TG 100 and the Report that Almost Never Happened

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Disclosure

I am the President of the Center for the Assessment of Radiological Sciences, a non-profit Patient Safety Organization listed with the Agency for Healthcare Research and Quality. The Center is dedicated to improving patient safety in radiotherapy and radiology.

Learning Objectives

1. To understand the motivation for TG 100.

2. To understand the hurdles faced by TG 100

3. To understand the basic concept of risk-based approach to quality-management development

What was the Genesis of TG 100?

- Originally TG 100 was to produce a prescriptive QA guidance for technologies new since TG 40.
- Original TG members in 2003:

Saiful Huq (Chair)
Dick Fraass
John Gibbons, Jr.
Geoff Ibbott
Paul Medin
Ben Mijnheer
Arno Mundt

Jatinder Palta
Frank Rath
Marc Sontag (Vice-Chair)
Bruce Thomadsen
Jeff Williamson
Ellen Yorke

TG 100's Original Charge

1. Review and critique the existing … to determine the specific areas that have been omitted….

2. Identify a structured, systematic QA program approach that balances patient safety and quality versus resources commonly available and strike a good balance between prescriptiveness and flexibility.

TG 100's Original Charge

3. …Develop the details of the QA program. Create a template that will fit each procedure and program for each individual modality

4. Finally, create a document that will supersede TG-40 and accomplish all the procedures identified in steps 1-3 above.

About TG-100 Report

- The report was going to be in three parts:
  - Brachytherapy
  - External Beam Therapy
  - Treatment Planning, later replaced by Special Procedures
- April 2004 the TG realized the difficulty of the task and decided to pick a treatment type (IMRT) and work through it starting with a process diagram.
- April 2005 the TG realized two problems.
  1. Everyone had a different process;
  2. The processes already included the different QA in each process.

About TG-100 Report

- July 2005, the TG proposes a change in approach toward a risk-analysis determination of an IMRT process, and

- Use as an example the process at one of the authors' facility.

- This acknowledged that the processes at most of the facilities were different and one set of recommendations did not fit all.

- It also recognized that a risk analysis could provide a QM program with rational reasons rather than opinion.

Personnel Change and Challenges

- August 2006, Ben Mijnheer starts a new position and left the TG as did Marc Sontag.

- Peter Dunscombe recommended as a replacement for Ben, having a good record in Patient Safety and chairing the Error Prevention WG. Sasa Mutic replaced Marc.

- The question arises whether our face-to-face meetings are worth the expense.

- Some on our parent committee (QAOISC) question the wisdom of the new approach.

- The TG adds a chapter on the risk-assessment process

Peter's Contributions Start

- Also in August, 2006, New member Peter writes:

1. What we do … is largely to assure our employer that a certain level of quality will be delivered by us. To do this we … have to manage for quality.

2. TG40 was largely, but not exclusively, a QC document. In spite of all the shortcomings of measuring things because you can and setting tolerances to levels that can be met, I believe the community still needs this. I don't see any reference to this traditional form of QC in the outline.

3. What we are really doing here, at least according to the outline, is to look for and assess modes of failure… I certainly believe we should be paying more attention to failure modes than we have in the past. We should also be moving towards evidence-based quality assurance and quality control. The way the outline is now, I'm not sure we are striking the right balance.

Peter's Contributions Start

- Also in August, 2006, New member Peter writes:

iv. 1. Finally, I'm not sure that I support [the] suggestion that we should leave each institution to do complete FMEA analyses. I think this is too much to ask particularly of small and under-resourced centres. … There will always be some customization required but, to serve the community, we should aim to do as much of the basic work as we can.

By 2008

- TG 100 added Frank Rath, an industrial and Systems Engineer and the person from whom I learned about FMEA.

- Paul Medin leaves.

- The membership remains stable from then.

TG 100's Report goes to Review

- The TG finished a draft of the report April 2010, 7 years after being formed. It had been working continually.

- The draft went to QASC, the former QAOISC for review.

- During that time, TPC was beginning to worry whether the TG 100 report was going to be at odds with Practice Standards and regulations.

- QASC, being concerned that the report is very long, directs that it be separated into two volumes: The first is a discussion on technique and the second the IMRT example.

- July 2011 the report goes back to QASC and comes back with extensive reviews.

Review and Review

- July 2012 Part 1 of the report goes back to QASC again and comes back with extensive reviews. Approximately December 2013 Part 2 goes to QASC.

- January 2013, QASC approves the TG-100 report.

- March 2013, a revised report is passed along to TPC.

- June 2013, TPC response with copious comments and questions. Also, Professional Council sends review comments. June also saw the AAPM Summer School in TG-100-related topics.

- September 2013 TPC approves the report. Passed on to Science Council.

Review and Review

- October 2013 – a snag: No Prescriptive recommendations? Seriously? Shouldn't ASTRO have some warning? How about roll-out? "…this is not your typical TG report but one that will shake the world as we know it."

- February 2014, Science Council has the President form a small committee to review the report, with representatives from Admin and Professional Councils.

- June 2014 SC and the ad-hoc submit comments on the report. Request made for section for regulators (good) and to change the emphasis (not so good!). Some talk by TG on withdrawing the report and submitting it for publication outside the AAPM. Cooler heads prevail.

