Implementing clinical safety barriers to stop accidents before they happen

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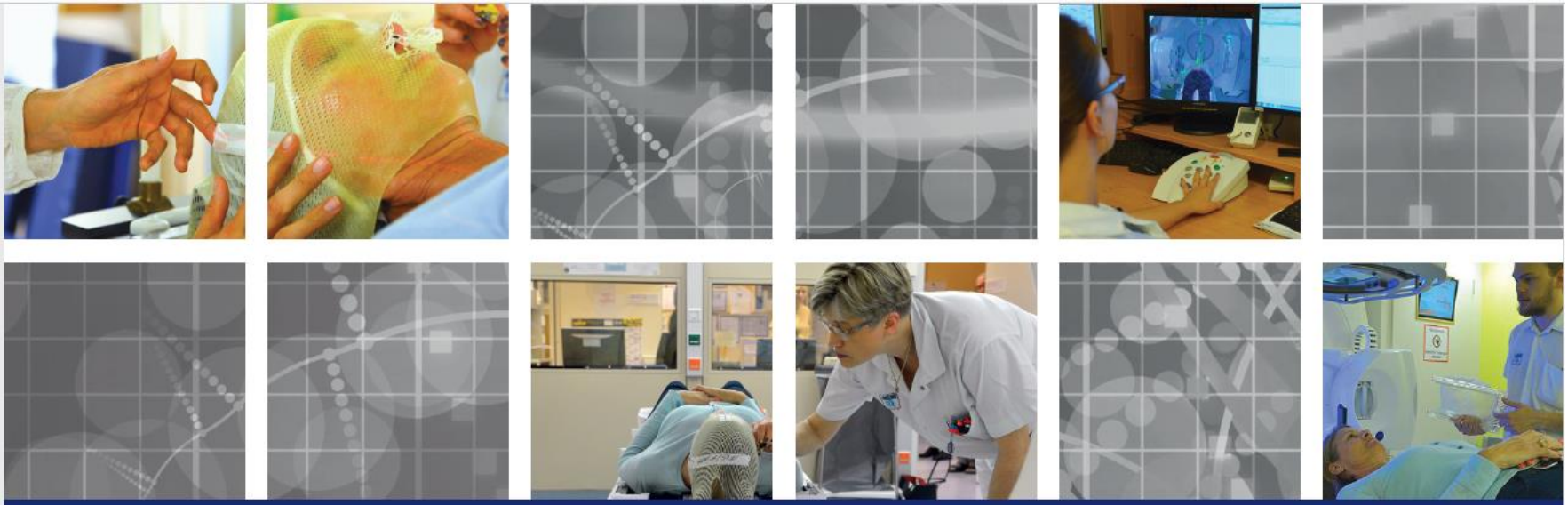
The challenge: toward safer radiotherapy

- **Since 2010, our profession produced a huge amount of resources toward safer radiotherapy:**
  - "Safety is no accident" **updated 2019** (ASTRO, AAPM, etc.)
  - ASTRO: Safety white papers (beginning in Jan 2010)[6-7]
  - AAPM: TG-100, TG-275, etc.
  - "Radiation Therapy Safety: The Critical Role of the Radiation Therapist" (ASRT 2012)
  - Hundreds of papers and editorials in major journals
  - RO-ILS national incident learning database launched in 2014
  - IAEA SAFRON, RPOP, SAFRAD, etc.

The challenge: toward safer radiotherapy



CAPACITY BUILDING

IAEA E-LEARNING COURSE: SAFETY AND QUALITY IN RADIOTHERAPY

What do we offer?

We have created an e-learning course explaining safety and quality in radiotherapy. This course consists of *twelve modules,* each looking at different aspects of the topic, with an estimated total duration of *five hours*. It is designed to help *radiotherapy professionals* to:

The *new* challenge toward safer radiotherapy

- **Recent studies confirm that:**
  A. Clinical professionals either remain unaware of safety resources (e.g., incident learning systems) or **do not use them**[1]
  B. Most new graduates from medical and physics residencies feel **inadequately trained and unprepared for ILS, RCA, FMEA**[2]

The *new* challenge toward safer radiotherapy

"The survey results demonstrate that **despite increasing interest**, residents in radiation oncology have limited exposure to important concepts of patient safety and treatment quality management and do not feel competent to lead clinical patient safety programs in the future. In spite of notable gaps, a sizable minority of residents has either formal training or practical experience with patient safety tools. The programs that do offer formal training may serve as models for program development in radiation oncology."

