



Prospective Risk Management in the Wild
Tales from an Academic Medical Center

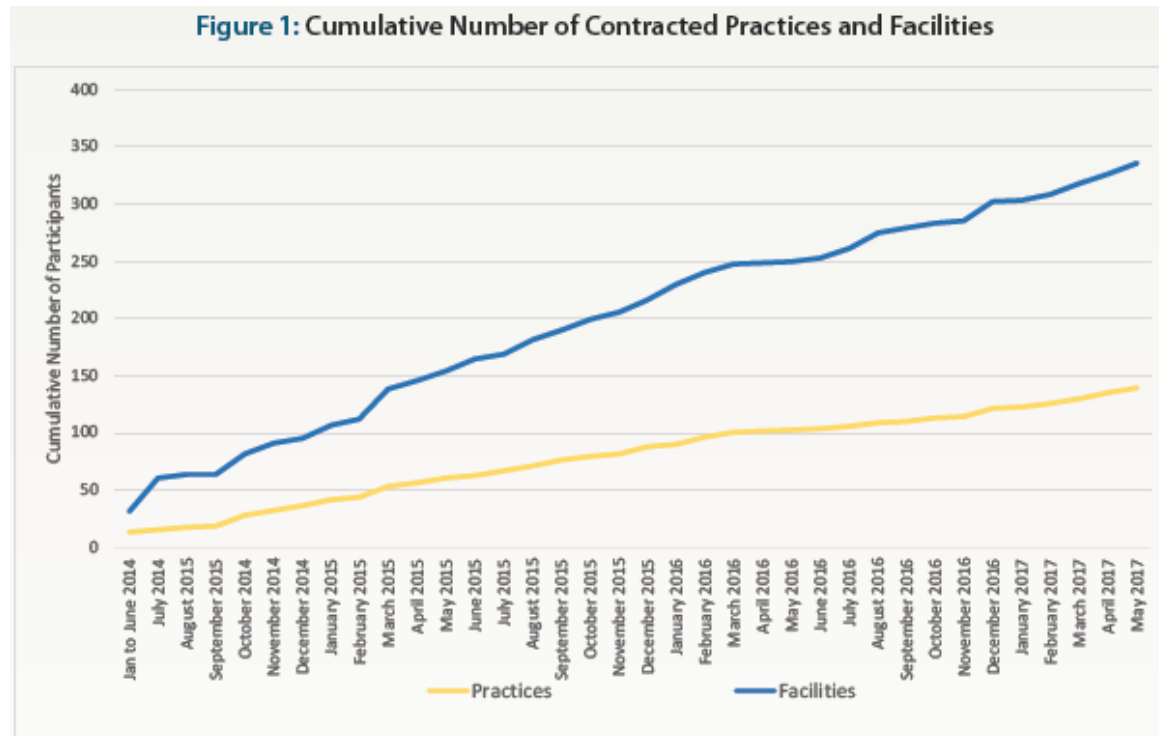
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RADIATION ONCOLOGY

Introduction – Prospective Risk Management in RadOnc

- Moving from reactive to proactive
 - Safety is No Accident : A framework for quality radiation oncology and care (2012)
 - RO-ILS: Radiation Oncology Incident Learning System (launched 2014)
 - TG-100: Application of risk analysis methods to radiation therapy quality improvement (2016)

