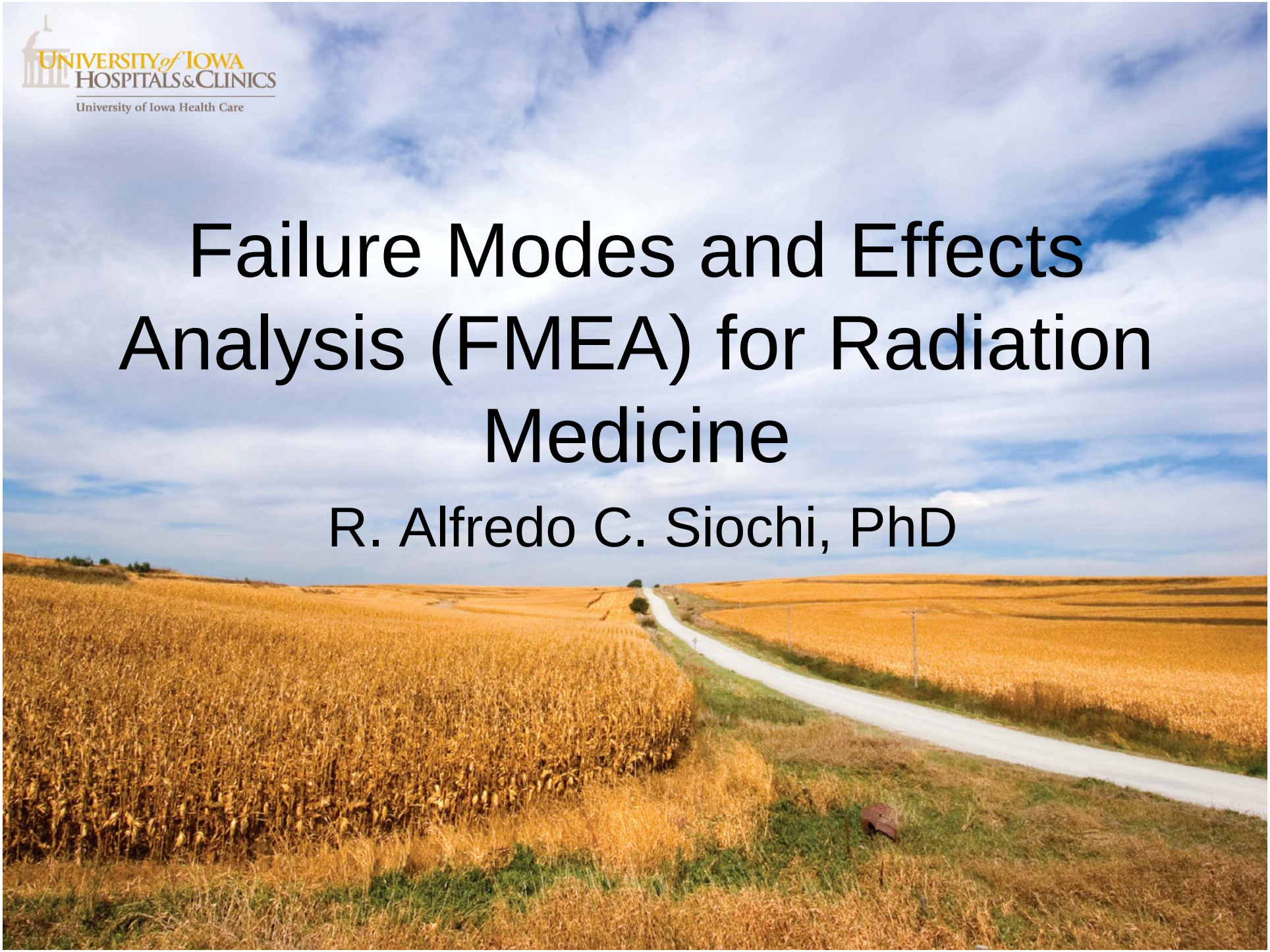


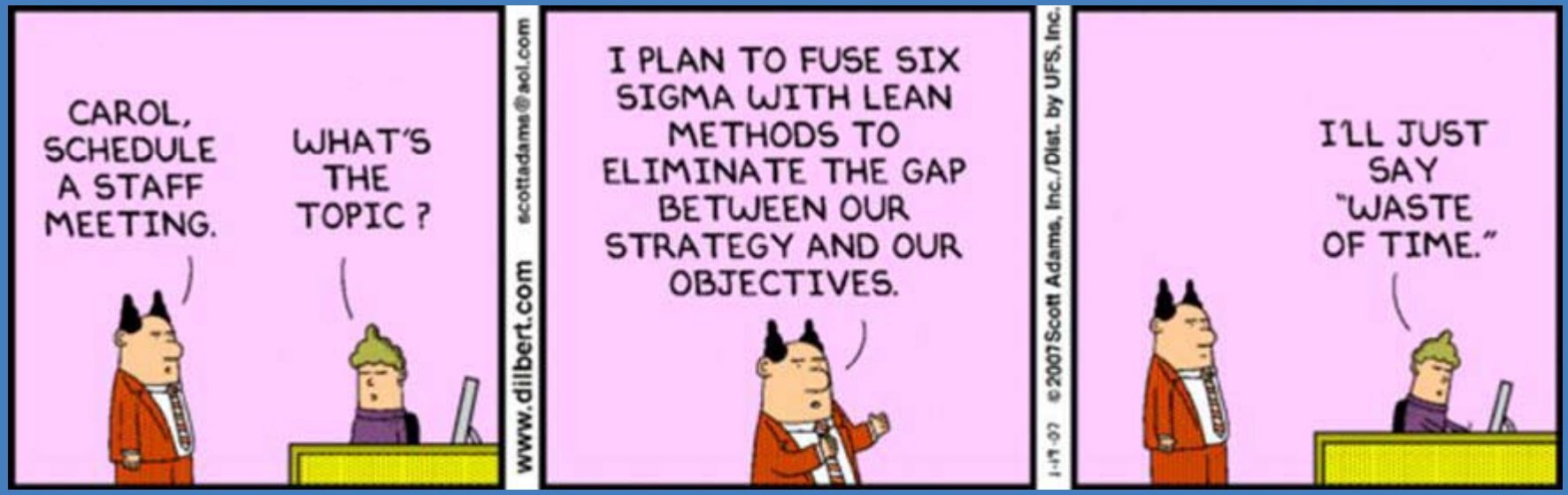
Failure Modes and Effects Analysis (FMEA) for Radiation Medicine

R. Alfredo C. Siochi, PhD

Outline

- An Introduction to FMEA
- FMEA for radiotherapy workflow improvement
- Reverse FMEA for implementation of new technology
- FMEA after an accident – what can we learn from the NY Times?

MOC PQI – hope you stay awake!



www.dilbert.com

FMEA

- Failure Modes and Effects Analysis
- FM: What could go wrong? And how?
- E: What are the consequences?
- Analyze: Probability of Occurrence, Detectability, Severity

Types of FMEA

- Process FMEA
- Design FMEA
- System FMEA
- Product FMEA
- Basic Methodology is the same

Failure Modes

- What could go wrong?
- And how!
- Requires Brainstorming Team
  - familiar with the subject of their analysis (process, system, product)
  - Identify everything at this stage
  - (even seemingly trivial or improbable items)


417
MURPHY'S LAW
MURPHY'S LAW

Murphy's Law

If anything can go wrong, it will!

Effects

- For each failure mode, identify the effect(s)
- These can be effects that happen to
  - Patients
  - Staff
  - Other processes or workflows (e.g. the effect may not be a problem in and of itself but if it is allowed to propagate it could become significant)

Analyze

- What is the Severity of the effect?
  - No harm = 1, Lethal = 10
- What is the probability of Occurrence?
  - not likely = 1, certainty = 10
- What is the likelihood that the failure mode will escape Detection before it causes an effect?
  - Always detected = 1, undetectable = 10

Risk Priority Number

- RPN = Severity x Occurrence x Detection
- Ranges from 1 to 1000
- Higher numbers have greater priority
- Multiple failure modes exist in a system, which one is the most critical to address?
- Risk management should consider regulatory issues

Proposed TG100 Rating Scales

Rank	Occurrence (O)		Severity(S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	1/10,000	No effect		0.01
2		2/10,000	Inconvenience	Inconvenience	0.2
3	Relatively few failures	5/10,000			0.5
4		1/1,000	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2%	Limited toxicity or underdose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5%			5.0
7		<1%	Potentially serious toxicity or underdose		10
8	Repeated failures	<2%			15
9		<5%	Possible very serious toxicity	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5%	Catastrophic		>20

IRACS1] A high value for detectability actually means that it is less likely to be detected. This can be confusing for a novice.

Risk Management

- Reduce the RPN
- Re-design the product or Improve Processes in order to:
  - Remove the failure mode, or
  - Increase the detectability of the failure mode, or
  - Reduce the severity by changing the effect

Risk Management by Signage?

www.classicalvalues.com/archives/2009_10.html

A more serious example…

- Failure Mode: HDR Door Interlock Fails
  Effect: Unintended radiation exposure
- Severity: ? Depends on source
- Occurrence: ? Depends on interlock reliability
- Detection: ? Depends on system design
- Risk Management: Daily QA of door interlock and all emergency switches

Multiple Fault Tolerance

- Many backup systems in case one fails
- redundant in purpose
- May be redundant in design
- Examples
  - Signage
  - Emergency stop button
  - Emergency Power off button

Part II: FMEA for RT Workflow Improvement

- A well run clinic has well established, understood, and implemented processes
- Processes affect the total environment of the clinic: business, technical, clinical aspects
- FOCUS here is on the safety of the clinical process

Process FMEA

- Process Map or Process tree
- Include Control Points
- Analyze sub processes
- Create Fault trees
- Mitigate Hazards

