

# AAPM Safety Certificate Course The Quality Gap Lessons Learned: Clinical Trials and Operations

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- I have no financial disclosures

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## Outcomes Data from Safety/Quality interventions in other Specialties

- Keystone Intensive care unit project, decreased central line infections<sup>1</sup>
- Safe surgery saves lives study group: introduction of surgical safety checklist reduced morbidity and mortality<sup>2</sup>

• 1 Pronovost, Am J Infect Control 2008; 2 Gawande, NEJM 2009

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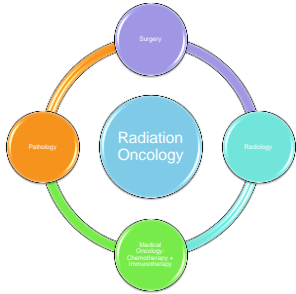
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## Measuring Quality in Radiation Oncology




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## Challenges in measuring oncology outcomes data from safety + quality interventions

- What's the endpoint?
- "Tainting" of survival by multimodality therapy
- Time to data accumulation
- Variety of diseases treated
- Numbers of patients with error; magnitude of error

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## What is Quality? Quality Standards in Radiation Medicine

454 standards identified from 8 publications. 20 classifications.

According to this...

Running a quality program is complex

- pro, donaldson/duncombe 2014

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But simply, according to AHRQ

"Quality health care means doing the right thing at the right time in the right way for the right person and having the best results possible."

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So...

- Quality healthcare is intrinsically safe health care.
- Improvements in safety are always improvements in quality as they enhance our ability to execute the prescription of radiation as it was intended.

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Spectrum of Errors: Plan versus Delivery

	Therapeutic prescription is perfect	
	No	yes
Therapy delivered as prescribed	No	Yes

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**Spectrum of Errors: Plan versus Delivery**

	Therapeutic prescription is perfect		
		No	yes
Therapy delivered as prescribed	No	Inaccurate, not quality	
	Yes		

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**Spectrum of Errors: Plan versus Delivery**

	Therapeutic prescription is perfect		
		No	yes
Therapy delivered as prescribed	No	Inaccurate, not quality	Inaccurate, quality compromised
	Yes		

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**Spectrum of Errors: Plan versus Delivery**

	Therapeutic prescription is perfect		
		No	yes
Therapy delivered as prescribed	No	Inaccurate, not quality	Inaccurate, quality compromised
	Yes	Accurate but not high quality	

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**Spectrum of Errors: Plan versus Delivery**

	Therapeutic prescription is perfect		
		No	yes
Therapy delivered as prescribed	No	Inaccurate, not quality	Inaccurate, quality compromised
	Yes	Accurate but not high quality	Quality care

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As physicians & physicists, our responsibility is to optimize delivery

Quality:

Right Person

Right Procedure/Intervention

Right Time

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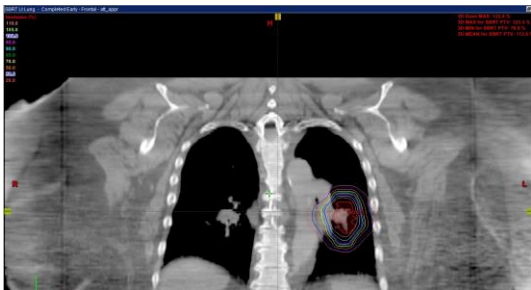
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Right Person! Right Time! Right Thing! In the wrong way



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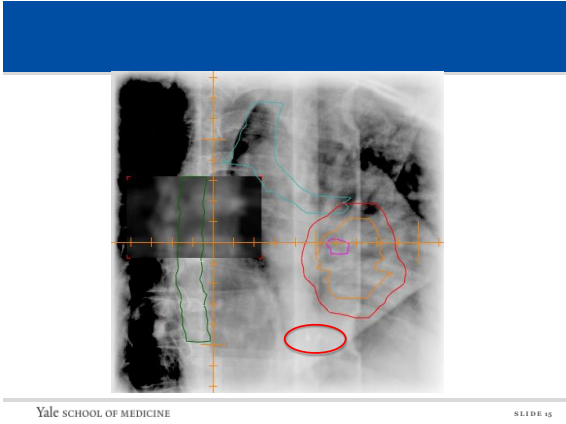
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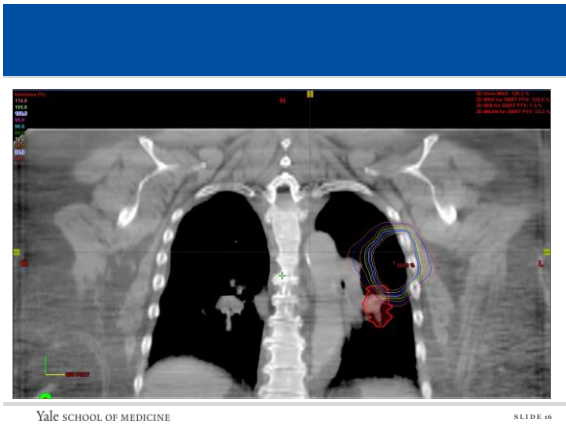
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How often does error happen in daily practice?