– Spraker, Matthew B., PRO 7(4), 2017[2]

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The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

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AAPM TG-100 quality management recommendations

- **Use the risk analysis tools that *you feel most comfortable implementing effectively***

"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."

- Thomadsen, Bruce. AAPM 2019.[3]

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AAPM TG-100 quality management recommendations

- **Use the risk analysis tools that *you feel most comfortable implementing effectively***
- **Multi-disciplinary team that includes experience from all professional disciplines in the department**
- **Start with a small project or small aspect of a larger procedural workflow (and maybe *keep it small)***
- **Suggested framework: Incident Learning System combined with FMEA**

AAPM TG-100 quality management recommendations

"Another way to gather safety-related issues is through prospective risk assessment using Failure Mode and Effects Analysis (FMEA) as described in AAPM Task Group 100. The failure modes gathered in this way can be entered and analyzed in the ILS as "unsafe conditions" or "process improvements". Risk assessment via FMEA is complementary to the use of ILS. One study reported a set of safety issues that were identified only by FMEA but not by ILS (57% of the total) and noted that another set identified only through ILS and not FMEA (17% of the total). This illustrates the value of combining FMEA risk assessment with ILS."

– Ford, Eric, et al. Med Phys 45(5), 2018[4]

Q. AAPM TG-100 review question 1

What is the *first step* of the Quality Management approach recommended by TG-100?

1. **Fault tree analysis**
2. **Process mapping**
3. **Implementing safety barriers**
4. **FMEA**

Q. AAPM TG-100 review question 1

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Q. AAPM TG-100 review question 2

What is the *primary purpose* of Fault Tree Analysis in the recommendations of TG-100?

1. **Shows how a process takes place**
2. **Maps the potential causes of a single failure mode**
3. **Traces back to the initial cause of an actual failure**
4. **Evaluates the efficacy of a safety barrier**

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AAPM TG-100 quality management recommendations

- **Suggested framework: Incident Learning System combined with FMEA**

  1. Understand the process **(Process Map)**
  2. Assess the risks **(FMEA)**
  3. Analyze each failure mode **(Fault Tree Analysis)**
  4. Intervene **(Quality Management)**
  5. Test and Evaluate **(Quality Assurance)**

Q. AAPM TG-100 review question 1

What is the *first step* of the Quality Management approach recommended by TG-100?

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Q. AAPM TG-100 review question 3

What is the principle aim of Failure Mode and Effects Analysis (FMEA)?

1. **Evaluation of safety barrier effectiveness**
2. **Quantifies relative levels of risk for each step in a given process**
3. **Determines the original cause of a failure mode**
4. **Documents pertinent details of an event**

Establishing effective safety barriers

- **Suggested framework: Incident Learning System combined with FMEA**

  1. Understand the process **(Process Map)**
  2. Assess the risks **(FMEA)**
  3. Analyze each failure mode **(Fault Tree Analysis)**
  4. Intervene **(Quality Management)**
  5. Test and Evaluate **(Quality Assurance)**

Establishing effective safety barriers

- **What is a safety barrier?**

"The 3.5-inch diskette is an example of mistake-proofing. The diskette can only be inserted if it is oriented correctly. It cannot be inserted sideways because it is not square; the sides are too long to fit. It cannot be inserted backwards or inverted. The drive is designed to stop the diskette unless the right front corner is chamfered (angled). When the disk is inserted correctly, the mistake-proofing device is not noticeable. When it is inserted incorrectly, however, the device completely stops the process. The only cost is that of initial design implementation. No user training is required. The members of the design team…[indicated] a preference for using design as an error-prevention strategy instead of alternatives such as training, instructions, or warning labels."

Grout, John. *Mistake-proofing the design of health care processes*. Agency for Healthcare Research and Quality, Department of Health and Human Services, 2007.

Establishing effective safety barriers

How can we employ quality management and safe engineering design principles to safe guard our RT processes so mistakes either don't happen or their effects are substantially limited when mistakes occur?

Establishing effective safety barriers

What is a safety barrier?

