Failure Modes and Effects Analysis (FMEA) for Accelerated Partial Breast Irradiation via High Dose-Rate Intracavitary Brachytherapy

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Disclosures and Acknowledgments

• Disclosures:
  – JFW has research/service contracts with Varian Medical Systems, NIH, and AAPM
  – JFW has never led formulation of FMEA in real-life clinical application
• Acknowledgments
  – Chapter coauthors: Ibbott, Thomadsen, and Mutic
  – Clinical input and advice from Douglas Arthur, M.D.
  – Statistics expertise from Nitai Mukhopadhyay, Ph.D.
  – Slides from Saiful Huq, Ph.D.
Learning Objectives

• Illustrate the application of TG-100 Risk analysis techniques to balloon-applicator HDR breast brachytherapy
• Review failure modes rated to be highest risk
• Review QA/QC strategies for mitigating high risk failures
Example: Risk-Informed QM Formulation for Brachytherapy

• Scenario: Accelerated partial breast irradiation using multi-catheter balloon HDR brachytherapy applicator
  – CT-based evaluation and planning
  – Multicatheter balloon applicator, e.g., Contura
  – Automated plan transfer but not full EMR charting

• History of this project
  – 2005: TG-100 assigns 4 coauthors to devise a brachytherapy risk analysis case study
  – 2008: dropped from TG-100 report
  – 2010 - 2013: JFW revives project. FMIs and scenarios revised and extended with feedback from BRT.
  – 2013: Chapter authors ranked revised FMIs.
Image-Guided Balloon Catheter Placement
Accelerated Partial Breast: MammoSite HDR BTx

Intraoperative Ultrasound
- Visualize Lumpectomy Cavity: Select Approach
- Assess conformality

D. Arthur, VCU

Intraop/PostOp CT
- Assess conformality
- Assess Skin Distance
- Assess Symmetry
Multi-Cath Balloon Applicator Mismatch errors

Asymmetric loading to spare skin and chestwall
TG-100 Risk Analysis Steps

• Steps
  1. Define process by creating a process map
  2. Failure modes and effects analysis (FMEA): Identify threats to success (failure modes) and rank according to risk
  3. Fault-tree Analysis (FTA): Propagation of failures through system and placement of QM interventions
  4. Develop QA or QC interventions to mitigate risk
TG-100 Risk Analysis Steps

• Process Map: Step 1
  – Delineate and then understand the steps in the process to be evaluated
  – Visual illustration of the physical and temporal relationships between the different steps of a process
  – Demonstrates the flow of these steps from process start to end

• Prospective risk analysis for hypothetical clinical process modeled on VCU and UW-Madison processes
  – Assumes NO QA or QC checks
  – Partial automation of EMR and data transfer
Breast Brachytherapy Process Map

1. **Pre-Implant Preparation**
   - Determine implantation technique
   - Schedule appropriate procedure room, intraoperative imaging equipment, postprocedure imaging
   - Assemble, sterilize applicator kit and accessories
   - Identify patient
   - Position patient on procedure table

2. **Patient database information entered**
   - Data into electronic database
   - Data into written chart
   - Information on previous or concurrent treatment

3. **Imaging and diagnosis**
   - Review of patient medical history
   - Scheduling for planning process
   - Decision of treatment technique

4. **Applicator placement**
   - Consultation and decision to treat

5. **CT imaging**
   - Patient positioned
   - Applicator prepared
   - Patient prepared
   - Insert applicator rotation
   - Secure applicator
   - Obtain images
   - MD reviews images
   - Initial treatment planning directive
   - Special instructions (parameters, algorithms, protocols)
   - Account for previous treatments or chemotherapy
   - Specify dose limits and goals
   - Suggest initial guidelines for treatment parameters
   - MD checks planner contours
   - Diameter of balloon
   - Volume of bubble
   - Fill balloon with contrast media
   - Insert in division box in center of cavity
   - Create access incision
   - Identify access site
   - Identify access site
   - Boolean operations
   - Specify CTV Margin
   - Protocol for CTV margin
   - CTV construction
   - Divide ROIs and planning structures
   - Protocol for delineation of targets
   - Delineate applicator
   - Import images into planning computer
   - Identify access site
   - Treatment planning
   - Import images into planning system
   - Identify and communicate planning process between dosimetrist, physicist, physician