- Incidents in radiation oncology are not uncommon.
- Rate of errors: 1/600 <sup>1</sup>
- 0.7% incident rate, 0.014% non minor<sup>2</sup> (5% threshold)

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<sup>1</sup> Ford, Int J Radiat Oncol Biol Phys 2010 <sup>2</sup> Clark, Radiat Oncol. 2013  
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Data regarding incidence of delivery error and outcomes not readily available

- However, RT QA is well documented in many clinical trials
- Incidence of Protocol variations
- Relationship between Protocol Variations & Overall Survival

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What are the protocol variations captured?

- Typically incorrect segmentation
- Incorrect field Design
- Incorrect dose
- Issues of Geometric miss & improper dosing

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Hodgkin's disease

Protocol Deviations	
Correction of disease involvement	49% early stage 67% intermediate stage
Required Enlargement of RT volume	34%

\*Centralized radiation oncologic review of cross-sectional imaging of Hodgkin's disease leads to significant changes in required involved field-results of a quality assurance program of the German Hodgkin Study Group." UROBP 2004

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## EORTC Dummy Run

<b>Trial</b>	<b>Rate of Major Deviations</b>
Prostate Salvage <sup>1</sup>	70%
EORTC 22042 Meningioma <sup>2</sup>	25%
EORTC AMAROS trial 10981/22023 Breast <sup>3</sup>	50%

<sup>1</sup>Use of EORTC target definition guidelines for dose-intensified salvage radiation therapy for recurrent prostate cancer: results of the quality assurance program of the randomized trial SAKK 0910. (JROBP 2013)  
<sup>2</sup>Quality assurance of radiotherapy in the ongoing EORTC 22042-20042 trial for atypical and malignant meningiomas: results from the dummy runs and prospective individual case Reviews. (radiat oncol 2013)  
<sup>3</sup>Quality assurance of axillary radiotherapy in the EORTC AMAROS trial 10981/22023: the dummy run. Radiat oncol 2003

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OK, so there were protocol variations. What does that mean?

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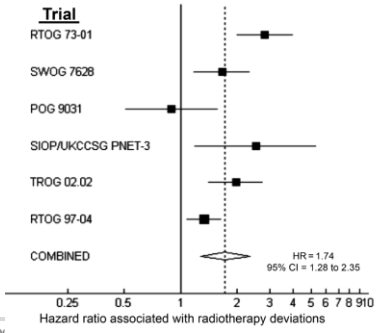
<b>Trial</b>	<b>major protocol deviations</b>	<b>Survival in Protocol Deviations</b>
NSCLC <sup>1</sup>	31%	13% decrement in survival
Head and Neck <sup>2</sup>	25%	HR 1.99 for death(p<0.001)
Pancreas <sup>3</sup>	48%	HR 1.336 for death (p=0.0077)
Meta-analysis <sup>4</sup>	32% (range 8-71)	HR 1.74 for death (p<0.001)

<sup>1</sup>; Perez Ca 1982; <sup>2</sup>; Peters JCO 2009; <sup>3</sup>; Abrams JROBP 2012; <sup>4</sup>; Ohri JNCJ 2013

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Overall Survival and Protocol Variation



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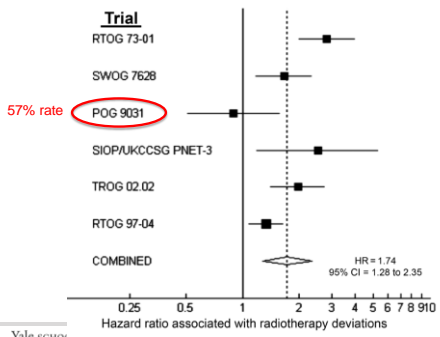
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Overall Survival and Protocol Variation



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Fairchild et al: "Does quality of radiation therapy predict outcomes of multicenter cooperative group trials? A literature review.

- 17 trials evaluated:
- Fourteen trials reported loco-regional failure rates (+/- distant)
  - In seven, these were significantly higher when RT was judged to be inadequate
- Progression free survival was examined in five trials
  - In two, there was significantly worse PFS in patients with poor quality RT

IJROBP 2013 Oct 1;87(2):246-60.

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Fairchild et al: "Does quality of radiation therapy predict outcomes of multicenter cooperative group trials? A literature review."

Nine trials examined the correlation of adequacy of RT with overall survival:

- five suggested that compliant RT significantly increased OS

IJROBP 2013 Oct 1;87(2):246-60.

