

UPMC CancerCenter

Partner with University of Pittsburgh Cancer Institute

Therapy symposium
Formal Radiation Therapy Safety Processes

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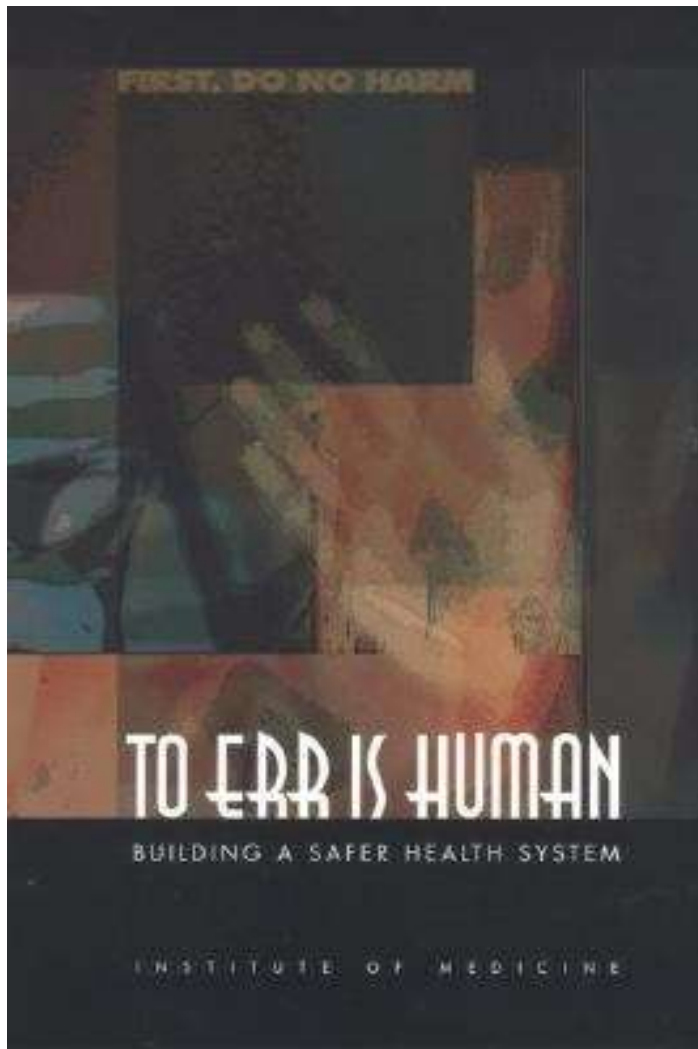
Outline

- Introduction to risk assessment and safety processes
 - External beam
- **Todd Pawlicki:** Brachytherapy
- **George Sherouse:** State diagrams as a tool to visualize hazard mitigation

Acknowledgement

- Many slides shown in this presentation has been taken from the presentations given by Frank Rath, Derek Brown at the summer school. Their contribution is gratefully acknowledged.

Institute of Medicine 1999



- Highlighted the need to make patient safety a high priority
- Priority has focused on identifying and reducing preventable events
- Adapt tools of ultra safe systems such as aviation industries ?