Review and Review

- June 2014 TG responds to SC and ad-hoc review.

- July 2014 TG meeting SC and ad-hoc.

- August 2014 Summit between small SC and ad-hoc reps and TG 100 to work out differences. A budget for the rollout generated.

- December 2014 Science Council Approves the report.

- January 2015 *Medical Physics* review begins, recommends one volume. A unified version resubmitted in May 2015.

- August 2015 *Medical Physics* conditionally accepts the report. Many requests for changes that were the same as earlier reviews. Resubmitted December 2015.

Review and Review

- February 2016 *Medical Physics* conditionally accepts the report again with several requests for changes (some the same!!).

- March 2016 *Medical Physics* accepts the report!!! The report is published June 2016.

- Thus concludes 13 years of work, 6 of those in review!!!!

What Was Wrong with the Old Approach?

- The old approach to QA mostly looked at tests to see if equipment was working (at the time of the test).

- Most of the time, events happen following a person's error, not machine failure.

- In part, that is *because* of all the good QA we did.

- But, the QA did nothing to prevent the effects of human errors.

What Else Was Wrong with the Old Approach?

- The number of tests were proliferating.
  - In radiotherapy alone, the AAPM has published 78 reports as of the end of 2014.
  - Many have recommendations for QA.
  - Not to mention other organizations and regulations.
- Time spent in QA left little time of other things (like thinking), *if* the QA could even be completed.
- The number of events were not decreasing.
- Also, procedures differed between facilities.

Some Systems-Based Principles

- Recognize that most incidents result from human failures rather than equipment failures.

- Most of the time, those in health care want to do a good job.

- Often, when someone fails, it is because something led them to the wrong action (or inaction).

- The goal is to design the "system:"
  - to support staff and equipment to prevent failures
  - to be resilient to failures

Very Important Principles

- Recognize that humans will fail – all humans.

- Recognize that equipment can fail.

What does TG 100 Look Like?

The report has:

- A tutorial on techniques to address quality and safety.

- An example using the techniques to establish a quality-management program for IMRT as practiced at one of the author's institution.

TG-100's Approach to Risk-Assessment-Based QM

- TG 100 considered various tools and approaches to development of QM.

- The approach chosen was felt to be the easiest adapted in the clinical environment and had a history of successful application in health care.

- There are a myriad of tools that could be used and TG 100 encourages the use of any tool that a user feels comfortable using.

Adopting the TG-100 Approach

- Start with a small project or a small part of a bigger procedure.
    - Build Confidence
    - Important to have the early project work
- Assemble a **team** of all the players
    - Important for getting information and generating ideas
    - Very important for buy-in and ownership
- Be open to new ideas
- Be wary of, but do not exclude, major departures

TG-100 Risk-Assessment-Based QM Development

1. Understand the process – Process Map
2. Assess the hazards - FMEA
3. Establish the failure propagation - Fault Tree
4. Address the hazards
    a. Roughly from the greatest risk and most severe
    b. Use the most effective tools available
5. Test and evaluate

Example Process Chart

Prescribe an antibiotic

↓

Check for the preferred antibiotic in app

↓

Check for allergy

— Yes → **Check for most effective, next possible antibiotic** → **Option found?**

No ↓

Generate prescription in system

Option found? — Yes → (loops back to Check for the preferred antibiotic in app)

