Using FMEA in Your Clinic with Your Colleagues

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Where I’m coming from

– A physicist in a very large academic cancer center
  • In a big, crowded, diverse city where space is tight
– Senior but not a ‘chief’ of anything
– 10 treatment machines at main campus, 3 simulators, > 200 external beam treatments/day
  • And 4 Regional Centers
– Medical Physics and Radiation Oncology are administratively different departments
– ~ 40 external beam physicists and dosimetrists
– ~ 18 senior MDs (main campus)
  • ~ 20-25 resident and fellow MDs
• Examples are for **small-scale processes** within this large enterprise
  – Do they apply to smaller, larger or differently located places?
    • For others to decide
  – Aim is to demonstrate feasibility and utility of one approach to help others try similar projects on their own
Starting FMEA

• Decide on a clinical process
  – Need not be huge

• Pull together a group of involved personnel
  – For a small process the group need not be large
  – Could be just yourself
    • Then you have to ‘sell’ your results to others

• Map out/list process steps in their clinical order
  – Need not be graphically fancy- a spreadsheet or a simple list is OK

• Get group consensus on process map
  – Process mapping is valuable in its own right!

• Start the FMEA
Doing FMEA

• For each process step ask and get group consensus:
  – What could possibly go wrong?
    • These are the potential failure modes
  – How could it happen?
    • Causes of failure mode
  – How likely is failure due to this cause?
    • Occurrence = O
  – How hard to detect before patient is affected?
    • Detectability = D
  – What are the effects of an undetected failure?
    • Severity = S
• There are quantitatively different O, S, D scales
• But they may lead to similar relative ranks
• In the long run, it’s the relative ranks that are important
  • Of course, decide on one scale for a particular analysis

RPN (=OxSxD) runs from 1 (extremely low risk) to 1000 (extremely high risk)
In my first example I used Ford’s scoring; in my second, I used TG-100’s
Using FMEA

• Score and prioritize the overall risk of each failure mode by the Risk Probability Number (RPN)
  — RPN=O x S x D
• Pool and discuss the group results
• First attack the highest RPN and any dangerously high severity failure modes
• A good FMEA helps identify where corrective actions are most needed
• Creating an FMEA sensitizes the group to weak points in the analyzed process
• Hopefully, one FMEA persuades others to make FMEA-guided interventions in other processes
Once the FMEA is done

• Work backwards from each chosen FM to identify its precursor causes
• This is Fault Tree Analysis (FTA)
  – For simple processes, this might be easy
• Identify causes that are not well covered by your existing procedures or QM program
• Devise **feasible** and **efficient** mitigations
• Implement mitigating QM changes
• And re-evaluate after a reasonable time
FMEA does not exist in isolation

- D and O may come from personal experience or from formal incident learning databases
  - Or both
- S may come from personal experience
  - especially MD’s
  - or potentially from biological models
- Devising mitigation strategies
  - Can use Fault Tree Analysis
    - TG100 (See Ch 4 of 2013 Summer School)
      - Conceptually similar to Root Cause Analysis (RCA)
    - For small processes, less formal methods are helpful
- Communication is key in performing FMEA and in devising mitigation
Example 1: MU Calculations for after-hours cases

• The group=1 (me)
• Results had to be discussed with others in order to implement changes
• The changes occurred incrementally, over several years

History:
• For ~ 10 years, I’ve in-serviced new personnel on physics/dosimetry aspects of after-hours treatments
  – New residents, new therapists
• Class responses sometimes revealed risky areas
• The hospital’s Reporting Database also revealed risky areas
• I lobbied for changes that would mitigate these FMs
  – And continue to lobby
Ground Rules for MU calculations outside normal clinic hours at my institution

- Photons: Parallel opposed or single fields only; blocks or static MLC only beam modifiers
  - Electrons after hours are very rare
- 1st calc by therapist (in-house program); check by resident (manual, from beam data tables)
- Differences > 2% must be resolved by a senior therapist
- Dose/fraction $\leq 400$ cGy
- Case must get complete dosimetrist check before treatment on the first working day
- Some patients are CT simulated during regular hours, a few are set up on the linac
Overall Process for Cases Calculated After Hours

