FMEA Analysis of TG-142

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Acknowledgements

- Thanks to Dr. Fang-Fang Yin and all of the physicists at Duke University Medical Center for many useful conversations regarding both FMEA and TG-142.

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Task Group 142

- Multitude of linear accelerator quality assurance tasks
- Prescribed acceptance limits and testing frequency

TABLE I. Daily.

Procedure	Machine-type tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy (all energies)			
Electron output constancy (weekly, except for machines with unique e-monitoring requiring daily)		3%	
Mechanical			
Laser localization	2 mm	1.5 mm	1 mm
Distance indicator (ODI) @ iso	2 mm	2 mm	2 mm
Collimator size indicator	2 mm	2 mm	1 mm
Safety			
Door interlock (beam off)		Functional	
Door closing safety		Functional	
Audiovisual monitor(s)		Functional	
Stereotactic interlocks (lockout)	NA	NA	Functional
Radiation area monitor (if used)		Functional	
Beam on indicator		Functional	

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Institution-specific TG142?

- "Institutional deviations from some of these recommendations are expected based upon the institution's policy and procedures…"
- To change the frequency of a particular test:
  - Review an appreciable history of results
  - Consider the potential impact of failure
  - Perform an FMEA analysis

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Failure-Mode & Effects Analysis

- Create a process map
- Identify weak points
- Score each weak point
  - Occurrence = frequency of failure
  - Severity = effect of failure
  - Detectability = probability of not detecting the failure
- Rank and prioritize by score
  - RPN = risk priority number = O*S*D
- Develop mitigation strategies

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S Huq et al, IJROBP 71, 2008
E Ford et al, IJROBP 74, 2009

TG100 FMEA analysis of IMRT

- Human error (44%)
  - Human failure
  - Inadequate training
  - Lack of communication
- Inadequate procedures/resources (31%)
- Hardware/software failures (13%)
- Design or commissioning failure (8%)
- Others (4%)

Saiful Huq, New paradigms for quality management in radiation therapy. Presentation at 2011 AAPM summer school. AAPM Virtual Library.

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Top ten failure modes of external beam radiotherapy

Ford et al, Med. Phys. 41, (2014);

Failure mode	Cause	Process step	S	O	D	RPN
Delay in film check.	Films not assigned to physician in queue.	Tx delivery	8	10	5	400
No pacemaker protocol/consent for patient with a pacemaker.	Simulation staff did not check H&P or query patient.	Simulation	10	5	5	250
Critical structure not contoured in treatment planning system.	Oversight of physician.	Tx planning	10	4	6	240
Pregnant patient simulated without the team's knowledge of the pregnancy.	Patient does not know she is pregnant and/or was not asked. Unclear policy.	Simulation	10	2	10	200
Tomotherapy blocks turned off. Directional blocking for critical structure.	Oversight by physicist in planning.	Tx planning	5	3	10	150
RTT unaware of Rx or fractionation change, e.g., change when boost starts.	Communication lapse between teams.	On-Tx Mgmt	3	8	5	120
Unclear setup instructions from simulation, e.g., two scans performed. (Supine vs prone) for planning evaluation.	Communication lapse between teams as to final directives for setup.	Tx planning	4	5	6	120
Prior treatment records not available.	Chart archived offsite or patient arrives without records.	Pt assessment	10	2	5	100
Wrong couch kicks or table angles entered in R&V system.	Oversight of planner. Confusion due to different labeling conventions on different machines.	Tx planning	10	9	1	90
n contouring is	Communication lapse between teams.	Tx planning	10	3	3	90

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Top ten failure modes of External Beam Radiotherapy

Ford et al, Med. Phys. 41, (2014);

- Human error = 4
- Communication lapse = 3
- Policy not followed = 2
- Outside our realm of influence = 1
- Hardware/software errors = 0

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How to determine the relative importance of TG-142 tests?

- Determine detectability
- Determine failure rate
- Determine the underlying machine failure
  - Determine the severity if that failure should occur
- Account for frequency of test performance
  - % of time the failure was present over a course of treatment
  - Number of patients affected by the error

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Ranking: Detectability

Rank	Detectability: Estimated probability of the failure going undetected(%)
	TG100 and this study
1	<= 0.01%
2	<= 0.2%
3	<= 0.5%
4	<= 1.0%
5	<= 2.0%
6	<= 5.0%
7	<= 10%
8	<= 15%
	<= 20%
	> 20%

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Data: Occurrence

- Occurrence: 3 Varian 21EX linear accelerators x 3 years = 9 years
  - Daily, weekly, monthly & annual QA
  - Post-TG142 implementation
- 2,348 treatment days analyzed
- Minimum detectable occurrence rate = 0.04%

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Ranking: Occurrence

Rank	Occurrence: Frequency of Failure (%)	
	TG100	This study
1	<= 0.01%	<= 0.01%
2	<= 0.02%	> 0.043% (0/2348)
3	<= 0.05%	<= 0.043% (1/2348)
4	<= 0.1%	<= 0.1%
5	<= 0.2%	<= 0.2%
6	<= 0.5%	<= 0.5%
7	<= 1%	<= 1%
8	<= 2%	<= 2%
9	<= 5%	<= 5%
	> 5%	> 5%

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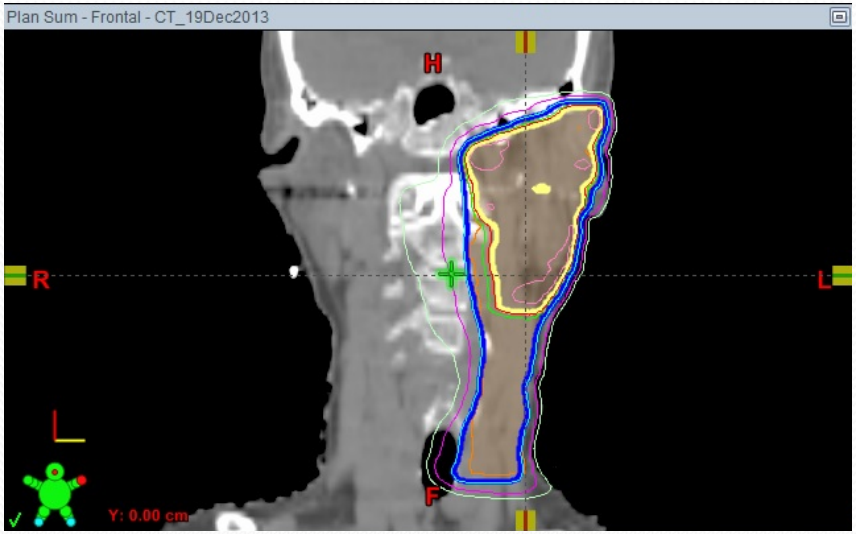
Data: Severity

- Severity: Model error in treatment planning system (Eclipse v11)
  - 10 head-and-neck IMRT patients
  - Primary PTV (40-50Gy) & boost PTV (50-70Gy)
  - Spinal cord



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Ranking: Severity

Rank	TG100	This study	
		Change in %-Volume of PTV at Rx Dose	Change in Maximum Dose to Cord
1	No effect	<= 1%	<= 45cGy (1%)
2	Inconvenience	<= 2%	<= 90cGy (2%)
3		<= 3%	<= 135cGy (3%)
4	Minor dosimetric error	<= 4%	<= 180cGy (4%)
5	Limited toxicity or tumor underdose	<= 5%	<= 225cGy (5%)
6		<= 10%	<= 450cGy (10%)
7	Potentially serious toxicity or tumor underdose	<= 15%	<= 675cGy (15%)
8		<= 20%	<= 900cGy (20%)
9	Potentially very serious toxicity or tumor underdose	> 20%	> 900cGy (20%)
10	Catastrophic	Medical Event	Medical Event

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Assumptions

- Routine preventative maintenance tasks are performed on schedule
  - E.g. Image quality is adjusted regularly (CBCT recalibrated annually, kV & MV dark/flood fields redone on a regular basis)
- When accidents/repairs/service occur, appropriate QA tasks are done afterwards.