No ↓

Send for infectious disease Consult
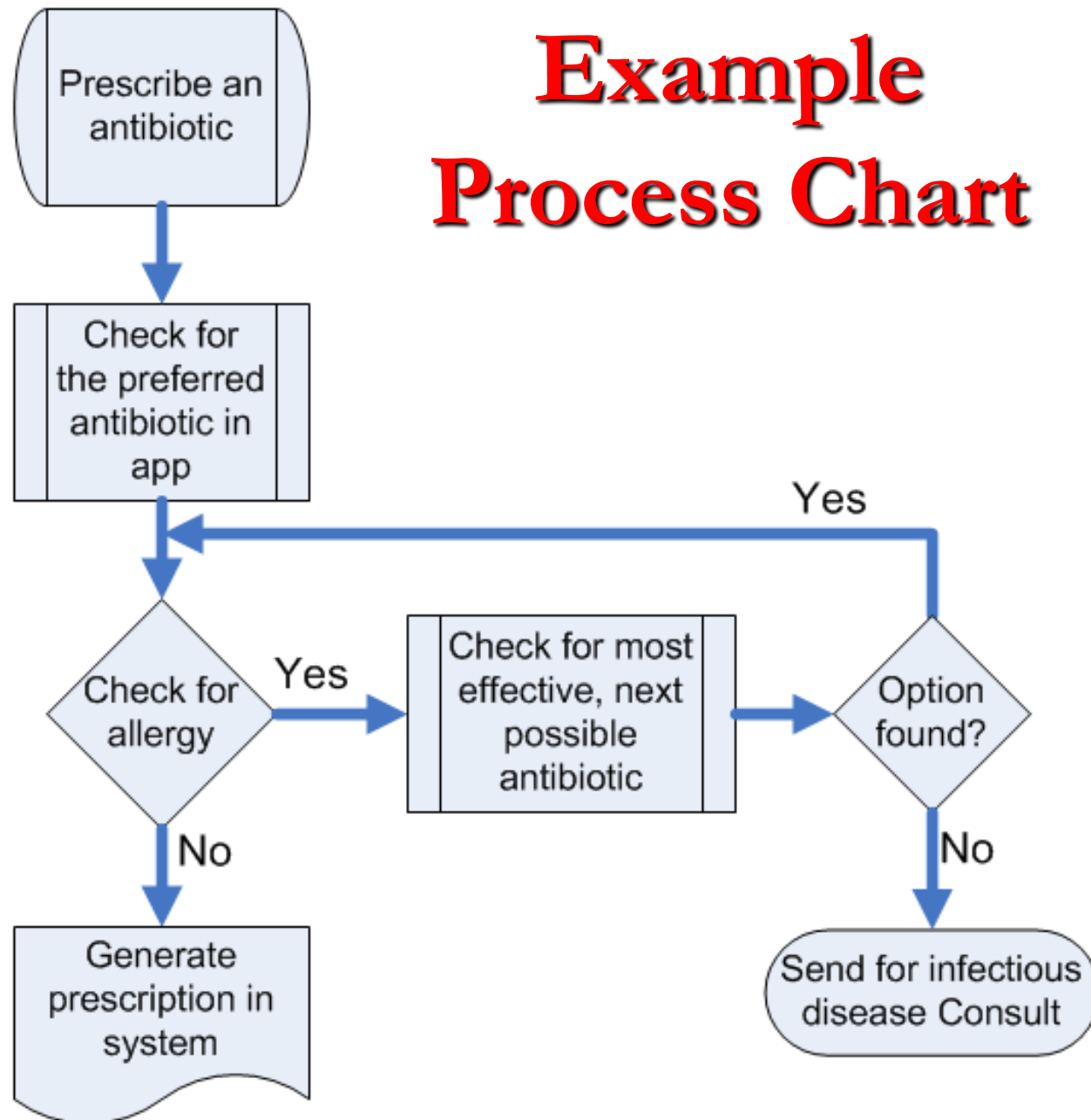
APBI with Contura Process Map
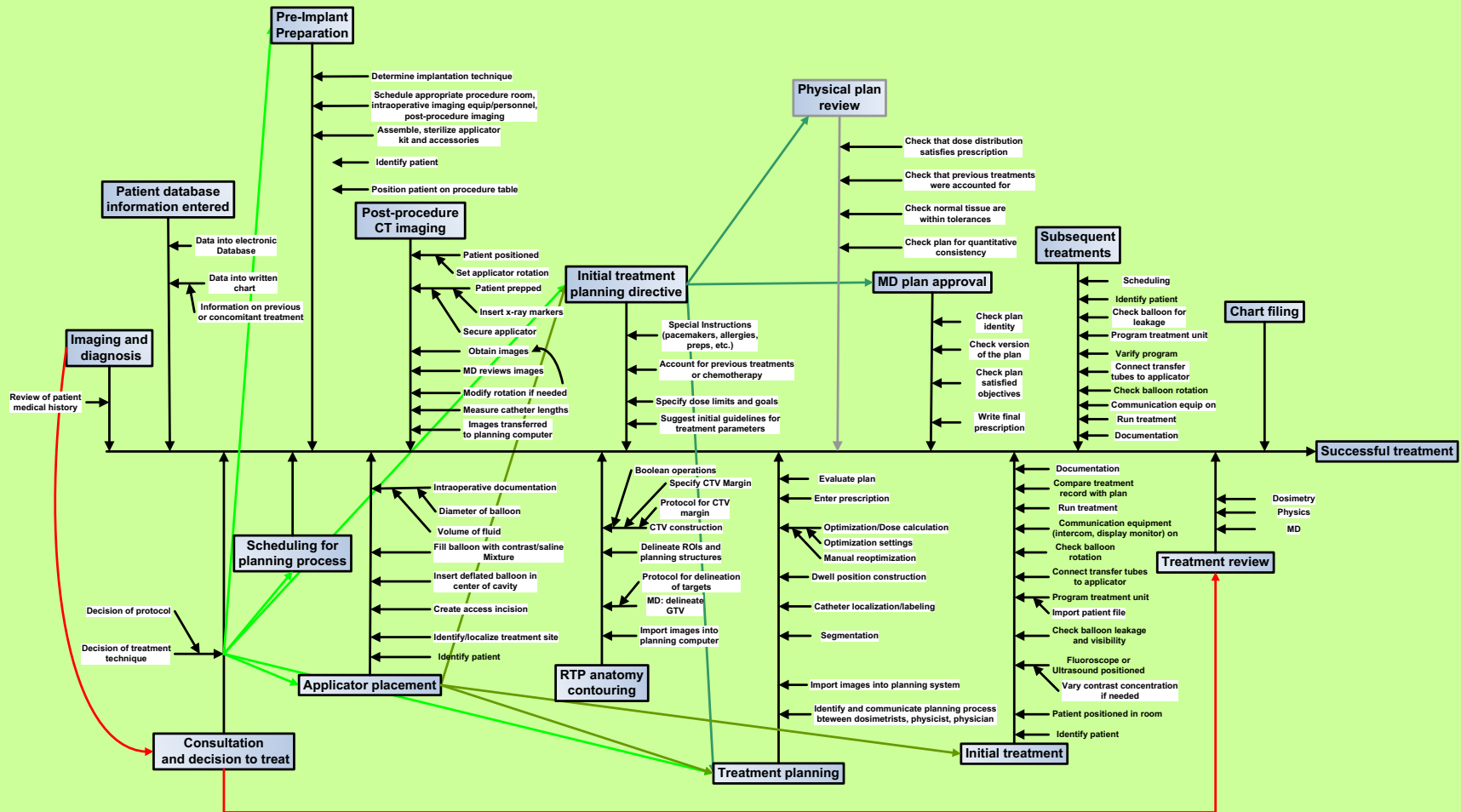
Do not try to read the labels; enjoy the organization