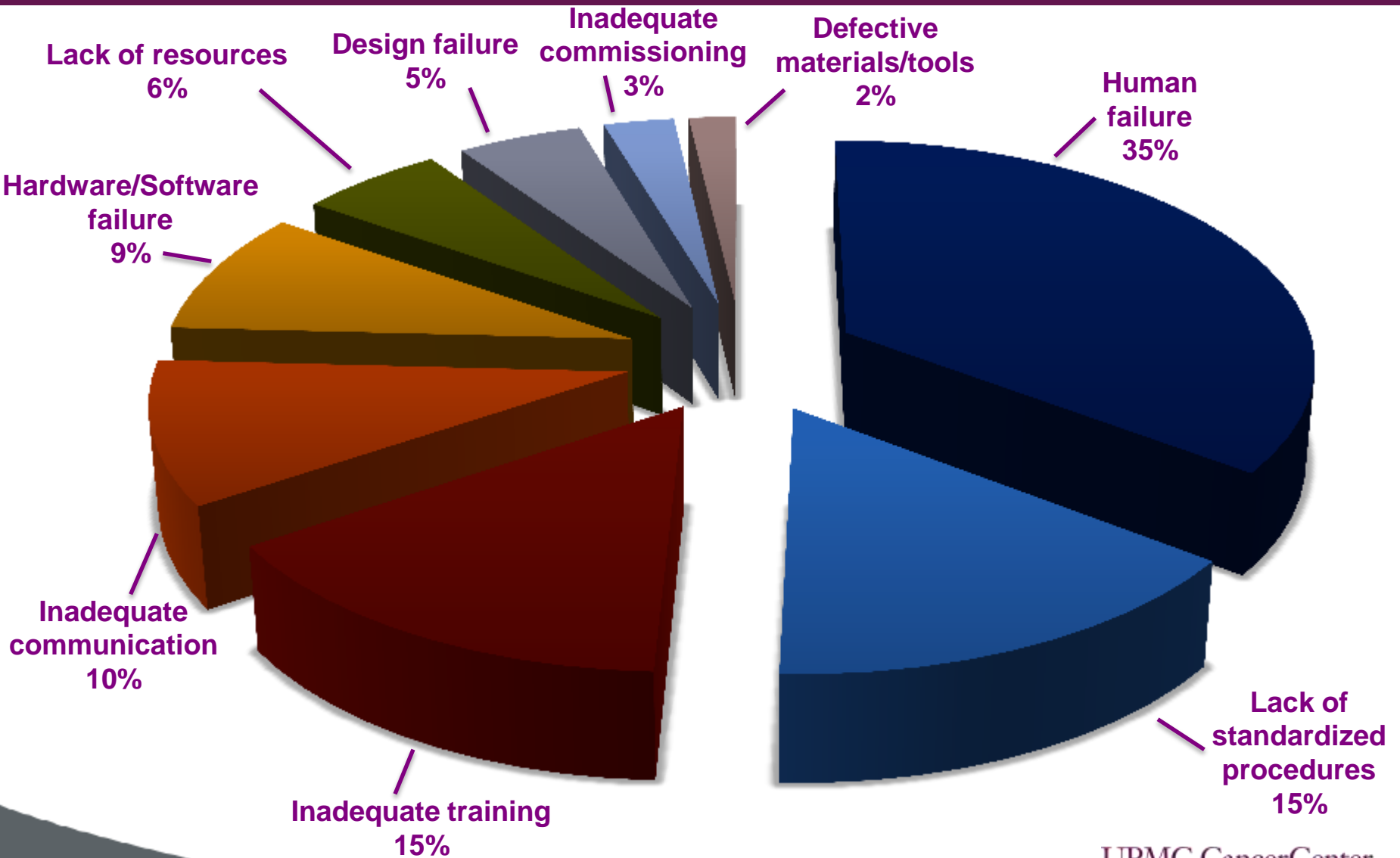
How safe is safe: Risk in radiotherapy



- Rate of misadministration in RT is 0.2 % (1 in 600)
- Rate of serious injury: airline accidents is 1 in 10 million
 - 16,000 times lower than that of RT
- Rate of serious injury in RT is 1000 times higher
- In reality no one knows
- Risk profiles of anesthesia: similar to airline industry

