Failure Mode and Effects Analysis (FMEA)

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Disclosures

- I am the Secretary Treasurer of the non-profit Center for the Assessment of Radiological Sciences, an organization dedicated to improving the safety of radiotherapy

Learning Objectives

- Introduction to FMEA

- Risk assessment, process improvement and the basics of Process FMEA

- How to perform a Process FMEA

- Process FMEA outputs

- Process FMEA exercise

- Wrap up and questions

Quality Management in Industry

- Systematic application of specific tools that improve <u>process controls</u> producing more consistent and closer to optimal outcomes and reduce the risk of mistakes, errors or hazardous outcomes

Process Controls

- Process controls for grilling a steak
  - Experience/training – how much charcoal to pile in the middle of the grill, etc.
  - Measurement tools – watch (steak goes on the grill 20 minutes after igniting the coals)
  - Because there are some variables that are difficult to control – meat thermometer (135 deg. F)

FMEA

- A risk assessment tool tool used to identify weaknesses or deficiencies (inadequate controls) in processes that could lead to mistakes, errors, and potential hazardous outcomes

FMEA

- Four separate and independent types of FMEA
  - Design FMEA – Focus on the product development and design process
  - <u>Process FMEA – Focus on the manufacturing, production, office or healthcare process</u>
  - Application FMEA – Focus on your product as used by your customers
  - Service FMEA – Focus on the service of your products

Design FMEA

- FDA requires that equipment manufacturers demonstrate design control – Quality System Requirements (QSR)
  - Recommend D-FMEA
  - Equipment performs (functions) as defined
  - However……
  - Equipment manufacturers almost never complete Application FMEA
  - FDA regulatory oversight somewhat lacking in this area

Nauseated and in severe pain, with ulcers in his mouth and throat, and his teeth falling out, Scott Jerome-Parks received nourishment through a feeding tube. His wife, Carmen, provided round-the-clock care. Soon after his radiation overdose, New York State health officials cautioned hospitals to be extra careful with linear accelerators, machines that generate high beams of radiation.

The New York Times

By Walt Bogdanich

The New York Times

updated 12:59 p.m. CT, Sun., Jan. 24, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with **ulcers** in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

http://www.nytimes.com/2010/01/24/healt 4radiation.html

2013 Summer School, Colorado Springs, CO

A Proactive Strategy for Improving Patient Safety and Healthcare Quality through the use of FMEA and FTA

- Begins with a complete and thorough understanding of the process – flow charts, value stream mapping, process maps

- Perform a Process FMEA (P-FMEA) to identify weaknesses or inadequate controls in the process

- Develop process controls that either reduce the risk or improve the process

- Use FTA to identify root causes of potential process failures and develop recommendations to improve quality control of the process

Completing an Process FMEA

- Create a team
  - Ideally cross functional representing every function involved in the process
  - Nurses, imaging technicians, oncologists, medical physicists, treatment planners, others (administrative staff, social workers, etc.)
  - Effort should be led by a facilitator trained in or familiar with the tools used in the analysis
  - Consider providing training