6. **Physical plan review**
   - Check that dose distribution satisfies prescription
   - Check that previous treatments were accounted for
   - Check normal tissue is within tolerances
   - Check plan for quantitative consistency
   - Check plan identity
   - Check version of the plan
   - Check plan satisfied objective
   - Write final prescription

7. **Subsequent treatments**
   - Scheduling
   - Identify patient
   - Check balloon for leakage
   - Program treatment unit
   - Verify program
   - Connect transfer tube to applicator
   - Check balloon rotation
   - Communication equipment is on
   - Run treatment
   - Documentation

8. **Treatment review**
   - Documentation
   - Compare treatment record with plan
   - Run treatment
   - Communication equipment in use, display monitor on
   - Check balloon rotation
   - Connect transfer tube to applicator
   - Program treatment unit
   - Import patient file
   - Check balloon leakage
   - and validity
   - Fluoroscope or ultrasound position
   - Very contrast concentration if needed
   - Patient positioned in room
   - Initial treatment
   - Identify patient
TG-100 Risk Analysis
Step 2 FMEA

• Step 2a: For each process step, ask the following questions
  – What could possibly go wrong? (enumerate/describe failure modes)
  – How could that happen? (what are possible causes of FM?)
  – What effect would such an undetected failure have? (Potential impact on quality)

• Step 2b: Assess risk of FM by estimating O, S, and P

• Present analysis: 96 Failure Modes
Step 2a: enumerate FMEA Failure Modes

Process tree

Sub-process #1

Sub-process #17

Sub-process #19

Step #1

Failure mode #1

Causes of failure #1

Effects of failure #1

Step #4

Failure mode #2

Causes of failure #6

Effects of failure #4

Step #j

Failure mode #k

Causes of failure #m

Effects of failure #n
Assess Risk Posed by Each FM

Step 2b

- For each subprocess, enumerate the possible scenarios, i.e., Failure Modes (FM), that could lead an unsuccessful treatment: 96 FMs
  - Identify causes and effect on process outcome
- Assess risk to successful outcome posed by each FM assuming no QA

\[
\text{Risk} = \left\{ \begin{array}{c} \text{Likelihood of occurrence} \\ \text{Severity of consequences} \\ \text{Likelihood Error} \end{array} \right\} \times \left\{ \begin{array}{c} O \\ S \\ P \end{array} \right\}
\]

- Assign O, S, and P a value from 1-10
- 4 Observers: Ibbott, Mutic, Williamson, Thomadsen
- Significant additions/modifications by JFW
- Reorder list in terms of descending RPN
## TG-100 FMEA Rating Scales

