CONNECTING LIFE AND SCIENCE

Treatment Planning System Commissioning and QA: *Incorporating the entire planning process (E2E Testing)*

Sasa Mutic, Ph.D.

Conflict of interest statement

- TreatSafely.org – partner and cofounder
- Radialogica – shareholder, cofounder, and CTO
- Varian – licensing, service, grants, honoraria
- Modus – licensing
- ViewRay – licensing, service, grants, honoraria

Overview

- What is commissioning
- Treatment planning as a part of broader process
- End to End (E2E) testing
- Automation and Standardization

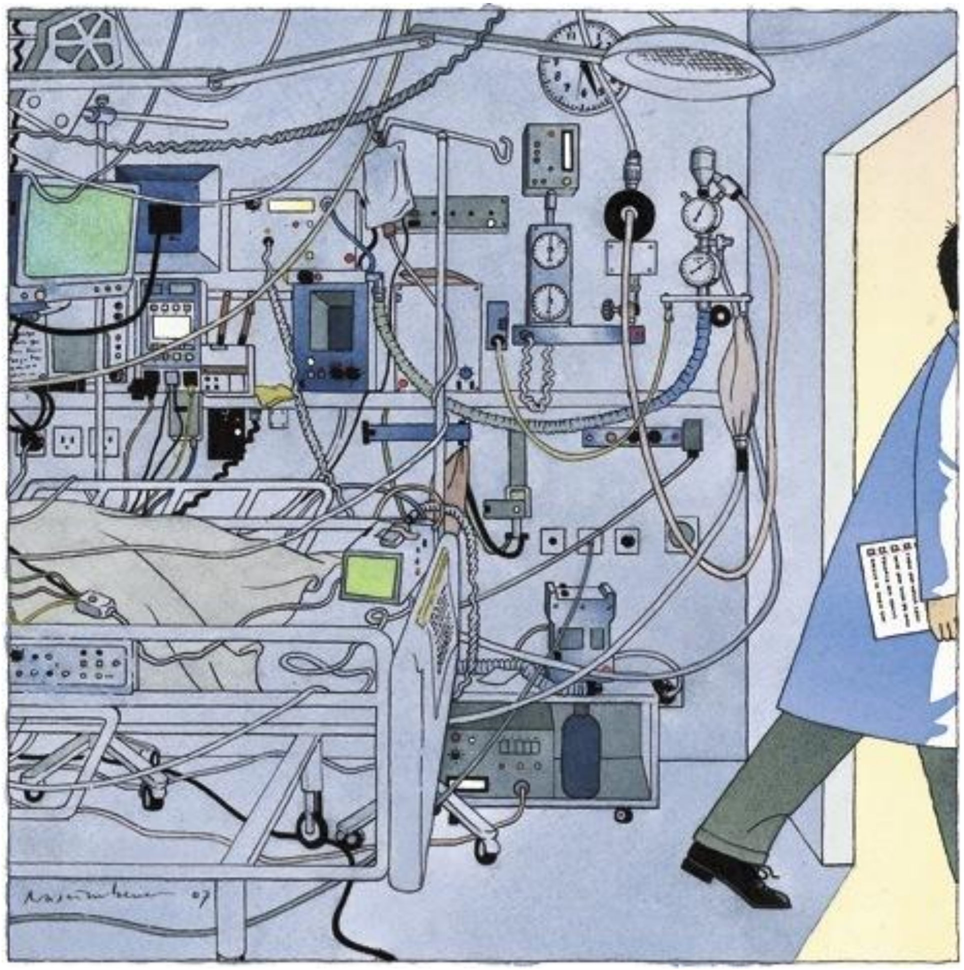
Commissioning

- The term commissioning comes from shipbuilding. A commissioned ship is one deemed ready for service. Before being awarded this title, however, a ship must pass several milestones. Equipment is installed and tested, problems are identified and corrected, and the prospective crew is extensively trained. A commissioned ship is one whose materials, systems, and staff have successfully completed a thorough quality assurance process.

http://cx.lbl.gov/definition.html

Modern RT - Complexity

- Recent sophistication – large fraction of modern treatment practices developed in the past ten years
- High technical complexity
- Multiple systems (software and hardware)
- Limited to non-existent guidance and regulations
- High pressure
- Increased potential for catastrophic failures



"To error is human. To really foul things up requires a computer."