Process Hazard Mitigation

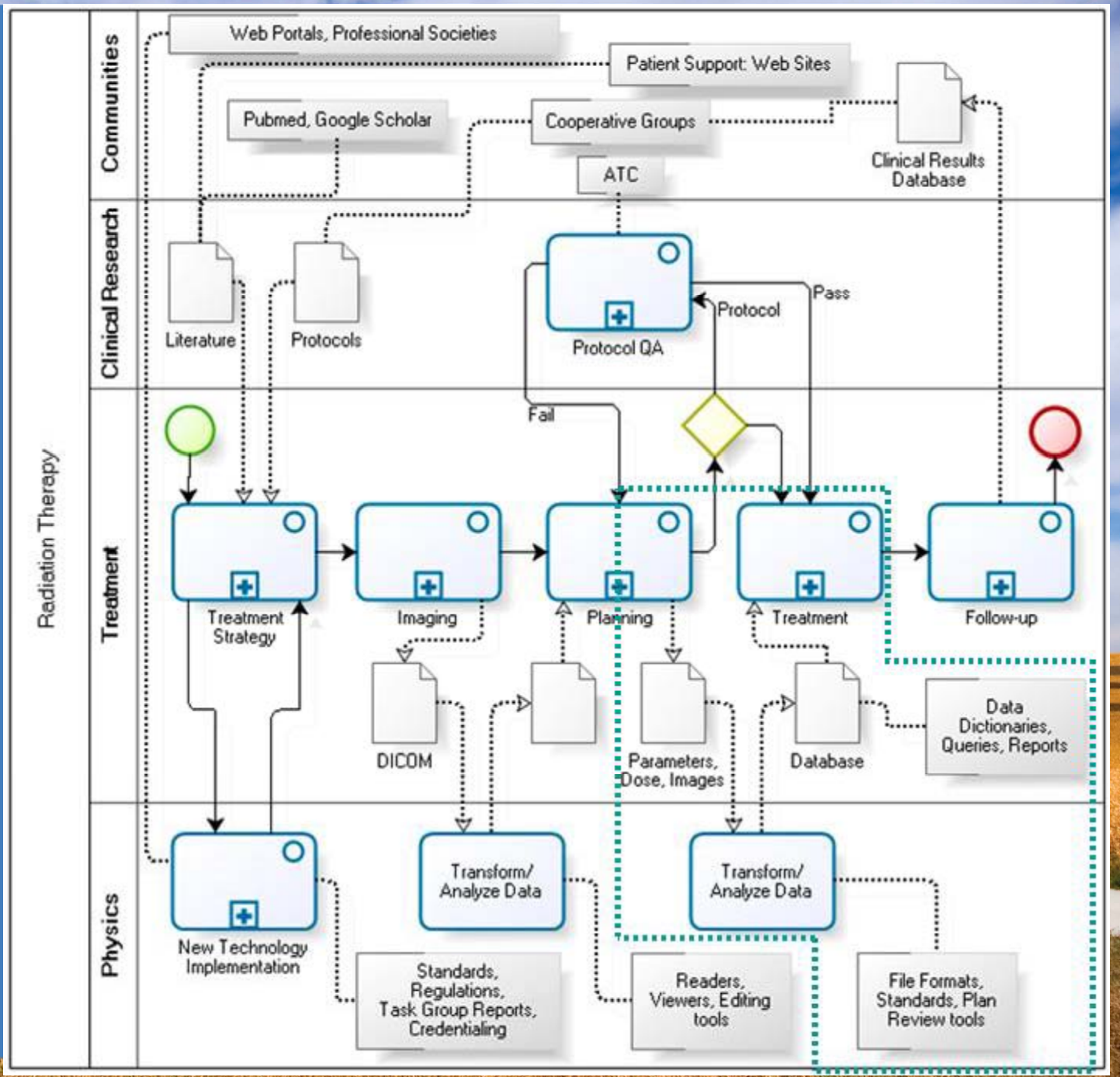
http://safety.lovetoknow.com/Funny_Safety_Pictures~1

Process Mapping

- Flowcharts to follow a product from beginning ("raw materials") to end (product in the hands of consumer)
- Radiotherapy: Very Data Driven
- One method: follow the data to create the process map

Data Flow in RO

**Fig. 11.1 from Siochi, Information resources for radiation oncology, Ch. 11 of a forthcoming book: Informatics in Radiation Oncology, G. Starkschall, B. Curran, editors.*



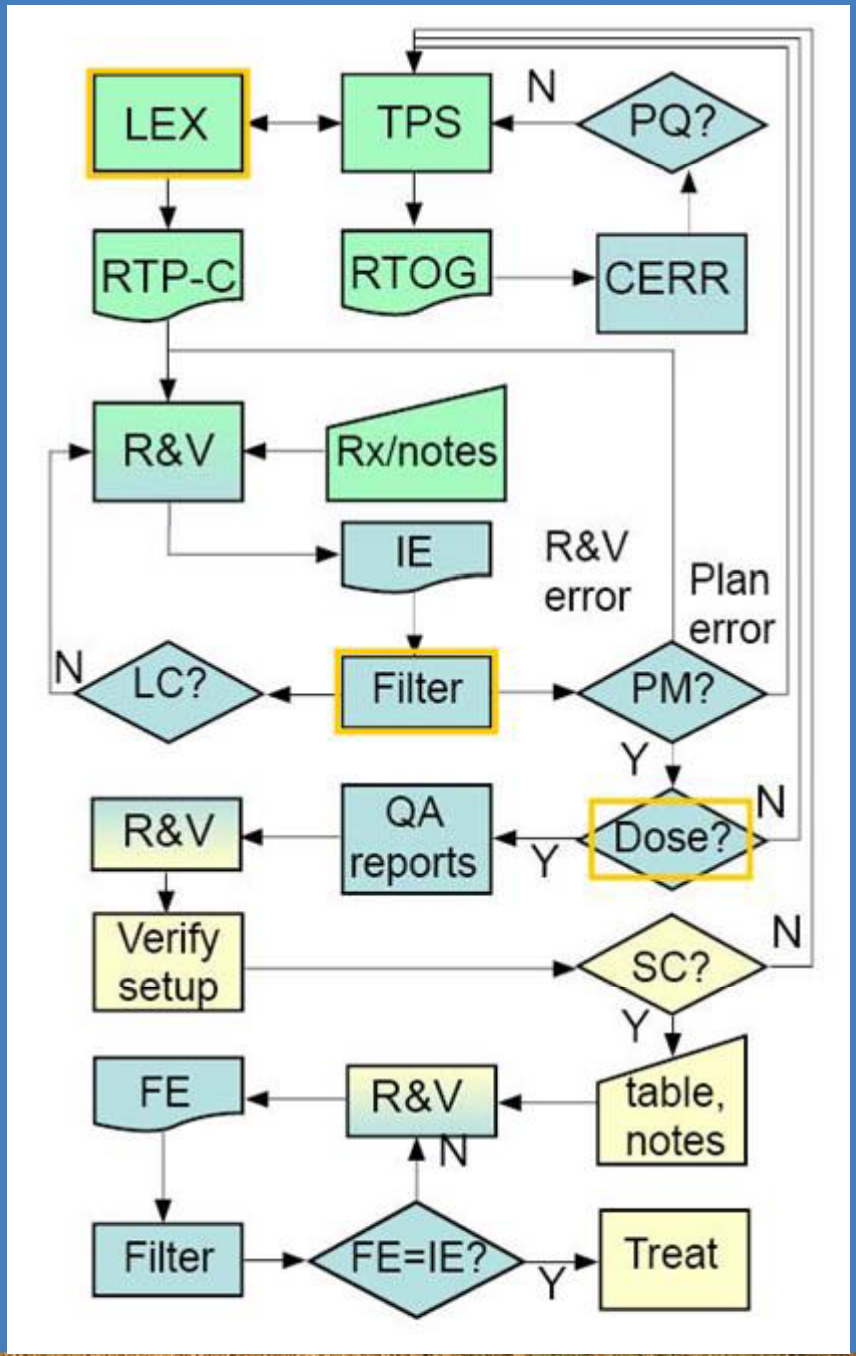
Clinical Work Flow, paperless checks

Physicists

Dosimetrists/Physicians

Therapists

In-House Software



Adapted from Fig 5. Siochi, et al. Radiation therapy plan checks in a paperless clinic, J. App. Clin. Med. Phys., 10(1):43-62.

Understand Your Process

- You can't determine failure modes if your process is a black box
- Break down process into single actions
- Identify interfaces between actions
- Identify resources for each action
- Determine failure modes
- Mitigate Hazards

Failure Modes: Device vs Process

- Example: Radiosurgery Ring Placement
  - Device: Plastic Support Snaps
  - Process: Pin was over-tightened
- Device Failure Mode:
  - Intrinsic Device Design Problem
  - May be mitigated by processes
- Process Failure Mode:
  - Sequence not followed
  - Step Forgotten
  - Step done incorrectly
  - Sequence produces undesirable side effects

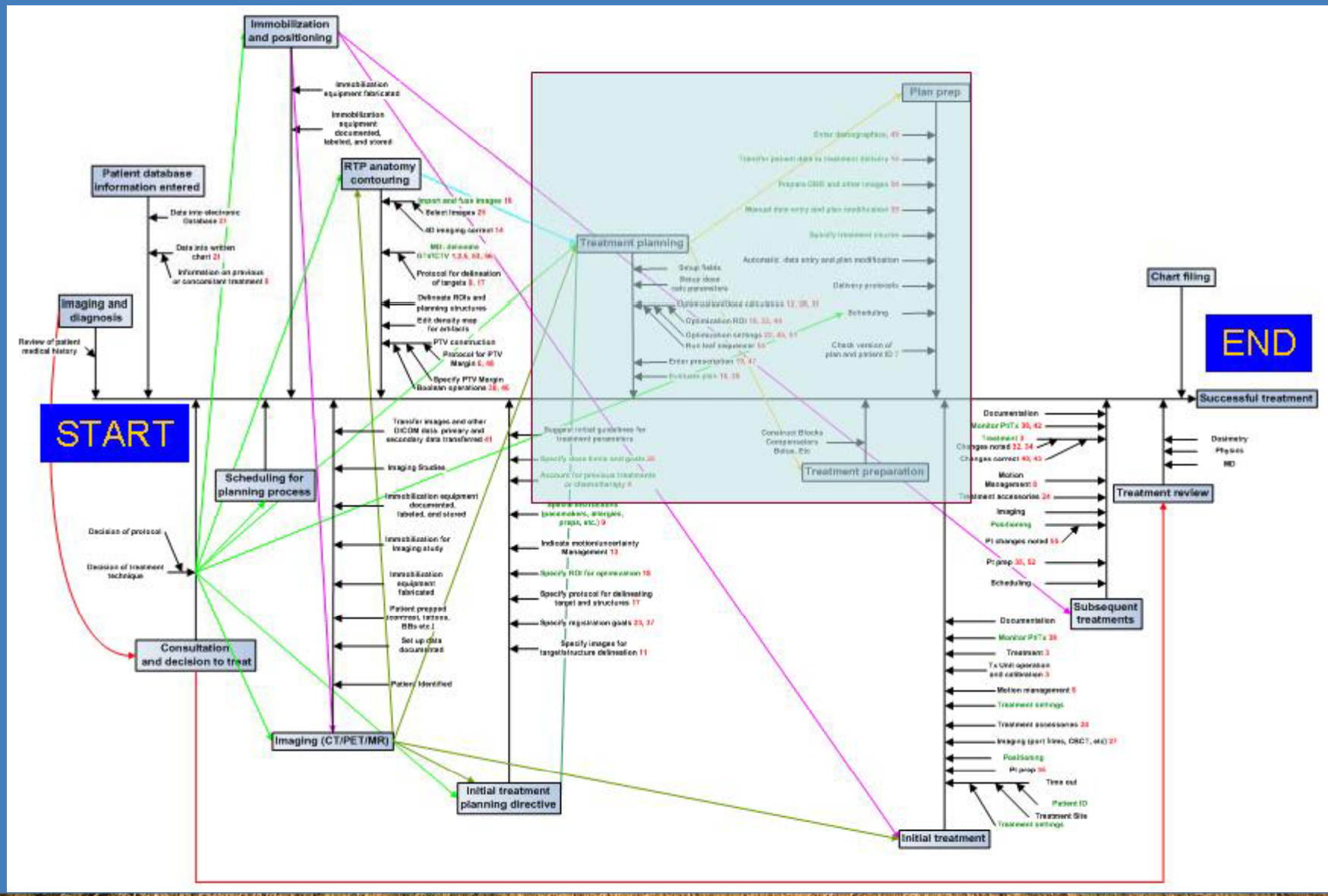
Process Failure Mode

http://www.darwinawards.com/

Example: IMRT Plan Preparation Process

- Example Process for FMEA
- Sub process of the IMRT treatment process
- Each clinic has to evaluate their own process