1. If RX is ready before ~ 6 pm, dosimetrist calculate and check, though the patient is treated after hours

2. After hours calcs may be used for 2-3 treatments, depending on weekends

Table 9–1. Process tree for emergency (on-call) treatments in my department

<table>
<thead>
<tr>
<th>Patients with CT simulation</th>
<th>Patients without CT simulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult with attending MD/resident – History and physical</td>
<td>Consult with attending MD/resident – History and physical</td>
</tr>
<tr>
<td>Decision to treat/treatment site(s), includes MD review of previous RT</td>
<td>Decision to treat/treatment site(s); includes MD review of previous RT</td>
</tr>
<tr>
<td>RT notations made in hospital database</td>
<td>RT notations made in hospital database</td>
</tr>
<tr>
<td>Immobilization at simulator (CT scan performed, setup information documented, alignment marks placed)</td>
<td>Immobilization at treatment machine (localization radiographs); setup information documented, alignment marks placed</td>
</tr>
<tr>
<td>Prescription by attending MD (disease site_Rx point, dose/fraction, # fractions, energy, specify beam arrangement)</td>
<td>Prescription by attending MD (disease site_Rx point, dose/fraction, # fractions, energy, specify beam arrangement)</td>
</tr>
<tr>
<td>Approval of field apertures (DRRs or radiographs) by attending MD</td>
<td>Approval of field apertures (radiographs at treatment machine) by attending MD</td>
</tr>
<tr>
<td>Separation and other relevant patient-specific measurements at simulator or from CT scan</td>
<td>Separation and other relevant patient-specific measurements at treatment machine</td>
</tr>
<tr>
<td>MU calculation (first calculation by therapist, check by resident)</td>
<td>MU calculation (first calculation by therapist, check by resident)</td>
</tr>
<tr>
<td>Entry of treatment information into Aria (therapist)</td>
<td>Entry of treatment information into Aria (therapist)</td>
</tr>
<tr>
<td>Patient set up at machine</td>
<td>Setup finalized</td>
</tr>
<tr>
<td>Radiograph(s) acquired, saved to database, approved (attending or resident)</td>
<td>Radiograph(s) acquired, saved to database, approved (attending or resident)</td>
</tr>
<tr>
<td>Treatment delivered</td>
<td>Treatment delivered</td>
</tr>
</tbody>
</table>

On first working day after initial treatment, all aspects of the case are reviewed by a dosimetrist or physicist; attending physician approves radiographs if not already done.

From 2013 | Summer School
• Here, I focus on the **MU calculations only**

• I leave out failure modes such as “inappropriate prescription”, “wrong isocenter”, “failure to account for previous treatment”, set-up and delivery FMs, etc

• One goal of the full dosimetrist check is to find such failures
  – To correct for subsequent treatments
  – To ameliorate, considering the dose already given
Many safety-related simplifications were in place before I did a FMEA

- Some of these were **longstanding**, some based on **feedback** from the crash-course and the clinic
- **Simplifications included**
  - Isocentric setups only for photons
    - No inverse square corrections for after-hours calcs
    - For parallel opposed treatments: Rx for equal doses to midplane
    - For single fields: Rx prescribed to isocenter
  - For adult whole brain, use 16x16 for Sp, TMR
  - If CAX is outside field or near field edge, measure separation for TMR calculation at mid-field
    - Dosimetrist will clean up on 1st working day
    - If no errors were made, MUs calculated by the dosimetrist are within 2-3% of those done ‘on call’
FMEA for on-call MU calculations

<table>
<thead>
<tr>
<th>Failure</th>
<th>O</th>
<th>S</th>
<th>D1</th>
<th>D2</th>
<th>RPN1</th>
<th>RPN2</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculate MU for information from wrong patient</td>
<td>2</td>
<td>8</td>
<td>6</td>
<td>3</td>
<td>96</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>Calculate MU for wrong beam energy</td>
<td>3</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>72</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Calculate MU for wrong depth (e.g. look up TMR for separation, not sep/2)</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>2</td>
<td>128</td>
<td>64</td>
<td></td>
</tr>
<tr>
<td>Dose doubling (Calculate MU to deliver total Rx dose from each beam)</td>
<td>3</td>
<td>10</td>
<td>3</td>
<td>1</td>
<td>90</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Calculate the equivalent square for the wrong collimator setting</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>75</td>
<td>15</td>
<td>Risk with independent jaws</td>
</tr>
<tr>
<td>Error in calculating equivalent square (but collimator setting correct) for Sc</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td>Error can only occur in the manual check calculation</td>
</tr>
<tr>
<td>Error in calculating equivalent square for Sp and TMR</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>24</td>
<td>8</td>
<td>Program allows error because the user can input an estimated equivalent square with blocking</td>
</tr>
<tr>
<td>Omission of transmission factor for blocks or support devices</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>25</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

| Failures to follow procedure | |
|-----------------------------|---|---|---|---|---|---|---|
| MUs used for treatment without second check (failure to follow procedure) | 2 | 9 | 1 | 18 | These are high potential S |
| Large discrepancy accepted without sensor therapist adjudication | 2 | 9 | 2 | 36 | Because they negate safety mechanisms in place |
| On-call case not given to dosimetrist before treatment on first working day | 2 | 9 | 6 | 108 | Might be detected in weekly checks chart rounds |

- I did this FMEA ‘for fun’
- Discussed results with Treatment Planning Chief to get implemented

- Green box: new simplifications
- New **stronger procedures** make **timely** dosimetrist review more certain
- **These are:**
  - Task sent to Treatment Planning via Aria
  - Aria Alert tells treatment machine that case must get physics review

- Alas! Aria inputs are not automatic! But information is automatically propagated from that point on.

