Failure Modes and Effects Analysis (FMEA)

Sasa Mutic

Washington University School of Medicine
St. Louis Missouri

Failure Modes and Effects Analysis

Objectives:

- To motivate the use of FMEA and to provide an introduction to the application of FMEA in RT
- To illustrate the dependence of the results of an FMEA on the approach used and on the individuals performing the analysis
- **FMEA is a tool**

Modern RT

- Recent sophistication – large fraction of modern treatment practices developed in the past ten years
- High technical complexity
  - Multiple systems (software and hardware)
- Limited to non-existent guidance and regulations
- High pressure
- Increased potential for catastrophic failures

"To error is human. To really foul things up requires a computer."

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

Systems Engineering

- The function of systems engineering is to *guide* the engineering of *complex* systems
- It is founded on a belief that individual components of an organization are dependent on each other
- It is very much about employing common sense in design of operations
- A set of tools for more effective management of interconnected components

Systems Engineering

- Applicable to systems with the following attributes:
  - Complex
  - Engineered
  - Advanced technology
  - High risk
  - High cost

Modern RT

Systems Engineering

- Systems Design
  - Quality systems
  - Human factors
  - FMEA
- Systems Analysis
  - Modeling and simulation
  - Enterprise management
  - Financial engineering and risk analysis
  - Knowledge discovery
- Systems Control
  - SPC
  - Scheduling

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

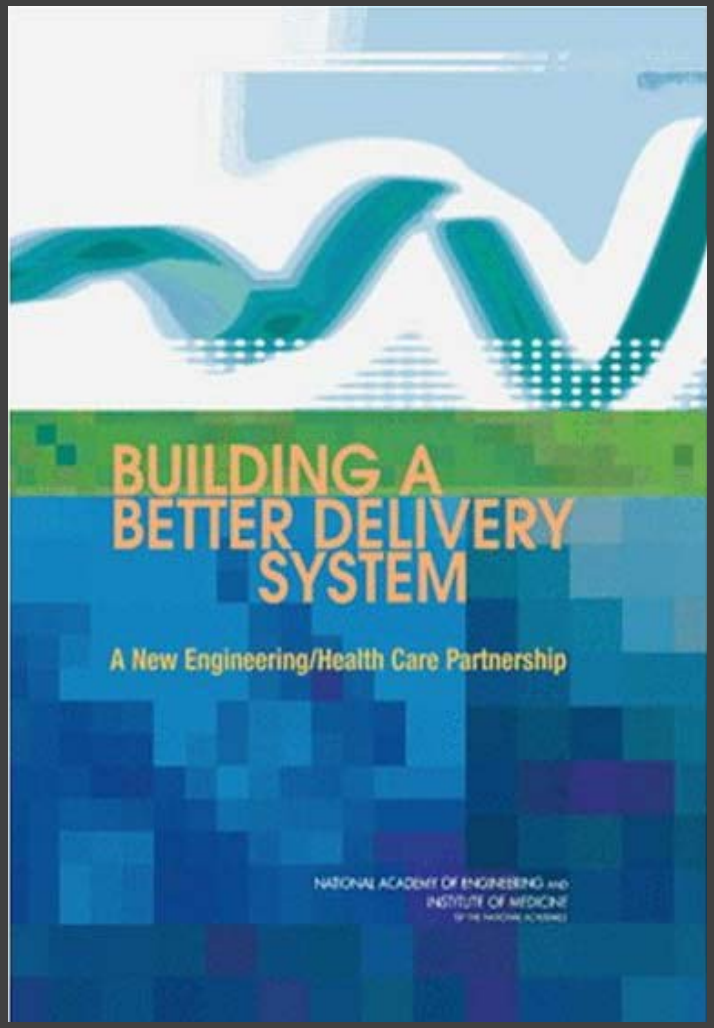
Systems Engineering

"It is difficult for engineers to change human nature and therefore, instead of trying to persuade people not to make errors, we should accept people as we find them and try to remove opportunities for error by changing work situation." *An engineers view of human error* - Trevor Kletz

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

Systems Engineering in Healthcare

An outline for use of Systems Engineering for improvement of national health care system



"We often call this arrangement a "health care system" even though it was never created as a system and has never performed as a system."