A Very Simple Example: Ordering Prostate Sources

Receive information from Plan → Highlight loading pattern by needle coordinate, S_K → Call vendor and place order → Receive order → Check the number of needles and vendor's strength → Store until preparing for implant
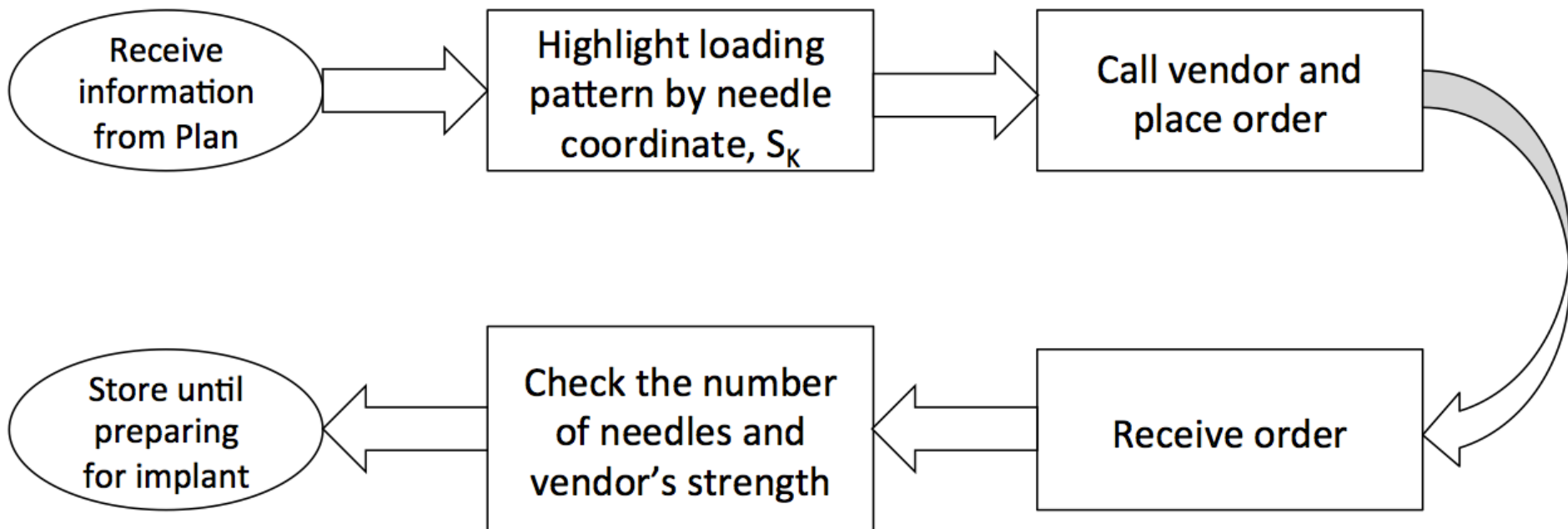
Failure Modes and Effects Analysis - FMEA

Step	Func-tion	Potential Failure	Potential Cause of Failure	Potential Effects of Failure	Current Controls	O	S	D	RPN

Risk Probability Number

- O = likelihood of occurrence;
- S = severity of the effects of the failure;
- D = likelihood failure would go undetected.

O	S	D	RPN

- Values for O, S, and D between 1 and 10,

  (1 = low danger, 10 = high).
- How to determine values?

Rank	Occurrence (O) of Cause		Severity (S) of Effect		Detectability (D) of Failure Mode	
	Qualitative description	Frequency in %	Qualitative description	Descriptive	Qualitative description	Probability of going undetected in %
1	Remote probability	0.01	No effect	No effect	Detection almost assured	0.01
2	Failure unlikely	0.02	Inconvenience	Inconvenience	Very high likelihood	0.2
3	Low probability – few failures	0.05	Minor effect	Only seen when reviewing large populations	High likelihood	0.4
4	Moderate probability	0.1	Noticeable effect	Suboptimal care for a patient	Moderate likelihood	1.0
5	Intermediate probability	<0.2	Limited toxicity	Minor under- or over treatment	Intermediate likelihood	2.0
6	Occasional failures	<0.5	Undesired effect	Worsens the patient's life	Some likelihood	5.0
7	High probability	<1	Serious effect	Failures that affect patient function	Low likelihood	10
8	Very high probability	<2	Possible very serious toxicity	Very negative effects	Very low likelihood	15
9	Repeated failures	<5	Sentinel failure	Serious injury	Serious detection problem	20
10	Failure inevitable	>5	Catastrophic effect	Death or very serious injury	Detection unlikely	>20

O, S and D Ranking Table

Risk Probability Number

- O = likelihood of occurrence;
- S = severity of the effects of the failure;
- D = likelihood failure would go undetected.