Introduction – Prospective Risk Management in RadOnc

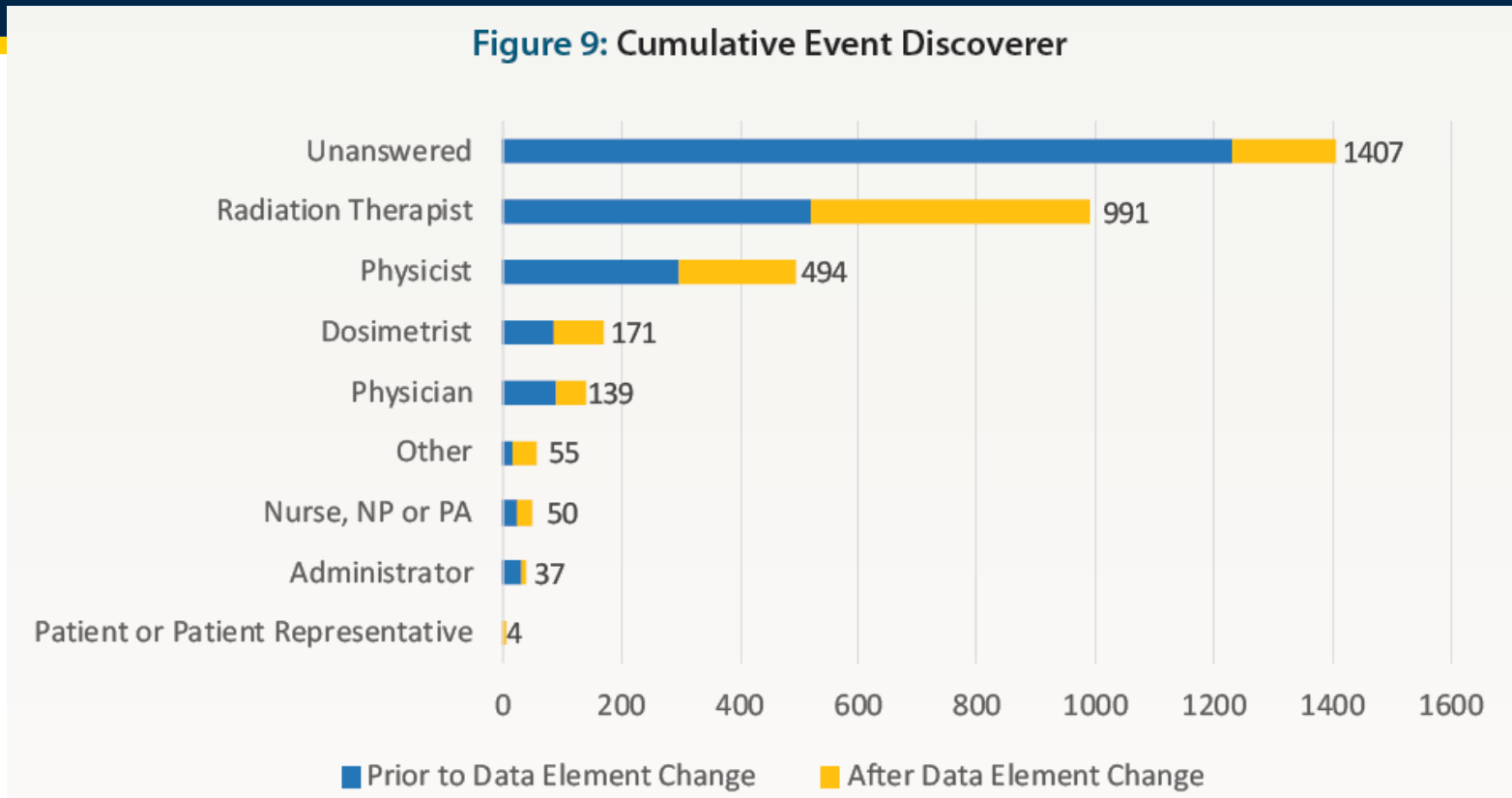


RO-ILS participation since inception

American Society for Radiation Oncology. RO-ILS® 2017 Year In Review.

https://www.astro.org/uploadedFiles/MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2017YearInReview.pdf. Published 2017. Accessed March 19, 2018.

Introduction – Prospective Risk Management in RadOnc



Event Discoverers

American Society for Radiation Oncology. RO-ILS® 2017 Year In Review.

https://www.astro.org/uploadedFiles/MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2017YearInReview.pdf. Published 2017. Accessed March 19, 2018.



MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Introduction – Prospective Risk Management in RadOnc

- Specific examples of prospective risk management
 - Academic medical center (University of Michigan, Ann Arbor, MI)
 - Community practice (McKee Medical Center, Loveland, CO)
- Tips and tricks: what worked well and what didn't!
- Encouraging participation, cost/benefit analysis, improving process efficiency while maintaining the project benefits
- Learn by doing

Outline

- Two examples of prospective risk management in an academic hospital
 - Failure mode and effects analysis of a newly implemented microsphere brachytherapy technology
 - Implementation of ILS-based therapist pre-treatment chart review
- Practical aspects, challenges, cost/benefit analysis

Project One

FMEA of a newly implemented microsphere brachytherapy technology

www.sirtex.com

SIR-Spheres[®]
Y-90 resin microspheres



www.btg-im.com

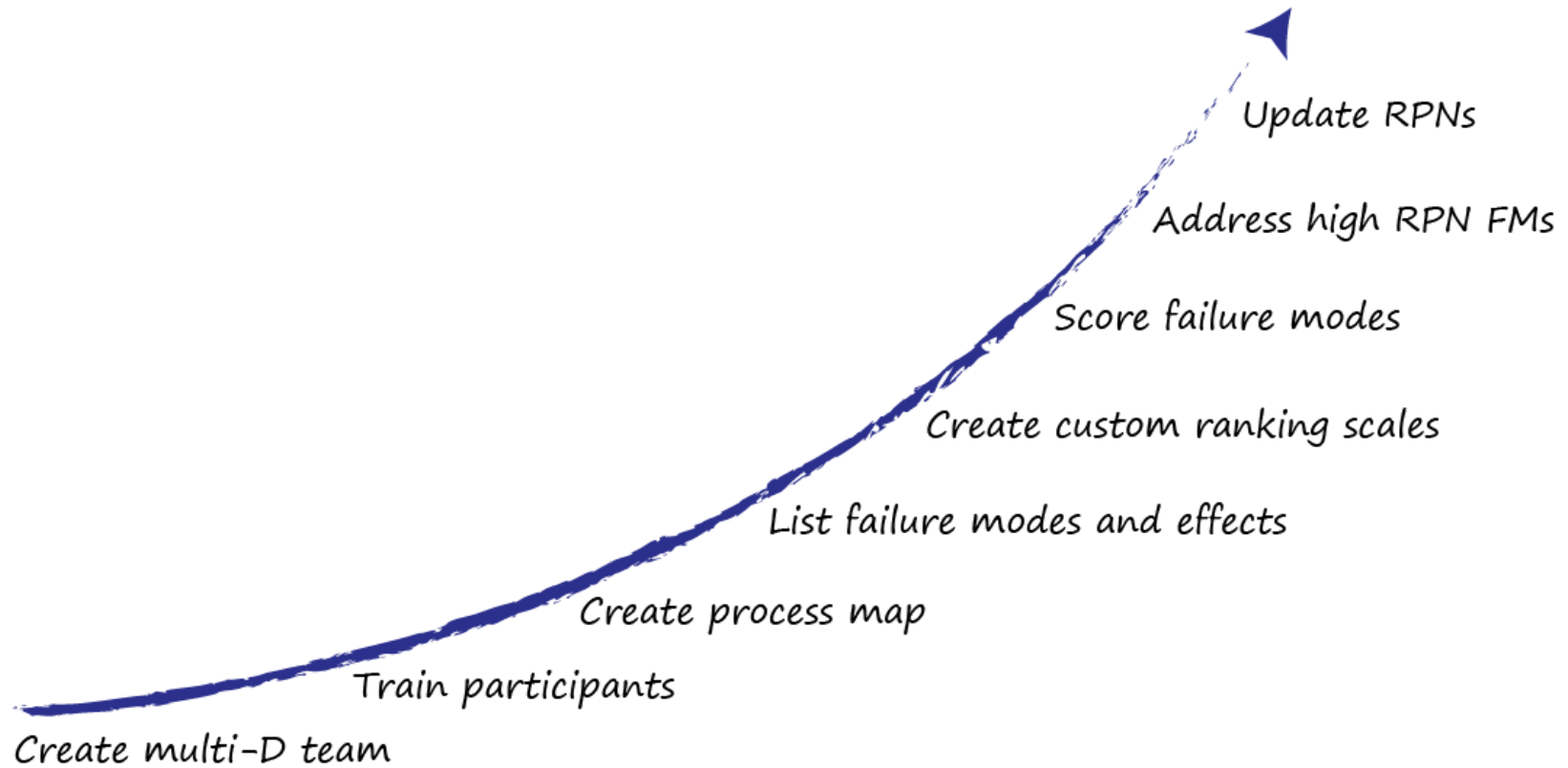
TheraSphere[®]



Background

- Ideal for new program or major change to program (implementing new technology)
 - Allows to start from scratch on QA program
 - Easier to motivate with team
 - New error pathways, opportunities for improved efficiency

FMEA takes a lot of effort...

