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

Table 1. Example scoring system of severity, frequency of occurrence, and detectability for input into failure mode and effects analysis

Score	Severity	Occurrence	Detectability
1	No effect	Less than every 5 years	
2	Dose Δ5%	Every 2–5 years	Very easy to detect
3		Once a year	
4	Minimal delay in care	Several times a year	Easy to detect
5		Once a month	
6	Allergic reaction; moderate delay in care	Several times a month	Mildly difficult to detect
7		Once a week	
8	Dose Δ20%, reportable	Several times a week	
9		Once a day	
10	Patient dies	Several times a day	Impossible to detect

O, S, D scoring from Ford et al

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

Rank	Occurrence (O)		Severity(S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01%	No effect		0.01
2		0.02%	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05%			0.5
4		0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5%			5.0
7		<1%	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2%			15
9		<5%	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5%	Catastrophic		>20

O, S, D scoring from TG-100

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

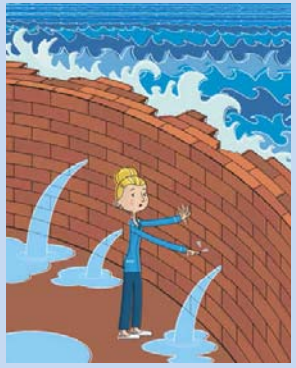
- Score and prioritize the overall risk of each failure mode by the Risk Probability Number (RPN)
  - RPN=O x S x D
- Pool and discuss the group results
- First attack the highest RPN and any dangerously high severity failure modes
- A good FMEA helps identify where corrective actions are most needed
- 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

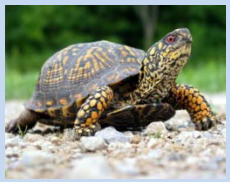
- D and O may come from personal experience or from formal incident learning databases
  - Or both
- S may come from personal experience
  - especially MD's
  - or potentially from biological models
- Devising mitigation strategies
  - Can use Fault Tree Analysis
    - TG100 (See Ch 4 of 2013 Summer 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 ≤ 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, dosimetrists 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

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

- 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 9–2. Example FMEA for on-call monitor unit calculations for parallel-opposed fields treated on-call in author's department. The isocenter and prescription points are always at mid-depth in these cases. This table covers MU calculation risks only. Delivery failure modes (e.g. treat at wrong isocenter) are not included.

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

D1 is Detectability on-call (before treatment delivered)
D2 is Detectability at or after dosimetrist's check

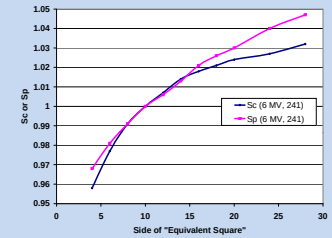
- I did this FMEA 'for fun'
- Discussed results with Treatment Planning Chief to get implemented

- 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**

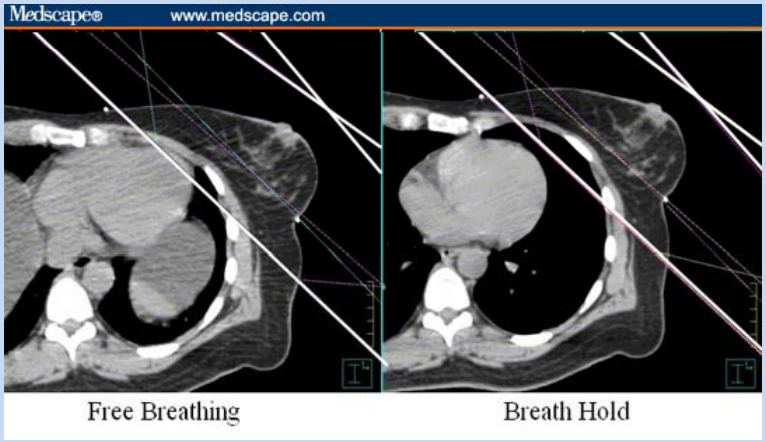
- Alas! Aria inputs are not automatic! But information is automatically propagated from that point on.