- RPN = risk priority number = product of OxSxD.

O	S	D	RPN

Establish the Failure Propagation Pattern

- This is the fault tree analysis.
- For the fault tree
  - Begin at the failure
  - Ask what are all the possible causes
  - Relate the causes through logical gates
  - For each cause, ask what would be the cause
  - Repeat as needed

Fault Tree for Ordering Prostate Sources

Underdose target, tumor recurs; overdose normal tissue, toxicity

Or

Wrong Needle Loading

Or

Failure checking order with plan **(AND)**

Needle missing in order **(Or)**
- Vendor error: Needle omitted
- Vendor error: Vendor mishears
- Physics skips needle
- Physicist starts after first needle
- Physicist misses second page

Vendor error in needle loading **(Or)**
- Vendor error: Loading pattern incorrect
- Vendor error: Vendor mishears

Physicist orders wrong needle loading: Human error - Failure reading from plan **(Or)**
- Orders activity instead of S_K
- Human error: Failure reading plan
- Human error: Failure saying S_K

Wrong S_K **(AND)**

Failure checking order with plan

Or
- Vendor error in S_K **(Or)**
  - Vendor error: Wrong S_K
  - Vendor error: Hears wrong S_K
- Order for S_K Incorrect **(Or)**
  - Orders activity instead of S_K
  - Human error: Failure reading plan
  - Human error: Failure saying S_K

Wrong Patient's Sources: Package mix-up in storage (not inc. vendor mix-up)

QA part of process

The Universe and Beyond

- The fault tree causes are followed to the end of your universe.

- Your universe consists of things you have control over.

- At some point, causes are beyond your control; you need to be ready to handle effects from beyond.

Characteristics of Fault Trees

- OR gates indicate increased hazard, AND gates indicate protection.

- Common causes indicate particularly hazardous causes

  - May show as a single box leading to multiple boxes
  - May simply be a cause, e.g., "lack of training" showing up often, even though each may be a different training lacking.