National Academy of Engineering and Institute of Medicine, 2005

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA)

Identifies ways that a sub-process or product can fail and develops plans to prevent those failures. FMEA is especially useful with high-risk projects.

The FMEA process is a **dynamic**, structured approach that has the goal of linking the FAILURE MODES to an EFFECT over time for the purpose of prevention.

http://www.webpages.uidaho.edu/~redgeman/Generic%20Presentations/FMEA-&-Measurement_Systems_Analysis.ppt

Failure Modes and Effects Analysis

What's the point?

•Provides a structured way of prioritizing risk.

•Helps to focus efforts aimed at minimizing adverse outcomes.

How does FMEA do that?

•Assembles a group of people (experts) and asks them to dream up potential risks (failure modes) and to assign a few numbers to them.

•Numbers are easy to sort.

"The purpose of computing is insight, not numbers! " R.W. Hamming

Failure Modes and Effects Analysis

- It can be used as a standalone tool or as a part of a broader quality system
- FMEA – part of FDA process
- Applications:
  - Equipment/product d
  - QA/QC development
  - Process development

Failure Modes and Effects Analysis

Vocabulary

Failure Mode: How a part or process can fail to meet specifications.

Cause: A deficiency that results in a failure mode; sources of variation.

Effect: Impact on customer if the failure mode is not prevented or corrected.

Failure definition and spectrum

Publicized - One side of the spectrum, usually large dosimetric errors – NY Times Articles

Semi-publicized – RPC data

- Approximately 30% of *participating* institutions fail to deliver IMRT dose indicated in their treatment plans to within 7% or 4mm to an anthropomorphic phantom (IJROBP. 2008;71(1 Suppl):S71-5).

Unpublicized/unnoted – everyday occurrences

- "Small" dosimetric errors and geographic misses
- Suboptimal treatment plans (contouring and dose distributions)
- Care coordination issues
- Unnecessary treatment delays

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

Organizational Goals

- RT - Service or Manufacturing Industry?
  - Quality
  - Patient and employee safety
  - Patient and employee satisfaction
  - Efficiency