Table 9-5. Descriptions of the O, S, and D values used in the TG-100 FMEA

<table>
<thead>
<tr>
<th>Score</th>
<th>Occurrence (O)</th>
<th>Severity (S)</th>
<th>Detectability (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Qualitative</td>
<td>Qualitative</td>
<td>Estimated probability of failure going undetected, %</td>
</tr>
<tr>
<td>1</td>
<td>Failure unlikely</td>
<td>No effect</td>
<td>0.01</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Inconvenience</td>
<td>0.2</td>
</tr>
<tr>
<td>3</td>
<td>Relatively few failures</td>
<td>Inconvenience</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Minor dosimetric error</td>
<td>Suboptimal plan or treatment</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Limited toxicity or tumor underdose</td>
<td>Wrong dose, dose distribution, location or volume</td>
</tr>
<tr>
<td>6</td>
<td>Occasional failures</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>5.0</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Repeated failures</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>Possible very serious toxicity or tumor underdose</td>
<td>Very wrong dose, dose distribution, location or volume</td>
</tr>
<tr>
<td>10</td>
<td>Failures inevitable</td>
<td>Catastrophic</td>
<td>&gt;20</td>
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<td>1</td>
<td>Imaging and diagnosis</td>
<td>RO reviews EMR prior to RO consult</td>
<td>Med Onc or Surgeon consultation misinterprets or misrepresents primary clinical findings (imaging studies, path reports, etc); incorrectly stages patient, and recommends BCT and APBI for patient that is not appropriate candidate</td>
</tr>
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<td>3</td>
<td>Patient database information</td>
<td>Entry of patient data in RO EMR or written chart</td>
<td>Incorrect patient ID data</td>
</tr>
<tr>
<td>4</td>
<td>Patient Database Information</td>
<td>Entry of patient data in RO EMR or written chart</td>
<td>Correct patient ID data but clinical findings/images from wrong patient loaded into RO EMR</td>
</tr>
<tr>
<td>5</td>
<td>Consultation and decision to treat</td>
<td>Decision of treatment technique and protocol</td>
<td>Clinically inappropriate patient selected for APBI</td>
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<tr>
<td>6</td>
<td>Consultation and decision to treat or Imaging/Diagnosis</td>
<td>Decision of treatment technique and protocol</td>
<td>patient with radiographically too large or closed seroma cavity selected</td>
</tr>
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**8 Highest Risk FM's**

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<td>Initial treatment</td>
<td>Run treatment</td>
<td>Incorrect balloon rotation</td>
<td>Inattention, missing required check, poor documentation</td>
<td>Failure to check that applicator rotation matches plan, so that wrong dwell position sequence is opposing skin bridge.</td>
<td>Wrong dose distribution</td>
<td>5.25</td>
</tr>
<tr>
<td>Plan approval</td>
<td>MD reviews plan</td>
<td>Plan fails to satisfy clinical intentions, bad plan approved</td>
<td>Inadequate or incomplete review, failure to reoptimize inadequate plan, miscommunication, inattention, lack of standardized procedures</td>
<td>Error is that MD approves a plan that violates constraints same physician previously approved and suboptimal plan is loaded into EMR in prep for treatment</td>
<td>Suboptimal plan, poor treatment used</td>
<td>5.75</td>
</tr>
<tr>
<td>Treatment Planning</td>
<td>Optimization settings</td>
<td>Specification of optimization method, dose-point locations, prescribed dose protocol not followed accurately</td>
<td>Inadequately trained personnel, inattention, poor interdisciplinary communication</td>
<td>Planners following different protocol for setting constraints and goals</td>
<td>Very wrong dose</td>
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<td>Dwell position construction</td>
<td>Distal-most dwell location inaccurately digitized</td>
<td>Inadequately trained, inattention, poor interdisciplinary communication</td>
<td>E.g., offset from tip to dwell 1 used as standard practice in clinic not known</td>
<td>Wrong dose distribution</td>
<td>4.50</td>
</tr>
<tr>
<td>Treatment planning</td>
<td>Catheter localization/labeling: single catheter</td>
<td>Catheter trajectory inaccurately localized</td>
<td>Wrong catheter slice images, inadequately trained personnel, poor interdisciplinary communication, inattention</td>
<td>Many possible scenarios: operator ignorance of (a) which visible structure denotes inner catheter tip, (b) offset from distalmost source center and catheter tip. Also sloppy contouring or importing wrong plan template</td>
<td>Wrong dose distribution</td>
<td>4.25</td>
</tr>
<tr>
<td>Treatment planning</td>
<td>Dwell position construction</td>
<td>Random error: Treatment length incorrect (wrong transfer tube length, wrong sounding information, wrong dwell spacing)</td>
<td>Inadequately trained personnel, inattention, poor interdisciplinary communication, default distances, equipment failure</td>
<td>Multiple error pathways: (1) Inaccurate sounding measurements from post-op imaging; (2) wrong spacing and/or offsets; (3) afterloader specific calibration corrections, e.g., Varian QuickConnect 14 mm correction, ignored; (4) arithmetic error</td>
<td>Very wrong/wrong dose distribution</td>
<td>5.00</td>
</tr>
</tbody>
</table>
Fault Tree Analysis and Designing QM interventions
Steps 3 and 4