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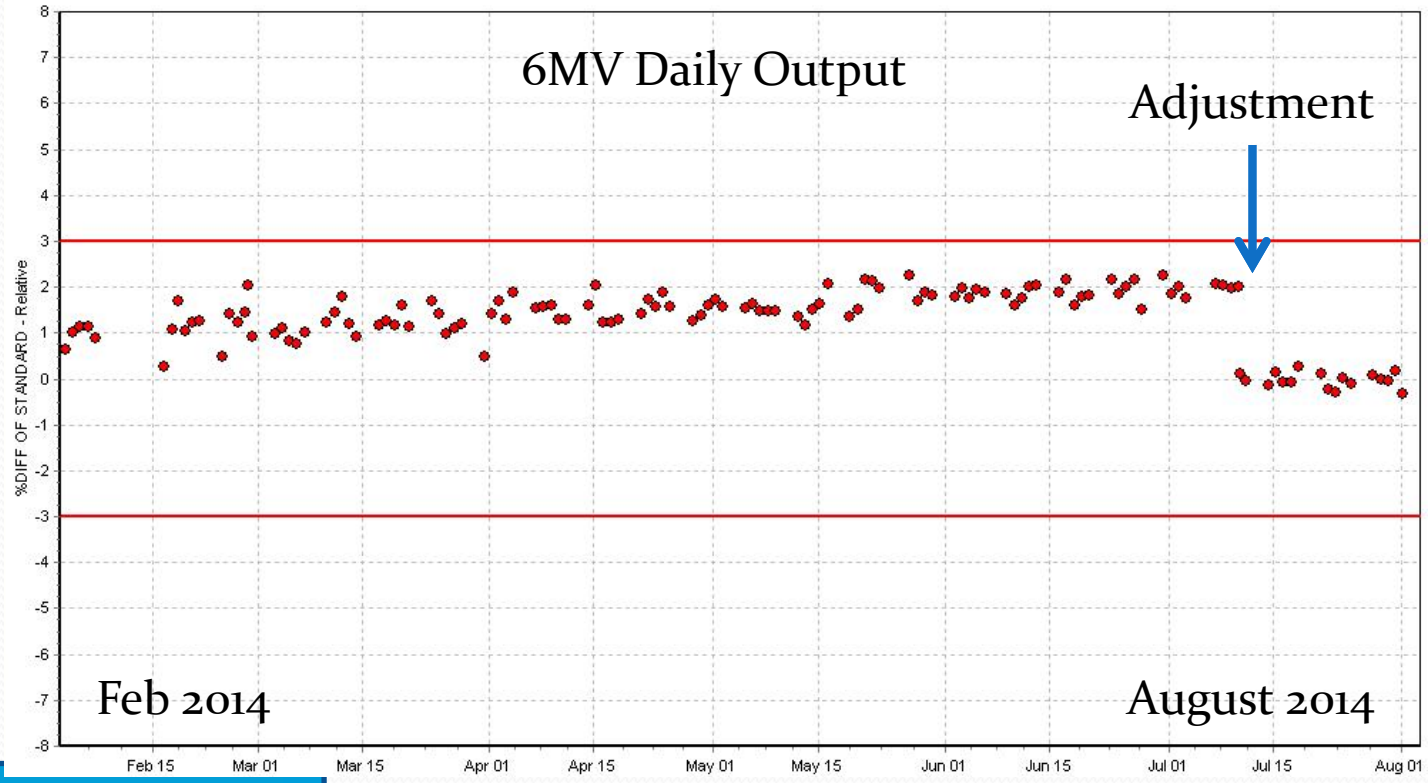
Assumptions: Drift

- Errors will be modeled at their tolerance limits.



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Analysis 1: Daily QA

1) Output (3%)
2) Laser localization (1.5mm)
3) ODI @ iso (2mm)
4) Jaws vs. light field (2mm)
5) MV/kV/CBCT: position/reposition (<= 2mm MV/kV; <= 1mm CBCT)
6) MV/kV/CBCT: imaging vs. treatment isocenter (<= 2mm)
7) Linac safety: door interlock, door operation, A/V, radiation area monitor, beam on indicator
8) Imaging safety: collision interlocks

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Occurrence: Daily QA

Daily QA Test	Number of Adjustments	Occurrence (% of total days of operation)
Output	86	3.7%
Laser	19	0.8%
CBCT Pos/Repos	10*	0.5%
ODI	2	0.09%
Jaws vs. Light Field	0	< 0.05%
kV/MV Pos/Repos	0	< 0.05%
Imaging vs. Tx Iso	0	< 0.05%
Imaging Safety	0	< 0.05%
Linac Safety	0	< 0.05%

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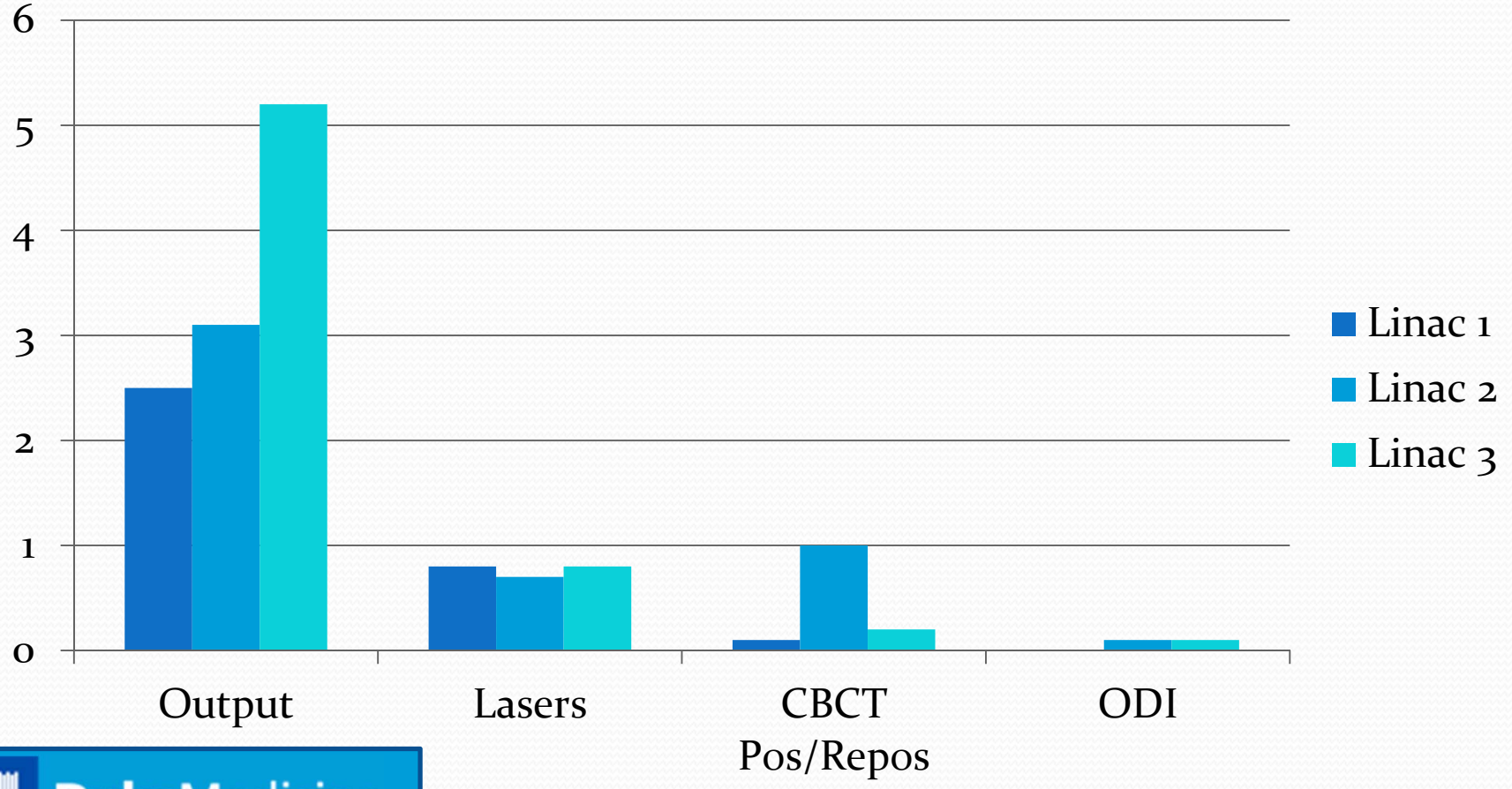
Occurrence: Daily QA