Ford and Terezakis; Red Journal 78, 321-322, 2010

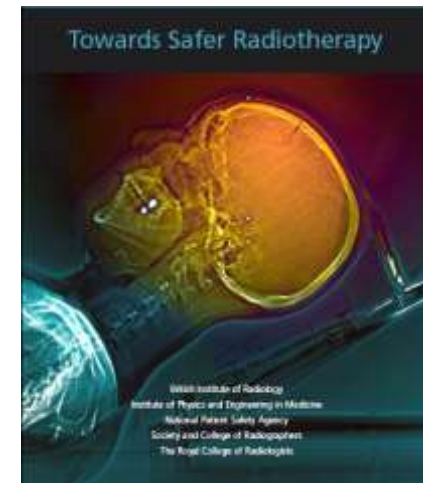
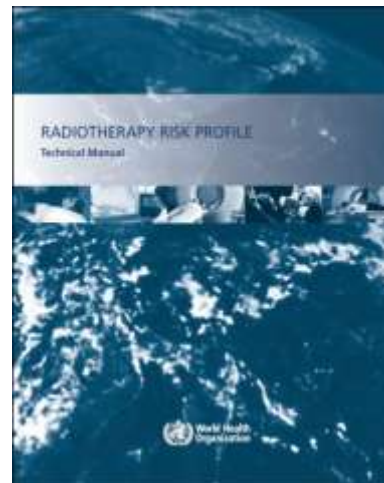
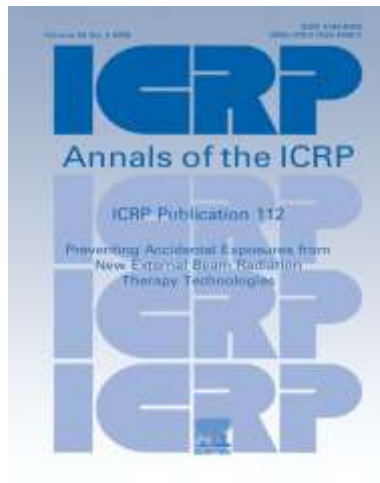
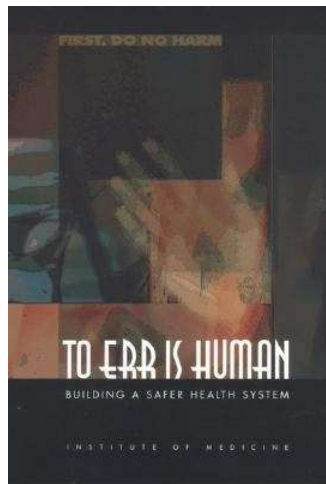
TG100 analysis of causes of failure for IMRT



Challenges with the current QA paradigm

- Current RT QA guidance is focused on equipment performance even though most RT events have resulted from human performance failures rather than equipment failure
- The QM guidance is different from a process centric QM approach which should be designed to mitigate all failures with detectable impact on patients, not just the ones resulting from equipment failure

What to do?



- As technology and processes change
 - Retrospective approaches to QM are not sufficient
 - All-inclusive QC checks may not be feasible
 - Develop proactive approaches to failure modes
 - Evaluate risks from each failure mode
 - Develop risk based approaches to QM

Prospective risk assessment

- Before introducing a new technology or technique, or developing a QM program figure out, through a formal process, what could go wrong and what the consequences might be

What is Quality Management ?

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

What is risk?

- Risk: frequently defined as the answers to three questions
 - What can go wrong?
 - How likely is it to go wrong?
 - What are the consequences if it goes wrong?

Risk assessment

- Risk assessment is the process of analyzing the hazards involved in a process
- Many risk assessment and analysis tools/techniques exist in industry
- These tools can be easily adapted to RT to enhance safety and quality of treatment process
- TG100 used some of these tools to develop new guidelines for RT QM