- Something that **prevent errors** from happening
- Something that makes an error **quickly and easily detectable** when it occurs
- Something that **mitigates impact** of an error ("fails safely")

Establishing effective safety barriers

- **What is a safety barrier in radiation therapy?**
  - **Any procedural step whose primary function is to prevent an error from either occurring or propagating through the radiotherapy workflow*[5]**

* Fong de los Santos 2015

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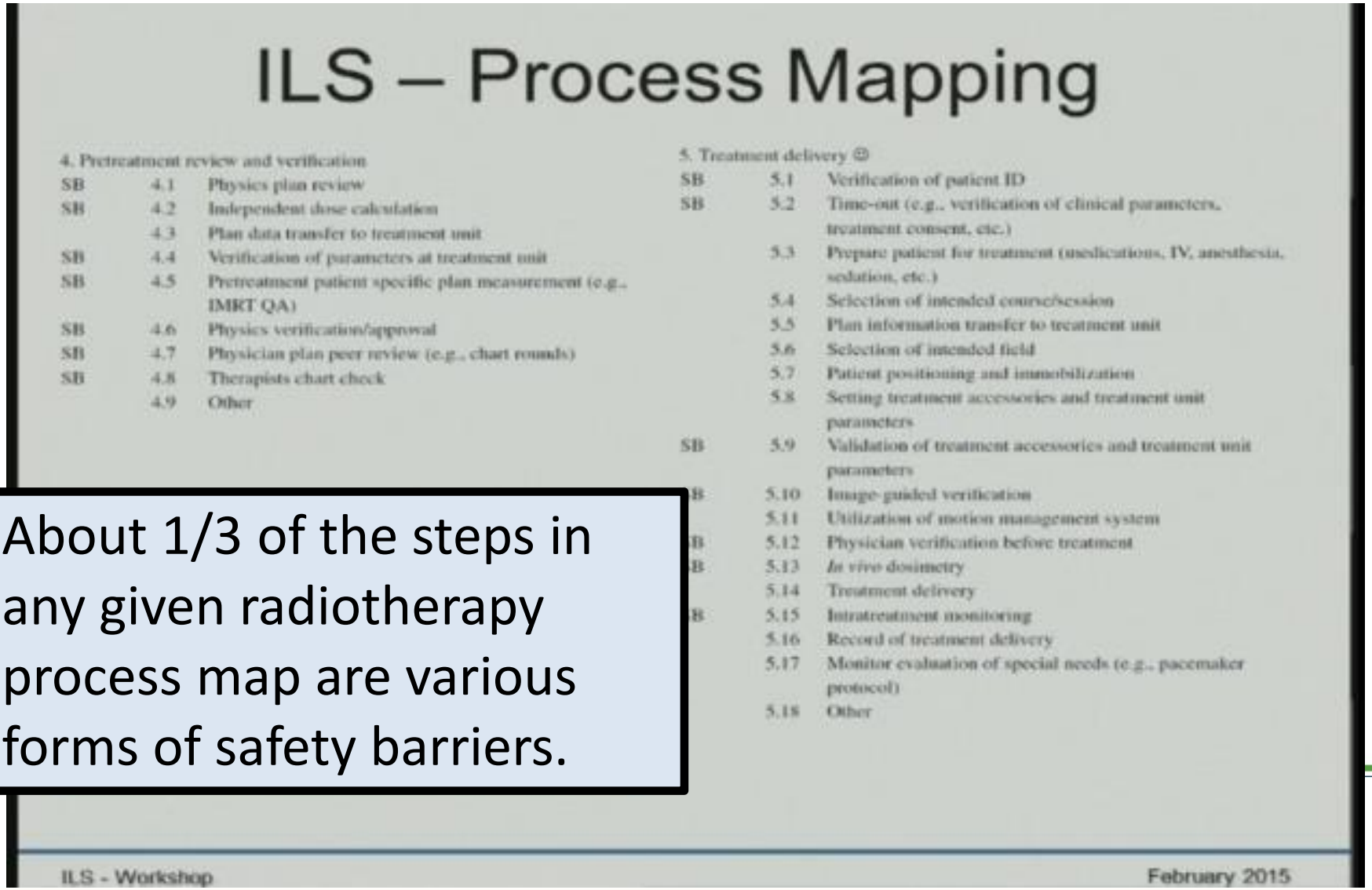
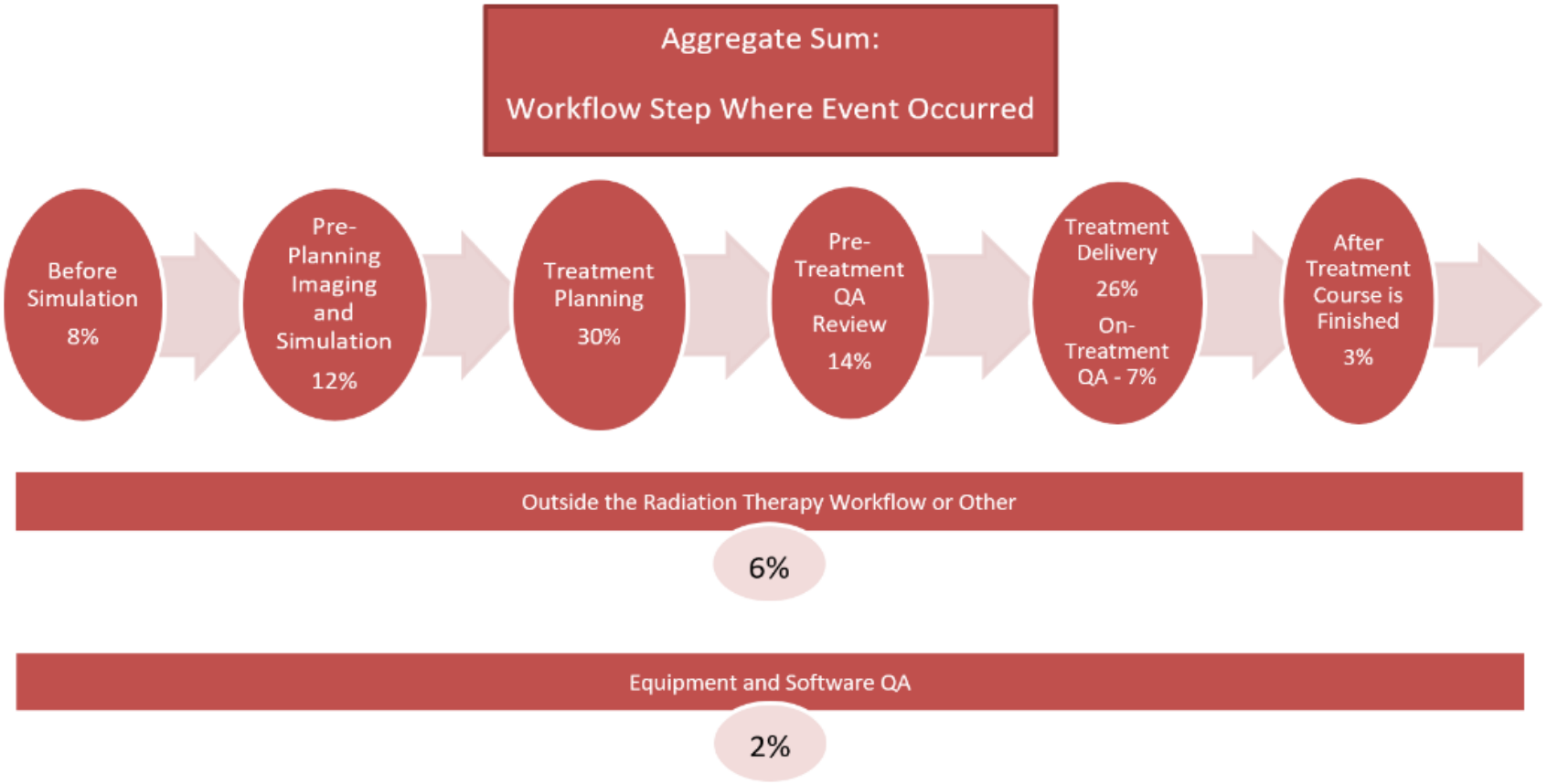
Establishing effective safety barriers