Intricate Common Cause

Tree from Jeff Williamson
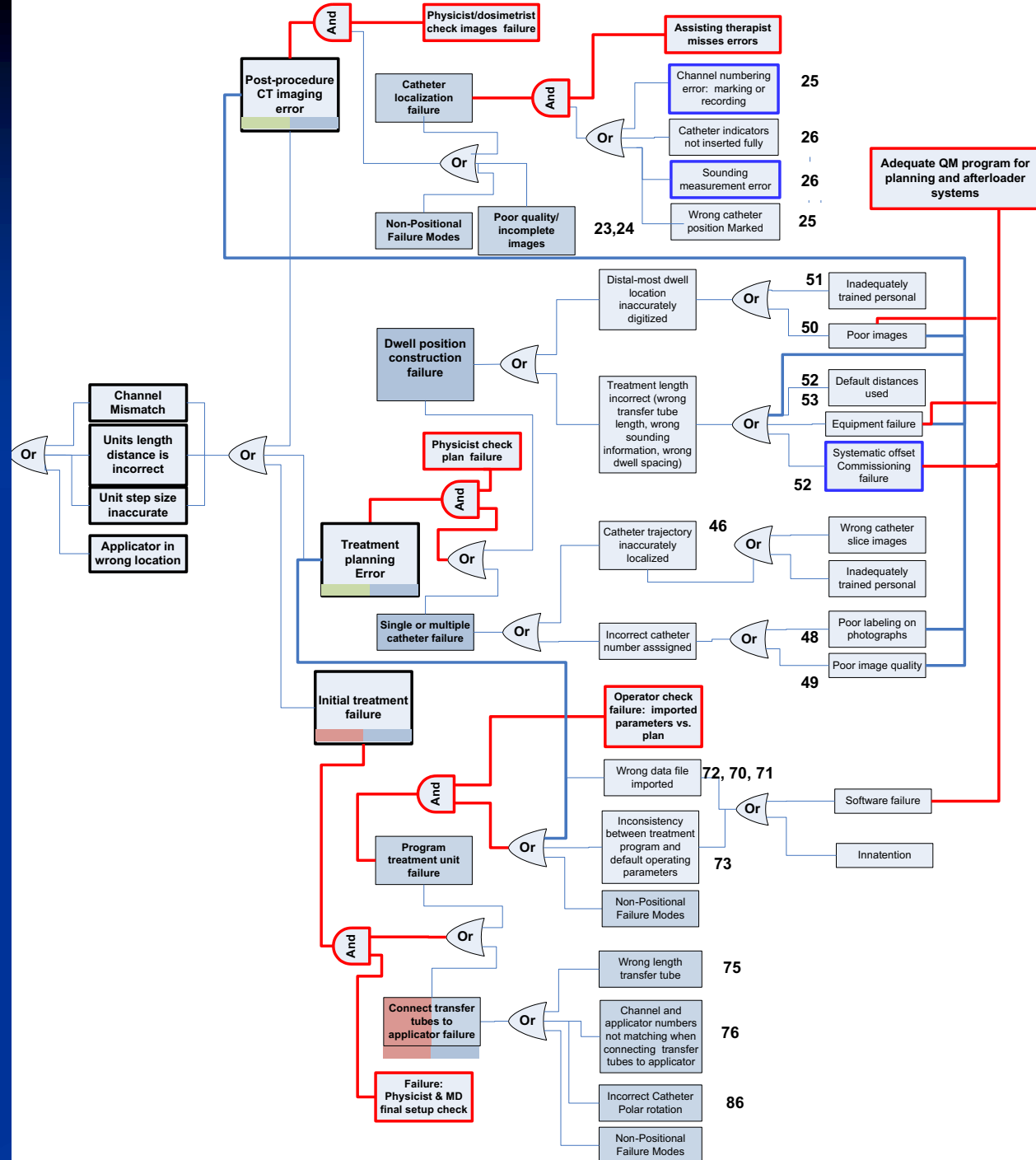
Redesign

- The best way to avoid potential errors at some step is to redesign the procedure so that error is not possible.

- Re-evaluate after a redesign because new possible errors may have been produced.

Possible Interventions

- First correct any environmental problems – that usually is a relatively inexpensive but effective operation.

- Fix technical problems.

Possible Interventions 2

Then consider Peter Dunscombe's *key core components* identified by AAPM TG 100:

- Standardized procedures

- Adequate staff, physical and IT resources

- Adequate training of staff

- Maintenance of hardware and software resources

- Clear lines of communication among staff

When Bad Things Happen

- First step is to recognize that humans and equipment will fail – Expect that.
- Then set up procedures to try to prevent failures from negatively affecting the patient.
  - This can be done by eliminating the cause, or
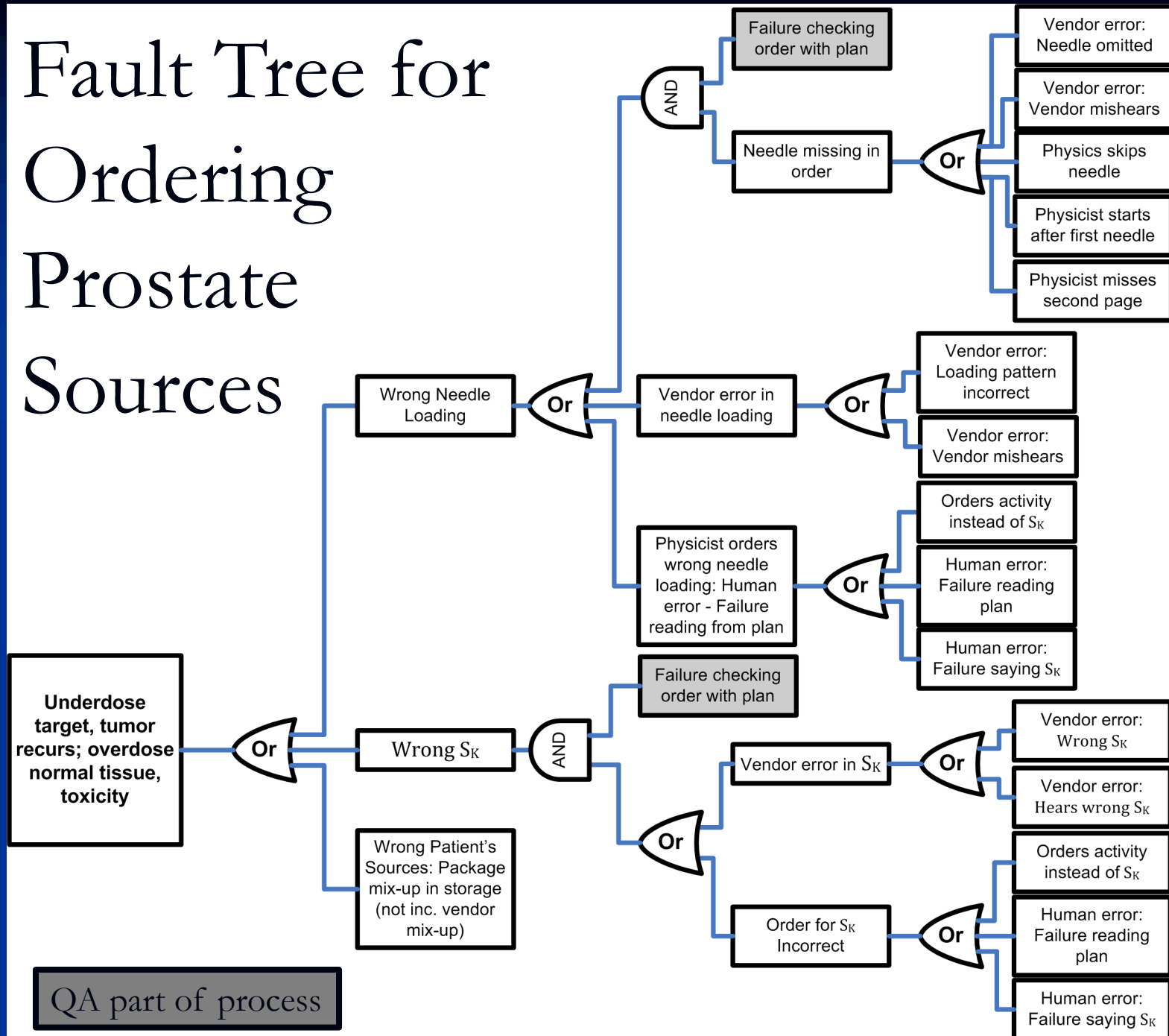 - Interrupting the propagation.
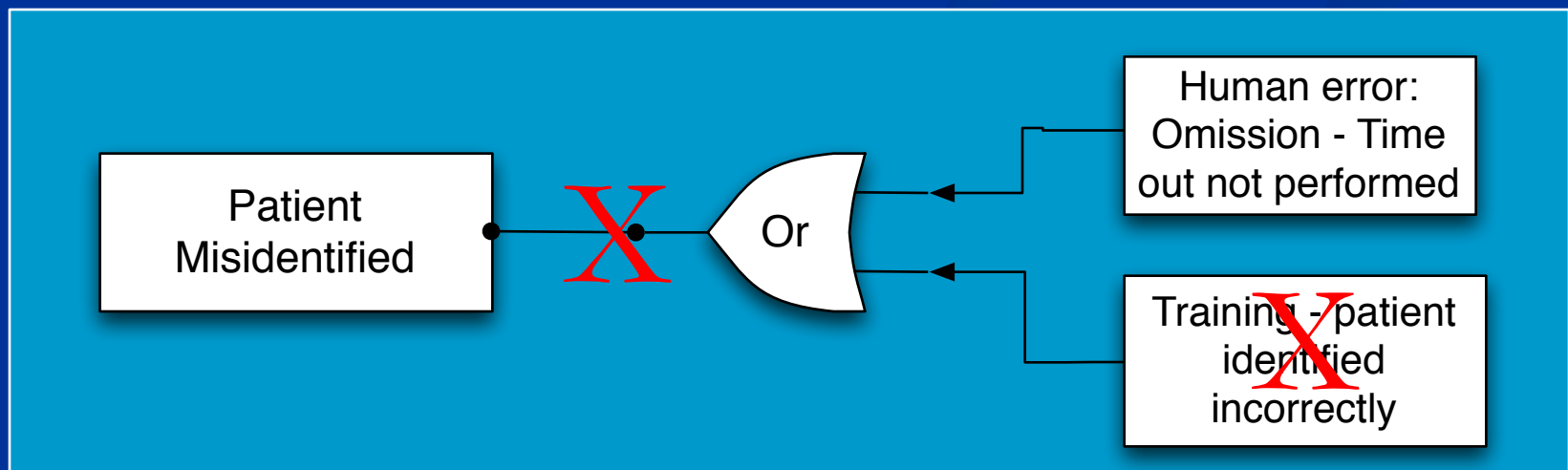
Possible Interventions 3