Risk assessment tools

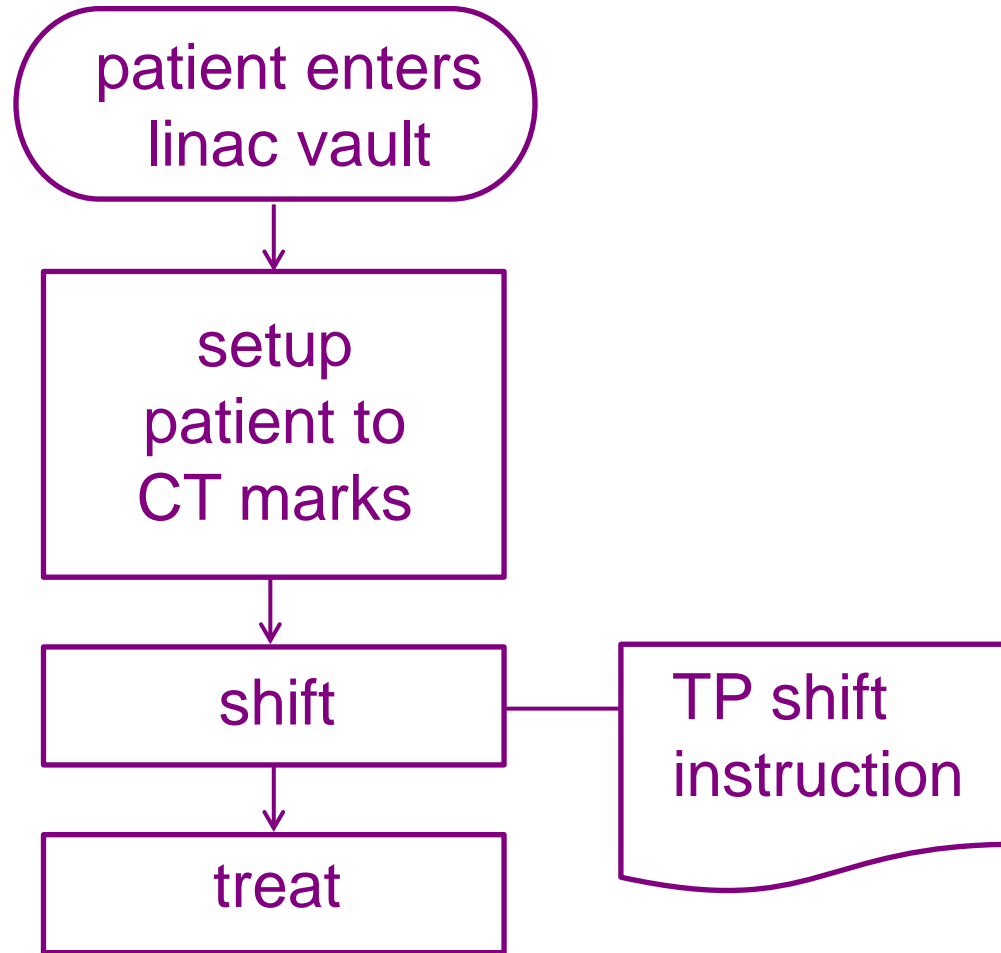
- Process tree (mapping)
- Failure modes and effects analysis (FMEA)
- Fault tree analysis (FTA)
- Establishment of a risk based QM program