Establishing effective safety barriers

- Physics plan/chart audit
- Independent dose/MU calculation
- Therapist pre-treatment audit
- Pre-treatment QA
- Physician peer review
- Verification of patient ID
- Pre-treatment timeout
- Verification of treatment accessories
- Verification of machine parameters
- Image-guidance
- Physician approval of images
- In-vivo dosimetry
- Intrafraction monitoring

Establishing effective safety barriers



ROILS. Aggregate Report: Q3-Q4 2018. Clarity PSO: 2019.

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Q. Where are the errors occurring?

For all the incidents reported via RO-ILS, what percentage were due to hardware or software failure?

1. **>95%**
2. **51-94%**
3. **10-50%**
4. **<10%**

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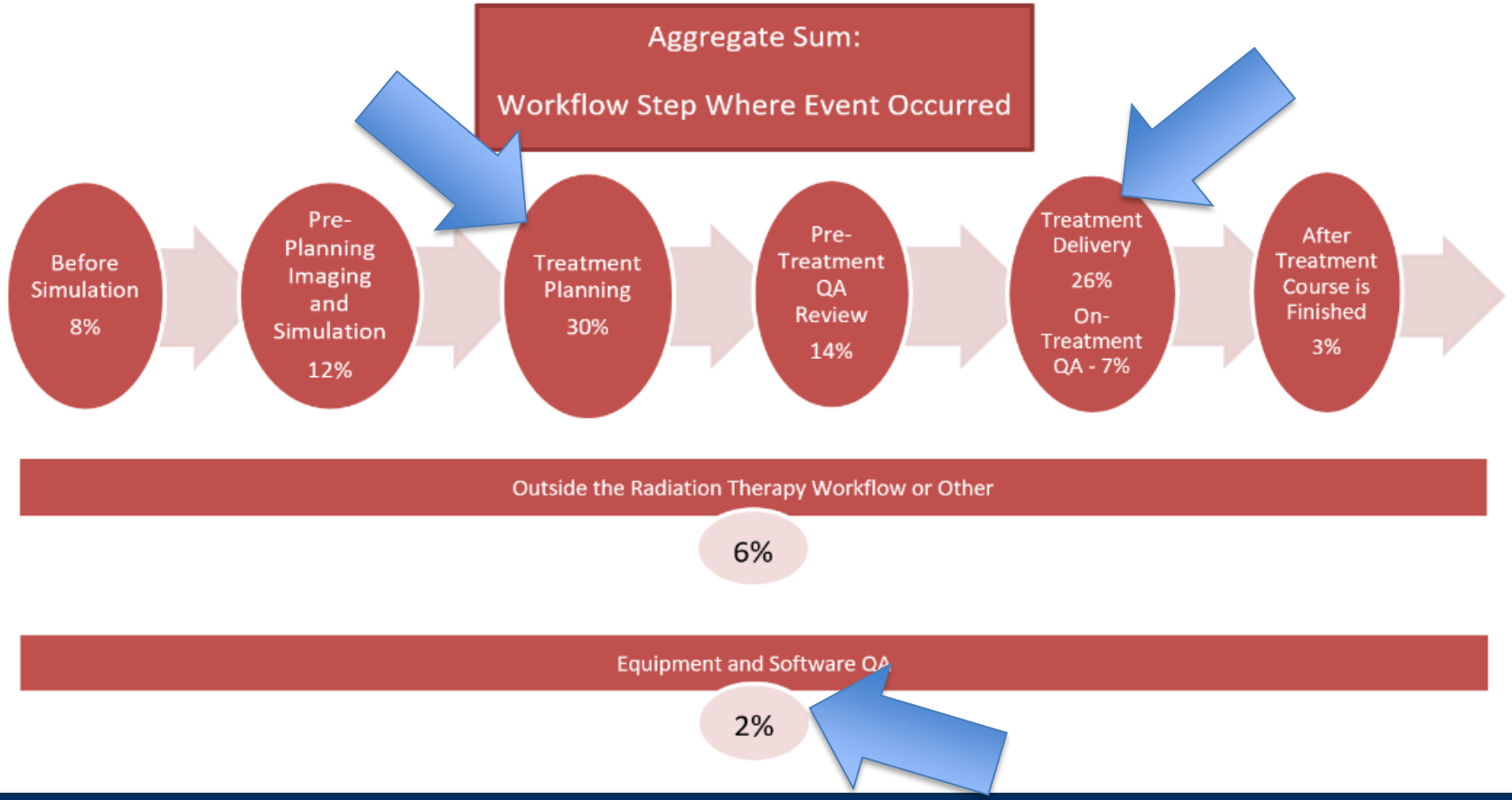
The Quality Assurance Myth

Following QA guidelines like TG 40 and TG 142 is what we chiefly need to prevent errors.



The Quality Assurance Myth

What's wrong with the "If It Can Be Measured, Let's Measure It" approach to safety[3]?

- Most QA tests only ensure equipment is working *at the moment of the test*
- Most actual medical events are caused by human error, not technological failure
- Good QA, smartly implemented, is good – **but it does nothing to prevent human error**
- Technology evolves (and evolves in testing itself): we cannot possibly keep up measuring everything

The Experience Myth[7]

All of my experience has made me so wise, mistakes are not an issue for me.

- More experience **makes you *older***
- **Evaluated** experience makes you wiser[7]

The Knowledge Myth[7]

I've gained so much knowledge now: since I KNOW better, I'll DO better.

