal error pathways unprotected by QA or QC checks
  - Probability data: allows QA/QC checks to be prioritized by risk
- Does not determine what kind of QA check is best

Reactive Strategies: RCA

- Medical errors: Factual data source for validating/refuting hypothesized QMP
- RCA is Fault-Tree like representation of the event sequence leading to an error
- Single-Event analysis
  - Suggests corrective strategies only for that event
  - Other tools needed to generalize or correlate with other events
Beyond FMEA
AAPM 2008 TG-100 Symposium
Jeffrey F. Williamson, VCU

Plotting RCA results on Process Tree

- 43 HDR brachytherapy Errors from NRC/IAEA database
- “Measurement-based” version of TG-100 process tree

Taxonomic Analysis of Errors

- Formal approach for facilitating transitions
  - What happened? ⇒ where? ⇒ why? ⇒ what caused it? ⇒ how can we correct it?
  - Find underlying causes common to groups of errors
  - Guide selection of corrective actions
- Thomadsen: Existing IE taxonomies (SMART, SCOPE, etc.) not useful for radiation therapy
- RT-specific schemes
Madison Medical Taxonomy
First and Second Tier Classifications

|----------------|------------------------|---------------------------------|-----------------------------|--------------------------|-----------------|------------------------------------|---------------------------|-------------------|

Third Tier Classification

- Human Error: Tripping
- Human Error: Slips
- Human Error: Blunder
- Human Error: Error in the Intention (Mistake)
- Hardware Failure
- Software Failure
- Enabling Factor: Hardware
- Enabling Factor: Software
- Enabling Factor: External
- Enabling Factor: Environmental
- Enabling Factor: Organizational

Madison Medical Taxonomy
Fourth Tier Classification

- What caused the error?
- Emphasizes psychological-perceptual mechanisms of human error
- Environmental and organizational factors also considered
- knowing “human error” origin ⇒ more optimal corrective action

Hardware - Design
Hardware - Construction
Hardware - Material
Hardware - Maintenance
Software - Design
Software - Construction
Software - Maintenance
Manual Variability (SB)
Topographic Misorientation (BB)
Stereotype Fixation (SB)
Stereotype Takeover (SB)
Familiar Association Shortcut (RB)
Familiar Pattern not Recognized (RB)
Mistakes Alternatives (RB)
Mistake Consequence (RB)
Condition or Side Effect not Considered (KB)
Lack of Vigilance (Arousal, Commitment, Complacency)
Information not Sought - Assumed, Negligent Omission, Not K
Organizational - Knowledge of Leader
Organizational - Management Priority
Organizational - Communication System
Organizational - Knowledge Transfer
Organizational - Lack of Experience
Competition for Attention (Background) - Lack of Staff or Time
Competition for Attention (Background) - Other Goals
Competition for Attention (Immediate) - Other Duties
Competition for Attention (Immediate) - Lack of Staff
Competition for Attention (Immediate) - Too Many Inputs to the System
Competition for Attention (Previous) - Fatigue due to Complexity
Environment - [Tangible] Noise (Non-Human Environmental F
Environment - [Tangible] Distraction (Human Related Environment)
Environment - [Intangible] Environmental Problem
Environment - [Intangible] End of Day, Holiday
Environment - [Intangible] Personal Problem
Others - Exceed Ability - Physical
Others - Exceed Ability - Mental
Others - Lack of Experience

Courtesy B. Thomadsen
Error Mitigation Strategies
Ranked in order of Effectiveness (Courtesy B. Thomadsen)

<table>
<thead>
<tr>
<th>0. Environment problem correction (Not tool)</th>
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<tbody>
<tr>
<td>• Sound Control</td>
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<tr>
<td>• Visual Control</td>
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<tr>
<td>• Cleaning</td>
</tr>
<tr>
<td>• Nesting</td>
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<tr>
<td>• Isolation</td>
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<tr>
<td>• Environmental Design</td>
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</tbody>
</table>

1. Focusing functions and constraints
   • Interlocks
   • Barriers
   • Computerized order entry with feedback

2. Automation and computerization
   • Bar codes
   • Automatic monitoring
   • Computerized verification
   • Computerized order entry

3. Protocols, standards, and information
   • Check off forms
   • Establishing Protocol / Clarify Protocol
   • Alarms
   • Labels
   • Signs
   • Reduce similarity

4. Independent double check systems and other redundancies
   • Redundant measurement
   • Independent review
   • Operational Checks
   • Comparison with standards
   • Increase monitoring
   • Add status check
   • Acceptance test

5. Rules and policies
   • External Audit
   • Internal Audit
   • Priority
   • Establishing / Clarify Communication Lines
   • Staffing
   • Better Scheduling
   • Mandatory Pauses
   • Repair
   • PMI (Preventive Maintenance Inspection)
   • Establish and Perform QC and QA
     (Hardware and Software)

6. Education and Information
   • Training
   • Experience
   • Instruction

Madison "Corrective Action" Matrix

- Judgment, reaction, perception failures
  - Emphasize interlocks, improved interfaces, alarms vs. redundant checks, training, check-off forms, etc.

Courtesy B. Thomadsen
Tolerances for Device QA Endpoints

- TG-100 FMEA: deviation of LINAC performance from specification is one of top 5 risk scenarios
- TG-40: Fixed tolerances and sampling intervals for many performance parameters
  - Examples: Isocenter coincidence < 2 mm; field size indicator < 2 mm
  - Sufficient or necessary for good IMRT outcomes?
    - Are tolerances technique- and device-dependent? dMLC vs. step-and-shoot IMRT?
    - What sampling frequency needed to maintain control?
- Unnecessarily small tolerance ⇒ Effort wasted

Sensitivity Analysis
Evaluate: Outcome error vs. parameter error

MLC Leaf Position Accuracy
(MLC Delivery)

Gap error → Dose error

- Error propagation device- and mode- (dynamic vs. static) dependent

Data from MSKCC; LoSasso et al.
**gEUD-guided Tolerance Evaluation**


- Introduce controlled errors into RTP beam model
- For typical plans, assess corresponding EUD error

**Palta: Confidence-interval guided treatment planning**

- Develop beam model to predict uncertainty at each point
- “Forward” Probabilistic Planning: Find plan that minimizes likelihood of poor outcome
Action Levels and QC frequencies

- Extract statistical model from repeated QC measurements
- LINAC Beam output

- Probability of Error > 2% vs. action level and measurement interval
- Select action level frequency

Statistical Process Control

- LINAC Output: Formal decision criteria for actionable systematic trends and changes in reproducibility
Recommendations for Future Steps
Jeff Williamson’s individual views

- **Individual Clinics**
  - Consider performing an FMEA for your IMRT/Stereo/HDRB program
  - Going through the process with your team is a major benefit
  - Every clinical implementation is different

- **TG-100 and AAPM**
  - Supplement TG100 FMEA with example FTAs and subsequent QM program development
  - Work towards a voluntary national error reporting database
  - Seed funding for industrial engineering RT demonstration projects

Recommendations for Future Steps
Jeff Williamson’s individual views

- **TG-100 and AAPM (cont’d)**
  - Broaden participation of physicians, therapists, industrial engineers, vendors, etc. in QA protocol development
  - More emphasis of process vs. device QA
  - Continue TG100 work in TPC QA WB

- **Medical Physics and Clinical Researchers**
  - Further development of prospective and retrospective analysis tools for specification of QA tolerances, action levels and test frequencies
  - Further analysis and development of RT-specific adverse event taxonomies
• Numbers indicate fraction of Medical Events in NRC and IAEA databases occurring in that step

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