Completing an Process FMEA

- Select a process – key step
  - Opportunity – Quality issues, past problems, not happy with the level of success, …
  - Realistic opportunity to make improvements
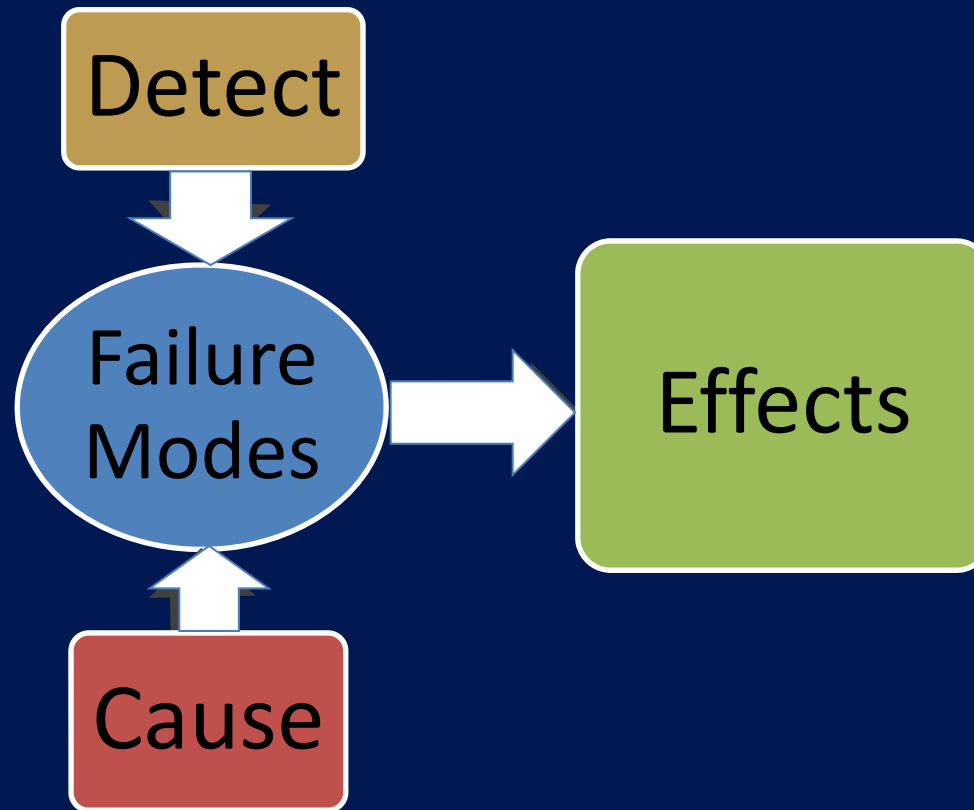 - Complexity or size
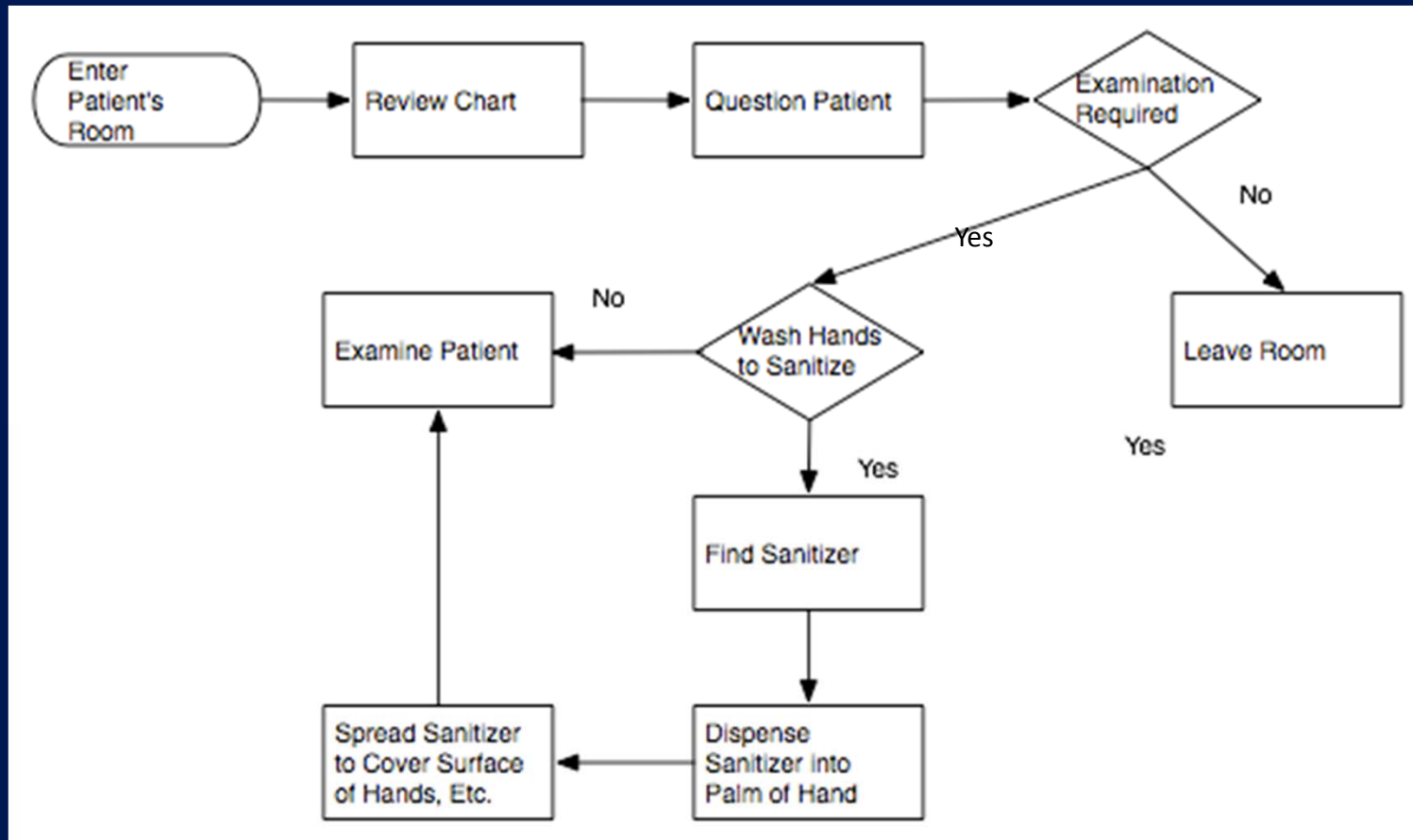
Completing an Process FMEA