TG 100 IMRT Process Tree- Draft

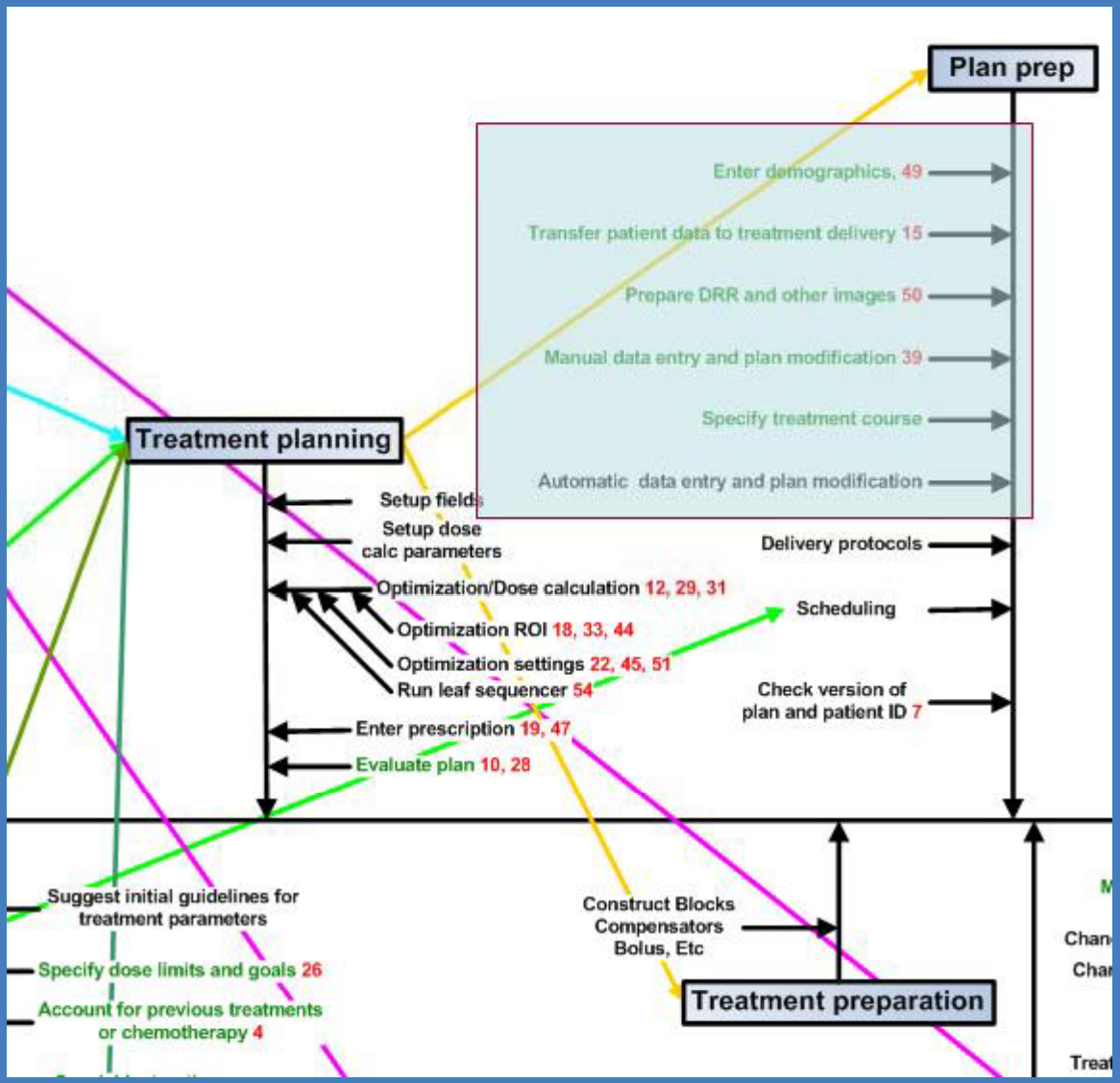


Where do I begin?

http://safety.lovetoknow.com/Funny_Safety_Pictures~14

TAKE IT ONE STEP AT A TIME- WORK WITH SUBPROCESSES

Sub Process – plan preparation



What are the failure modes for each of the steps in each subprocess?

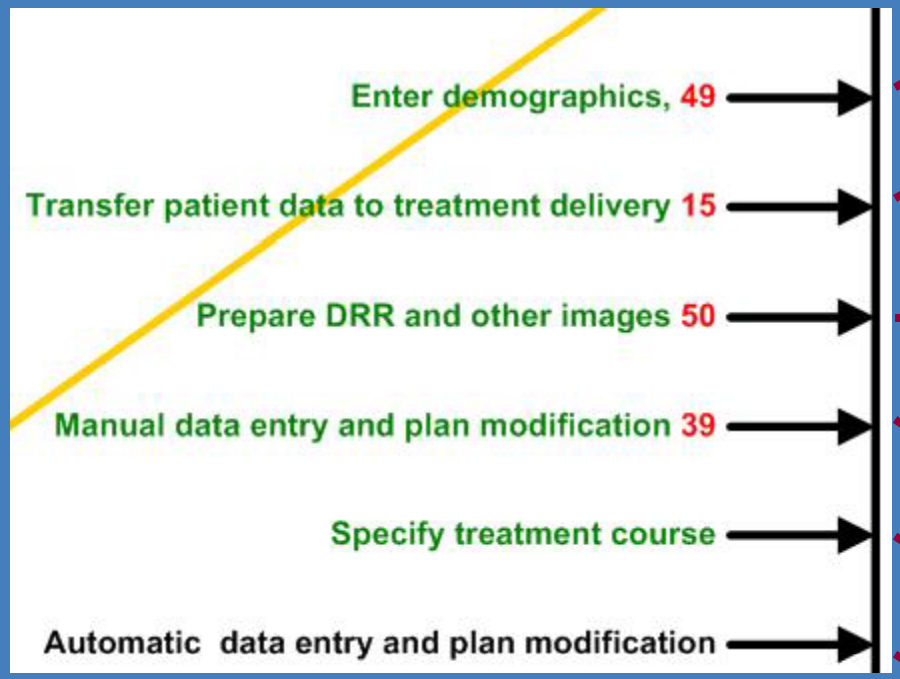
What are their effects?

How do they propagate?

How do they interact?

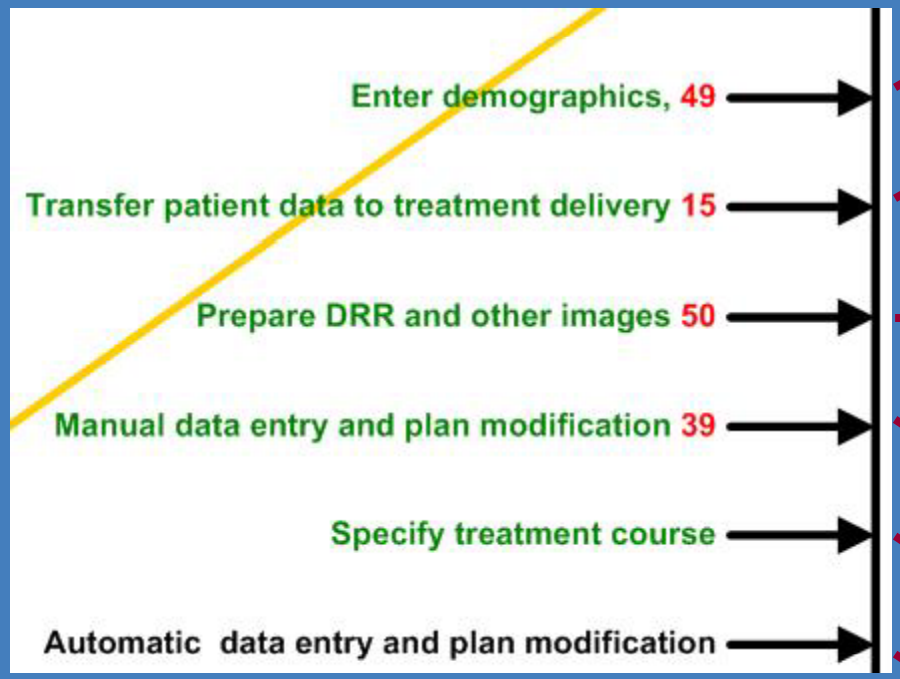
How do we mitigate them?

plan preparation failure modes



- Wrong patient
- Wrong coordinate system
- Wrong Isocenter for DRR , e.g. calc point was chosen
- Typographical errors
- Course change without re-plan
- Missing data

plan preparation effects



Patient receives wrong treatment

Dose distribution changes, Dose to wrong site

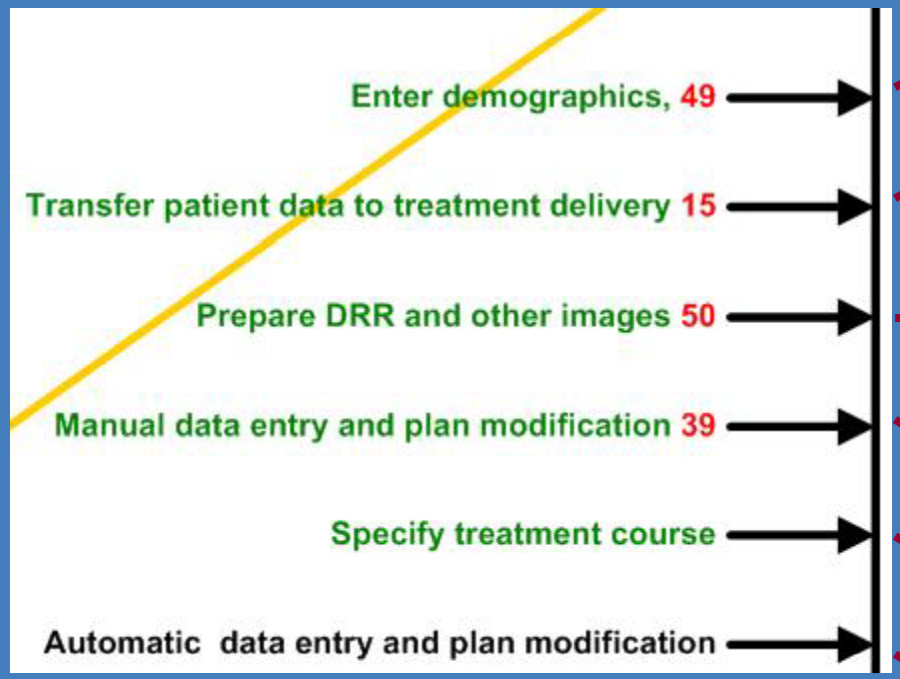
Dose to wrong site

Depends on which element was a typo

Radiobiological Effects

Depends on what is missing

plan preparation - analysis



S = 10, O = 1, D = 10?

Systematic error, O = 10, S = 10, D=10?

S = 10, O=7 (many cases, iso= calc), D = 7 (verification day – images look strange?)