• **Step 3: Create Fault Trees (optional)**
  – Time consuming: Limit FTA to selected FMs
  – Visualize interactions between FMs possibly in different process tree branches
  – JFW: helped me refine list of FMs and scenarios

• **Step 4: Design QM intervention**
  – Rank FMs according decreasing risk and severity
  – Mark high RPN/S FMs on fault and process trees
  – FTA guides optimal placement of intervention
  – Design intervention: balance cost, specificity, sensitivity and benefit
Fault Tree Analysis
Step 3: TG100 risk analysis methodology

- FTA compliments process tree
- Leftmost box is the failure (error)
  - Each daughter node is a FM that could cause the error
- Works backwards in time (to the right) until root cause is reached
- Models propagation of error through system

- ‘OR’ means error occurs if any one of antecedent FMs occurs
- ‘AND’ means all antecedent FM’s must be realized for error to occur
Source Positioning Error Fault Tree

- No QA/QC assumed
- Relevant FM scattered across at least 4 PT branches
- Interactions

<table>
<thead>
<tr>
<th>Rank</th>
<th>RPN</th>
<th>Step#</th>
<th>Process</th>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>374</td>
<td>76</td>
<td>Initial treatment</td>
<td>Connect transfer tubes to applicator</td>
</tr>
</tbody>
</table>

FM: Channel and applicator numbers not matched

Related FMs:
- 52 (RPN 349; rank 3): Systematic error in treatment length computation
- 26 (RPN 347; rank 4): Errors in catheter sounding measurements
- 46 (RPN 326; rank 5): Inaccurate catheter localization
- 75 (RPN 310; rank 7): Incorrect length transfer tube selected
- 50 (RPN 288; rank 13): Distal-most dwell position inaccurately localized: wrong offset
- 53 (RPN 284; rank 15): Random error in treatment length computation
- 51 (RPN 281; rank 16): Distal-most dwell position inaccurately localized: poor image quality
- 47 (RPN 286; rank 14): Catheter trajectory localization error
- 86 (RPN 302; rank 10): Incorrect balloon rotation: initial treatment
- 49 (RPN 278; rank 17): Multi-catheter localization error from poor image quality
• Error types
  – Channel mismatch
  – Incorrect Tx length
  – Incorrect step length
• Top level causes
  – Post procedure imaging error
  – Tx Planning error
  – Error in treatment setup or device programming
Post-procedure CT imaging Localization Errors

- Incorrect information /poor images ⇒ Dwell position programming error
  - Channel numbering or documentation
  - Catheter length measurement
  - Imaging performed with incorrect marker position

- QM interventions
  - QC: second therapist assists with measurements
  - QA: Independent check of localization data before patient leaves imaging suite

Non-Positional Failure Modes

- Poor quality/incomplete images

Post-procedure CT imaging error

Physician/dosimetrist check images failure

Assisting therapist misses errors

- Channel numbering error: marking or recording
- Sounding measurement error
- Wrong catheter position Marked

Adequate QM program for planning and afterloader systems
Post-Procedure Imaging
Localization steps
Localization FMs: Treatment Planning

- Catheter trajectory delineation error
  - Dwell 1 length error
    » Systematic positional offset error
  - Dwell position digitization error
- channel mismatch error
Example: Systematic Offset Error

- Systematic source positioning error: caused by invalid treatment length estimation protocol
- Varian “quick connect” indexer interface
  - 14 mm offset compared to standard transfer tube connector with usual transfer tube-applicator combination length measurement
  - No Software offset or hardware interlock initially provided
TG-56 Structured HDR Positional Accuracy Tests

L1 (programmed length) = 1500 mm

Tube Length: L (1218 mm)

Radioactive Source Programmed to 1500 mm

Transfer tube

Indexer reference L1 = 0.0

Compare for Coincidence

dwell 1 (1500 mm) position

Fully inserted Radiographic Marker

d : Dummy Insertion Depth

Applicator Orifice

calibrated dummy ribbon
Mitigating RTP Localization FMs

- **Adequate device QA:**
  - Maintain image quality
  - Eliminate offsets and incorrect default parameters
  - Consistency of procedure with device function