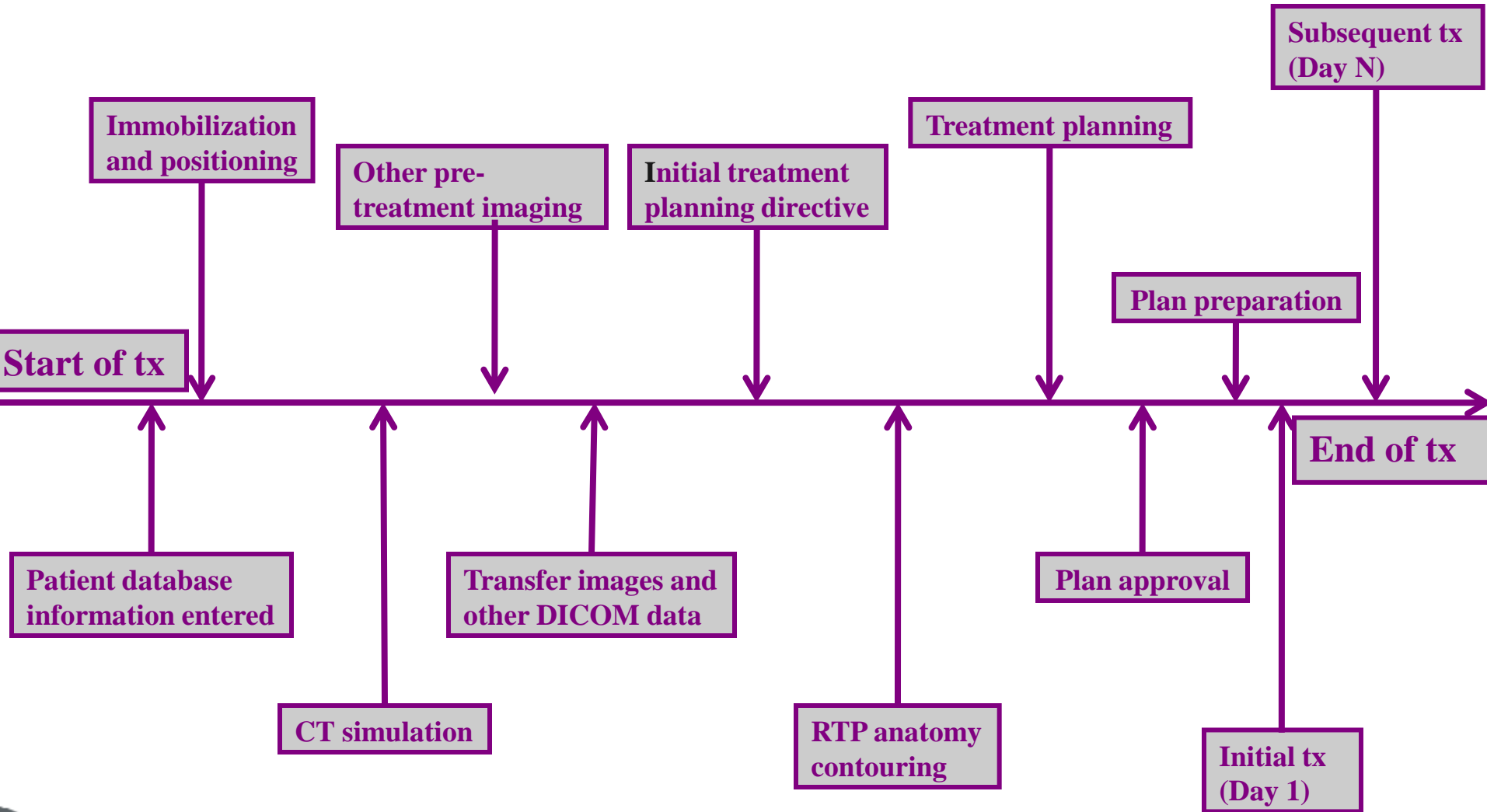
What is a process tree?

- Visual representation of the various steps in a process
- Demonstrates the flow of steps from process start to end
- Delineate and then understand the steps in the process

Simple example of a process map



Complicated example: TG100 IMRT process tree



FMEA

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

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

Strategy for Improving Patient Safety: use of FMEA and FTA

- Begins with a complete and thorough understanding of the process – flow charts, 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

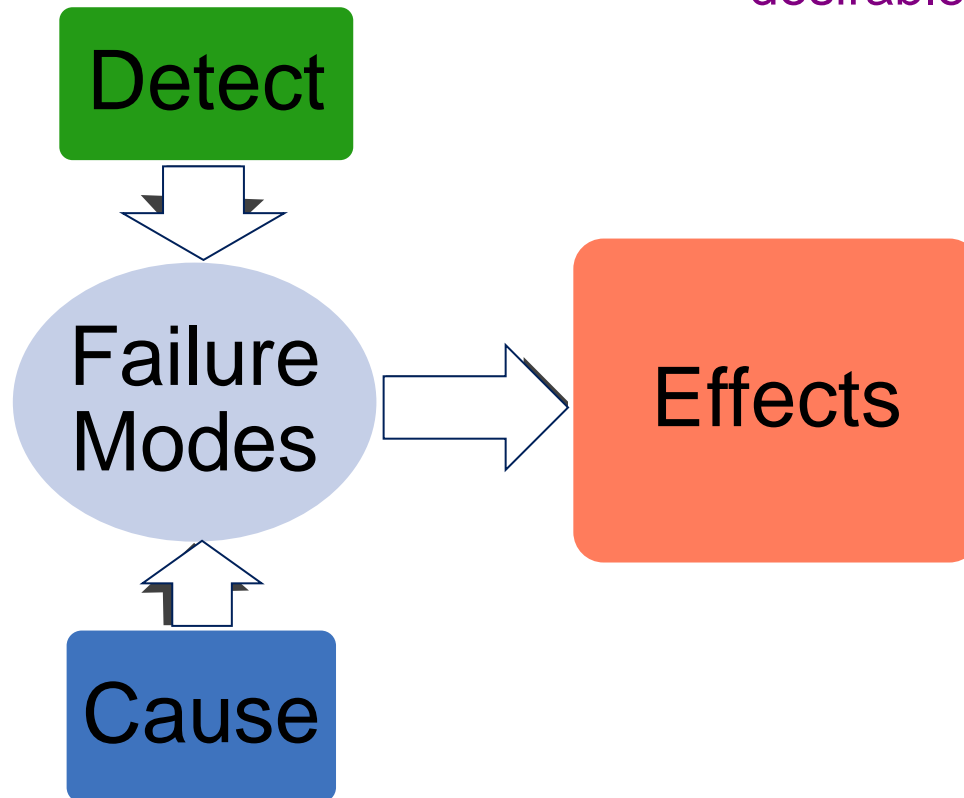
- **Create a team**
 - Oncologists, medical physicists, dosimetrists, therapists, IT personnel, administrators
 - Effort should be led by a facilitator trained in or familiar with the tools used in the analysis
 - Consider providing training