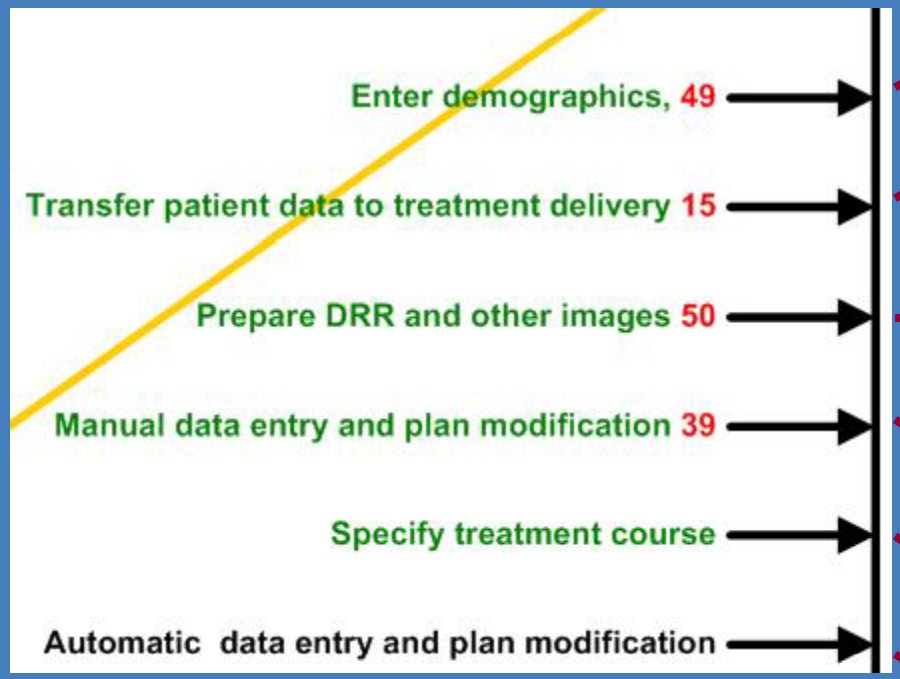
Depends on which element was a typo

S = 6?, O =5 (protocols are well established), D = 10

Depends on what is missing

Assessing Detectability means you know the whole process. Are there other sub processes that will catch the error before it affects the patient?

plan preparation - RPN



100

1000

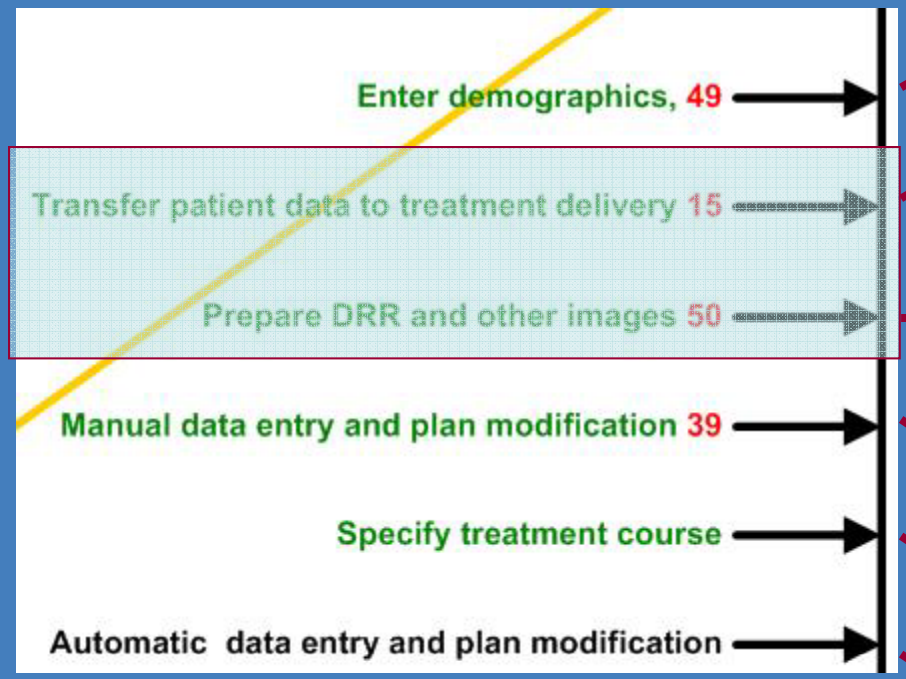
490

Depends on which element was a typo, could be 1000

300

Depends on what is missing, could be 1000

plan preparation – Risk Management Phase 1



100

Implement plan check process

490

Implement plan check process

300

Implement plan check process

Reduce the value of D for the highest RPN processes, i.e.
Make the failure mode more detectable

plan preparation – Risk Management Phase 2, 3, etc.

D= 1, S=10, O=10.
New RPN = 100.

Modify transfer software configuration, O = 1
RPN = 10

Implement IGRT check process

Mitigate the next highest RPN values. Adjust the RPN values of mitigated items. Consider other mitigation steps to reduce D or O. S will not change for the given effect.

Overwhelmed?

http://safety.lovetoknow.com/Funny_Safety_Pictures~6

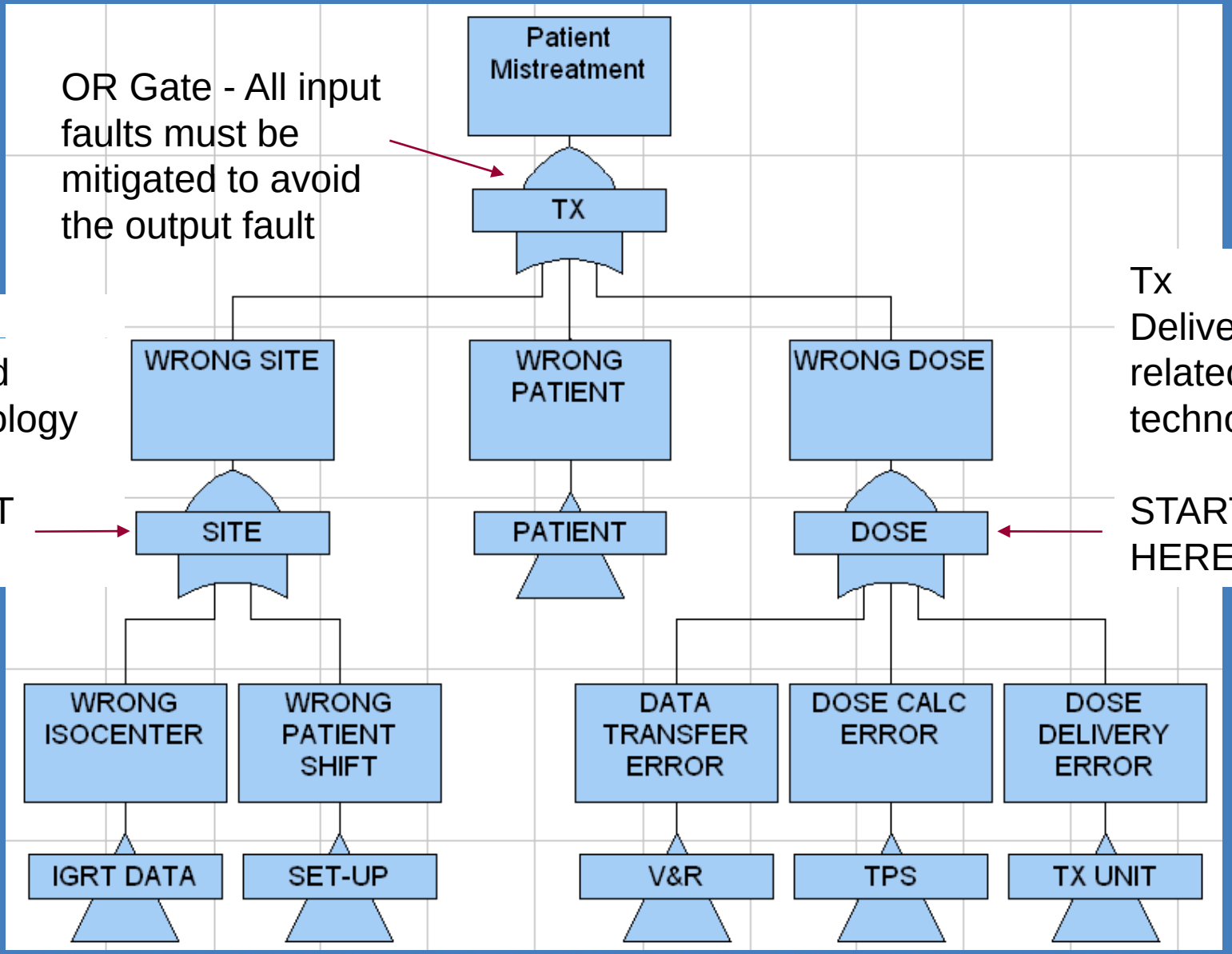
Part III – Reverse FMEA for implementation of new technology

- New– unfamiliar – hard to know failure modes
- Start with "Effects"
- Prioritize by effects – no need for RPN
- Then use fault tree analysis.
  - requires learning more about failure modes, but the learning is now guided.
- Examine fault tree to build in mitigations
  - Process design
  - Device Modification

Generic RT Effects

- Wrong Patient
- Wrong Site
- Wrong Dose Distribution
- Which of these top level elements does your new technology affect directly?
- Develop that element in greater detail

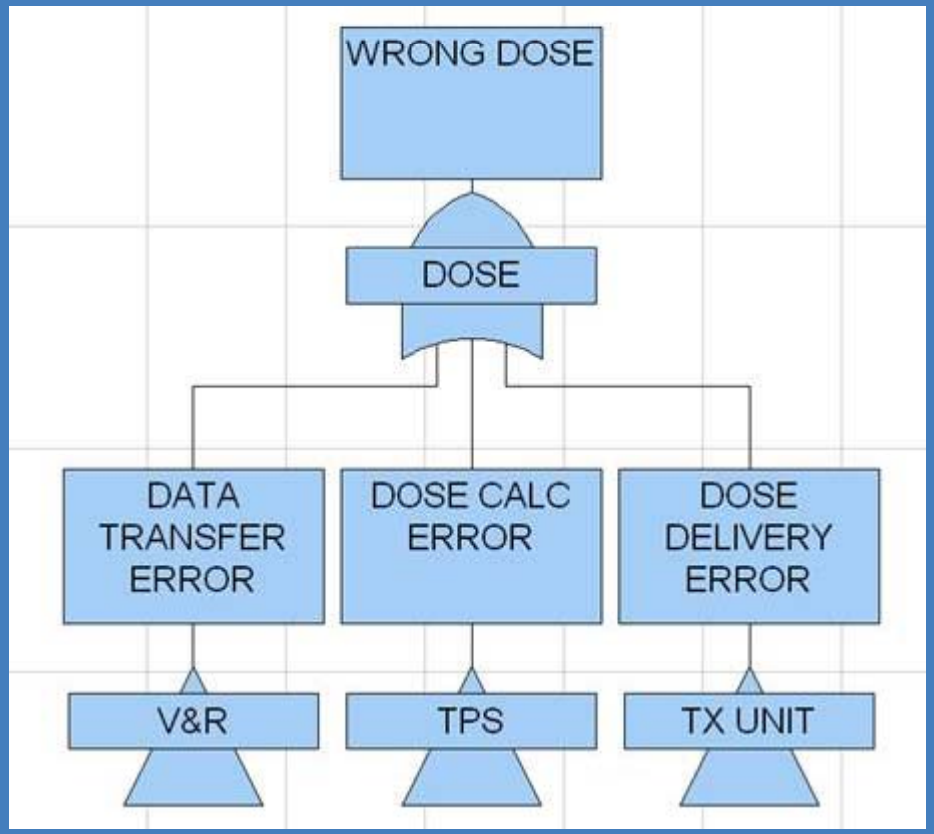
Fault Tree


Patient Mistreatment
OR Gate - All input faults must be mitigated to avoid the output fault
TX
IGRT related technology
Tx Delivery related technology
WRONG SITE
WRONG PATIENT
WRONG DOSE
START HERE
SITE
PATIENT
DOSE
START HERE
WRONG ISOCENTER
WRONG PATIENT SHIFT
DATA TRANSFER ERROR
DOSE CALC ERROR
DOSE DELIVERY ERROR
IGRT DATA
SET-UP
V&R
TPS
TX UNIT