- **Implement well-defined, rigidly followed procedures:**
  - Adequate patient volume

- **QC:** use only one transfer tube length & use equi-length catheters

- **QA:** Final physics plan review focus on dwell position

**Non-Positional Failure Modes**

- Poor quality/ incomplete images

**Dwell position construction failure**

- Distal-most dwell location inaccurately digitized

**Physician check plan failure**

- Treatment length incorrect (wrong transfer tube length, wrong sounding information, wrong dwell spacing)

**Operator check**

- Incorrect catheter number assigned

- Inadequately trained personal

- Poor image quality

- Inadequately trained personal

- Default distances used

- Equipment failure

- Systematic offset Commissioning failure

- Inadequately trained personal

- Poor images

- Inadequately trained personal

- Poor labeling on photographs

- Default distances used
Mitigating Source Positioning Errors

- QA/QC in red
- Adequate device QA protocol
- Written procedures
  - Redundancy
  - Uniformity
  - Patient volume
- Physics Checks
  - Simulation
  - Tx plan
  - Setup/RAL programming
Patient Selection Error FTA with QA

- Two major FMs
  - Rad Onc misses or ignores API clinical or technical contraindication
  - Upstream medic error in EMR “Imaging-Dx”

- Med or surg Onc error: recommends APBI
- Upstream histopath /biomarker error
Are Pathology Errors Common?

- **ASTRO guidelines for APBI**
  - T1 uni-focal/centric GTV < 2 cm with margins > 2 mm
  - Negative SLN biopsy or ALND
  - Favorable histology/biomarkers

- **Pignol**: outside specimens of 77 patients referred for APBI reviewed inhouse

- **18.6% of patients deemed suitable for APBI on initial path, reclassified as “unsuitable”**.
Mitigating Patient Selection Errors

- QM interventions and process redesign
  - QC checklist to guide MD consultation
  - QA: Peer- and technical-review of MD decisions
  - QC: National electronic medical record

Second review of pathology and biomarkers
TG-100 Site-Specific Treatment Schemas

• Clinical parameters
  – Pre-Tx eligibility criteria (Site, stage, histology, etc.) for this care pathway
  – Overall plan, including sequencing of chemo, surgery, external and brachytherapy courses
  – Pre-Tx Simulation and clinical instructions, e.g., fiducial marker placement, MR or PET imaging, dental extractions

• Planning parameters
  – GTV, CTV, normal tissue delineation guidelines; image selection and registration
  – Prescribed dose, fractionation, IMRT class solution, planning goals, and constraints.
  – Motion and uncertainty management techniques
Conclusions-I: Major lessons

• FTA/FMEA is not rocket science: reinforces decade-old TG-59 philosophy
  – Adequate device QC is essential to avoid systematic errors
  – Planning & delivery processes must have built-in catastrophic error detection and correction mechanisms
  – QA/QC must emphasize
    » Redundancy (QC) when capturing key data
    » Compensating for weaknesses of devices, i.e., key actions where interlocks don’t “force” desired outcomes

• QM of physician decision making is essential
  – Upstream histopath/biomarker error not uncommon
  – Fundamental departure from “MD command/control” model: ancillary staff must be trained and empowered to question MD actions
Conclusions-II

• Process mapping and FMEA advantages
  – Focuses attention on process as well as device failures
  – Provides a vehicle for team to work collaboratively to
    » better understand the process
    » Appreciate each other’s vulnerabilities
    » buy into core QM/QI values
  – Most expert member gets to fix FM
  – Promotes clinical process uniformity so that desired
    process-step outcomes get internalized
  – Better understanding of device-process interactions
    helps physicist prioritize device QA

• Downsides
  – Resource intensive to build/use FMEA expertise
  – Not a mechanical, one-size-fits-all prescriptive
    approach: requires judgment and individualization