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Severity: Associated Errors

1) Output
2) Lasers
3) ODI
4) Jaws vs. LF
5) Imaging pos/repos
6) Imaging vs. tx isocenter
7) Linac safety
8) Imaging safety

1) Dose variation
2) 3D translational displacement (1.0mm, 1.5mm & 2.0mm)
3) A/P translational displacement
4) Jaw size change

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Linac and imaging safety

- Door interlock & closing safely -> irradiation of RTTs and other nearby personnel or patients
- A/V monitors -> safety of patient within room
- Beam-on indicator -> secondary safety check
- Imaging collision interlocks -> patient injury

- Conclusion: Perform daily.

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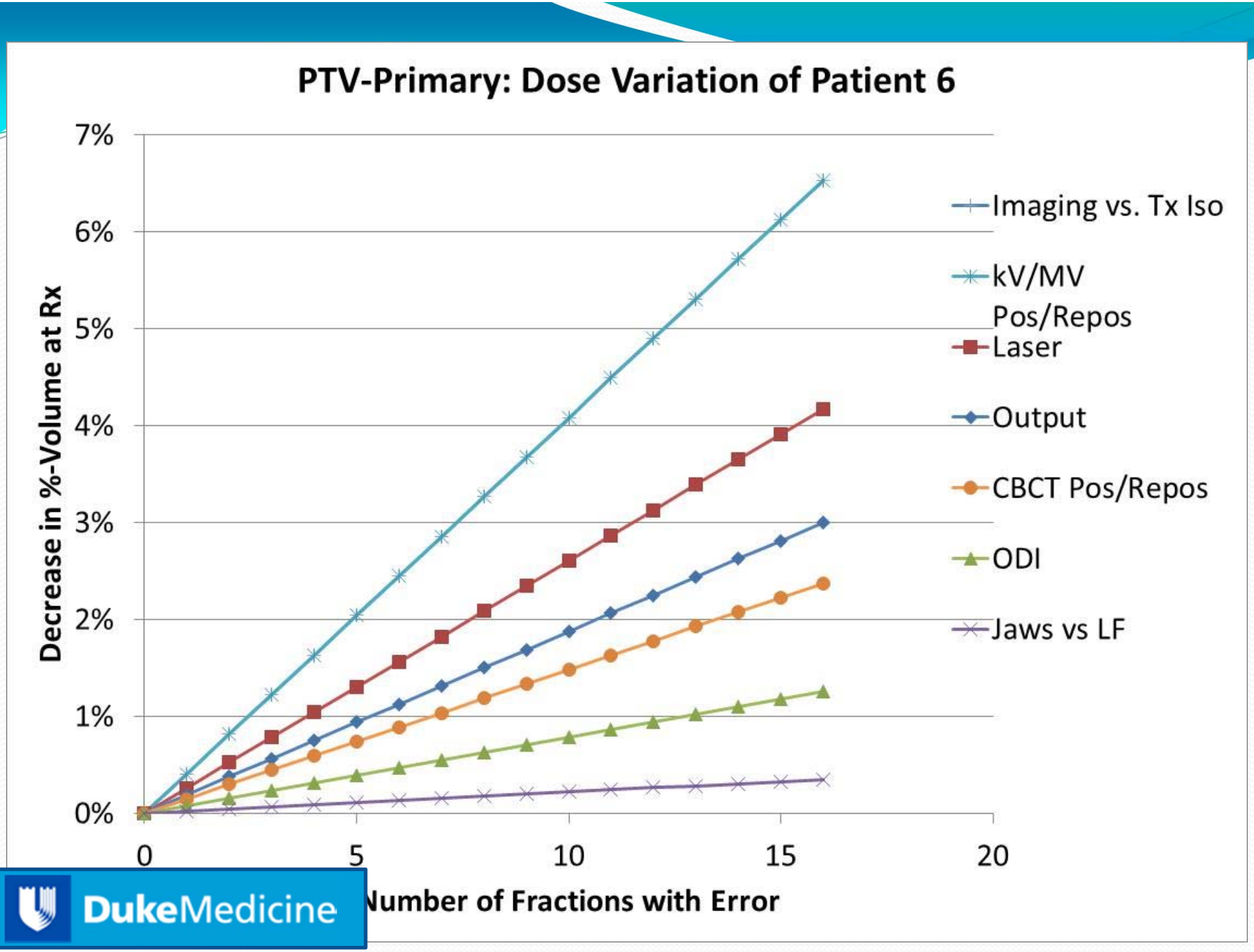