- Defining the current process
- "One picture is worth ten thousand words"
- Flow charts, process trees, and value stream maps

Process FMEA – for each step in a process

Detect

Failure Modes → Effects

Cause

High Level Flow Chart - Physician Completing Rounds

Process FMEA

Process Description   _____

_____

_____

FMEA Dates   Original Analysis   _____   Latest Revision   _____   Approved By   _____

Review Process Step Name & Seq #	Review Process Step Function	C S C	Potential Failure Modes	Potential Causes of Failures	Potential Effects of Failures	Current Controls	Existing Conditions				Recommended Actions	Resulting				Responsible Party And Date of Completion
							O c c	S e v	D e t	R P N		O c c	S e v	D e t	R P N	

Completing an FMEA

1. For each process step – identify all <u>potential</u> failures – always best to define failure modes as "not" meeting process requirements

2. For each potential failure – identify all of the causes that could produce that failure

   a. Focus on process related causes of failure modes

Completing an FMEA

3. For each potential failure – identify the effects of that failure mode

   a. Priority of effects (safety, function, convenience)

Completing an FMEA

4. Current controls – judge the <u>current</u> capabilities of the process controls to:

   a. Prevent the cause of a failure from occurring

      – Documented work procedures or instructions, standard work, formal training programs, visual work instructions, skill set certification program, resource modeling and planning, formal process development programs , process capability studies, Statistical Process Controls, cross training, etc.

Completing an FMEA

b. Detect a failure when it occurs

- Inspection

- Radiation dose/location monitoring technology (21st Century Oncology)