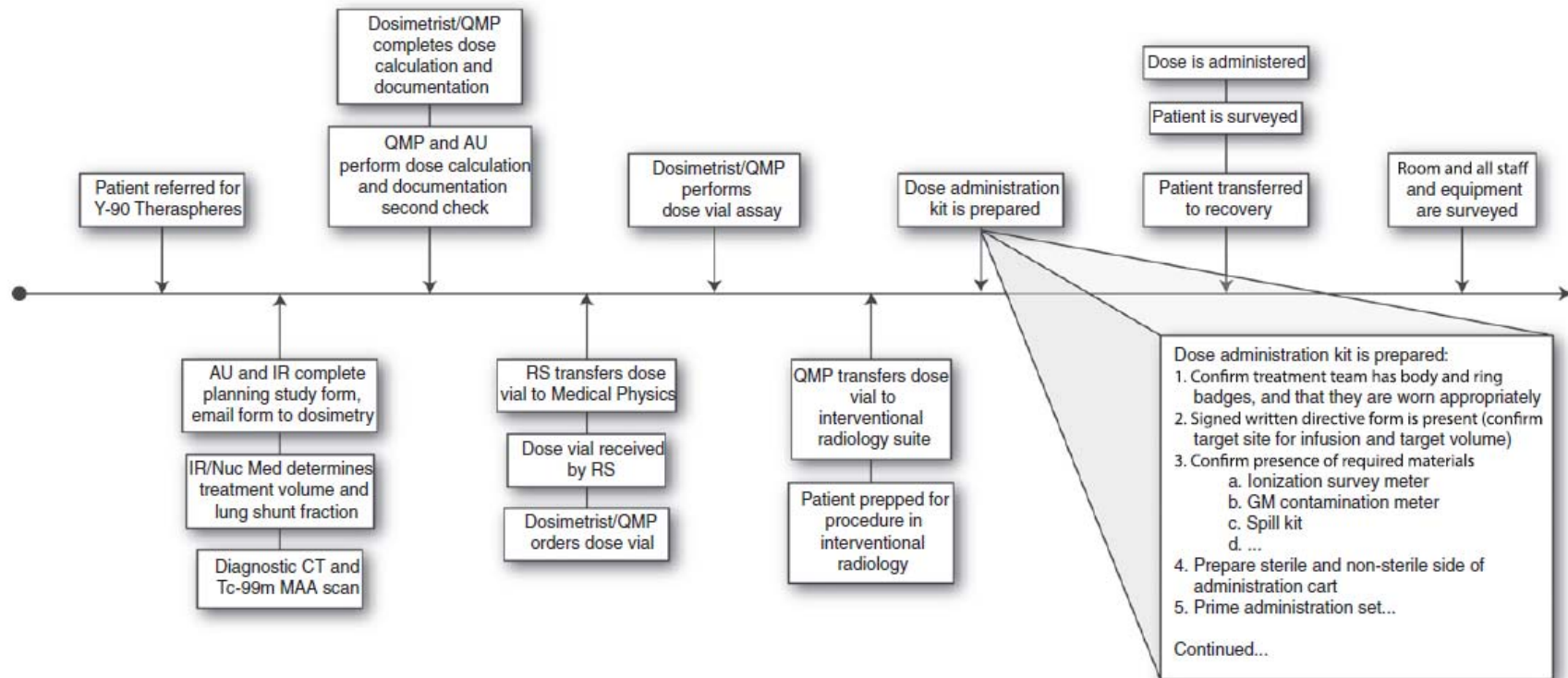


Things we learned...