Learn about your device

Ask yourself questions about how your device works and how it will be integrated with other devices in your clinical workflow

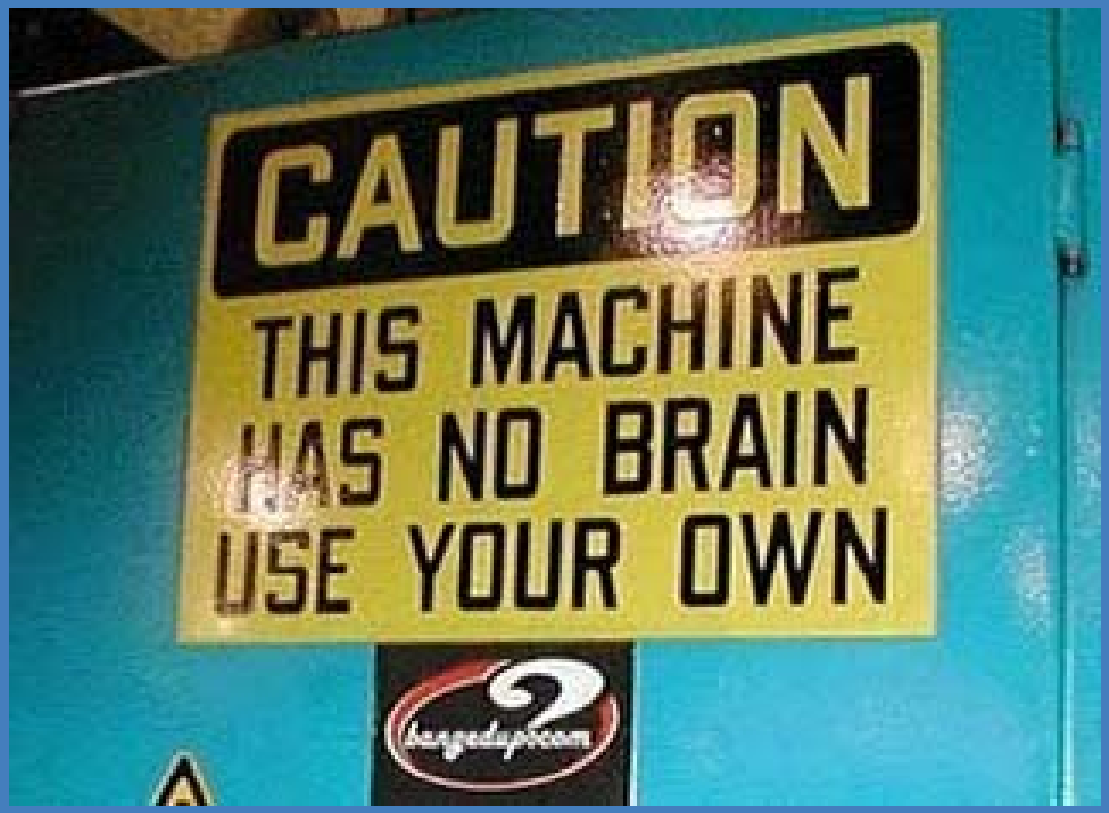
How does the new technology communicate treatment parameters to other subsystems?



How does the new technology deliver dose?

What are the special considerations for modeling the device or treatment technique in the planning system ?

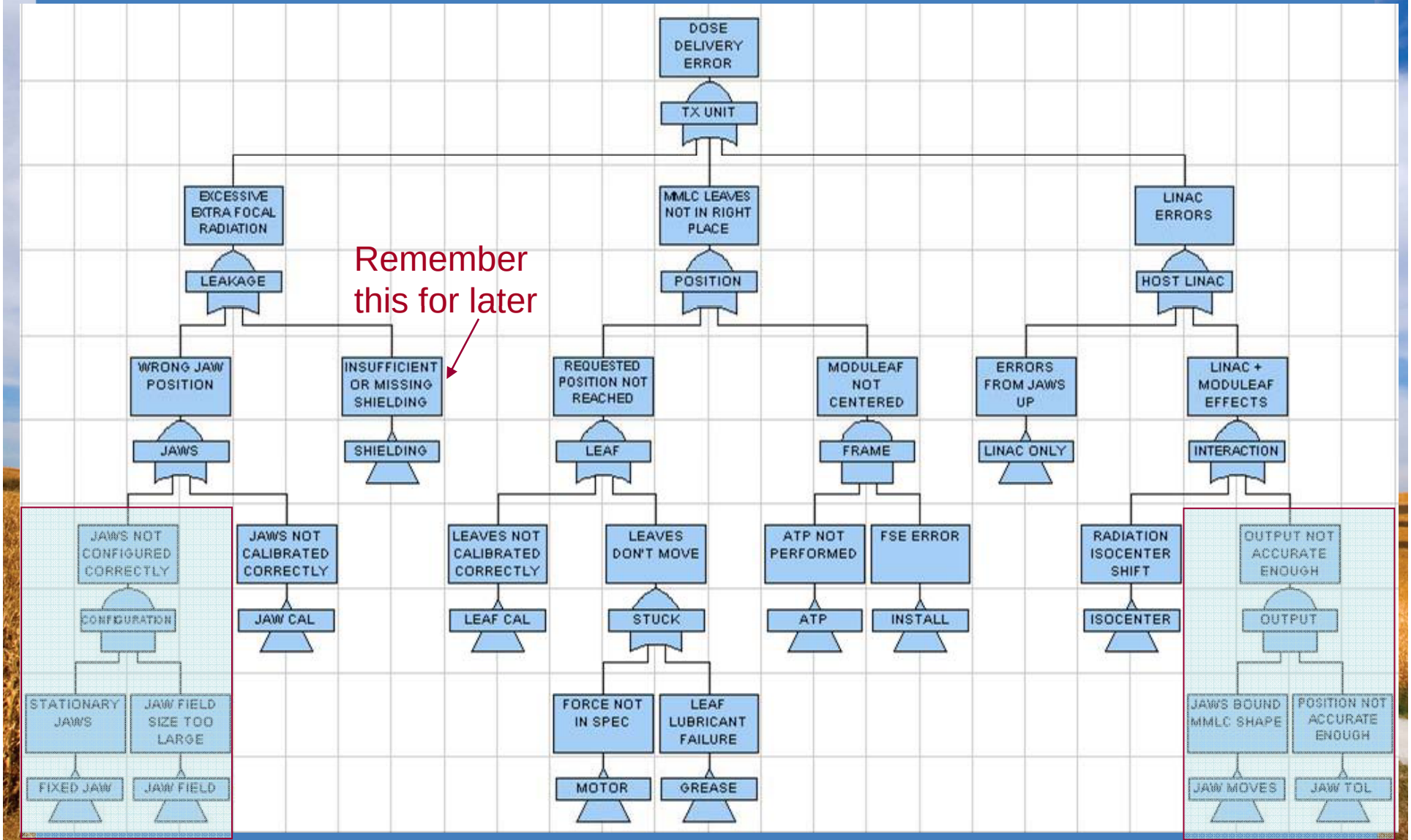
Learn about your device



Example: Moduleaf - Hardware

- Add on mini-MLC
- 40 leaf pairs
- Leaf width = 2.5 mm
- Leaves move from – 6 cm to + 6 cm
- Max field size is 12 x 10
- Leaf position tolerance = 0.5 mm
- Closed leaves parked 5.5 cm away from central axis
- Rounded leaf tips
- Slight tilt from divergence on leaf side

Moduleaf Dose Delivery Error



USING THE FAULT TREE

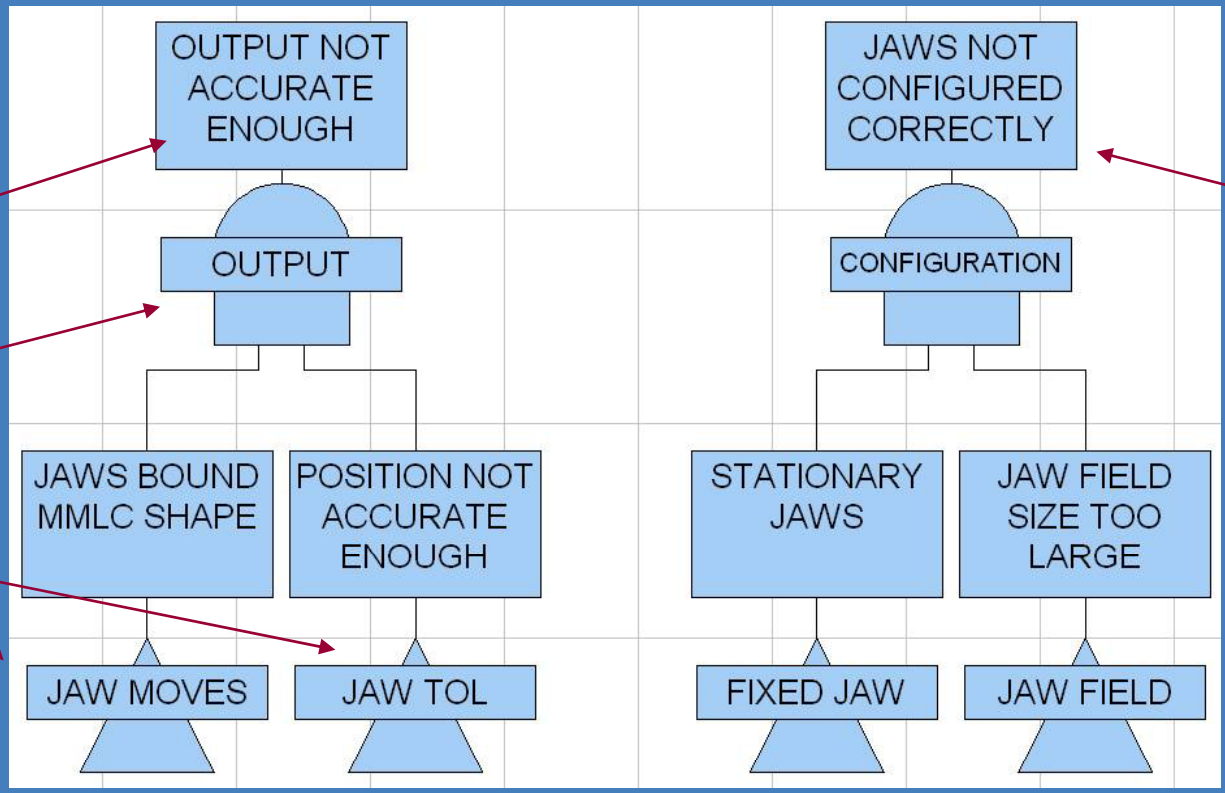
- Device configuration decision: given options, which one presents the least risk?
- Is the fault true for the device?
- Test procedures: should be general enough to test all possibilities for the error
- Clinical Workflow Design: write procedures that reduce occurrence of error or increase detection of error