- Error, incident or accident detection/reporting

Completing an FMEA

c. Moderate the severity of a failure when it
    occurs

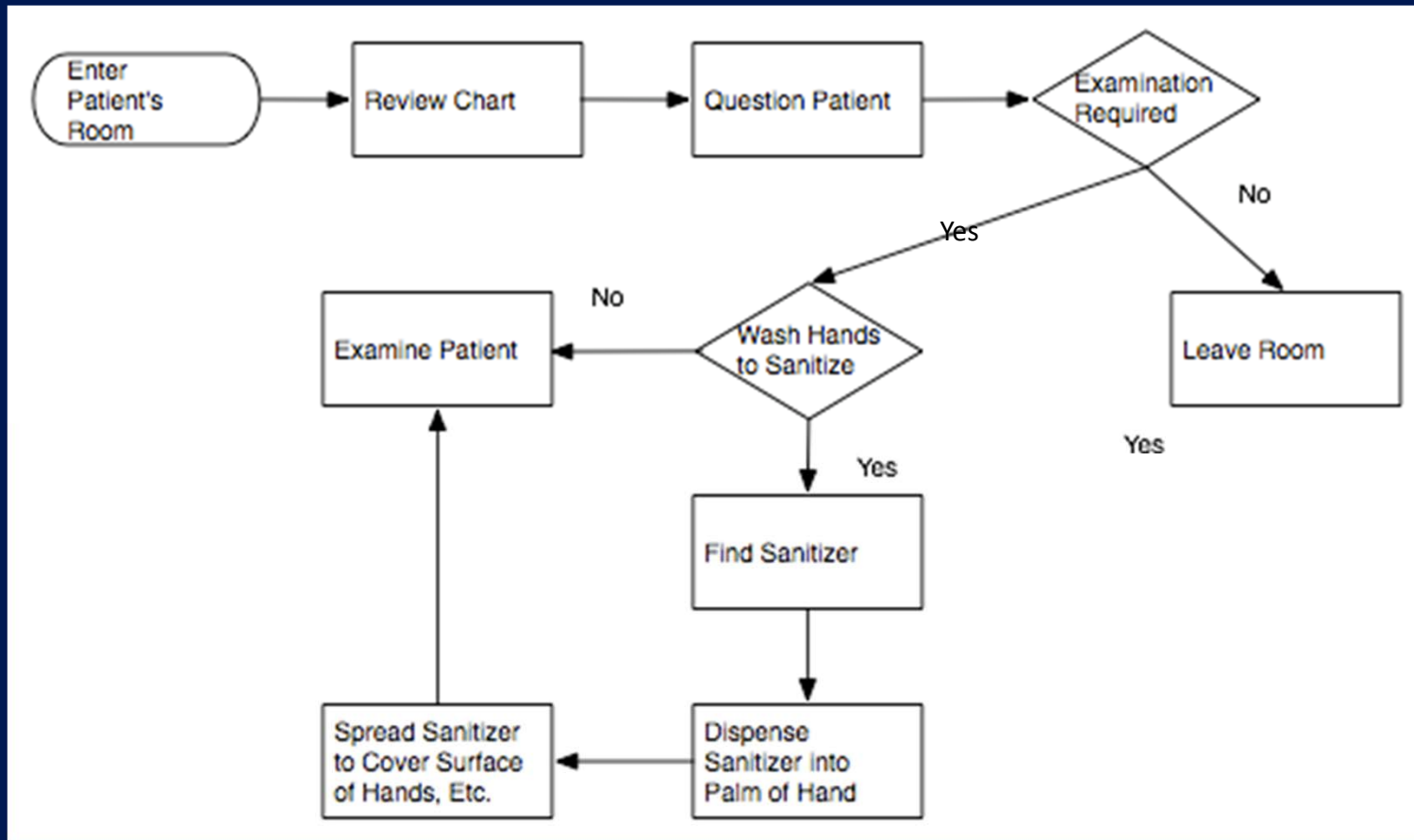   – Almost impossible for radiation therapy

Completing an FMEA

- Most effective and lowest cost controls are those that prevent causes of failure modes

High Level Flow Chart - Physician Completing Rounds

POTENTIAL FAILURE

Check Type				
❑ **Design FMEA**			❑ System	
☒ **Process FMEA**			❑ Subassembly	
			❑ Component	

Design Responsibility:

Item / Function	Potential Failure Mode	Potential Cause(s) / Mechanism(s) of Failure	Potential Effect(s) of Failure	Current Design Controls	OCCUR	SEV
Wash hands to sanitize						

Occurrence of the cause of failure mode
Detection of failure mode
Severity of the effect when a failure mode occurs

Rank	Occurrence	Detection	Severity
	Probability that the cause will occur and lead to the failure mode	Probability that the failure mode will be detected before resulting in the end effect	Seriousness of the end effect when it occurs
1	Remote probability	Always	No effect
2	Low probability	High likelihood	Minor effect
3			
4	Moderate probability	Moderate likelihood	Moderate effect
5			
6			
7	High probability	Low likelihood	Serious effect
8			
9	Very high probability	Very low likelihood	Injury
10	100% probable	Never	Death

FMEA ranking scales for Occurrence, Detection and Severity.

- Completing an FMEA
- Risk Priority Number (RPN) –
  - Occurrence ranking **X** Severity ranking **X** Detection ranking
  - Range of RPNs (1 -1000)
  - RPN of 125 or higher is problematic either in terms of safety or process capability
  - Typical scenario –RPNs over 400!
  - Highest RPNs must be addressed first
  - Then work down to lower risk process steps

Completing an FMEA

- Risk Priority Number (RPN) –
  - Beware of patterns potentially hidden by low overall RPNs
    - Occurrence = 10, Severity =10, Detection=1 - RPN of 100 but ……
    - Occurrence=1, Severity=10, Detection=10 – RPN of 100 but ….
    - Severity of 10 – even if Occurrence and Detection are both a 1 can you or do you want to risk it?