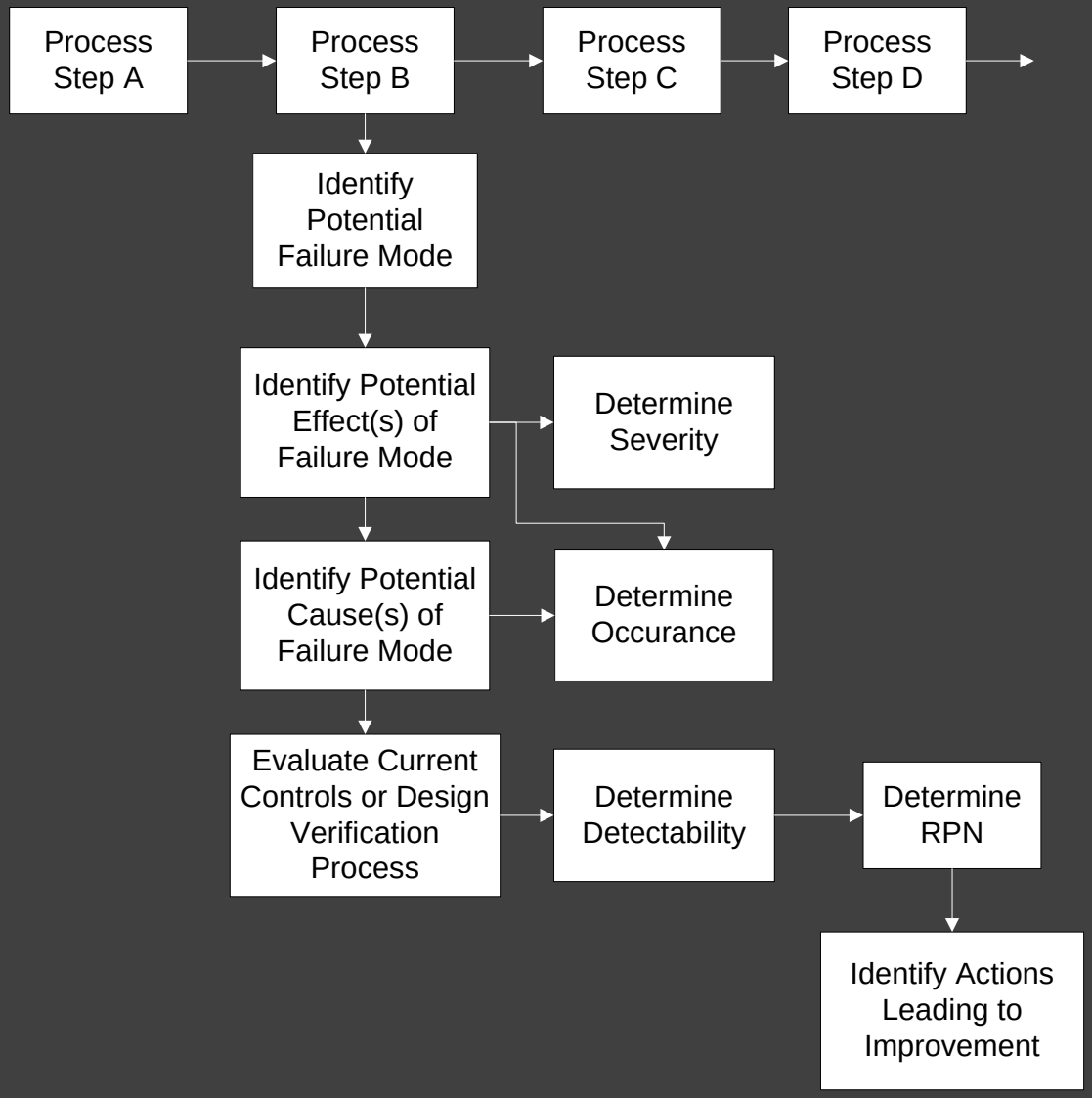
Process Itself Matters

"High-quality" means minimizing process variation and moving the average closer to the optimum value - *Med. Phys., 2007. 34(5): p. 1529-1533.*

Stable and well defined processes enable:

- Standardization
- Quantification
- Benchmarking
- Improvements
- Quality Control

FMEA Structure/Process



Failure Modes and Effects Analysis

Identifying potential failure modes

- Must be comprehensive
- Must be unambiguous – remove interpretation
- May be linked to severity

Identifying potential effect(s) of failure mode

- Use most severe
- Easiest one to agree on

FMEA in Numbers

Occurrence (O) describes the probability that a particular cause for the occurrence of a failure mode occurs. (1-10)

Severity (S) describes the severity of the effect on the final process outcome resulting from the failure mode if it is not detected or corrected. (1-10)

Lack of Detectability (D) describes the probability that the failure will not be detected. (1-10)

RPN Score

- Three part system
  - Probability of failure - O
  - Severity of failure - S
  - Probability that a failure would NOT be detected - D

Probability of error	Severity	Probability no detection	RPN
A	B	C	A*B*C

Risk Priority Number (RPN) =

Frequency * Severity * Probability

Scoring frequency of failure

Qualitative Review	Ranking	Failure Rate
Failure is unlikely	1	< 100 ppm
Few failures	3	< 500 ppm
Occasional failure	6	< 0.5 %
Repeated failures	8	< 2.0 %
Failures are inevitable	10	> 5.0 %

Six Sigma Levels of Performance

Sigma Level	DPMO	Error as %	Quality Yield	Cost of Quality/Cost of Poor Quality as % of Total Operating Cost
2	308,537	30.8%	69.0%	Uncompetitive
3	66,807	6.7%	93.3%	24-40%
4	6,219	0.6%	99.4%	15-20%
5	233	0.0233%	99.98%	5-15%
6	3.4	0.00034%	99.9997%	World Class