D1 is Detectability on-call (before treatment delivered)
D2 is Detectability at or after dosimetrist’s check
• Simplifications remove items that distract from more serious factors. They may introduce small errors that are clinically insignificant for a few treatments and are easily cleaned up on first working day.
  • Set transmission factors to 1 in on call calculations
  • Calculate Sp and TMR for equivalent area from jaws
    – Or 16x16 for whole brain

• In-service emphasizes to new personnel the importance of bringing case to dosimetrist attention on first working day
• Most recently _ Take advantage of TMS (Aria) features:
  • Send Task (to tx planning) and Alert (to Machine) to make sure cases get suitable physics review
• We have not yet implemented a policy to limit # of fractions given with after-hours calculations and setups
Example 2: DIBH for left breast tangents

- For some left-breast patients, the heart is very close to the inner chest wall; tangents would give full dose to part of the heart.

- For some of these, deep inspiration raises the breast and chest wall more than the heart
  - Some can do reproducible breath holds without undue stress

- For this group of patients, Deep Inspiration Breath Hold (DIBH) reduces heart dose during breast tangent treatment
  - Lung mean dose also reduced
DIBH for left-breast tangents

• Varian RPM system can be used to monitor a coached breath-hold

• For ~ 3 years, my department has used RPM-DIBH on selected pre-menopausal, left-breast cancer patients treated with tangents
  – 50-60 to date

• Simulations are on one Philips Brilliance; treatments are on a Trilogy with RPM
The FMEA for Breast DIBH Group

Physicists
- Alison Kelly
- Nicholas Stein
- Ellen Yorke

Therapists
- Andre Houston
- Hilary Piszko
- Jill Topf
• All 6 of us are
  – Directly involved in breast DIBH
  – In position to suggest and implement changes
• This FMEA+Mitigation project is still ongoing
• Analysis started in early January 2014
  – Meetings via email and informal conversation
  – Worked from spreadsheets rather than more artistic (but labor intensive) graphics
• Starting with sim, we listed 45 process steps
  – 4 done by MD, 23 by therapist, 18 by physics team
  – 4 steps in red bracket repeated at each treatment
• We identified 105 FMIs peculiar to DIBH
  – Did not consider FMIs that can happen with free-breathing breast tangent cases
  – Most FMIs were obvious
    • Think of the right thing and imagine not doing it
    • There are few forcing functions available in our process
  – 25 FMIs had been seen at least once before (giving us a handle on worst-case O’s). Procedures had been designed on the fly to address them
  – 12 new potentially consequential FMIs were identified