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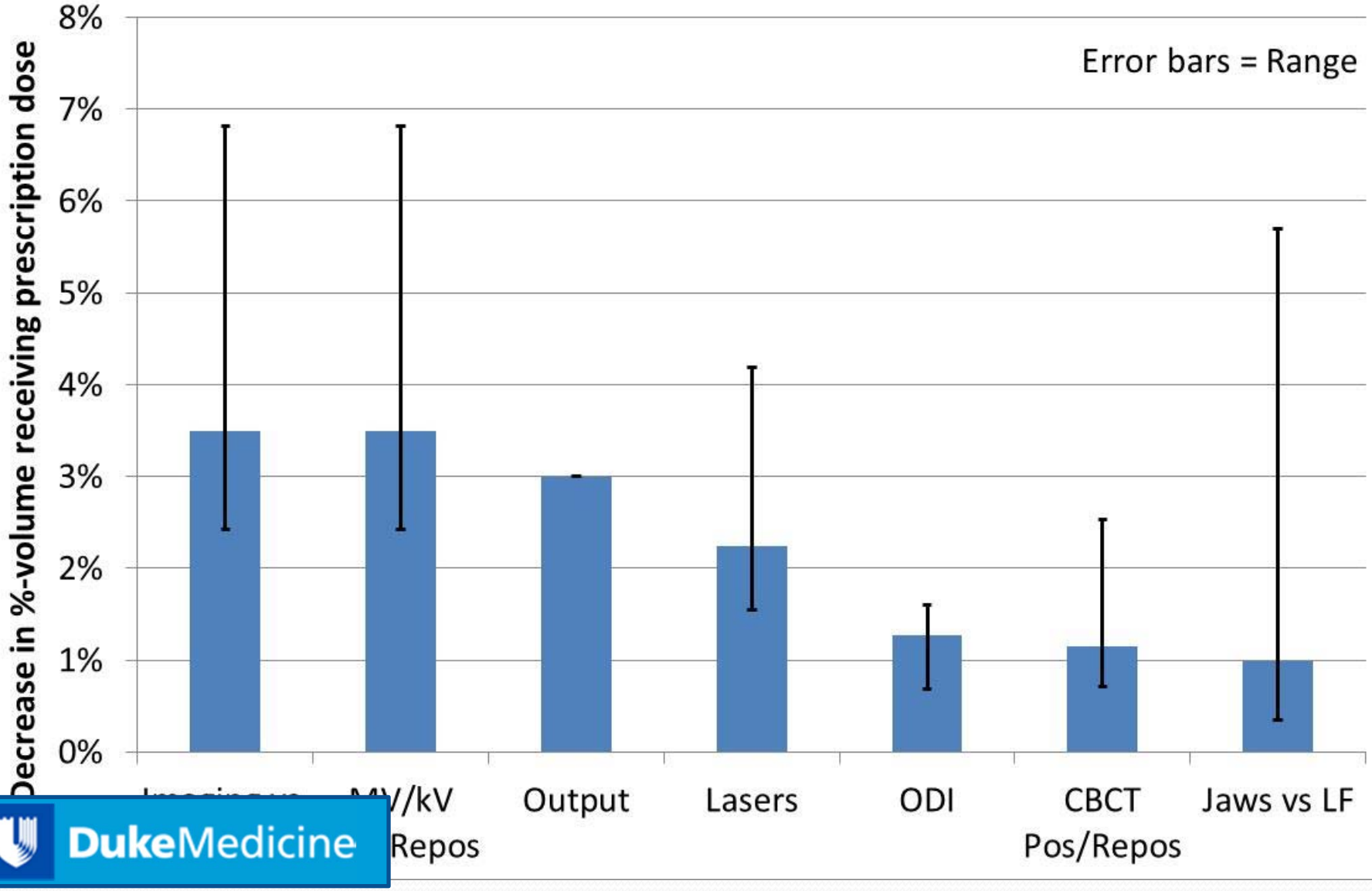
Median of 10 Patients: Decrease in %-Volume Coverage of Prescription Dose for PTV-Primary



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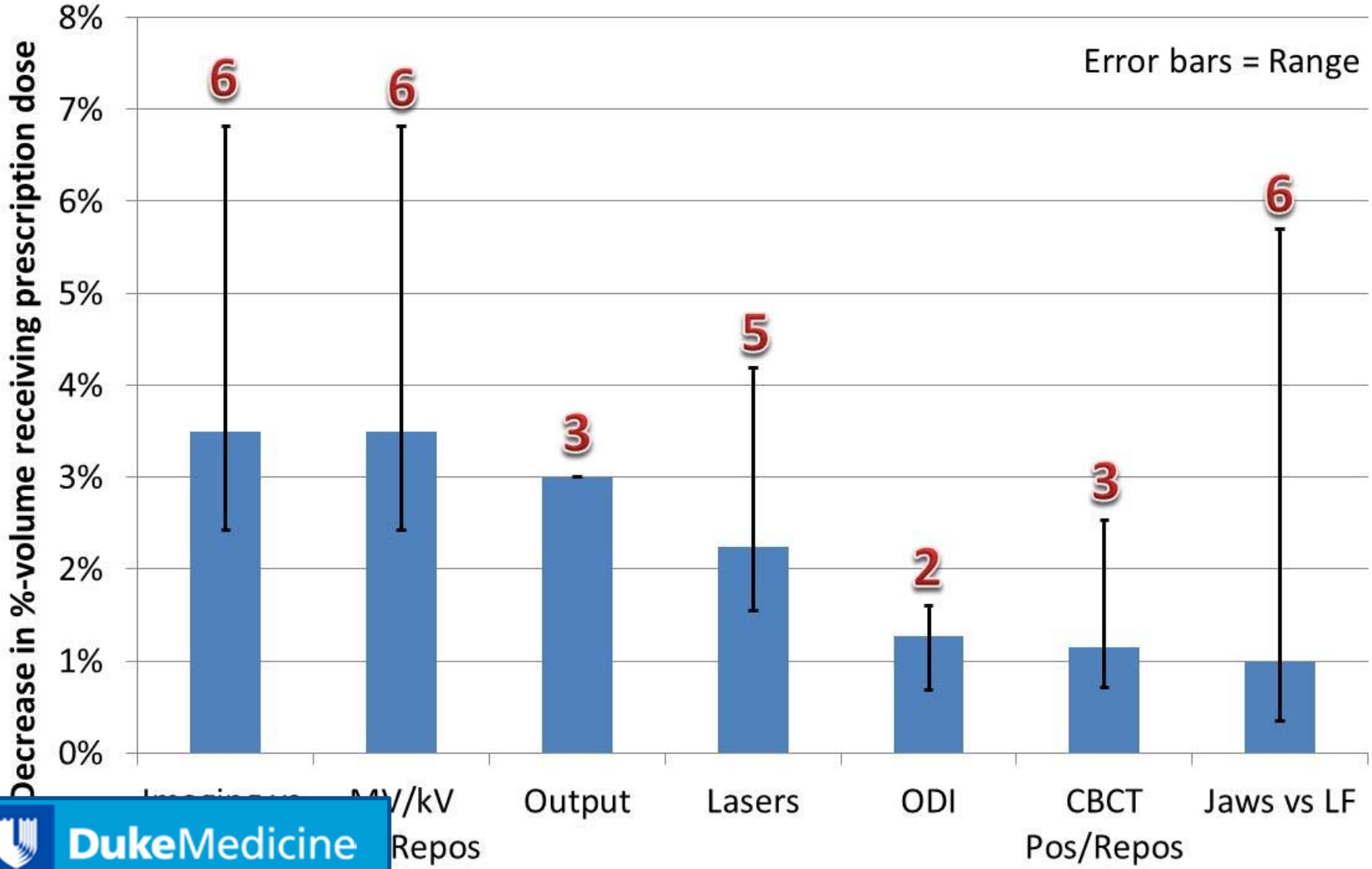