The Journal of Emergency Medicine, Vol. 38, No. 1, pp. 70–79, 2010

Scoring Severity of Failure

Severity	Rank
Minor to Inconvenience	1-3
Minor dosimetric error	4
Limited toxicity	5-6
Serious toxicity	7-9
Catastrophic	10

Probability that a failure will NOT be detected

Probability	Rank
1/10,000	1
1/5000	2
1/2000	3
1/1000	4
1/200	6
1/50	8
1/20	9
1/10	10

Failure Modes and Effects Analysis

- *NO* special QA\QC in place for any of the processes or equipment
- Errors are discovered only downstream through routine processes
- Drastically different from all our training and beliefs
- Challenging to continuously remember

Failure Modes and Effects Analysis

Identifying potential cause(s) of failure mode

- Depends on experience
- Often get a wide spread

Evaluate current controls or design verification process

- Assume no QC
- This is difficult to do for us

Failure Modes and Effects Analysis

Each failure can have multiple causes
Each failure can have multiple consequences

Example – Isocenter misplacement

- Causes
  - Laser misalignment
  - Patient setup misinterpretation
  - Many others…..
- Consequences/Severity
  - Depend on magnitude of misplacement
  - Use the most sever one

Failure Modes and Effects Analysis

Two major challenges in completing an FMEA

1.To be confident that all possible significant failure modes have been identified.

- This requires that experts contributing to the FMEA have a wide range of experience

2.The description of the failure mode must be completely clear and different sources that result in the same failure must be differentiated.

- Different sources may result in the same failure but will have different likelyhoods of occurrence.

ICRP Publication 112 - Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies

AAPM - TG100 FMEA

Application of Risk Analysis Methods to Radiation Therapy Quality Management

TG100 IMRT Example STEP 1. Process Steps

1. Diagnosis, Staging, History and Physical
2. Patient entered in database, assigned db keys, etc
3. Decision to Treat with Radiation
4. Scheduling for Planning Process
5. Immobilization and Positioning
6. Each Imaging Procedure (CT, MR, PET…)
7. Transfer Images