- 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

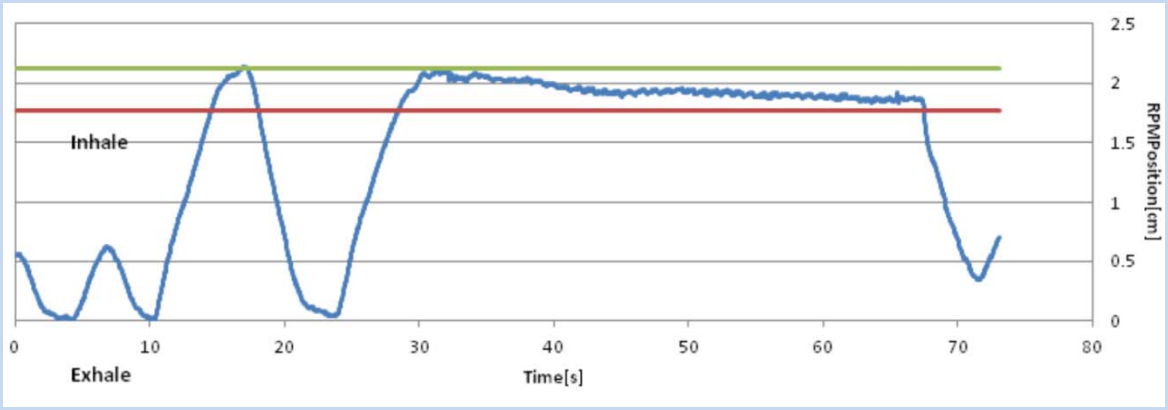
The FMEA for Breast DIBH Group

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 FMs peculiar to DIBH
  - Did not consider FMs that can happen with free-breathing breast tangent cases
  - Most FMs were obvious
    - Think of the right thing and imagine not doing it
    - There are few forcing functions available in our process
  - 25 FMs 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 FMs were identified
  - Since breast DIBH is an 'elective' treatment, most S's were at worst 'limited toxicity'
    - loss of benefits of DIBH

	A
1	**Process Map_ DIBH for left breast tangents treated on Trilogy (443)**
2	Patient identified and tested by MD (heart-chest wall anatomy will benefit) - MD decision to go for DIBH
3	Simulator set up for DIBH (camera, cable)
4	MD 'wires' treatment volume (often done by resident)
5	Simulator calls physics
6	Patient trained and monitored visually (in room)
7	Patient input to RPM database
8	Reference session set up in RPM database
9	RPM block placed on patient/camera view checked
10	Patient approximately positioned
11	Patient monitored (without scanning) on RPM screen to establish audio connection, feasible breath-hold amplitude
12	Overall Process explained to patient
13	Patient in final position; Therapist places temporary alignment marks for position verification
14	Free breathing scan acquired
15	Therapists set isocenter coordinates at console
16	Therapists go into room and.....
17	Therapists check alignment marks still on;
18	Therapists make temporary isocenter marks (sharpie pen)
19	Therapist prepares scanner for DIBH scan
20	Physicist starts RPM and coaches patient to breathhold
21	DI scan acquired during breath-hold
22	Physicist sets tolerance (~ 5 mm) window around breath-hold level
23	Physicist saves and exports reference trace
24	Therapist sets DI isocenter at same couch coordinates as free-breathing
25	Therapist tattoos setup points and RPM box corners, all documenting photos taken
26	Both studies saved
27	Free breathing and DIBH scans exported to Physics
28	Therapist exports treatment field DRRs to SPIN (our RT mini-pacs)
29	Therapist writes instructions for free-breathing setup, adds "setup FB, treat DIBH"
30	MD writes Rx specifying DIBH (and dose, beam energy, bolus, etc)
31	Dept scheduler schedules machine
32	Patient-specific equipment sent to Tx machine
33	Planner assigned to case
34	Treatment planner imports FB and DIBH scans to planning system
35	Planner rigidly registers spine between FB and DIBH scan (registration should require minimal translations or rotations if patient did not move between scans)
36	Planner assesses potential for problems, need for intervention at planning or first-day treatment level.
37	Planner may also assess benefit to heart and communicate potential problems to MD
38	Treatment plan done on DIBH scan
39	Reference DRRs generated from DIBH scan and exported OR physicist checks already-exported (from sim) reference DRRs
40	Planner adds field-edge information to setup instructions
41	Reference DIBH trace (with threshhold lines) printed for use at treatment machine
42	Plan and Aria entries checked in normal fashion
43	**At our institution, the first day at the linac is for 'films' (EPID imaging) only; imaging more frequently than weekly is at MD's discretion**
44	Therapist opens RPM reference session
45	Therapist sets up patient and places RPM block
46	Patient set up free breathing, according to skin marks, at treatment machine; RPM block placed
47	Therapist coaches patient to breath hold , acquires radiographs within RPM gate
48	MD reviews/approves first-day setup radiographs
49	
50	If radiographs are approved, patient is treated in breath-hold at the level set from the simulator reference
51	session for the duration of her treatment course

- 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

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