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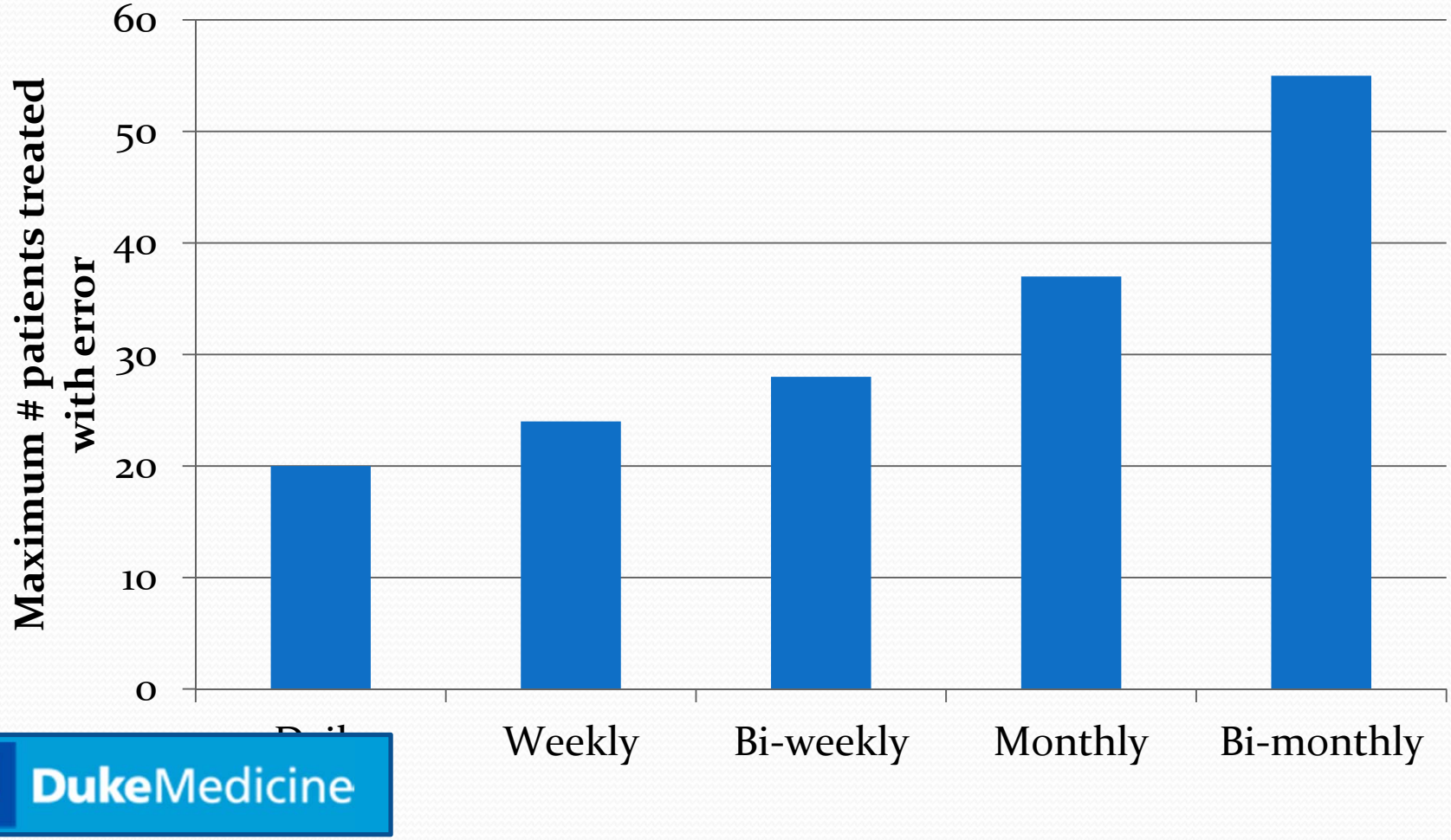
QA Frequency vs. Number of Patients



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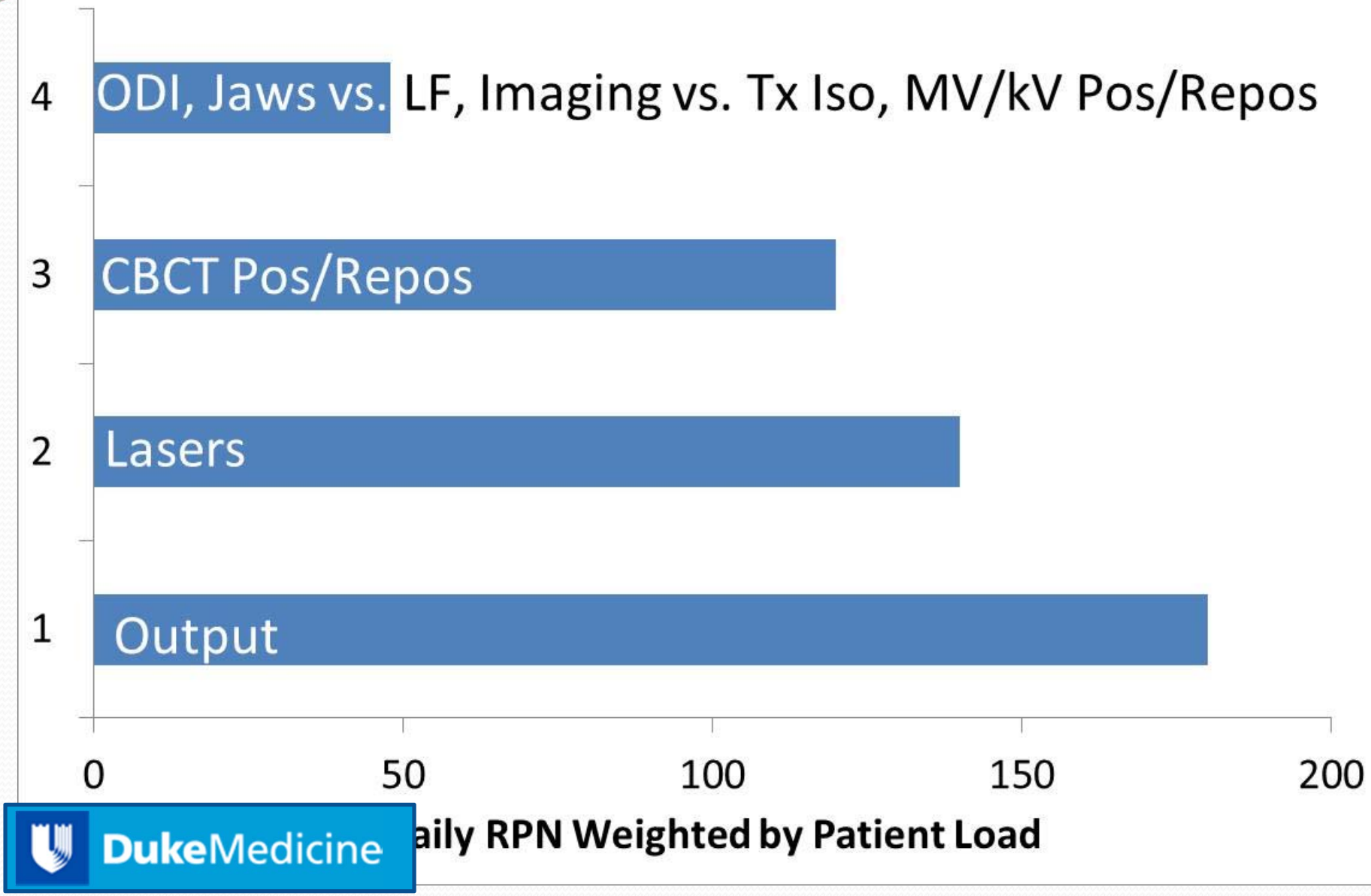
Daily QA Weighted RPN

	Daily	Weekly	Bi-weekly	Monthly	Bi-monthly
Output					
Lasers					
CBCT Pos/Repos					
Image Quality					
ODI					
Imaging vs. Tx Iso					
MV/kV Pos/Repos					
Jaws vs. LF					

Patient-Load-Weighted RPN: Occurrence * Severity (QA frequency) * Number of Patients Affected (QA frequency)