- Be strategic about group vs individual work
- Rankings can be done more efficiently
 - H/M/L (but avoid bias)
 - Only need select people
- Motivate team members
 - Share the benefits early and often (safer patients, safer staff, improved efficiency, improved awareness of role)
 - Publications!

Younge et al., Practical implementation of failure mode and effects analysis for safety and efficiency in stereotactic radiosurgery. *Int J Radiat Oncol Biol Phys.* 91(5):1003-8 (2015).

High level process map – increasing awareness



Failure mode and effects analysis in a dual-product microsphere brachytherapy environment. *Pract Radiat Oncol.* 6(6):299-306 (2016).

How we are making our patients safer

Table 5 New RPNs for high-ranking failure modes after program improvements were made

Failure mode	Program change	S	O	D	RPN
Patient-related failure modes					
Error in dosimetry worksheet calculation (SIR-Spheres)	Expand monthly/annual QA and add hand calculations	8.5	5	4 (-3)	170 (-127.5)
Error in dosimetry worksheet calculation (TheraSphere)	Expand monthly/annual QA and add hand calculations	8.5	3	4 (-3)	102 (-76.5)
Incorrect target volume on planning study	Improve documentation and incorporate additional checks throughout workflow	9	5	2 (-1)	90 (-45)



Failure mode and effects analysis in a dual-product microsphere brachytherapy environment. *Pract Radiat Oncol.* 6(6):299-306 (2016).

How we are making YOU safer



Staff-related failure modes					
Slurry not removed before removing needle from dose vial (SIR-Spheres)	Add warnings to process checklist	3.5	4 (-3)	6	84 (-63)
V-vial septum integrity compromised (SIR-Spheres)	Add warnings to process checklist	4	4 (-1)	7	112 (-28)
Catheter disconnected from outlet line	Add warnings to process checklist	4	2 (-1)	9	72 (-36)

Failure mode and effects analysis in a dual-product microsphere brachytherapy environment. *Pract Radiat Oncol.* 6(6):299-306 (2016).

Other FMEA examples

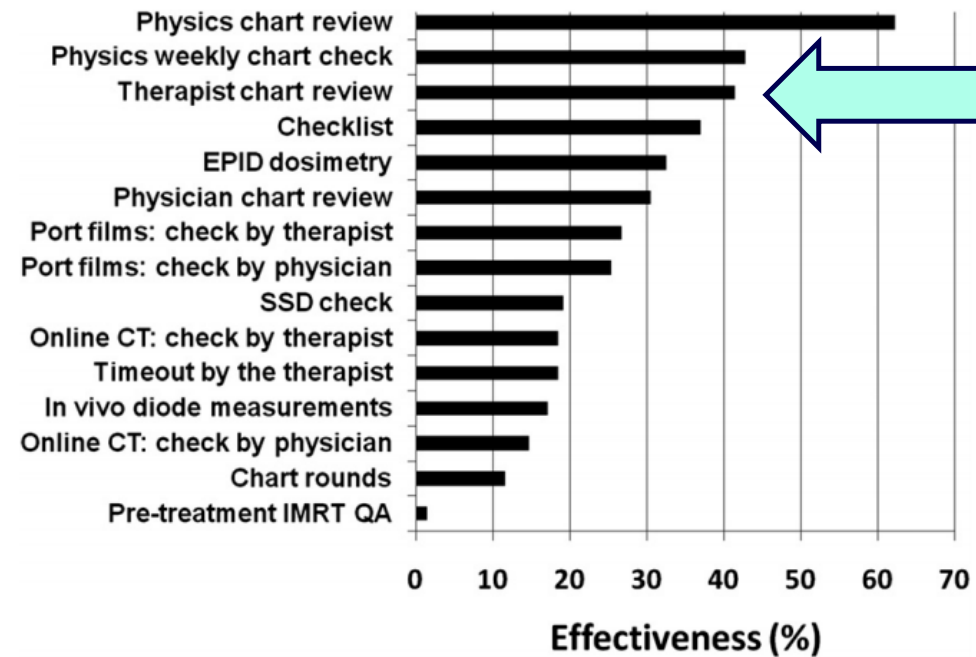
- Ford et al., A streamlined failure mode and effects analysis. Med Phys. 41(6):061709 (2014).
- Success factors
 - Support by local and health system department leadership
 - Clearly defined plan
 - Experienced / dedicated facilitator
 - Take-home assignments

Project Two

Implementation of a Formal Therapist Pre-treatment Chart Review

Therapist pre-treatment chart review

- #3 most effective to catch high severity incidents



Ford et al., Int J Radiation Oncol Biol Phys. 84(3):e263-269 (2012).