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Weber et al. "QA makes a clinical trial stronger: evidence-based medicine in radiation therapy."

	Major Deviations (n)%	Relevant outcome
RTOG 0411	13 (13.4)	Grade GI $\geq$ 3 toxicity with D:45% vs. Grade GI $\geq$ 3 toxicity without D:18%

Radiother Oncol. 2012 Oct;105(1):4-8.

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Weber et al. "QA makes a clinical trial stronger: evidence-based medicine in radiation therapy."

	Major Deviations (n)%	Relevant outcome
RTOG 0022	6(11.0)	LRF with major D: 50% 0.04 vs. LRF with no major D: 6%

Radiother Oncol. 2012 Oct;105(1):4-8.

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Weber et al. "QA makes a clinical trial stronger: evidence-based medicine in radiation therapy."

	Major Deviations (n)%	Relevant outcome
HD 4	141 (37.5)	7-year RFS with D: 72% vs. 7-year RFS with no D: 84%
EORTC 20884	63 (46.7)	5-year RFS with D: 90% vs. 5-year RFS without D: 84%

Radiother. Oncol. 2012; Sep 14.

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Weber et al. "QA makes a clinical trial stronger: evidence-based medicine in radiation therapy."

	Major Deviations (n)%	Relevant outcome
RTOG 9704	200 (48.0)	mOS with D: 1.46 yo 0.008 vs. mOS without D: 1.74 yo
TROG 0202	97 (11.8)	OS with major D: 70% <0.001 vs. OS without major D: 50%

Radiother. Oncol. 2012 Oct;105(1):4-8. Yale SCHOOL OF MEDICINE SLIDE 34

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Why is this inconsistent?

- In order for local therapy to have a benefit in survival the following conditions must be met:
  - The therapy must be effective
  - There must be a sufficient risk of failure without treatment
  - They must not die of metastatic or comorbid disease
    - Inherent low risk of metastases
    - Effective systemic therapy

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Quality of radiation oncology MATTERS

- Quality of radiation oncology MATTERS

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Lessons Learned: OPERATIONS

- What happens to institutions that engage in continuous quality improvement??
- (data shown: experience with incident learning)

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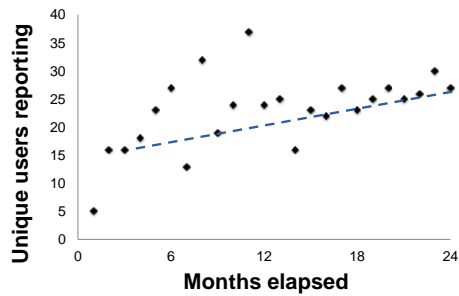
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Staff Engagement (courtesy Eric Ford)




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### Safety Culture (courtesy Eric Ford)

	2012	2013	2014
In this unit, we discuss ways to prevent errors from happening again	66%	81%*	86%*
After we make changes to improve patient safety we evaluate their effectiveness.	46%	66%*	64%*
I have confidence that my error/near miss reports get used to improve our system.	53%	74%*	76%*

\* p < 0.01

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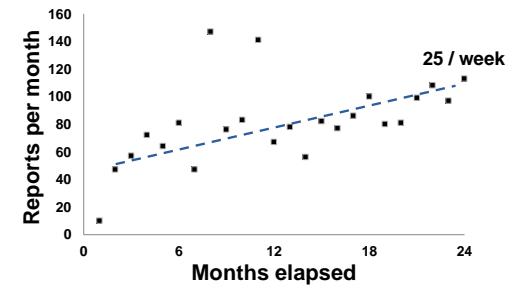
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### Reporting Volume (Courtesy Eric Ford)



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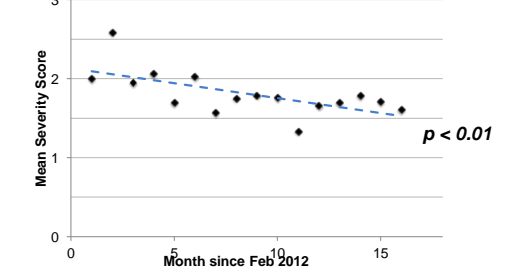
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### Severity of Reports (courtesy Eric Ford)



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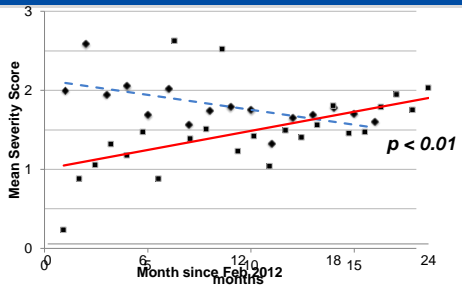
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### Overlay Severity/reporting volume



Zeng et al. 2014

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### Summary:

- Safety matters, Quality matters
- Measurements of Safety culture improve
- Severity of incidents reported \*may\* decrease

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