DECISIONS? SLOW DOWN

Jaw Configuration Decision

ELIMINATE THIS

AND GATE: Mitigate either input



KEEP THIS AND ANALYZE

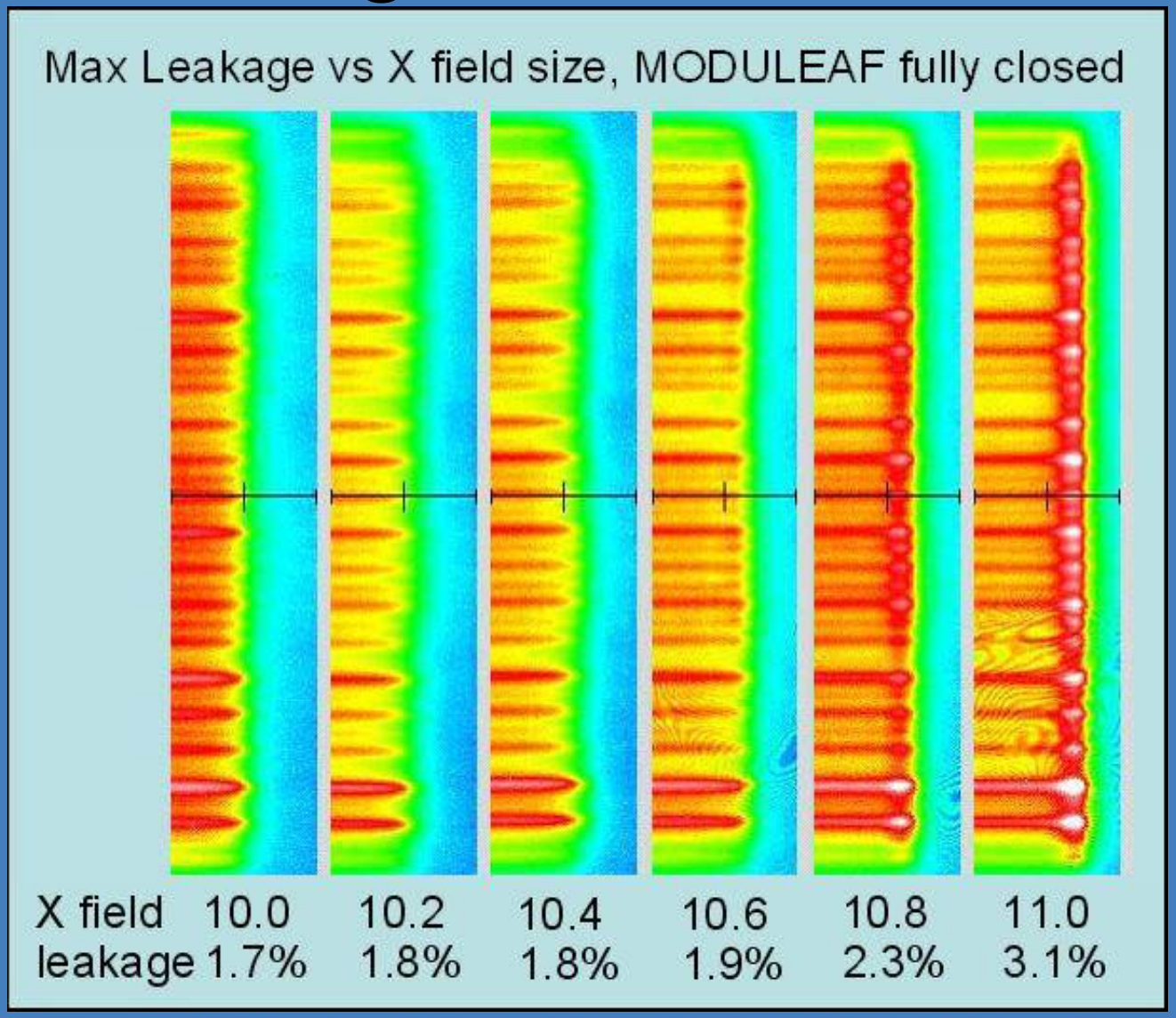
WHAT SIZE DO WE USE?

We decided to keep the Jaws fixed since we have no control over the jaw tolerance of 2 mm. For small fields, a 10% or greater error can occur due to positioning inaccuracy. The errors from using a fixed jaw can be reduced to a much lower value (dose uncertainty due to leakage modeling in TPS).

MODULEAF field size

- Decided on 10.4 x 10.4
- With jaw tolerance this means jaws range in position from 5 to 5.4
- Closed leaves at 5.5 cm are blocked
- Jaws don’t invade mMLC fields up to 10x10
- Output factor change minimal

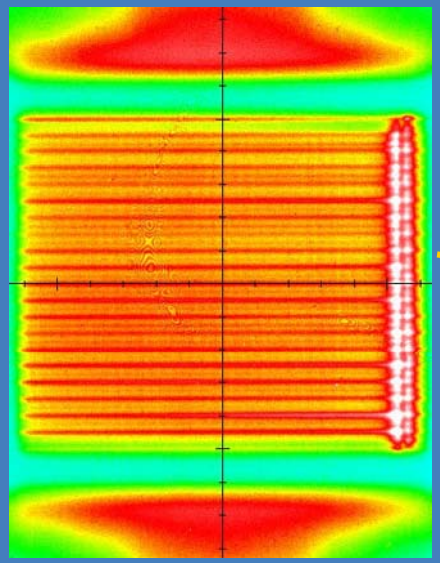
Leakage vs X field size



Leakage measurement method?

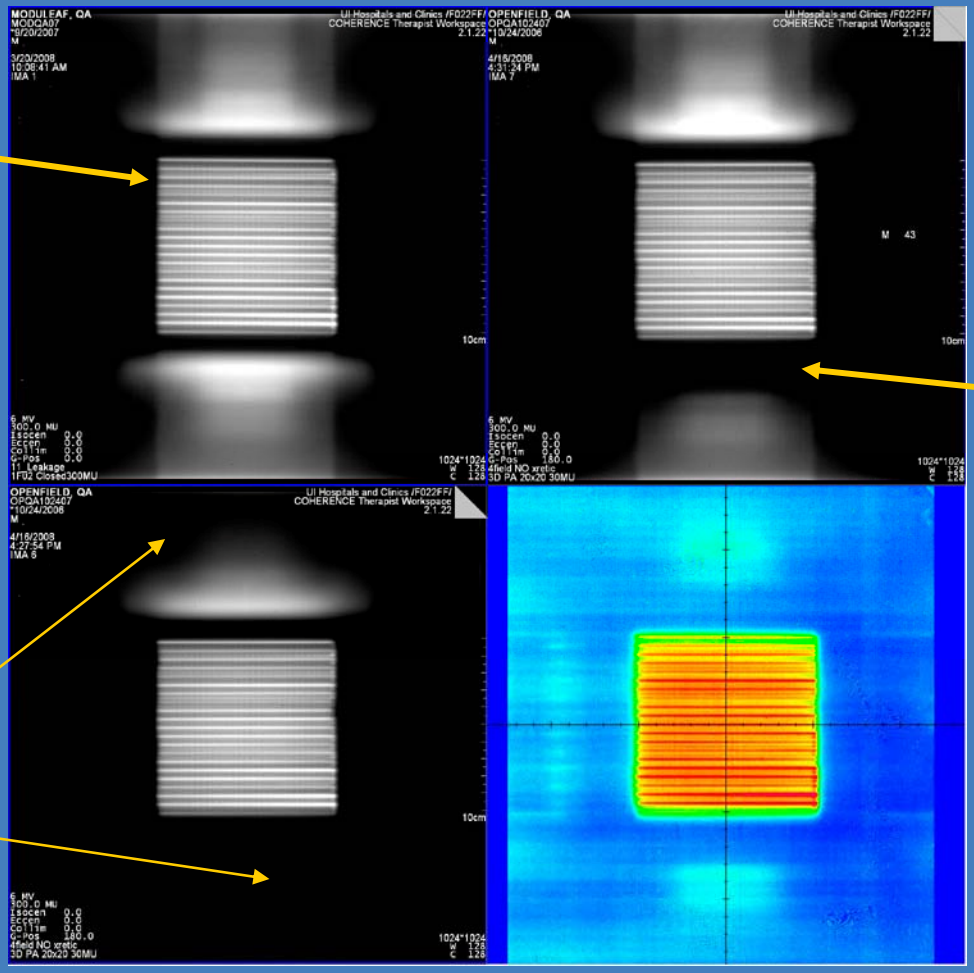
- Don’t assume anything
  - “Gafchromic is expensive, maybe I can just test the 10x12 area”
- Go back to the fault tree
- Remember the item “missing shielding”?
- That could be anywhere
- Test a full field, not just the MMLC field

Missing Shielding



Manufacturer Configuration 10.4 x 12.4

Reduced field size 10.4x10.4



Lead added Y1 side

Lead added Y1 side & Linac MLC closed leaves behind Jaws

Lead both sides & Linac MLC closed leaves behind Jaws

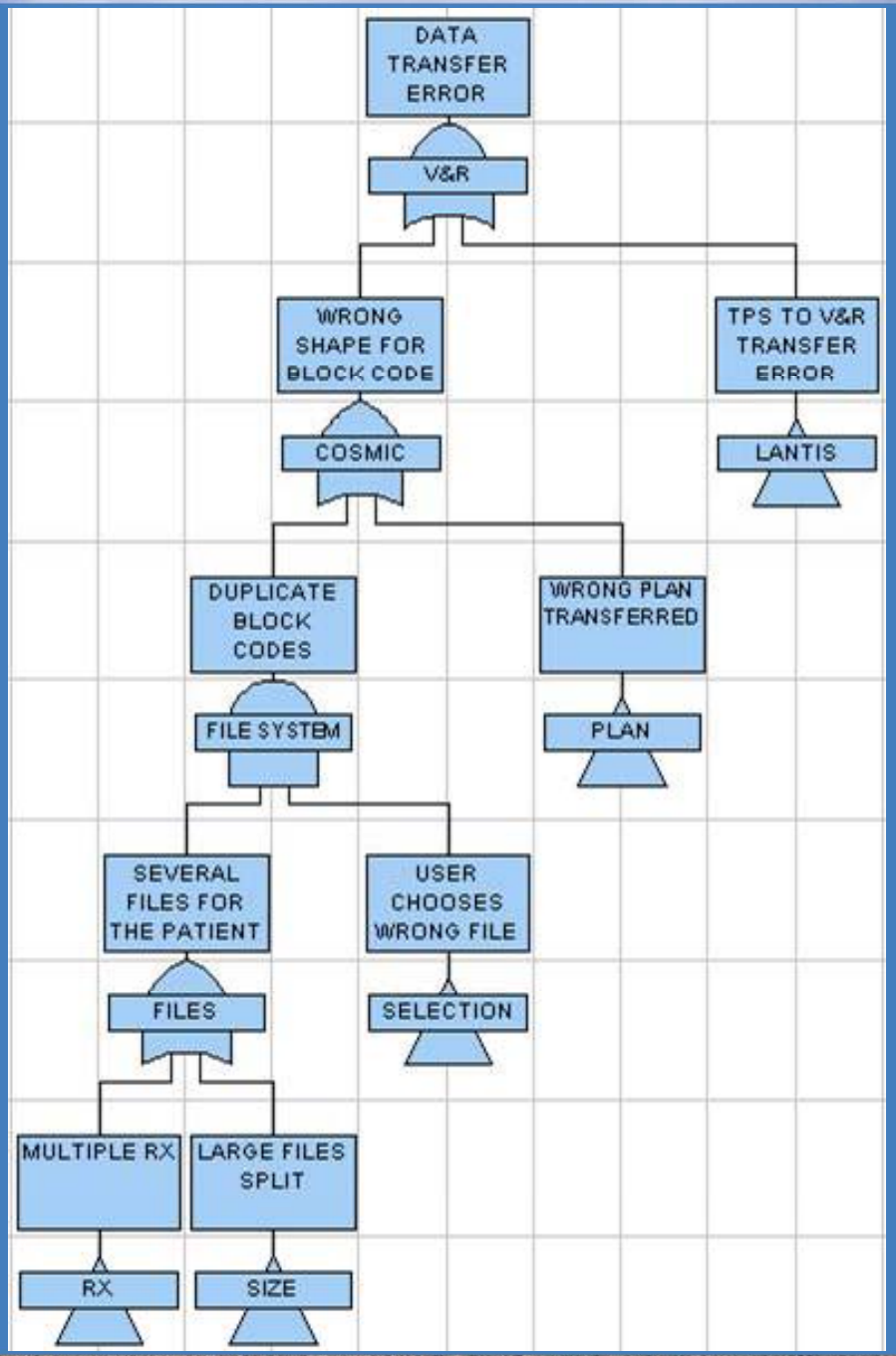
Never Assume Anything

V&R – Data Transfer Error

- Separate fault tree
- Several items were mitigated related to data integrity
- Most significant change we adopted was a process