Therapist pre-treatment chart review

- #3 most effective to catch high severity incidents
- #1 check to have in place to catch low severity incidents
- Use UM in-house ILS to track related incidents

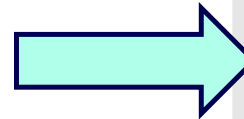


Table 4 Combinations of QC checks and associated error-detection effectiveness for low-severity incidents

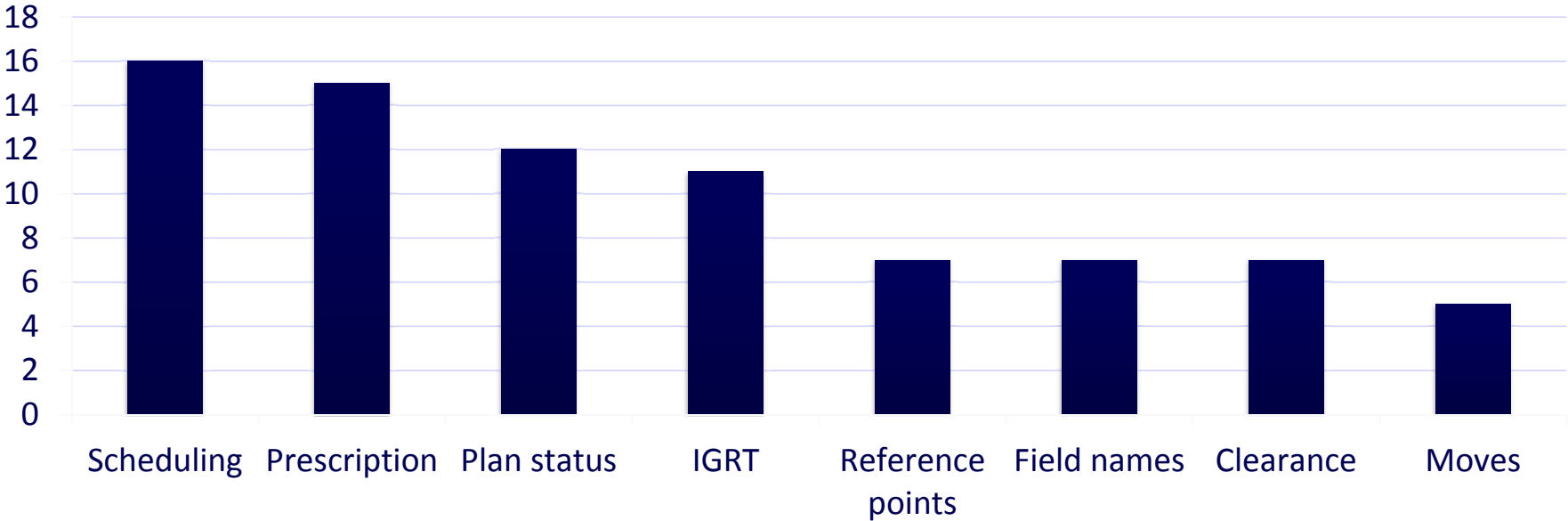
	No. of checks in combination				
	1	2	3	4	5
1. Physician chart review					#
2. Physics chart review			x	x	x
3. Therapist chart review	x	x	x	x	x
4. Pretreatment IMRT QA					
5. Chart rounds					#
6. Timeout by therapist		x	x	x	x
7. SSD check					
8. Port films: check by therapist					
9. Port films: check by physician					
10. Online CT: check by therapist					
11. Online CT: check by physician					
12. <i>In vivo</i> diode measurements				o	o
13. Physics weekly chart check				o	o
14. EPID dosimetry				o	o
15. Checklist					#
Effectiveness (%)	70	90	93	97	97

Abbreviations: CT = computed tomography; EPID = electronic portal imaging device; IMRT = intensity modulated radiation therapy; QA = quality assurance; QC = quality control; SSD = source-to-skin distance. The “o” and pound “#” indicate checks for which the effectiveness is the same regardless of which is used in combination.