- As you start with the highly ranked potential failures, it is useful to consider all the given branches of the fault tree at once.

- It is also efficient to work though all the branches of the process tree at once.
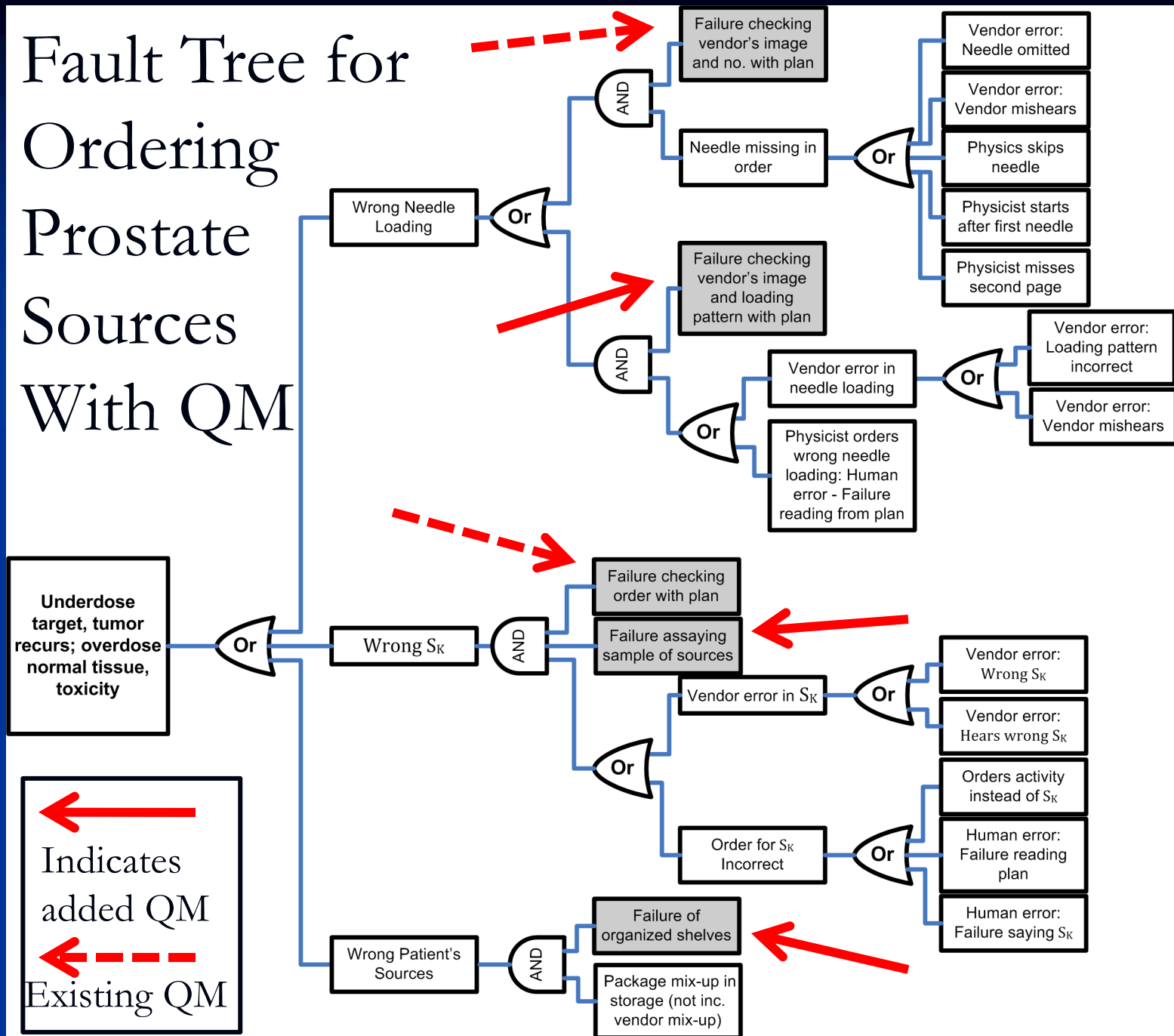
- Work down through the tree.