POTENTIAL FAILURE

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		❏ Component	

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Wash hands to sanitize						

Top/Down FMEA Approach

- Start with the major "branches" of the selected process

- Perform a PFMEA to identify which 'branches" are the weakest (most likely to produce sub-optimal results or errors/mistakes

- Drill down deeper into those "branches" – more detailed process map and PFMEA

IMRT Process Tree
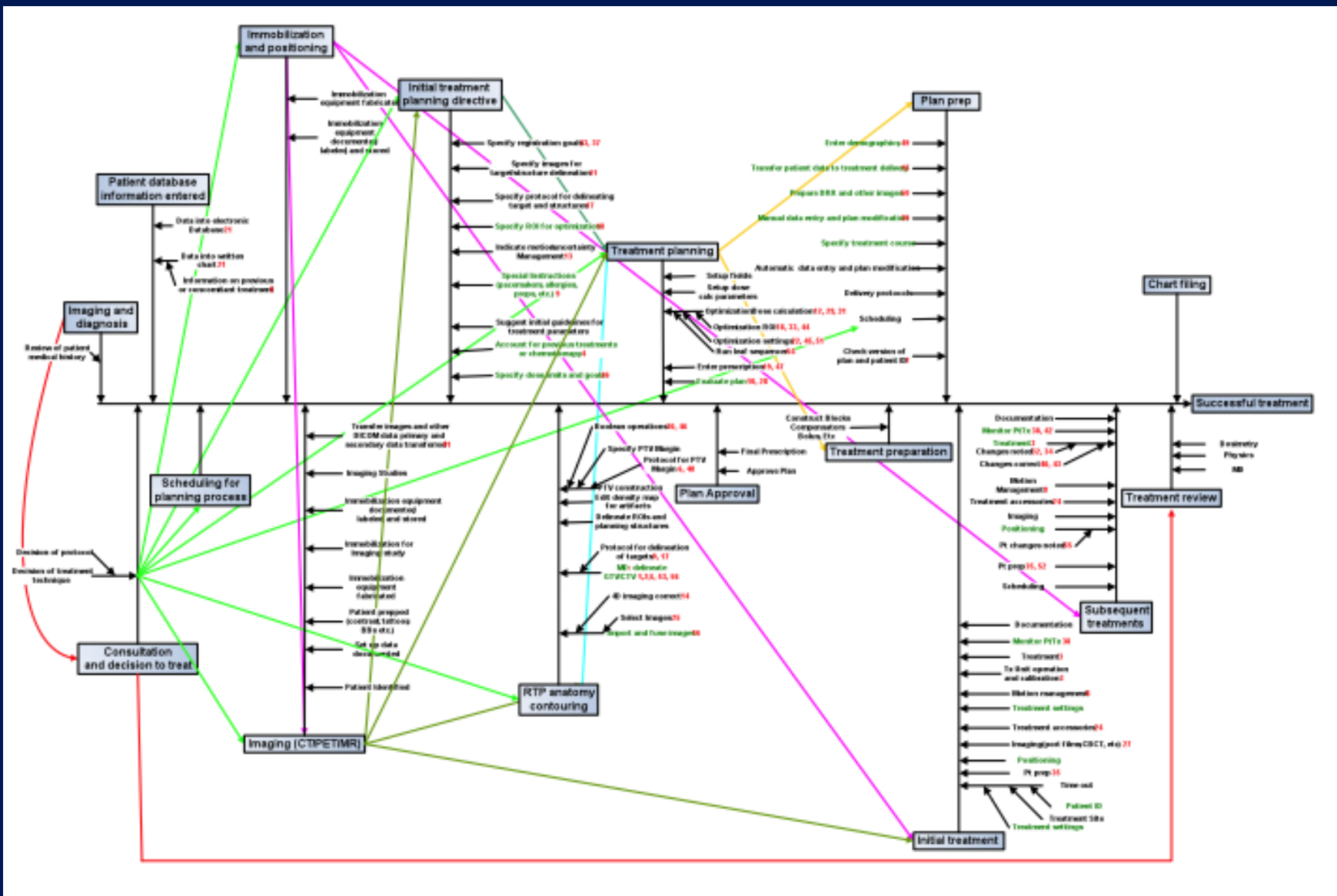
Exercise 4
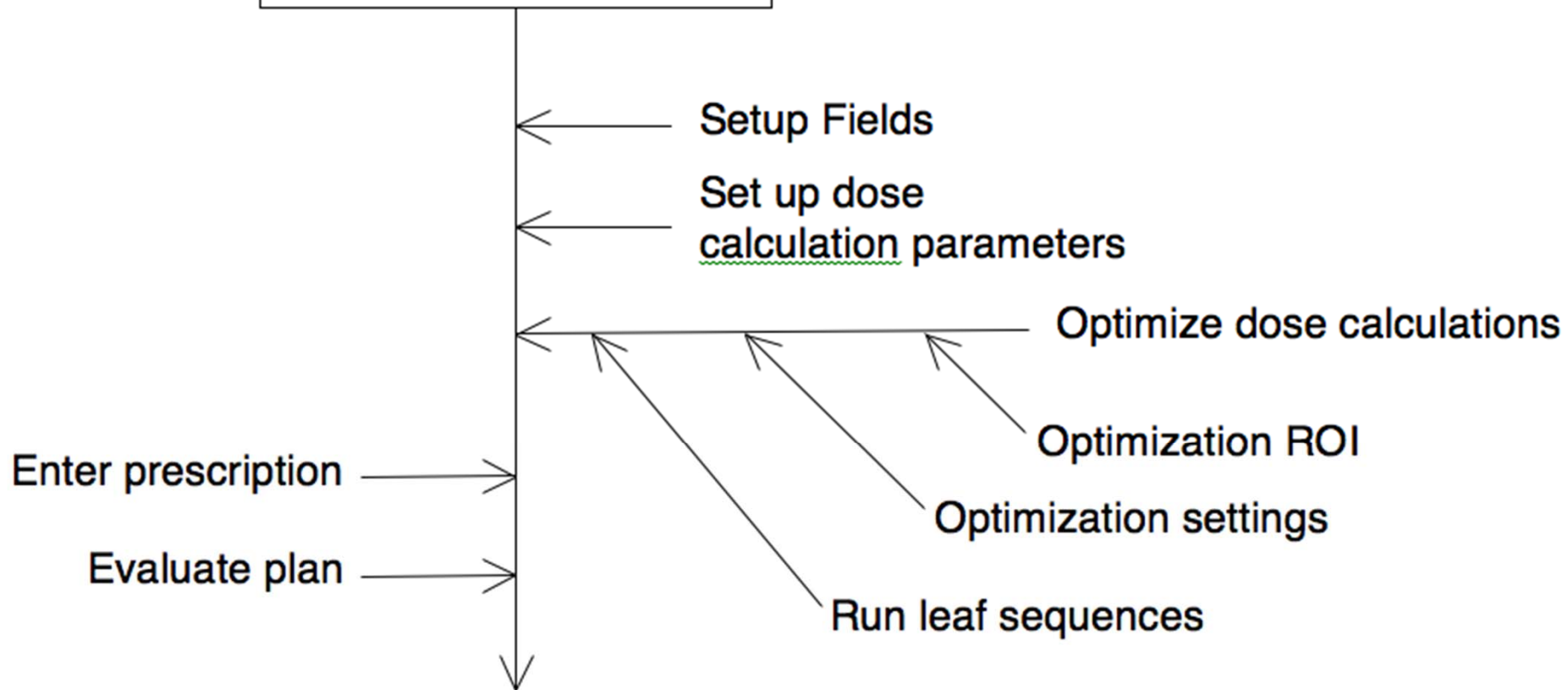
Failure Modes and Effects Analysis