Ford et al., *Int J Radiation Oncol Biol Phys*, 84 (3), e263-269 (2012)

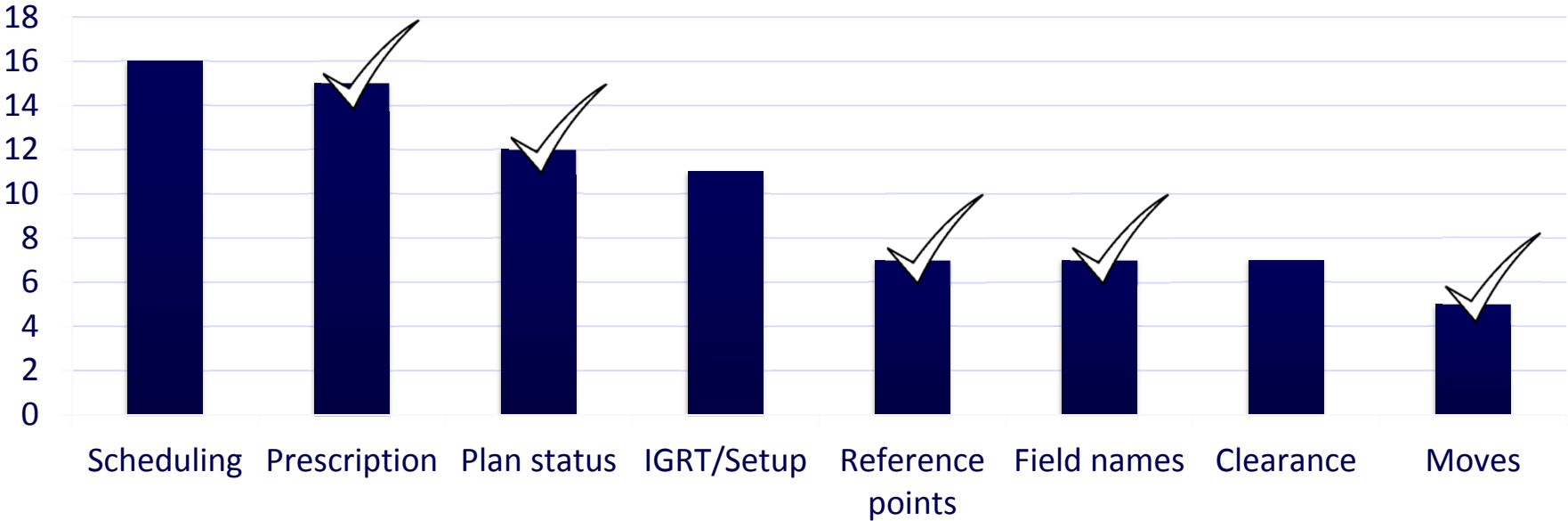
Error Tracking

Sources of Treatment Chart Errors



Error Tracking

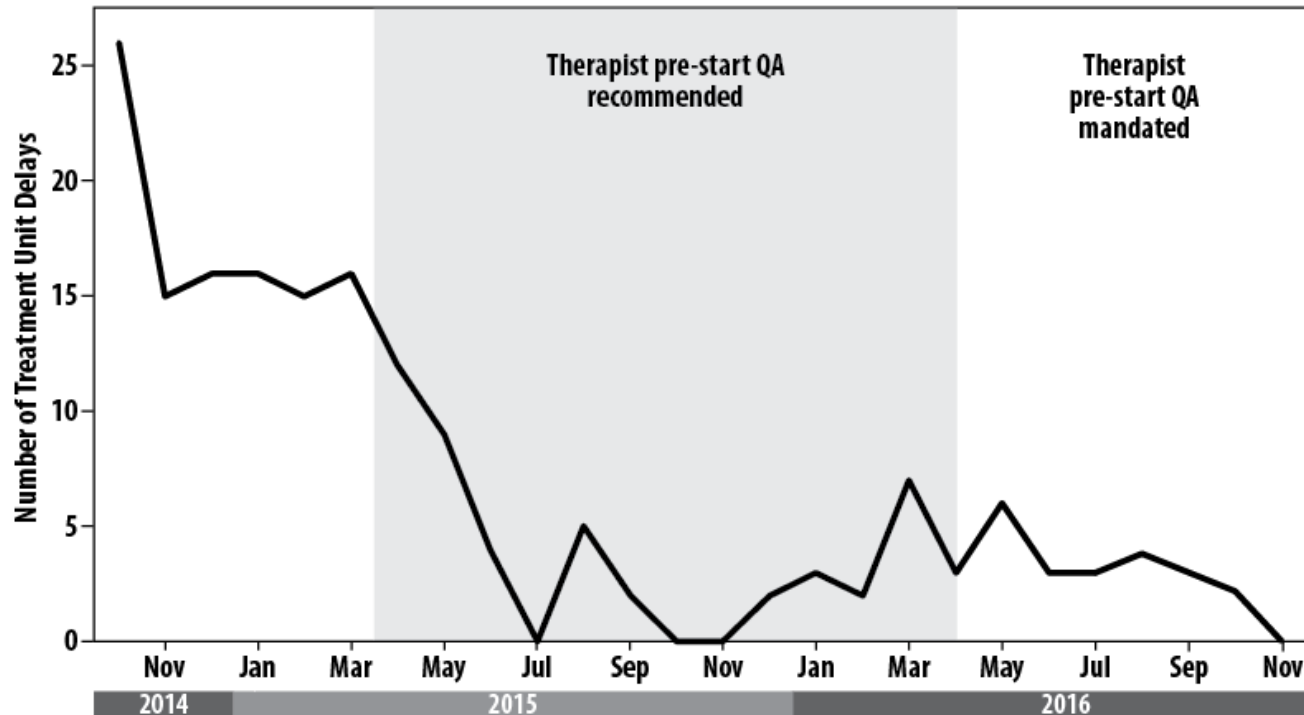
Sources of Treatment Chart Errors



Implementation of therapist pre-treatment chart review

Plan #'s Checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Script linked to and matches plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clear setup instructions (photo, dosim moves, bolus, cutout, consent)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Present and clear IGRT document	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Clear plan revision instructions	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Treatment related patient alerts and journal notes clear	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Laterality consistent on all documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Electron specific checks (docs, coding)	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Setup fields appropriate and labeled correctly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correct match anatomy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correct treatment field	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Implementation of therapist pre-treatment chart review