Data Transfer Error

- LANTIS sends block code to LINAC on DMIP
- Cosmic listens to DMIP
- Cosmic sets leaf positions from the record with the corresponding block code
- BLOCK CODE is crucial



Field shape communication

- Problem: Lantis block code does not have to be unique
- Lantis field IDs are unique
- Moduleaf block codes in separate files for same patient can be the same
- Potential error: wrong Moduleaf shape is chosen
- Mitigation:
  - block code to Lantis field id mapping
  - One file per patient in Cosmic at a time

Documenting the FMEA

article | discussion | edit | history | move | watch

Moduleaf Failure Modes and Effects Analysis

The typical FMEA involves brainstorming to create a list of Failure Modes. The associated Effects of these failures are assessed in terms of their probability and severity. The need to address a particular failure mode is then determined by a cutoff score for the product of probability and severity.

The design of clinical processes, QA programs and supporting software for the Moduleaf were implicitly developed through the use of a **modified Failure Modes and Effects Analysis (FMEA)**. The Effects are first determined and graded. Failure Modes that cause these effects are then determined by brainstorming. This requires a knowledge of the basic clinical workflow required to treat a patient with the Moduleaf. It also requires familiarity with the Moduleaf control software. Changes to the basic workflows are then designed to avoid or minimize the effects of these failures. These changes in turn can create new failure modes, resulting in an iterative cycle of designing, brainstorming, testing the possible failure modes, and addressing those failure modes that are valid concerns.

Another reason for working in reverse, from the effects towards the failure modes, is that the device or process in question may not actually have a given failure mode, and testing needs to be done to determine if in fact a particular type of failure can occur. The flipside of this coin is that one should not assume that a failure mode does not exist just because the manufacturer said so in the manual (this should be part of the ATP). Additionally, there may be other failure modes that one may not think of if the focus of the brainstorming is only on the questionable properties of the device or process. By starting with the effects and listing failure modes associated with these effects rather than with the device or process (yet within the context of the device or process), one is more likely to generate a thorough list of properties that should be tested and, if proven to be a true failure mode, mitigated. This also allows us to organize our analysis process by ranking the effects in the order of importance (considering both the severity of the effect and regulatory compliance issues).

This page serves as a summary of the Failure Modes and the mitigations of their corresponding effects that were considered in the clinical implementation of the MODULEAF. Links are provided to procedures that address the failure modes. As items are added to the list, new procedures and/or links to existing procedures will be added to document that the item has been addressed.

Contents [hide]

UIHC Rad Onc Department WIKI:
Moduleaf Project, FMEA section:
The Effects are listed first, with the faults beneath them. Mitigations are described in each section for each fault, with links to the clinical procedures, design changes, and configuration decisions.

Documentation - II

Link to our field naming convention and block code mapping

Link to procedure that involves this convention

Patient receives wrong dose distribution [edit]

Cosmic RTPLink plan file corruption [edit]

Various changes were made to the plan file (changes within a record, deleting field_defs, mlc_defs). Cosmic picked up on every one of these problems due to the crc at the end of each record and a file consistency check for the number of expected fields for each rx_def. However, exchanging a whole file went undetected. Hence, step 6 of the pre-treatment QA requires verifying the correctness of the plan files in the cosmic database.

Wrong Plan Selected [edit]

Multiple files for the same patient should be avoided. In all cases, unique block codes should be used, even across plans and files for the same patient. A block code convention was adopted: Moduleaf Block Codes. See also Step 4 of the plan check.

Wrong Field Selected [edit]

This can occur if two fields have identical parameters except for the MODULEAF field shape, but the block codes for these fields are the same. Step 4 of the plan check requires a block code uniqueness check. Systems that generate block codes should use the field ID to block code mapping scheme to enforce unique block codes.

Wrong Moduleaf leaf positions [edit]

Wrong coordinate system [edit]

Transmission of field shapes with a definite orientation (asymmetrical both left and right and top to bottom) such as an arrow pointing to the bottom right should be done prior to delivery (Step 10 of pre-treatment QA). This ensures that the Cosmic operating system and configuration files that define the coordinate system are intact.

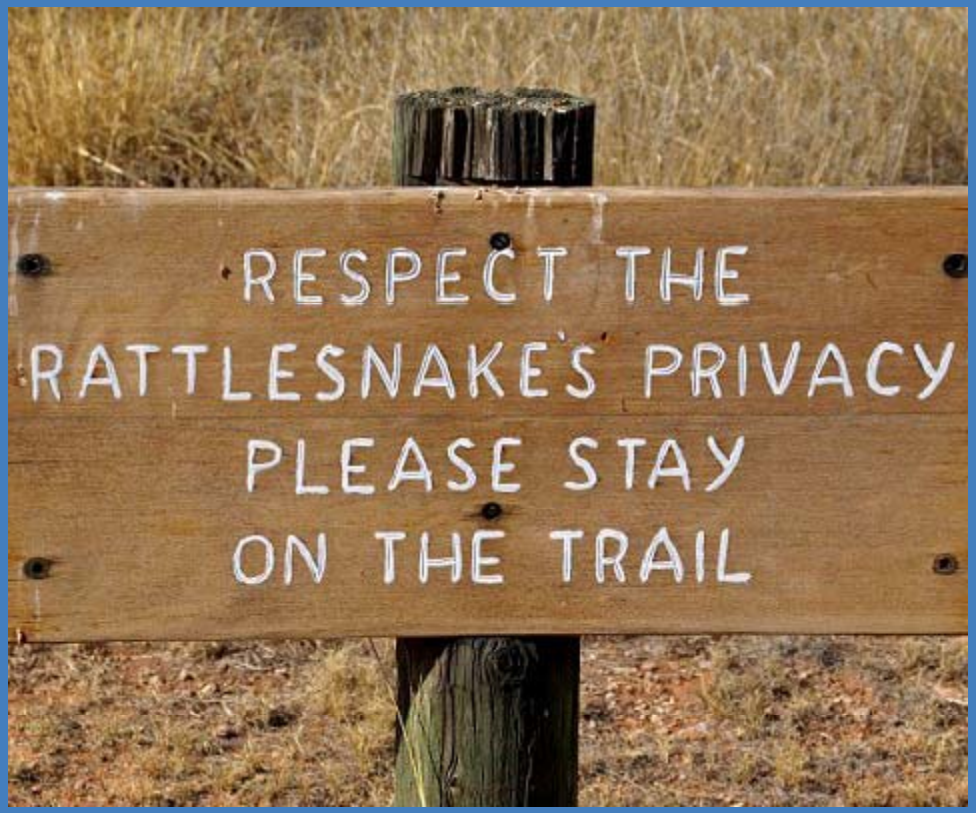
Leaves not properly calibrated [edit]

An MLC strip test (step 13 of pre-treatment QA) should be run prior to treatment and the EPID images or light field images should be analyzed to ensure no gross miscalibration, drift or accidental change has occured.

Attenuation through devices not accounted for [edit]

If the beam goes through an immobilization or positioning device that was not modeled within the planning system, the device will attenuate the beam and produce a different dose distribution. The use of light-projected footprint fields on the patient can help determine if the beam is being clipped. Alternatively, a fully open MODULEAF can be used as a footprint. See step 2 of Pinnacle Planning Considerations for all plans.

Follow your documented procedures!



http://safety.lovetoknow.com/Funny_Safety_Pictures~3

Block Code Mapping

Our convention for naming Lantis field IDs makes it possible to keep field IDs unique- caveats noted for number of beams, segments, Rx

Mapping a unique Lantis field ID to the Moduleaf block code makes the block codes unique

Field ID Structure

- 5 characters long
- has the form cnAxx
  - c = course number
    - omitted if c = 1
    - set to a letter for QA fields (Q for course 1, R for course 2, etc.)
  - n = prescription number
    - corresponds to chronological order of prescription within the course
    - imaging fields are assigned a value of zero (not counted)
    - QA fields have the same prescription number as the prescription that they are checking on
  - A = Beam letter
    - capitalized, from A to Z (maximum of 26 beams)
    - Lantis will treat lowercase and uppercase as the same when considering ID uniqueness
    - You can extend your number of beams (e.g. multiple sub-arcs) by using 0-9 and),!,@,#,$,%,^,&,*,(.
    - corresponds to an initial estimate of the order of delivery
  - xx = segment number
    - from 01 to 99 (leading zero is needed)
    - corresponds to an initial estimate of the optimal order of segment delivery

Patient Treatment Fields

- Field ID examples
  - Course 1, first boost, 7 beams, each with 12 segments
    - c=1, n = 2, beams A through G, segments 01 to 12
    - (1)2A01, (1)2A02,...,2A12, 2B01,..., 2G12
    - note that we omit the (1) of the course number to be consistent with current naming conventions.
  - Course 2, initial plan, 9 beams, each with 6 segments
    - c=2, n = 1, beams A through I, segments 01 to 06
    - 21A01, 21A02,...,21A06, 21B01,..., 21I06
  - (9Z99 is incompatible with block codes, see below. The highest field ID might be 8I25 since we typically don't have more than 25 segments for a given beam and more than 9 beams.)

- Note that each RX_DEF can then have 2574 unique IDs. For a given RX_DEF we will rarely have more than 100 fields. If we limit the number to 676, then we can **map these IDs to block codes**:
  - nAxx -> MMnyyy, where yyy is the alphabetical sort order of Axx
  - e.g. 1A01 to 1A09, 1B01 to 1B11 -> MM1001 to MM1009, MM1010 to MM1020
  - note that this limits our allowed field IDs
  - we can only have 8 different RX_DEFs for a given course.
  - the block codes may have to be recycled for later courses.
  - the mapping, more generically is cnAxx -> MMnyyy where
    1. c is the course number, not needed for the first course.

Mapping scheme

Segue to NY Times

- What if Moduleaf block codes were not sent?
- What if we did not check it?
- A 10x10 field opening with high MU!
  - Fractionated IMRT (350 – 500 MU)
  - SRS (2000 to 5000 MU)
- NY Times article: from descriptions, it is IMRT without MLC shapes

IV: FMEA after an accident

- Reported Effects are extremely severe
  - (OR they wouldn't get so much attention!)
- High Priority
- We should analyze the Failure Modes
- How does this relate to our practice?
  - Do we mitigate this FM?
  - Is the mitigation effective?