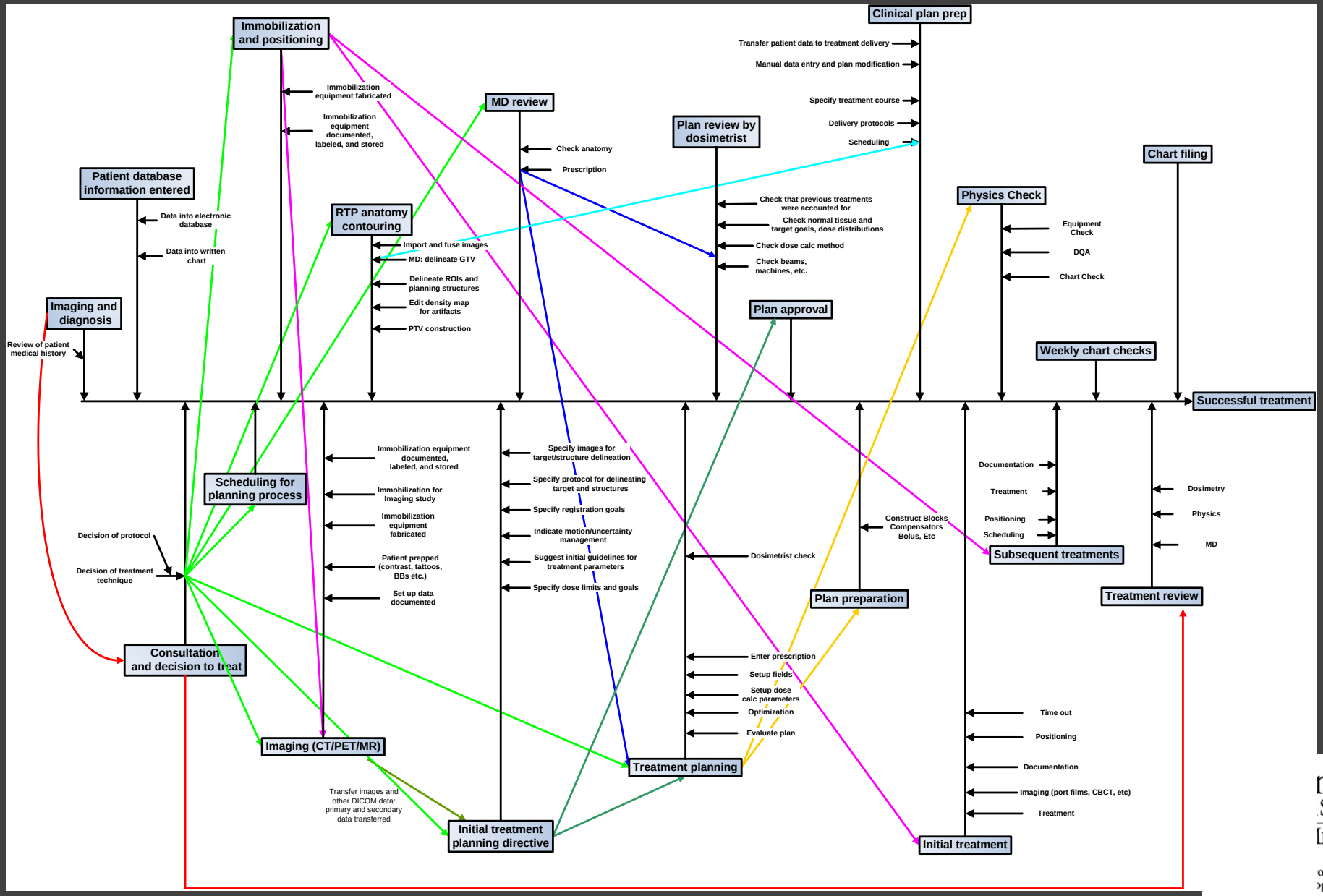
TG100 IMRT Example STEP 1. Process Steps

8. Initial Treatment Planning Directive (from MD)
9. RTP Anatomy
10. MD Review
11. Plan Review
12. Plan Approval
13. Plan Prep
14. IMRT QA
15. Clinical Plan Prep
16. Day 1 Treatment:
17. Day n Tx:
18. Weekly Chart Check:
19. Therapy Complete

TG100 IMRT Example Single Step - Subcategories

9. RTP Anatomy :
   - Import images into RTP system db
   - Create case (anatomy)
   - Import appropriate image datasets into case
   - Dataset registration (fusion) of multiple datasets
   - Delineate targets (MD) and normal structures for planning, optimization
   - Complete anatomical description (objects, fusion, 3-D review, etc)

TG100 IMRT Example STEP 2. Process Map



TG100 IMRT Example – Failure Modes

Process	Number of Failure Modes
Patient Entered into database	3
Immobilization and positioning	7
CT Simulation	13
Other imaging studies	7
Transfer of images and other DICOM data	8
Initial treatment directive from MD	9
Define anatomy for treatment planning	31

TG100 IMRT Example – Failure Modes

Process	Number of Failure Modes
Treatment planning	53
Plan approval	11
Prepare plan for delivery	30
First session treatment	20
Subsequent treatments	23