Completing an Process FMEA

- **Select a process – key step**
 - Scale of process
 - Opportunity – Quality issues, past problems, not happy with the level of success, ...
 - Realistic opportunity to make improvements
 - Complexity or size

Process FMEA – for each step in a process

FM: Inability of a process step to produce the desirable optimal outcome



Completing an FMEA

1. For each process step – identify all potential 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 current capabilities of the process controls to:
 - a. Prevent the cause of a failure from occurring
 - b. Detect a failure when it occurs
 - c. Moderate the severity of a failure when it occurs

Completing an FMEA

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

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

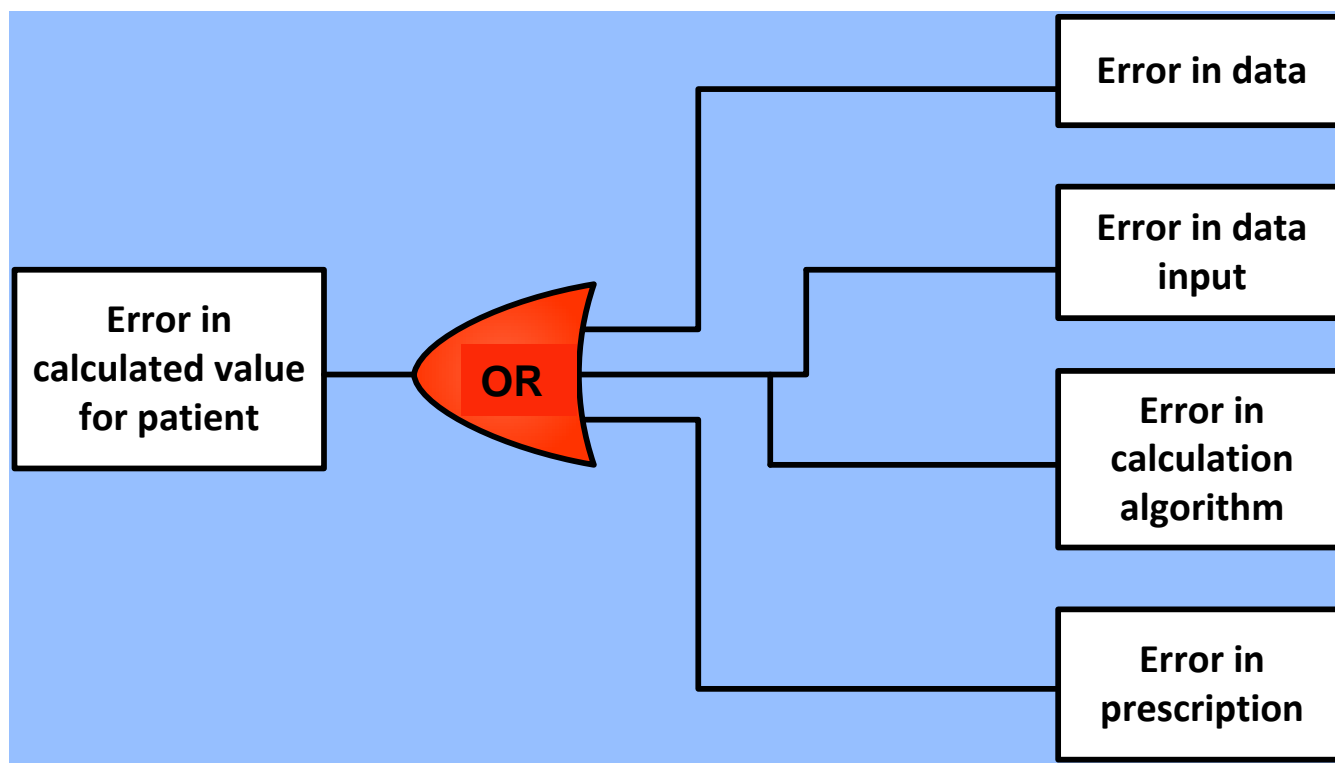
- Risk Priority Number (RPN)
 - Beware of patterns potentially hidden by low overall RPNs
 - Occurrence = 10, Severity =10, Detection=1 - RPN of 100 but
 - Occurrence=1, Severity=10, Detection=10 – RPN of 100 but
 - Severity of 10 – even if Occurrence and Detection are both a 1
can you or do you want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