- ***Possessing*** **knowledge does not change the human factors and environmental factors that lead to errors!**

The Knowledge Myth

"People who make these errors are not unmotivated or negligent. More importantly, they cannot eliminate the errors simply by telling themselves to do better and deciding not to commit them. The Joint Commission on Accrediation of Healthcare Organizations (JCAHO) adds that "it assumes that **no matter how knowledgable or careful people are, errors will occur** in some situations and may even be likely to occur."[8]

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Safety Barrier Effectiveness

What makes a good safety barrier?[5,9]

1. Effective in preventing errors or harm
2. Inexpensive
3. Minimize need for training & implementation resistance
   - Godfrey, et al. proposed **"Solution Priority Number"** (i.e., effectiveness x cost x ease of implementation) to quantify the usefulness of any particular safety barrier.
   - "The best designs will not be cumbersome or slow the process down. Rather, design changes that reduce errors and speed up processes go together."

Safety Barrier Effectiveness

Components of Hazard Mitigation[5,9]

- Forcing functions and constraints
- Automation and computerization
- Simplification and Standardization
- Reminders and checklists
- Policies and procedures
- Training and education

Safety Barrier Effectiveness

Most Effective

Least Effective

- Forcing functions and constraints
- Automation and computerization
- Simplification and Standardization
- Reminders and checklists
- Policies and procedures
- Training and education

Q. Order these safety barriers from most effective to least effective:

A. Policies and Procedures
B. Training and Education
C. Forcing Functions and Constraints
D. Simplification and Standardization

1. A, B, C, D
2. D, C, B, A
3. C, D, A, B
4. B, D, A, C

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A. Policies and Procedures
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C. Forcing Functions and Constraints
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1. A, B, C, D
2. D, C, B, A
3. C, D, A, B
4. B, D, A, C

Training and Education

Recognized that every member of the treatment team (includes planning and QA) is adequately trained.

- But training in what? And what does it look like?
- "Training, interpreted as including education for the purposes of this study, is a recommended initiative in all seven of the sources. However, it is not always clear what the training is in. The UK document does recommend training in Quality Management but what exactly does this mean?"*[10]

* Dunscombe 2012

Training and Education

1. Trained thoroughly (including error procedures) in all aspects of immediate responsibilities.

School or Vendor

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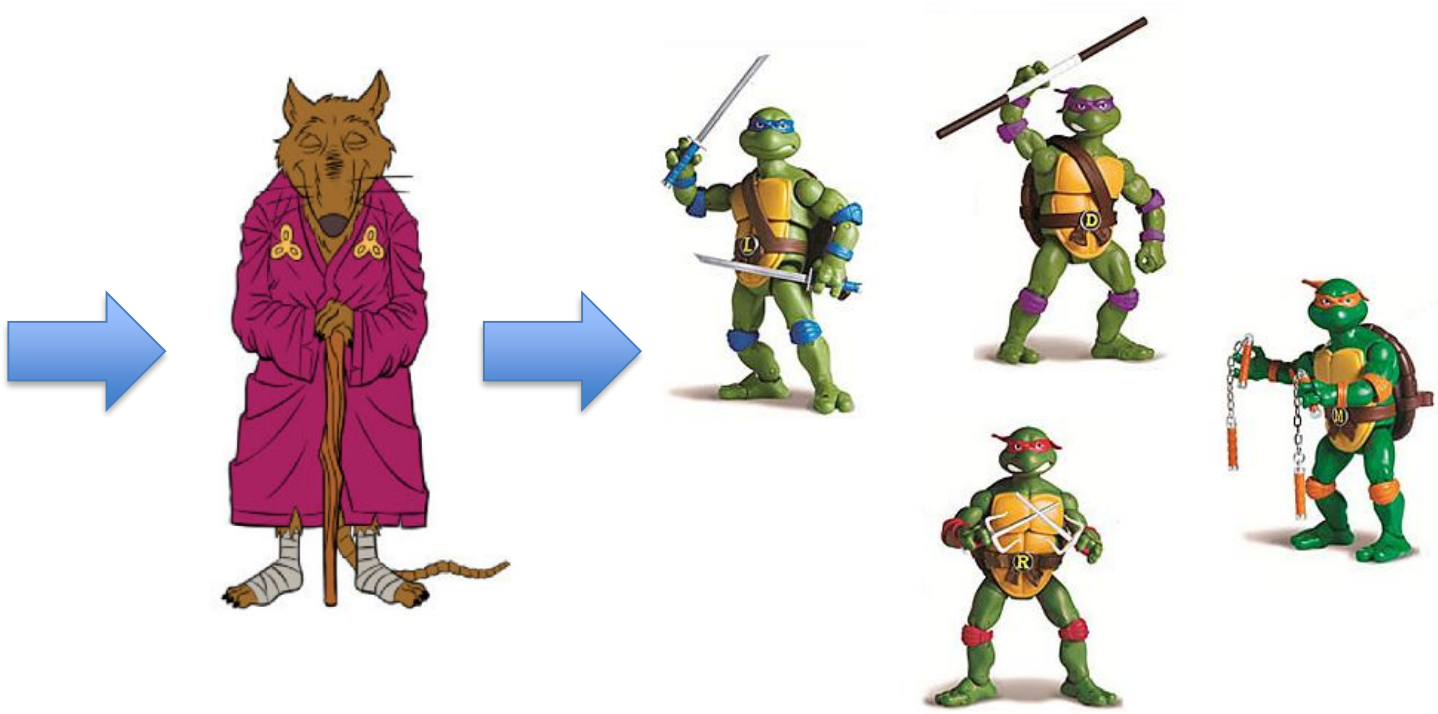