Table Example

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
1	2- Patient Database Information	Entry of patient data in electronic database or written chart	1. Incorrect Patient ID data	Errors in manual entry: Many basic causes: 8.X (Human transcription error; 5,3 (wrong data communicated to RO data entry)	Very wrong dose	3.78	7.89	3.89	106.78	Patient name is typed into the database incorrectly (misspelled; e.g. Yorke is spelled without the 'e') Information is requested from another department for Ellen York, a different person who actually exists. Information regarding Ellen York is sent back to the requesting dept..Incorrect staging/labs transcribed to pt chart from outside. Suboptimal dose prescribed
2	2- Patient Database Information	Entry of patient data in electronic database or written chart	1. Incorrect Patient ID data	Errors in manual entry Many basic causes: 8.X (Human transcription error; 5,3 (wrong data communicated to RO data entry)	Very wrong dose	3.78	8.11	3.78	98.44	Two patients in the department with the same name. In entering their information into the database, the operator gets data crossed (e.g. mixes the medical record numbers for the two patients or attaches Pt A's digital photo to Pt B). Pt A is simulated for and treated for Pt B's disease and vice versa. This is most likely if both patients have the same disease (e.g. both have left breast cancer). BUT- in principle, the two patients could have different diseases (even disease sites)
3	2- Patient Database Information	Entry of patient data in electronic database or written chart	2. Incorrect or incomplete previous. treatment history	1. Omission in entry 8.X (Human transcription error), 1.2, 1.3, 1.4 2. Incomplete patient history 5.3 (Source of data incomplete)	Very wrong dose	4.13	8.88	6.88	245.75	Historical information about patients treated in the dept. is maintained in a database. The archive is incomplete and there are no other records (or no effort is made to get the other records such as paper chart). The patient & family don't remember treatment (or details) and no-one notices physical changes from the prior treatment (tattoos). Part of previously treated area is re-treated.

TG100 IMRT Example STEP 3. FMEA

- Three part system
  - Probability of failure - O
  - Severity of failure - S
  - Probability that a failure would NOT be detected - D

Probability of error	Severity	Probability no detection	RPN
A	B	C	A*B*C

Risk Priority Number (RPN) =

Frequency * Severity * Probability

Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

TG-100 OSD Scores

- Nine of the TG members assigned O, S, D values
- Average OSD and RPN values and corresponding standard deviations created
- Highest and lowest median RPN scores used to identify most and least critical steps
- 10% and 20% values in both directions used as threshold
- Result is
  - High risk steps (HM10 and HM20) and
  - Low risk steps (LM10 and LM20)
- Steps with severity higher than 8 are given special priority regardless of RPN value

Your OSD Scores

- Start with TG-100 scores – VERY GOOD LEARNING TOOL
- Start with blank process and develop your own program
- Involve multiple groups
  - Administrative
  - Dosimetry
  - Physics
  - Clinical (Physicians)
  - Therapy
  - Nursing
- Develop individual OSD and RPN scores and analyze the data

Interactive Example – Incorrect Capping

Step	Evaluate ROIs (targets and structures)
Potential failure mode	Incorrect ROI volumes
Cause	Inadequate design/programming
Potential Cause	Inadequate contour capping algorithm (3D expansion)
Potential Effects	Wrong dose, suboptimal plan

Interactive Example – Incorrect Capping

- Frequency – O
  - 1 to 3
  - 3 to 7
  - 7 and higher
- Severity – S
  - 1 to 3
  - 3 to 7
  - 7 and higher
- Detectability – D
  - 1 to 3
  - 3 to 7
  - 7 and higher

Interactive Example – Incorrect Capping TG-100 Scores

	Probability of error	Severity	Probability no detection	RPN
Mean	4.67	6.78	6.89	221.11
SD	1.58	0.83	1.27	105.45