K. C. Younge et al.: Improving patient safety and workflow efficiency with standardized pre-treatment radiation therapist chart reviews *Practical Radiation Oncology* 7(5): 339-345, 2017.

Implementation of therapist pre-treatment chart review

1 delay ~ 10 minutes → 1 day



4.3 to 0.5 hr/month → 624 to 72 hr/month

- ✓ Eliminates delays propagated to other patients
- ✓ Eliminates time wasted by therapists, dosimetrists, physicists, physicians

K. C. Younge et al.: Improving patient safety and workflow efficiency with standardized pre-treatment radiation therapist chart reviews *Practical Radiation Oncology* 7(5): 339-345, 2017.

Difficulties in implementation

- Major change to workflow – therapists take ownership
- Major culture change / shift in outlook
 - “What are you doing with our reports?”
- How can we motivate team members?
 - Monthly data tracking
 - Continuous presentations to RTTs + Multi-D Groups
 - Adding automation upstream
 - Adjustments of checklist as needed – make it easier



Conclusions and Final Thoughts

- Microsphere FMEA
 - Major cost / hurdle: time and effort
 - Major benefits: patient and staff safety, workflow efficiency
- Therapist pre-treatment QA
 - Major cost: staff dissatisfaction with workflow change
 - Major benefits: patient safety, reduced treatment unit delays
- Learn by doing!