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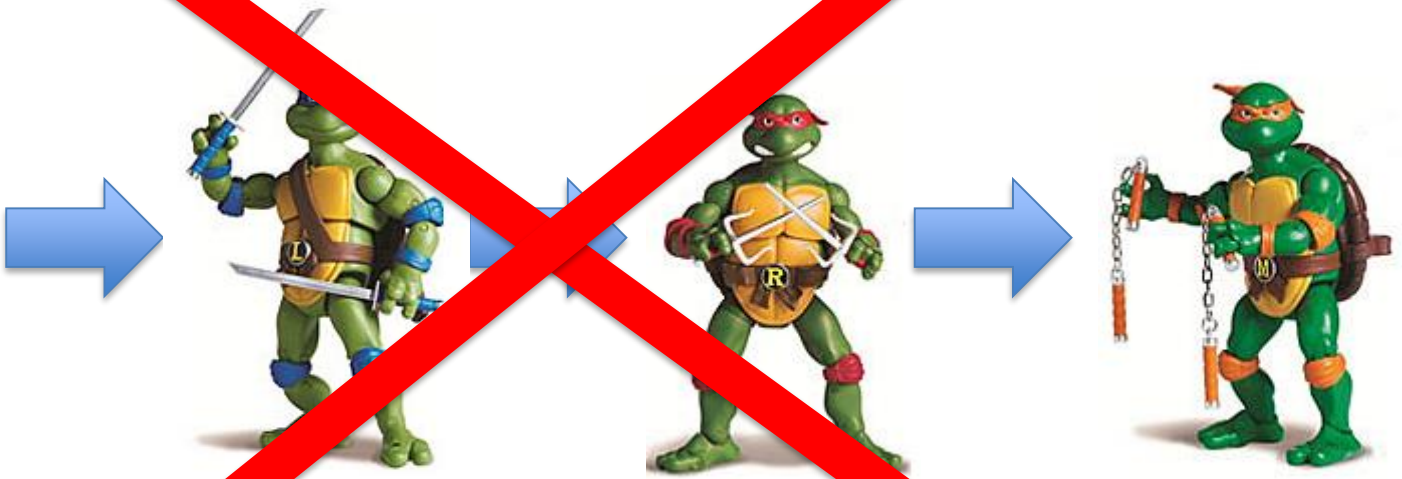

Training and Education

1. Trained thoroughly (including error procedures) in all aspects of immediate responsibilities.
2. Trained generally in the departmental procedural workflow
   - Walk in my shoes
3. Educated at least generally in departmental implementation of quality management
   - Incident learning system
   - Timeout/No Fly Zone/Culture of safety

Training and Education

"It is, of course, acknowledged that the vendors generally have well developed training programs run by experienced instructors. However, these are obviously geared to the use of the specific equipment which the particular vendor supplies. Perhaps what is required to complement these events is more training in specifically safety related topics, such as human factors, and in process flow, and related failure modes, as they apply to particular processes in a particular clinic. A multidisciplinary approach to such training might mitigate some of the communication difficulties encountered in a busy clinic environment."

- Dunscombe, P. (2012)[10]

Training and Education

"Retaining large volumes of instructions in memory so that they are ready for use requires significant ongoing training efforts. When adverse events occur in health care, **organizational responses also tend to involve attempts to change what is in the memory of the health care worker.** These include retraining the worker who errs, certifying (i.e., testing) workers regularly, attempting to enhance and manage worker attentiveness, and altering standard operating procedures. **The passage of time will erase any gains made once the efforts to change memory are discontinued.**"

- Grout, J. (2007)[8]

Policies and procedures

Including documentation, it is recognized that absence of clear policies and procedures is a common source of errors.