Daily QA Priorities



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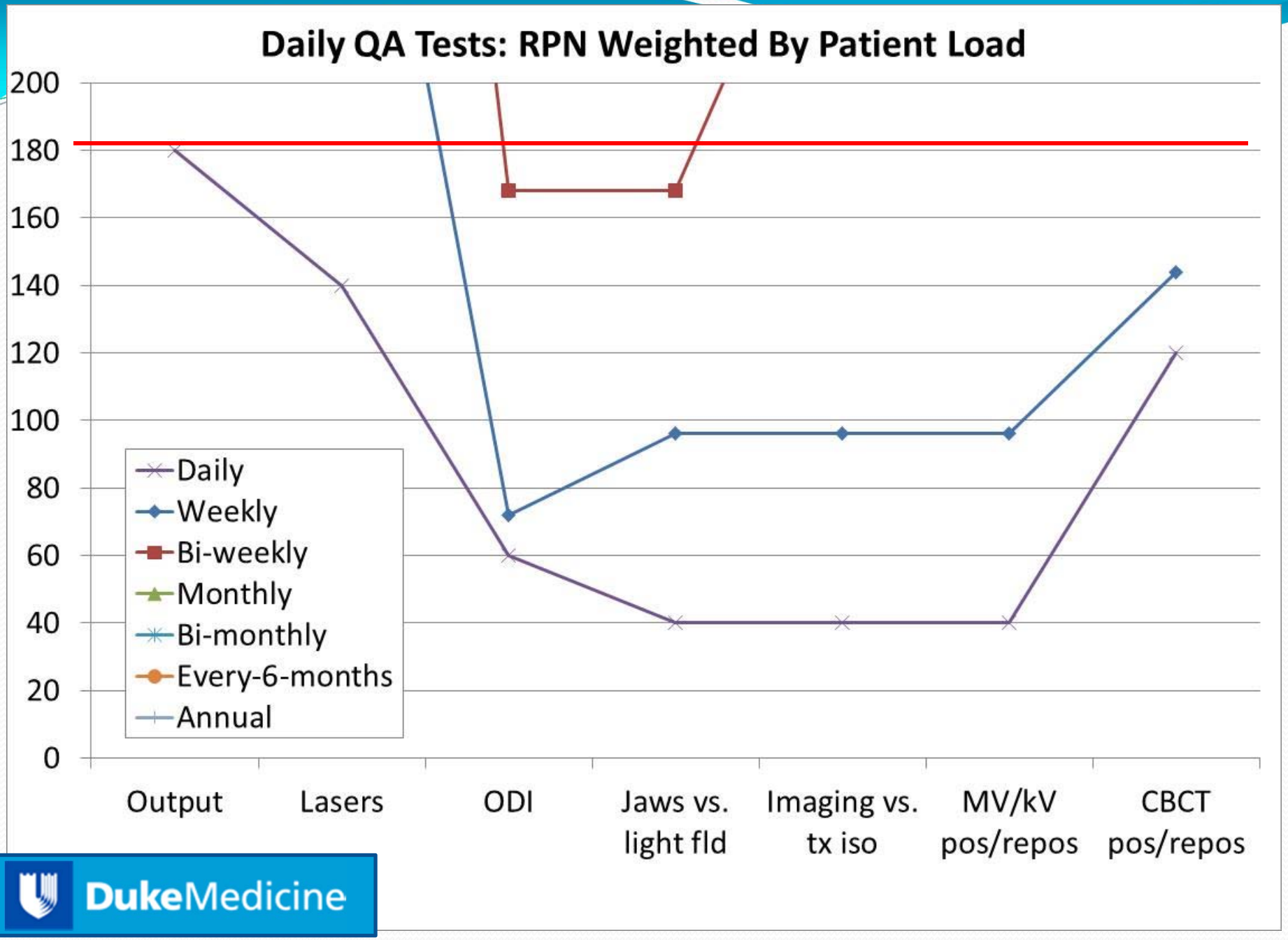

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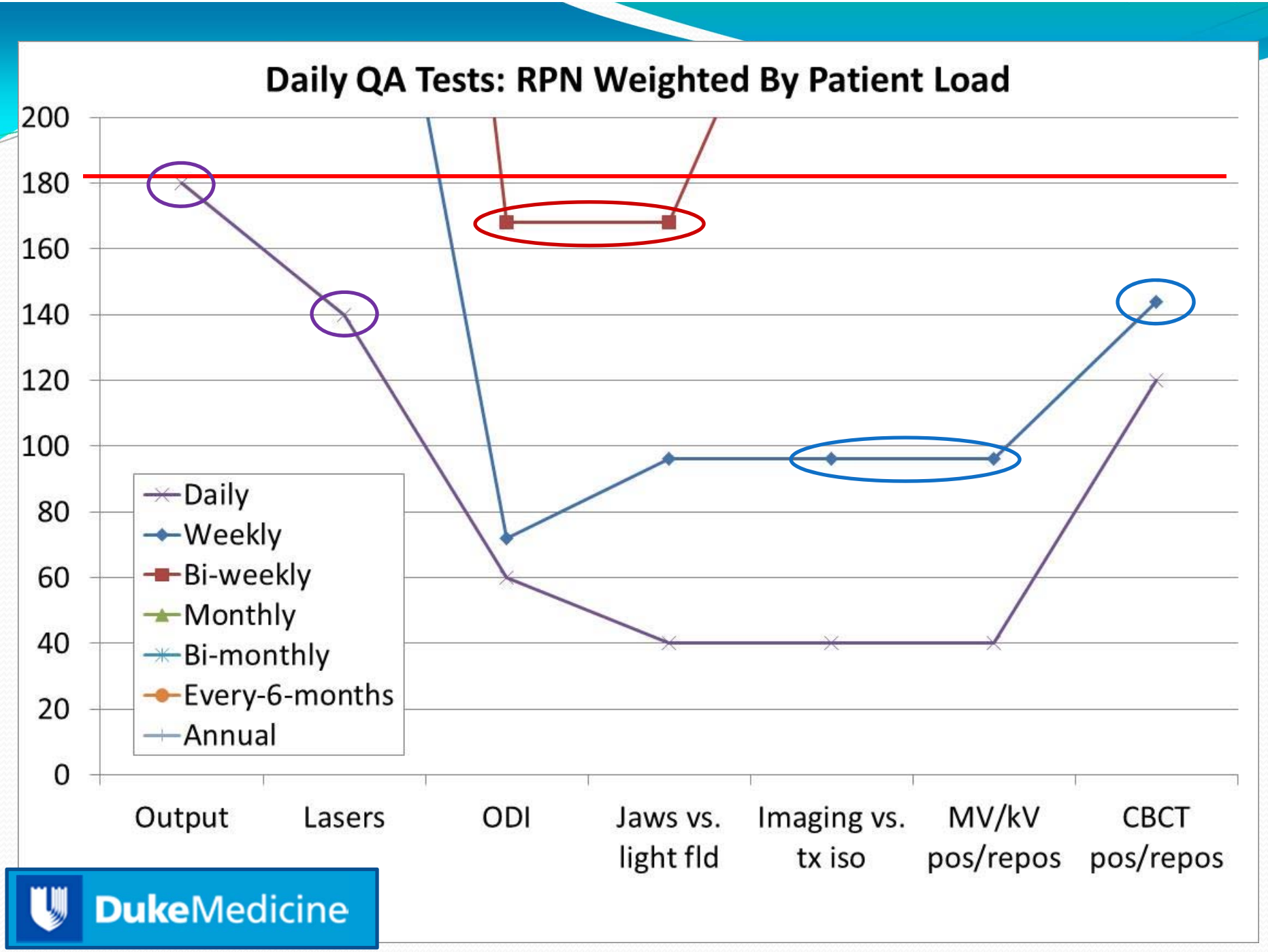

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FMEA of TG-142 Monthly QA

Output

Dosimetry

X-ray output constancy
Electron output constancy
Backup monitor chamber constancy