Pulitzer Prize Winner reports on radio-therapy accidents

Walt Bogdanich became the investigations editor for the Business and Finance desk of The New York Times in January 2001. He was named an assistant editor for the paper's newly expanded Investigative Desk in 2003.

Before joining The Times in 2001, he was an investigative producer for "60 Minutes" on CBS and for ABC News. Previously, he worked as an investigative reporter for The Wall Street Journal in New York and Washington. He also worked for The Cleveland Press and The Plain Dealer.

Born in Chicago on Oct. 10, 1950, Mr. Bogdanich graduated from the University of Wisconsin in 1975 with a degree in political science. He received a master's degree in journalism from Ohio State University in 1976.

In 2008, Mr. Bogdanich won the Pulitzer Prize for Investigative Reporting for the series "A Toxic Pipeline," which tracked how dangerous and poisonous pharmaceutical ingredients from China have flowed into the global market. Mr. Bogdanich also won the Pulitzer Prize in 2005 for National Reporting for his series "Death on the Tracks," which examined the safety record of the U.S. railroad industry, and in 1988 for Specialized Reporting, for his articles in The Wall Street Journal on substandard medical laboratories.

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By WALT BOGDANICH

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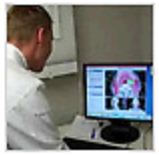


THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

http://topics.nytimes.com/top/reference/timestopics/people/b/walt_bogdanich/index.html

Example 1: Failure Modes Reported

"In another case, an unnamed medical facility told federal officials in 2008 that Philips Healthcare made treatment planning software with an obscure, automatic default setting, causing a patient with tonsil cancer to be mistakenly irradiated 31 times in the optic nerve."

Is this IGRT related? What was the failure mode? Wrong isocenter chosen?

Some clues as to what happened?

"Many of these mistakes could have been caught had ***basic checking protocols*** been followed, accident reports show. But there is also a growing realization among those who work with this new technology that some safety procedures are outdated."

Is your safety procedure effective?

Example 2: Effect and FM

"…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…A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days."

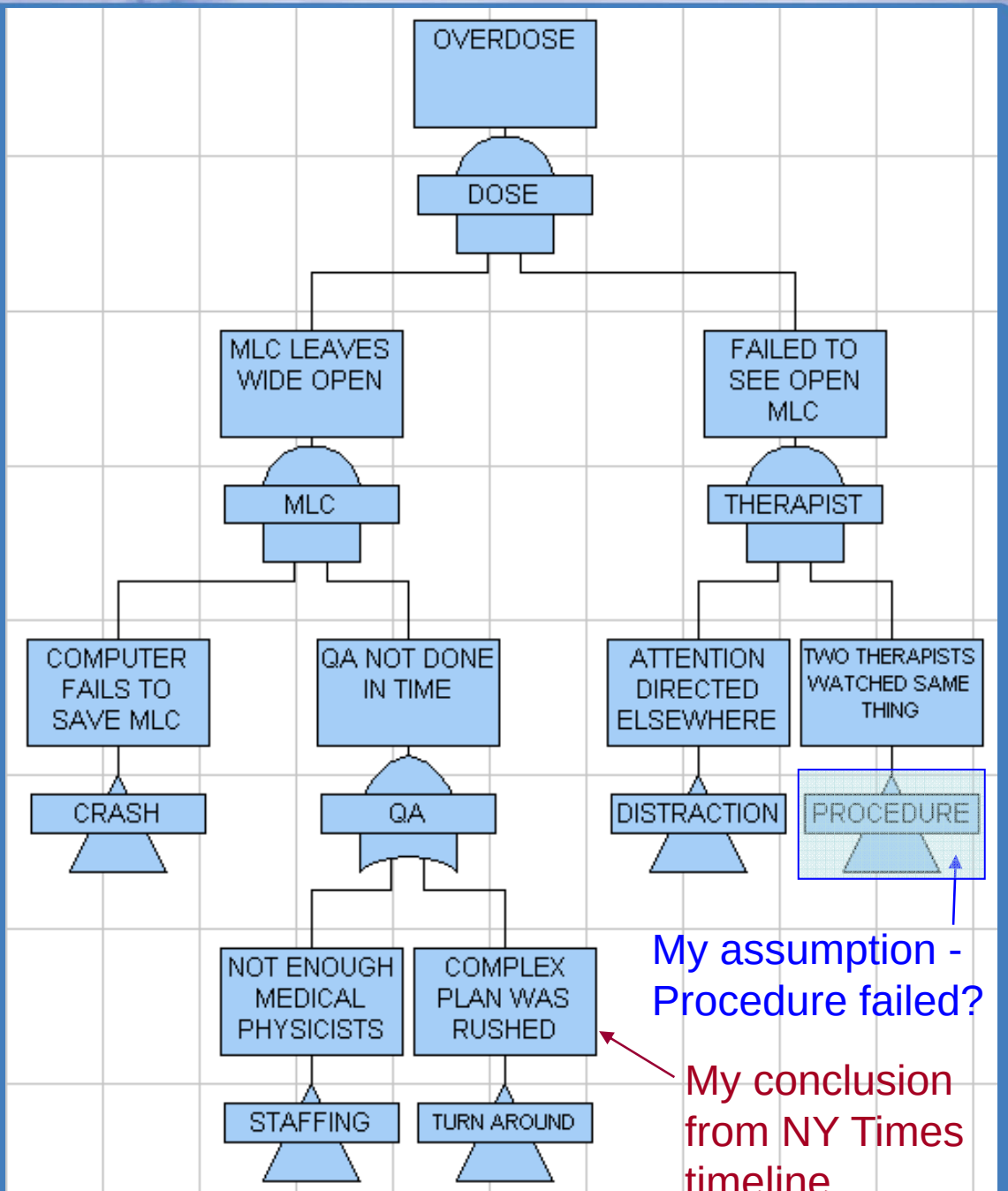
Example 2: more FM

"The Times found that on 133 occasions, devices used to shape or modulate radiation beams… were left out, wrongly positioned or otherwise misused."

"…I.M.R.T. The unit … was made by Varian …The first four had been delivered as prescribed. Now Dr. …wanted the plan reworked to give more protection to [his] teeth... Shortly after 11 a.m… the computer began seizing up, displaying an error message… system crashes 'are not uncommon with the Varian software, and these issues have been communicated to Varian on numerous occasions.' … at 12:24 p.m., Dr. approved the new plan …At 12:57 p.m. — six minutes after yet another computer crash — the first of several radioactive beams was turned on. …several hours after [he] received his third treatment under the modified plan…she ran a test … the multileaf collimator… was wide open. …[he] had received seven times his prescribed dose…When the computer kept crashing, the medical physicist did not realize that instructions for the collimator had not been saved …hospital waited so long to run the test … 'a staffing shortage for the medical physicists' …All the therapists had to do was watch the computer screen — it showed that the collimator was open … Instead, their eyes were fastened on [him], out of concern that he might vomit into the mask. "

NY Times Fault Tree

This could be made more generic and the tree could be expanded

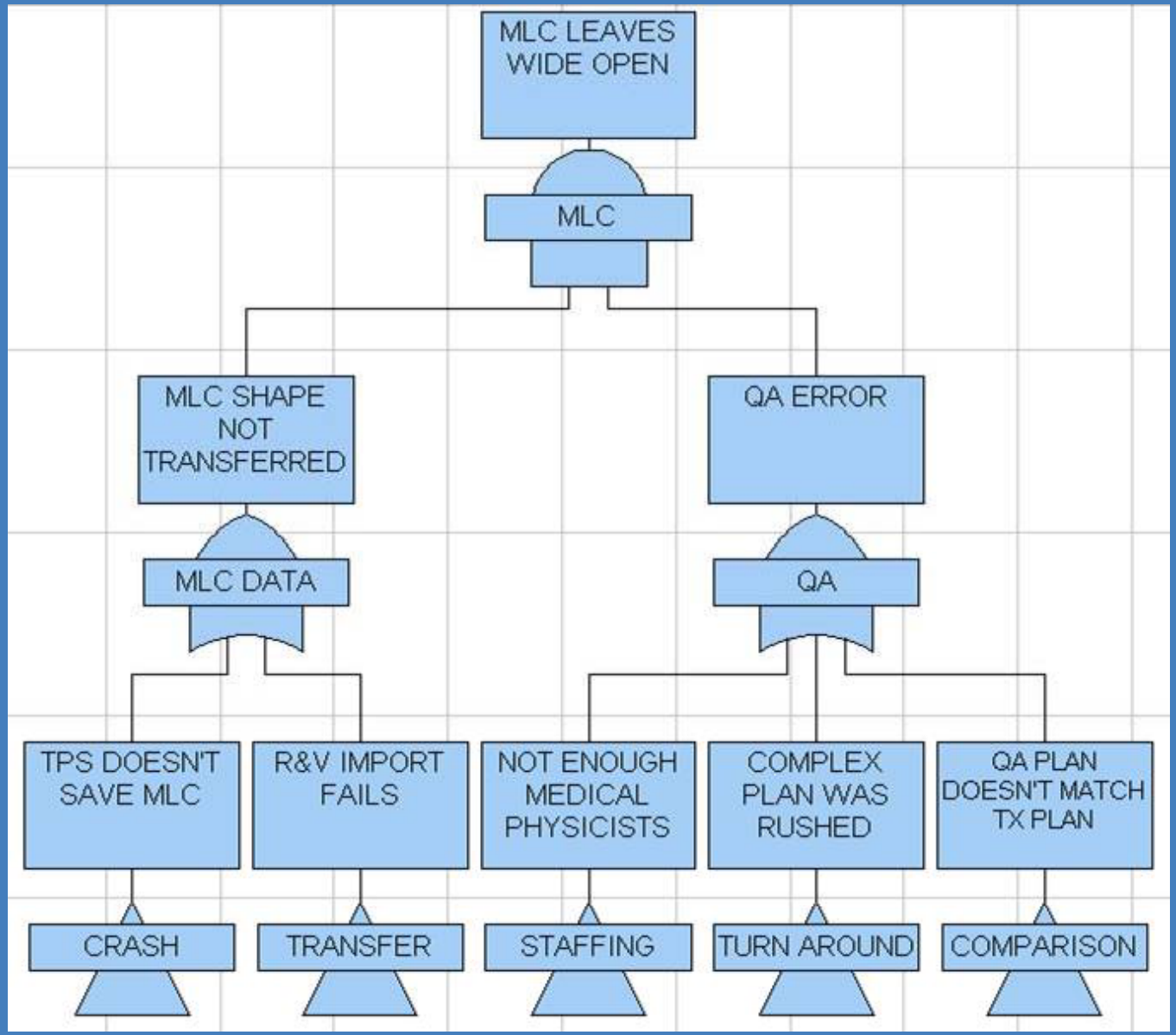


Too Late to do anything?

- By the time the article came out Varian had already issued a fix
- Varian Users found out before the article was published
- HOWEVER:
  - Non-Varian users can improve their procedures to prevent such errors
  - Varian users can learn from clinic errors and improve their procedures
  - Extend the fault tree – other ways for error to happen?

Is there a way non-Varian users can hear about these things when Varian users do?

Expanded Fault Tree



Files for QA have MLC, file for plan don't

FINAL WORDS

- FMEA, FAULT TREES organize thoughts
  - Most of us can think of grocery items
  - But if you don't write them down, you will most likely forget something
- FMEA takes time up front
  - Whole Clinic needs to invest time to map their processes and make sure there are control points for hazard mitigation
- REMAIN VIGILANT

The End

Source: KOTV

Thank you for not falling asleep!