Commissioning

- Identify those potential failures that can be eliminated through commissioning.
- Commissioning is not only for equipment but also for procedures.
- This is likely to be many.

Fault Tree for Ordering Prostate Sources

QA part of process

Fault Tree for Ordering Prostate Sources With QM

Underdose target, tumor recurs; overdose normal tissue, toxicity

Or

Wrong Needle Loading

Or

- **AND**
  - Failure checking vendor's image and no. with plan
  - Needle missing in order — Or
    - Vendor error: Needle omitted
    - Vendor error: Vendor mishears
    - Physics skips needle
    - Physicist starts after first needle
    - Physicist misses second page

- **AND**
  - Failure checking vendor's image and loading pattern with plan
  - Or
    - Vendor error in needle loading — Or
      - Vendor error: Loading pattern incorrect
      - Vendor error: Vendor mishears
    - Physicist orders wrong needle loading: Human error - Failure reading from plan

Wrong S_K

AND

- Failure checking order with plan
- Failure assaying sample of sources
- Or
  - Vendor error in S_K — Or
    - Vendor error: Wrong S_K
    - Vendor error: Hears wrong S_K
  - Order for S_K Incorrect — Or
    - Orders activity instead of S_K
    - Human error: Failure reading plan
    - Human error: Failure saying S_K

Wrong Patient's Sources

AND

- Failure of organized shelves
- Package mix-up in storage (not inc. vendor mix-up)

Indicates added QM

Existing QM

Ranking of QM Tools

The strength of actions varies:

1. Forcing functions and constraints

2. Automation and computerization

3. Protocols and standard order forms

4. Independent check systems and other redundancies

5. Rules and policies

6. Education and Information

From the Institute for Safe Medical Practices toolbox (ISMP, 1999)

Is This Really a Change?

While the recommendations reflect the careful considerations… and while it is important that reasonable attempts should be made to follow them, it is also important that they not be followed slavishly. There will be instances where other approaches may prove equal to or better than the recommendations in this report; however, modifications should be instituted only after careful analysis demonstrates that quality would not be compromised. – TG 40

Is This Really a Change?

These recommendations are guidelines for QMPs to use and appropriately interpret for their individual institution and clinical setting. Each institution may have site-specific or state mandated needs and requirements which may modify their usage of these recommendations.

– TG 40

Is This Really a Change?

… we do recommend using the tests and frequencies outlined in the tables that follow until methods such as TG-100 supersede this report .

– TG 142

TG 100's Recommendations

1. Start either on small projects or small, self-contained parts of a larger procedure.

2. Evaluate thoroughly deviations for conventional practice, with experts and experience.

3. The AAPM is working on posting vetted examples.

4. Go to workshops.

Help with the Process

- The participants in workshops come away feeling confident and that it could work in their facility.

- Patient Safety Organizations (PSO) listed by the Agency for Healthcare Research and Quality could provide assistance.

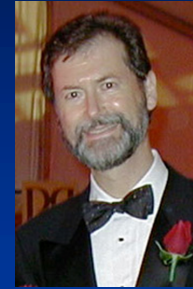# TG 100

M. Saiful Huq (Chair)

Peter Dunscombe
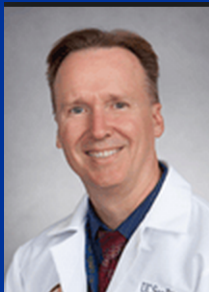
Benedick Fraass

John Gibbons

Geoffrey Ibbott

Sasa Mutic

Ellen Yorke (Vice Chair)

Arno Mundt

Jatinder Palta

Frank Rath

Bruce Thomadsen

Jeffrey Williamson

Slide from Saiful Huq

Me at the Beginning of TG 100

Summary for the Process

- The new approach to development of QM focuses on the weaknesses of the procedure but also includes equipment.

- All failures are system failures.

- QM development is a team sport.

- Most of the approach is to understand the nature of potential failures.

- Start small. Maybe even stay small, working on parts of larger processes.