1. Creation of documentation is labor- and resource-intensive:
   - **Use FMEA techniques** to evaluate the procedures most vital for patient safety, prioritize by potential consquence
2. Head knowledge does not always translate to real life knowledge
   - **Human and environmental factors make us forget!**

Policies and procedures

"However, it is a common observation that even when adequate documentation does exist it is not always followed. It is unlikely that failure to follow established procedures is for some malicious reason. It is more likely to be due to the procedure either having been forgotten or the significance of not following it not being fully appreciated."

- Dunscombe, P. (2012)[10]

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2. Head knowledge does not always translate to real life knowledge
   - **Human and environmental factors make us forget!**
   - **Turn most vital instructions *into* real life knowledge**

Reminders and checklists

Checklists and timeouts can be highly effective safety barriers in preventing catastrophic error.

- **They are too easy to blow through**
- **Poorly structured checklists and/or timeouts quickly become unusable.**
- **If *patient safety* is your main objective, shape your reminders and checklists *intelligently***

Reminders and checklists

McLaughlin, Anne Collins. "What makes a good checklist." *AHRQ--Agency for Helthcare Research and Quality* 1 (2010).

- *https://psnet.ahrq.gov/perspectives/perspective/92*

Reminders and checklists

"In guarding against the propagation of errors resulting from interruptions, slips, and lapses, check lists clearly have a role. A well known challenge in the use of check lists is automaticity where the checker essentially does a "copy and paste" from the last ten check lists he or she completed. **Automating the checking procedure is one way to at least partially overcome this difficulty...** Inevitably there will be a residual amount of hand checking that will have to be done and, whilst not eliminating automaticity, emphasizing those checks which are safety critical may mitigate its effects."

- Dunscombe, P. (2012)[10]

Result	Plan Information
Pass	The correct treatment couch type, Exact IGRT Couch, thick, is in the plan
Pass	The CT orientation: HeadFirstSupine, matches the plan orientation: HeadFirstSupine
Pass	Plan name does not contain special characters
Alert	the max dose is 112.5% and greater than 110%
Info	The plan normalizaiton mode is: 100.00% covers 95.00% of Target Volume
Info	The target volume is: PTV_50.4
Pass	Correct grid size,2.5 mm, selected
Pass	The user origin is (0.90, 1.36, 72.50) and has been adjusted by the planner
Pass	Heterogeneity Correction is ON
Pass	The CT slice thickness of 1.142578 mm is valid
Pass	the calculation algorithm,AAA_GBDs_13714, is correct for photons

Result	Beam Information
Pass	All beam X and Y jaw sizes are above minimum value of 3.0 cm
Pass	All Field couch tolerance tables: Pelvis/Abdomen, are set correctly for Pelvis
Pass	All Arc field collimator angles are non-zero
Pass	All beam names do not contain special characters
Fail	All Arc field X jaw sizes are not less than the 18 cm max
Pass	The field name is 1 CW PELVIS and the gantry direction is Clockwise
Fail	The field name is 2 CCW PELVIS and the gantry direction is Clockwise
Pass	the beam isocenters X:2.30 Y:-0.86 Z:45.00 all match
Pass	Beam dose rates are 600 or greater

Simplification and standardization

"[The literature] suggests several process design principles that make errors less likely. He recommends avoiding wide and deep task structures. **The term "wide structures" means that there are lots of alternatives for a given choice, while "deep structures" means that the process requires a long series of choices.** Humans can perform either moderately broad or moderately deep task structures relatively well. Humans have more difficulty if tasks are both moderately broad and moderately deep, meaning there are lots of alternatives for each choice, and many choices to be made. **Task structures that are very broad or very deep can also cause difficulties.**"

- Grout, J (2007)[10]

Forcing functions and constraints

Difficult application to radiotherapy since the system must have enough flexibility to accommodate highly unique treatments and multiple modalities.

- **Vendor-driven interlocks and data-integrity interlocks: highly specific to single failure modes**
- **Gating devices, such as SGRT**
- **Password protection**
- **Accessory uniqueness and non-interchangability**
- **How can we expand forcing functions and constraints to make errors *impossible?***

Make Prospective Risk Assessment Your New Safety Paradigm

We have enough data and guidelines – over a decade of recommendations!

- **Even for the busy clinical professional, none of these quality management techniques are beyond your grasp, especially if you assemble a team.**
- **Take the initiative to move beyond a reactive system of addressing singular issues**

References

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