Top/Down FMEA Approach

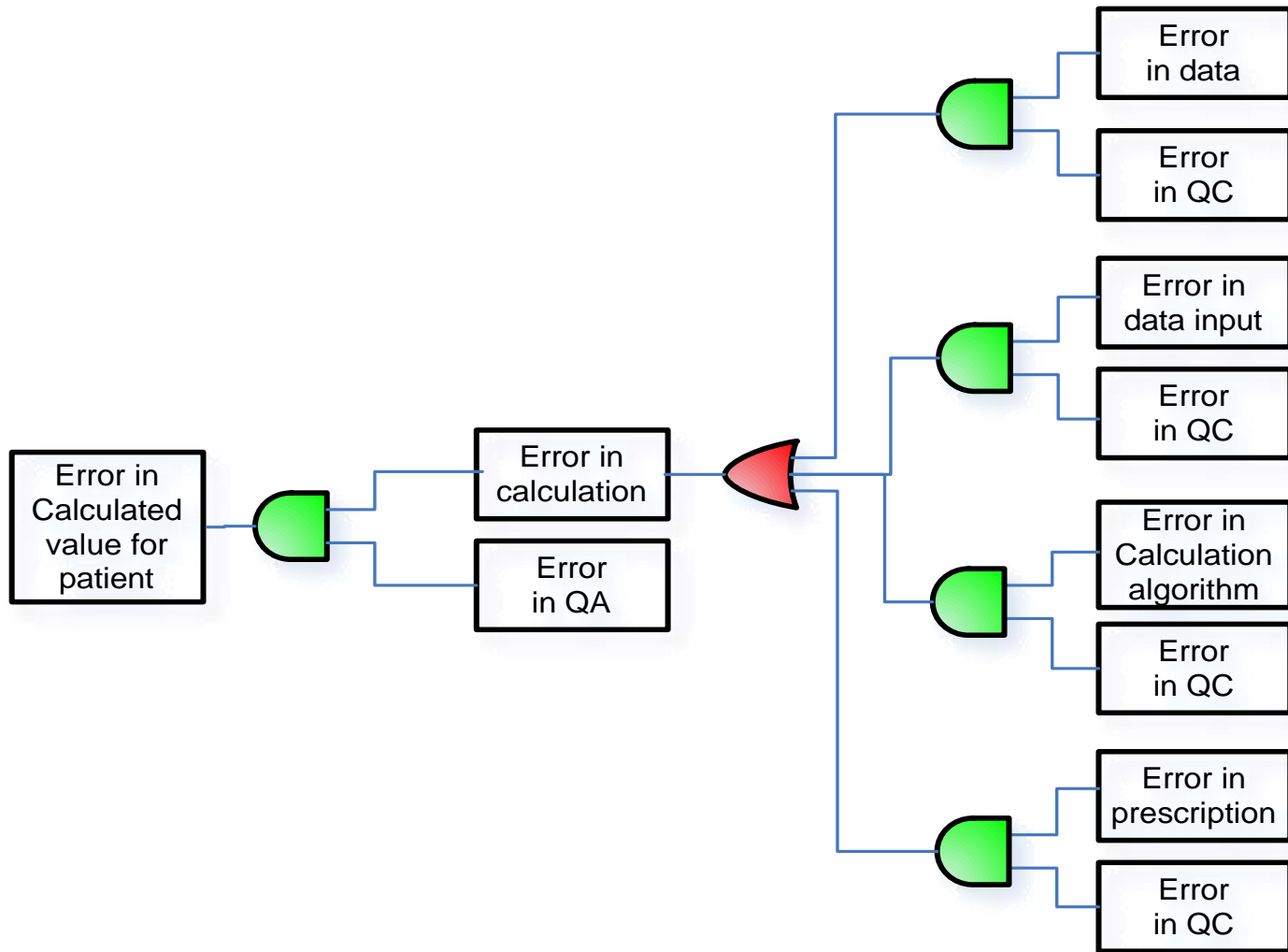
- Start with the major “branches” of the selected process
- Perform a PFMEA to identify which ‘branches’ are the weakest (most likely to produce sub-optimal results or errors/mistakes)
- Drill down deeper into those “branches” – more detailed process map and PFMEA