Overview

- Participants working in small teams will complete a PMFEA for a step(s) identified in the process tree segment for Intensity Modulated Radiation Therapy below. "Evaluate Plan" will be used to generate FMEA and FTA examples in this and following workshops.

Steps 1

1. Form your team. Teams familiar with the process being analyzed always produce a higher quality PFMEA than an individual.

2. Select one of the steps from the treatment planning process tree segment and use the paper handed out to perform a PFMEA on that step.

Steps 2

3. Performing the PFMEA
   – List the process step your team selected.
   – Identify ways in which the process step can fail. List at least four.
   – For one of the failure modes you identified, list several causes that could result in that failure mode. Typical causes of failure modes include but are not limited to the following:
     • Lack of formal and written procedures, work instructions or work methods
     • Inadequate training
     • Insufficient time to complete a task due to other tasks requiring attention
     • Equipment or software malfunction
     • Stressful work environments leading to mistakes

Steps 3

4. Identify the potential effects that could result when the failure mode occurs. It is important to identify the worst possible outcome of a failure mode. Your team should not consider how likely an effect is to occur. Very serious effects could occur as a result of many failure modes in radiation therapy.

5. List all process controls currently in place and being used. There are three categories of process controls.

6. Judge the effectiveness of the current controls

Steps 4

1. Calculate the Risk Priority Number (RPN).

2. Identify and list new process controls that will improve:

    – Preventing specific causes of failure modes from occurring and

    – Detecting a failure mode before any serious effects occur

3. Estimate the improvements resulting from the recommended actions and recalculate RPN.

Rank	Occurrence	Detection	Severity
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Exercise Discussion Points

1. How did your team's PFMEA effort go?
   - Participation
   - Discussion
   - Confusion

2. How will the PFMEA tool be accepted, used, etc. in your clinic or organization?

3. What were the results of your team's PFMEA
   - Highest RPN process steps
   - Recommended corrective actions/process controls

	A	B	C	D	E	F	G	H	I	J	K	L
1	Rankl Number	step #	Major Processes	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	AVG O	AVG S	AVG D	AVG RPN	Examples of Causes and Failures
2	91	125	8 - Treatment Planning	11. Evaluate leaf sequences	2. Incorrect evaluation (ie, ok when not, etc)	1. Poor training. 2. Inattention. 3. Poorly designed evaluation tools, 4. Software error.	Very wrong dose	3.78	7.89	5.89	179.33	Similar to the last one : How do you evaluate the leaf sequence? I do not know how to evaluate the leaf sequence?
3	120	124	8 - Treatment Planning	11. Evaluate leaf sequences	1. Unintentional modification of sequences	1. Software error, 2. User error	Very wrong dose	3.44	7.89	5.78	157.22	In order to understand whether the leaf sequence is right or wrong, one will have to generate i) the fluence profile using the final leaf sequences generated by the sequencer and compare it with the desired fluence profile; ii) one will have to generate the dose distribution and then determine whether the distribution is the desired one or not. If it is not then it could be due to many reasons, one of which is an incorrect leaf sequence. But the question is how does one know whether the leaf sequence is correct or not?

Next – Perform a Fault Tree Analysis to Identify Root Causes of High Probability Failures Identified in FMEA

- Fault tree analysis (FTA) is a top-down approach to failure analysis, starting with a potential undesirable event (accident) called a TOP event, and then determining all the ways it can happen

- TG100 "poured" the Process FMEA into a Fault Tree to get a visual representation of the most frequent root causes of failure modes
  - Most common root causes were lack of formal procedures or work instructions, lack of communication and lack of time/stress

Case Study

- Radiotherapy & Oncology
  - Journal of the European Society for Therapeutic Radiology and Oncology and affiliated to the Canadian Association of Radiation Oncology
  - Applying failure mode effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement; *Radiotherapy and Oncology, Marta Scorsetti, Chiara Signori, Paola Lattuada, Gaetano Urso, Mario Bignardi, Pierina Navarria, Simona Castiglioni, Pietro Mancosu, Paolo Trucco*

From the Discussion Section of this Article

Our study attempted to enhance patient safety performance in a radiation oncology department by introducing clinical risk management principles and techniques, achieving the following goals:

(1) to set up an efficient and systematic procedure to assess the risk of the entire RT process;
(2) to disseminate patient safety and risk management culture among all the professionals involved (physicians, physicists, technicians and clerks).

It is likely that the study contributed to an observed reduction in the number of errors reported, mainly by means of the improvement of technical procedures, quality checks and communication flows. This reduction was particularly evident as regards errors in patient identification, that had been evaluated as the FM with the highest CI by the experts.

As an example we report the fact that, after the present study, the adverse events registered by the hospital incident reporting system, showed an important decrease in the RT unit, in terms of severity of the event.

In fact, while the criticalities or near misses reported and corrected together with the risk management team increased, thanks to the strict involvement and awareness of the RT operators, the adverse events and near misses that could be classified as dangerous for the patient were set at zero. For example, errors in patient identification during the treatment, happened a pair of times in the months before the present study, were never pointed out in the following year.

This was probably due to the implementation of new procedures introduced as corrective actions derived from the FMECA analysis.

Beside this, the FMECA study was very well accepted by the operators and further increased their commitment to patient safety, mainly thanks to an improved understanding of clinical risk: they became very proactive during FMECA sessions and after that they showed a continuous effort in promoting patient safety. Thus our experience further supports one of the major reported benefits of prospective analysis in clinical risk management, that is the promotion of organisational learning and the enforcement of safety culture among healthcare professionals [15].

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Questions?