TG-100 Lessons

Scoring overall inconsistent with unclear trends

High and low RPN values scored much more uniformly

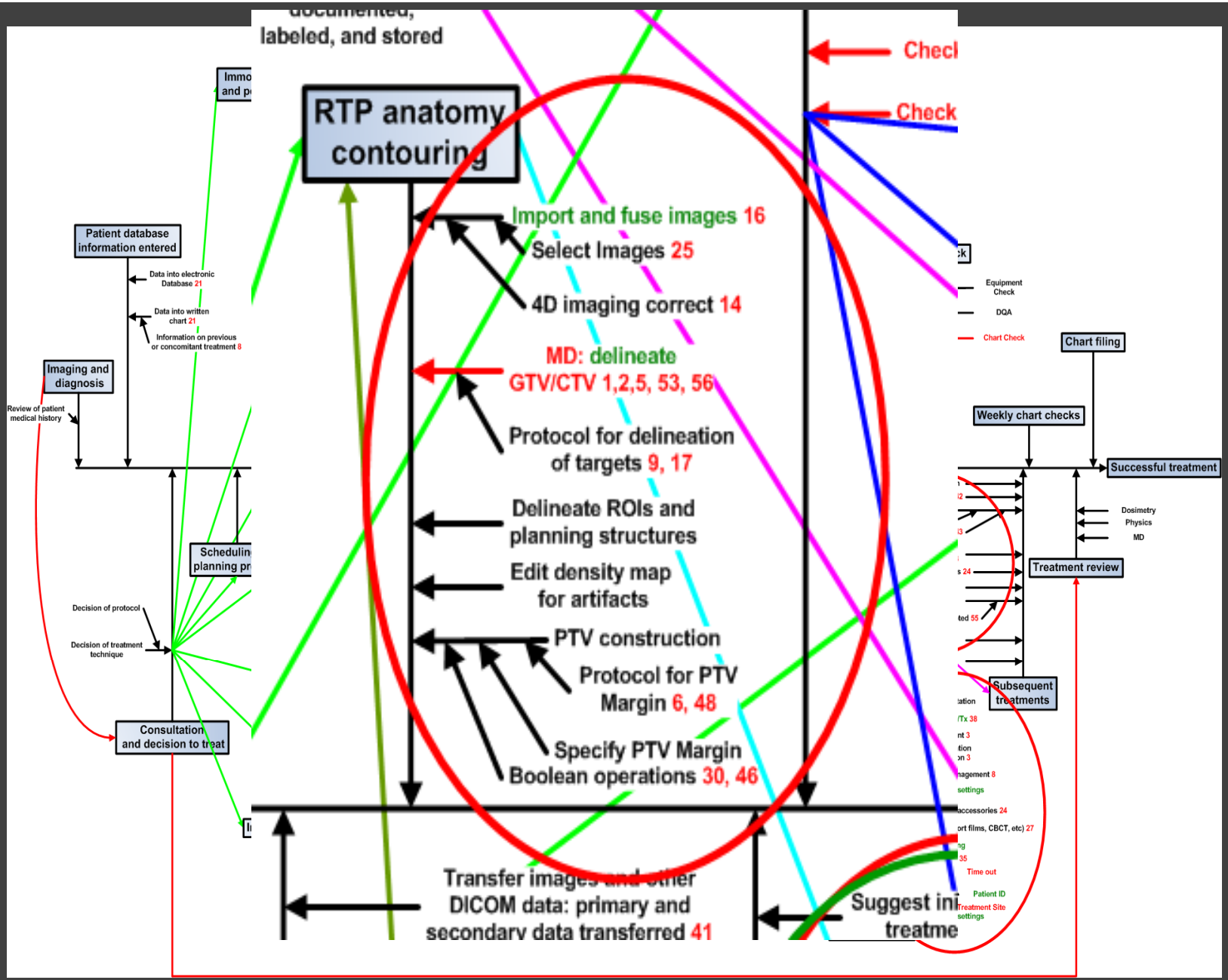
– Example High RPN: Failure to notice that MLC leaves are not moving

- O (3.33 ± 0.87),
- S (8.22±1.2),
- D (8.22±1.56) and
- RPN (221.7 ± 64.8)

STEP 5/6. Process Map Marking

- Shows if potential failures are uniformly distributed through the process or clustered
- If clustered, should consider the major step as a hazard
- Design QM processes according to clustered areas and severity scores

Process Map Marking



Washington University in St. Louis
School of Medicine
MIR Mallinckrodt Institute of Radiology

Conclusions

- FMEA can be used as a standalone effort or as a part of a broader process improvement effort
- Best performed with all involved groups (content experts)
- Need a facilitator – lead person with expertise in FMEA
- A broad spectrum of outcomes, from better insight and understanding to a much better product or service