Mechanicals

Mechanical

Light/radiation field coincidence[b]
Light/radiation field coincidence[b] (asymmetric)
Distance check device for lasers compared with front pointer
Gantry/collimator angle indicators (@ cardinal angles) (digital only)
Accessory trays (i.e., port film graticle tray)
Jaw position indicators (symmetric)[c]
Jaw position indicators (asymmetric)[d]
Cross-hair centering (walkout)
Treatment couch position indicators[e]
Wedge placement accuracy
Compensator placement accuracy[f]
Latching of wedges, blocking tray[g]
Localizing lasers

Imaging

Planar MV imaging (EPID)

Imaging and treatment coordinate coincidence (four cardinal angles)
Scaling[b]
Spatial resolution
Contrast
Uniformity and noise

Planar kV imaging[d]

Imaging and treatment coordinate coincidence (four cardinal angles)
Scaling
Spatial resolution
Contrast
Uniformity and noise

Cone-beam CT (kV and MV)

Geometric distortion
Spatial resolution
Contrast
HU constancy
Uniformity and noise

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Occurrence: Monthly QA

Daily QA Test	Number of Adjustments	Occurrence (% of total days of operation)
Output	86	3.7%
Laser	19	0.8%
CBCT pos/repos	10*	0.1%
Light field vs. Radiation	3	0.13%
ODI	2	0.09%
MV spatial resolution & contrast	1	0.04%
Everything else!	0	< 0.05%

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Severity: Associated Errors

1) Output
2) Mechanicals
3) Imaging

1) MU variation
2) 3D translational displacement (1.0mm & 2.0mm)
3) A/P, R/L, and S/I translational displacement
4) Jaw size change
5) Gantry/collimator/couch angle change

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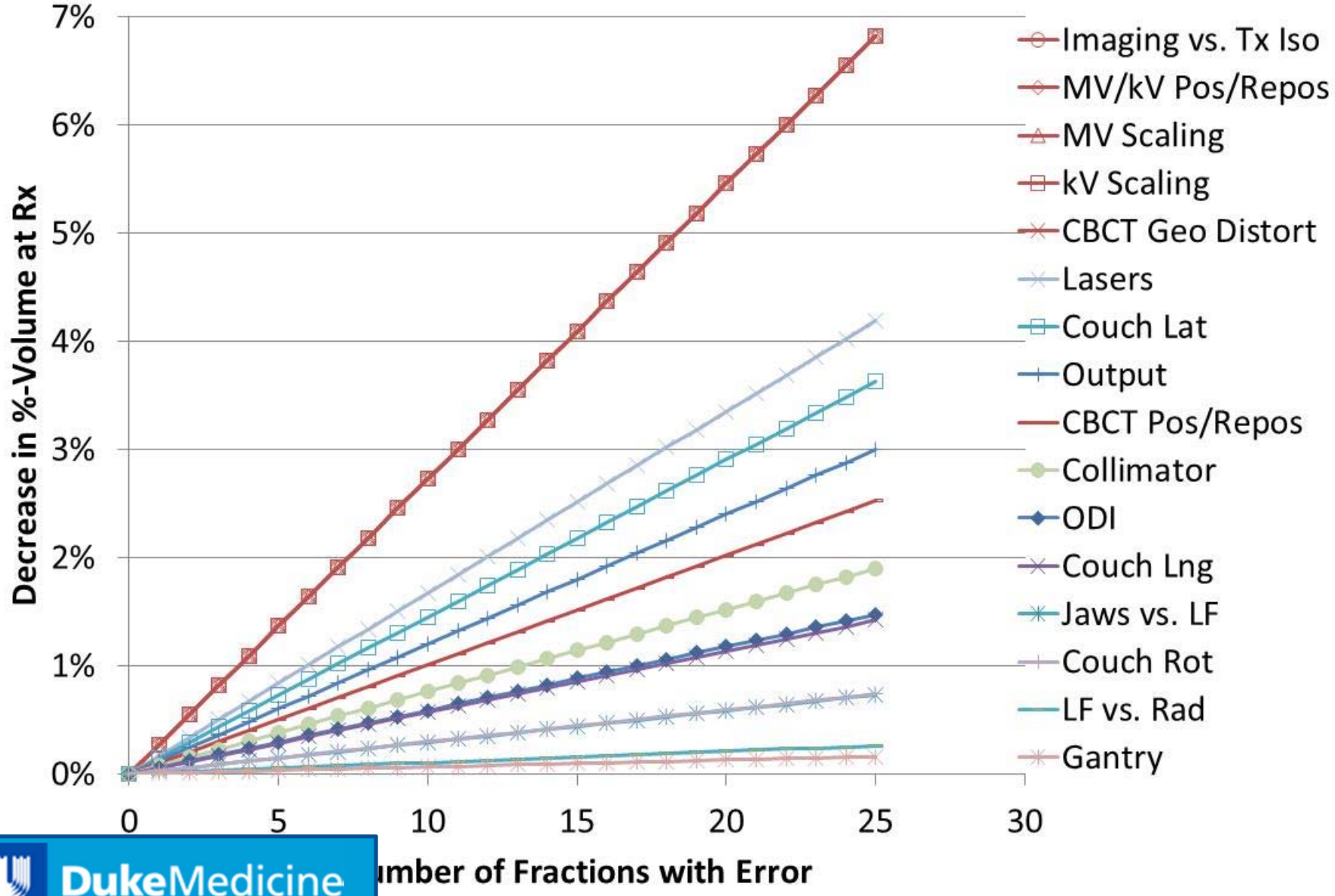

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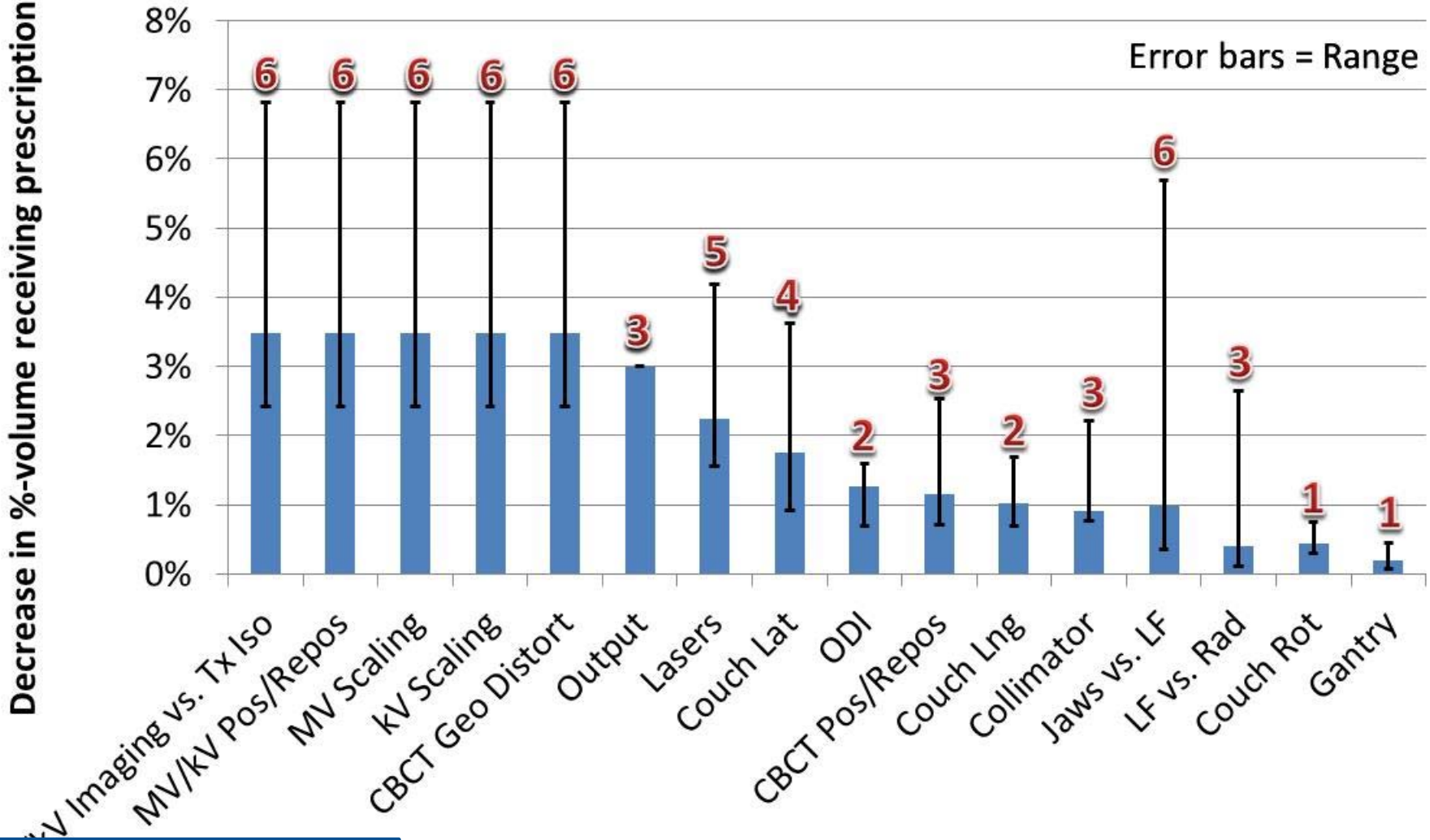