– Since breast DIBH is an ‘elective’ treatment, most S’s were at worst ‘limited toxicity’
  • loss of benefits of DIBH
<table>
<thead>
<tr>
<th></th>
<th>Process Map_DiBi for left breast tangents treated on Trilogy (443)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient identified and tested by MD (heart-chest wall anatomy will benefit). MD decision to go for DiBi.</td>
</tr>
<tr>
<td>2</td>
<td>Simulator set up for DiBi (camera, cable).</td>
</tr>
<tr>
<td>3</td>
<td>MD wires treatment volume (often done by resident).</td>
</tr>
<tr>
<td>4</td>
<td>Simulator calls physics.</td>
</tr>
<tr>
<td>5</td>
<td>Patient trained and monitored visually (in room).</td>
</tr>
<tr>
<td>6</td>
<td>Patient input to RPM database.</td>
</tr>
<tr>
<td>7</td>
<td>Reference session set up in RPM database.</td>
</tr>
<tr>
<td>8</td>
<td>RPM block placed on patient/camera view checked.</td>
</tr>
<tr>
<td>9</td>
<td>Patient approximately positioned.</td>
</tr>
<tr>
<td>10</td>
<td>Patient monitored (without scanning) on RPM screen to establish audio connection, feasible breath-hold amplitude.</td>
</tr>
<tr>
<td>11</td>
<td>Overall process explained to patient.</td>
</tr>
<tr>
<td>12</td>
<td>Patient in final position; therapist places temporary alignment marks for position verification.</td>
</tr>
<tr>
<td>13</td>
<td>Free breathing scan acquired.</td>
</tr>
<tr>
<td>14</td>
<td>Therapists set isocenter coordinates at console.</td>
</tr>
<tr>
<td>15</td>
<td>Therapists go into room and...</td>
</tr>
<tr>
<td>16</td>
<td>Therapists check alignment marks still on.</td>
</tr>
<tr>
<td>17</td>
<td>Therapists make temporary isocenter marks (sharpie pen).</td>
</tr>
<tr>
<td>18</td>
<td>Therapist prepares scanner for DiBi scan.</td>
</tr>
<tr>
<td>19</td>
<td>Physicist starts RPM and coaches patient to breath hold.</td>
</tr>
<tr>
<td>20</td>
<td>DiBi scan acquired during breath-hold.</td>
</tr>
<tr>
<td>21</td>
<td>Physicist sets tolerance (±5 mm) window around breath-hold level.</td>
</tr>
<tr>
<td>22</td>
<td>Physicist saves and exports reference trace.</td>
</tr>
<tr>
<td>23</td>
<td>Therapist sets DiBi isocenter at same couch coordinates as free-breathing.</td>
</tr>
<tr>
<td>24</td>
<td>Therapists tattoo setup points and RPM box corners, all documenting photos taken.</td>
</tr>
<tr>
<td>25</td>
<td>Both studies saved.</td>
</tr>
<tr>
<td>26</td>
<td>Free breathing and DiBi scans exported to physics.</td>
</tr>
<tr>
<td>27</td>
<td>Therapist exports treatment field DRRs to SPIN (our RT mini-pacs).</td>
</tr>
<tr>
<td>28</td>
<td>Therapist writes instructions for free-breathing setup, adds &quot;setup FB, treat DiBi&quot;.</td>
</tr>
<tr>
<td>29</td>
<td>MD writes fix specifying DiBi (and dose, beam energy, bolus, etc).</td>
</tr>
<tr>
<td>30</td>
<td>Dept scheduler schedules machine.</td>
</tr>
<tr>
<td>31</td>
<td>Planner assigned to case.</td>
</tr>
<tr>
<td>32</td>
<td>Treatment planner imports FB and DiBi scans to planning system.</td>
</tr>
<tr>
<td>33</td>
<td>Planner rigidly registers spine between FB and DiBi scan (registration should account for translations or rotations if patient did not move between scans.</td>
</tr>
<tr>
<td>34</td>
<td>Planner assesses potential for problems, needs for intervention at planning or first-day treatment level.</td>
</tr>
<tr>
<td>35</td>
<td>Planner may also assess benefit to inter, and communicate potential problems to MD.</td>
</tr>
<tr>
<td>36</td>
<td>Treatment plan done on DiBi scan.</td>
</tr>
<tr>
<td>37</td>
<td>Reference DRRs generated from DiBi scan and exported OR physicist checks already-exported (from sim) reference DRRs.</td>
</tr>
<tr>
<td>38</td>
<td>Planner adds field edge information to setup instructions.</td>
</tr>
<tr>
<td>39</td>
<td>Reference DiBi trace (with threshold lines) printed for use at treatment machine.</td>
</tr>
<tr>
<td>40</td>
<td>Plan and Aria entries checked in normal fashion.</td>
</tr>
<tr>
<td>41</td>
<td>At our institution, the first day is for &quot;film&quot; (EPID imaging) only. Imaging more frequently than weekly is at MD's discretion.</td>
</tr>
<tr>
<td>42</td>
<td>Therapist opens RPM reference session.</td>
</tr>
<tr>
<td>43</td>
<td>Therapist sets up patient and places RPM block.</td>
</tr>
<tr>
<td>44</td>
<td>Patient set up free breathing, according to skin marks. Treatment machine RPM block placed.</td>
</tr>
<tr>
<td>45</td>
<td>Therapist coaches patient to breath hold, acquires radiographs within RPM gate.</td>
</tr>
<tr>
<td>46</td>
<td>MD reviews/approves first-day setup radiographs.</td>
</tr>
<tr>
<td>47</td>
<td>If radiographs are approved, patient is treated in breath-hold at the level set from the simulator reference.</td>
</tr>
<tr>
<td>48</td>
<td>Session for the duration of her treatment course.</td>
</tr>
</tbody>
</table>
• Hardware/software FMs are immediately obvious
  – D=1; Can’t proceed till they are resolved
• A tighter integration with the treatment machine (e.g. TrueBeam) would greatly reduce RPN for FMs such as
  – “Breathing trace associated with wrong patient”
  – Failure to treat with DIBH as planned
• Our highest risk FMs are caused by human factors
  – Training, clear procedures, education of new staff
• Only ‘soft’ mitigating strategies at our disposal so far:
  – Improve documentation
  – Tighten procedures, stress naming conventions
  – Facilitate communication within ‘team’
    • Enlarge the team in line with increased demand
• We find discussion and sensitization to potential problems is beneficial on its own
A Few References


• “Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond”, Bruce Thomadsen, editor (AAPM 2013 Summer School Proceedings)