Fault Tree

- Evaluates propagation of failures
- Visual representation of propagation of failure
- Begins on the left with a failure mode
- Works backwards in time (to the right) to identify causes of failure



Fault tree



Summary

- Risk analysis gives guidance for developing a QM program
- QA/QM should be more process centric
- Should be based on rigorous sensitive analyses of all components of radiotherapy process
- Be based on industrial engineering approaches of risk analysis and mitigation
- Will be infrastructure dependent and may shed light on how much QA is enough for a given institution

Thank you

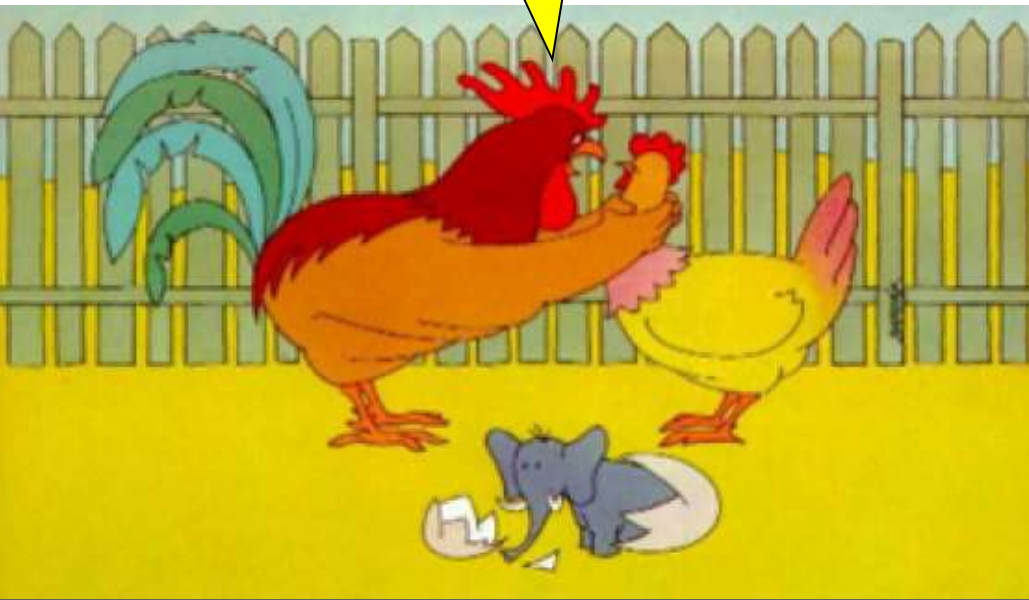
**It is useful to report
all accidents before
consequences appear**

It is impossible to make anything foolproof because fools are so ingenious.

Arthur Bloch, Murphy's law

Our job is not to prevent errors, but to keep the errors from injuring the patients.

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