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Image Quality Severity

- Estimate
  - Less severe than a consistent 1.5-2mm 3D translation

	Daily	Weekly	Bi-weekly	Monthly	Bi-monthly
Imaging vs. Tx Iso/Image Scaling/ MV/kV Pos/Repos	1	2	5	6	6
Jaws vs LF	1	2	3	6	6
Lasers	1	2	3	5	5
Image quality	**1**	**2**	**3**	**4**	**4**

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Monthly QA Weighted RPN

	Daily	Weekly	Bi-weekly	Monthly	Bi-monthly
Lasers					
Output					
CBCT Pos/Repos					
Light Field vs. Rad					
Imaging vs. Tx Iso, MV/kV Pos/Repos, Scaling					
Jaws vs. LF					
Image Quality, ODI					
Couch Lateral					

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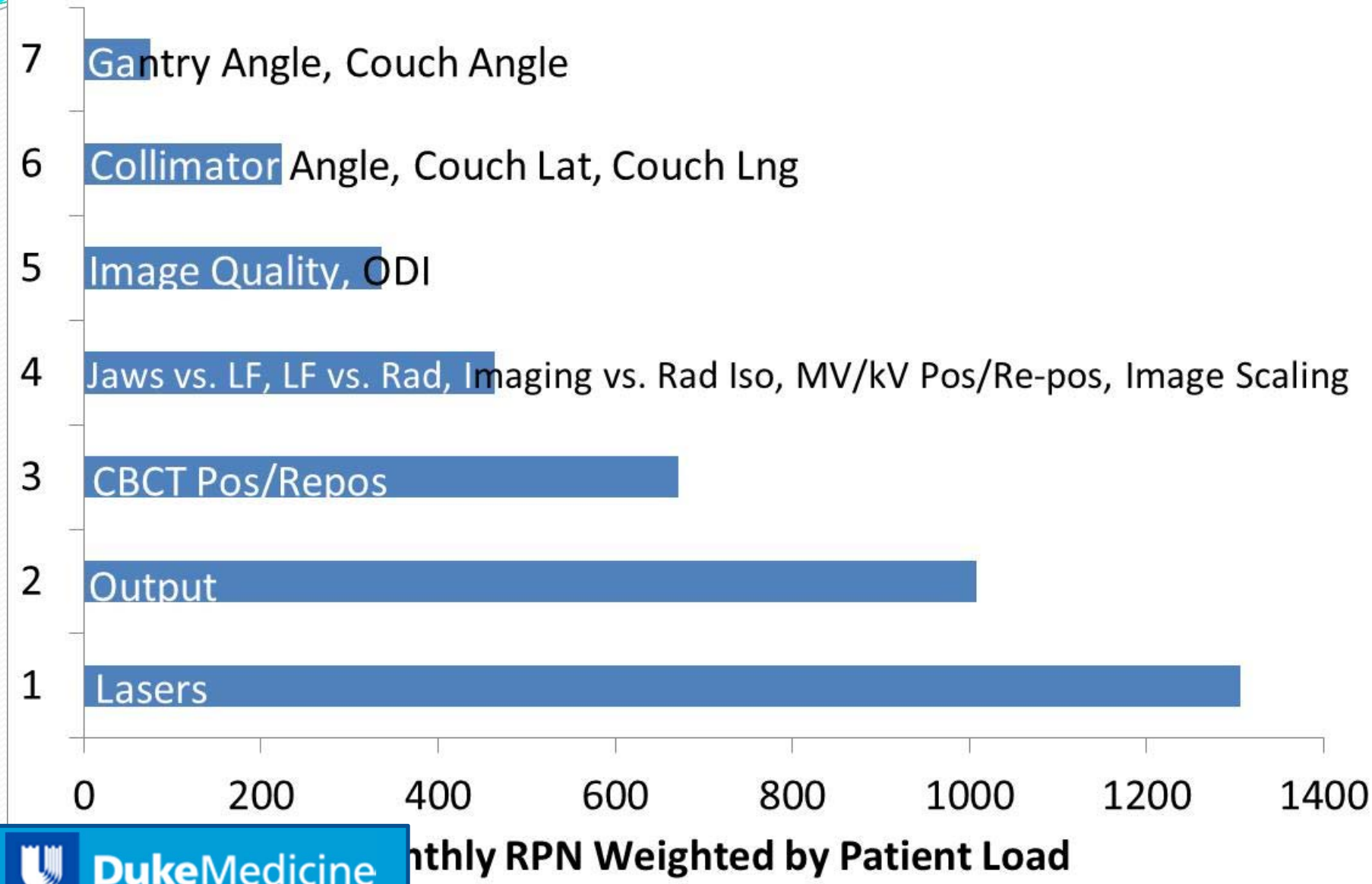
Patient-Load-Weighted RPN: Occurrence * Severity (QA frequency) * Number of Patients Affected (QA frequency)

Monthly QA Priorities



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Discussion: TG142 Monthly QA

Monthly:	Bi-Monthly:	Every-6-Months:	Annual:
Output Lasers Jaws vs. LF, LF vs. Rad Imaging vs. tx iso Image scaling Imaging pos/repos	Collimator Couch Lat ODI Image quality	Gantry Couch Lng	Couch Angle

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Open questions

- What is the appropriate severity for image quality failures?
- If daily imaging is used, should lasers become less essential?

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Efficient and Effective Linac QA:

- "…the QA program should be flexible enough to take into account quality, costs, equipment condition, available test equipment, and institutional needs." – TG142

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Efficient and Effective Linac QA:

- Depend upon equipment & patient population
- Focus on tests with high severity and/or high occurrence ranks
- Varian 21EX linacs & H&N IMRT patients:
  - Focus on lasers and output
  - Daily QA: consider reducing imaging QA to weekly frequency, certain mechanicals to bi-weekly frequency
  - Monthly QA: consider reducing frequency of image quality QA & certain mechanical QA tests

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Thanks for your attention!

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