Systems Engineering

- The function of systems engineering is to guide the engineering of complex systems
- It is founded on a belief that individual components of an organization are dependent on each other
- It is very much about employing common sense in design of operations
- A set of tools for more effective management of interconnected components

Systems Engineering

- Applicable to systems with the following attributes:
  - Complex
  - Engineered
  - Advanced technology
  - High risk
  - High cost

Modern RT

Systems Engineering

Systems Design
- Quality systems
- Human factors
- FMEA (This is coming up in TG-100)

Systems Analysis
- Modeling and simulation
- Enterprise management
- Financial engineering and risk analysis
- Knowledge discovery

Systems Control
- SPC
- Scheduling

The upcoming TG100 report predominantly relies on:

2%	a.	SPC
1%	b.	ILS
10%	c.	QC/QA
87%	d.	FMEA
1%	e.	RPC

•The upcoming TG100 report predominantly relies on:
(a) SPC
(b) ILS
(c) QC/QA
(d) FMEA
(e) RPC

Answer: d) FMEA

Ref: M.S. Huq, B.A. Fraass, P.B. Dunscombe, J.P. Gibbons, G.S. Ibbott, P.M. Medin, A. Mundt, S. Mutic,
J.A. Palta, B.R. Thomadsen, J.F. Williamson, E.D. Yorke. A method for evaluating quality assurance needs in radiation therapy.
Int J Radiat Oncol Biol Phys, 2008; 71(1 Suppl), S170-3.

Systems Engineering

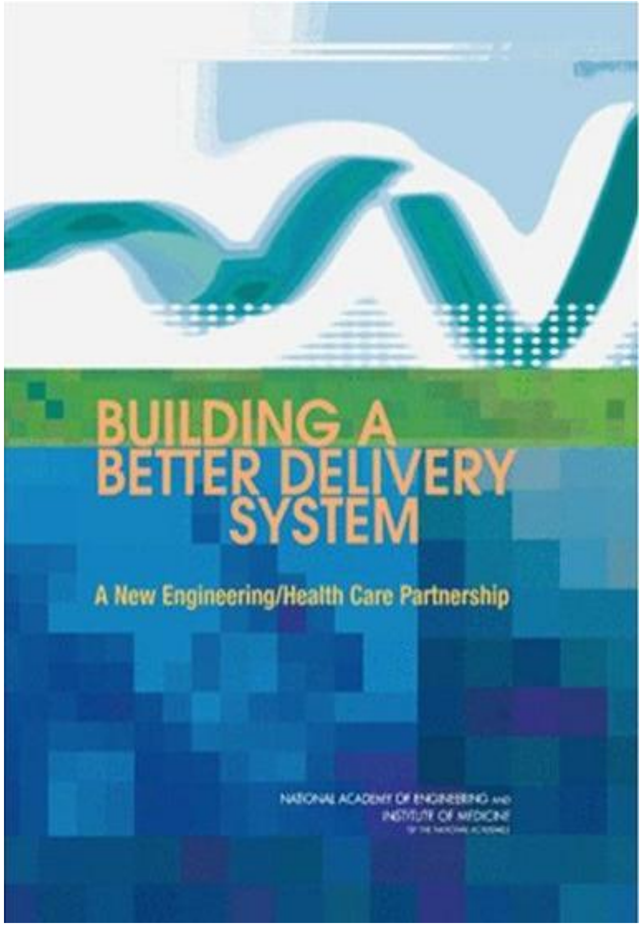
“It is difficult for engineers to change human nature and therefore, instead of trying to persuade people not to make errors, we should accept people as we find them and try to remove opportunities for error by changing work situation.”

An engineers view of human error - Trevor Kletz

Systems Engineering in Healthcare

An outline for use of Systems Engineering for improvement of national health care system

"We often call this arrangement a "health care system" even though it was never created as a system and has never performed as a system."



National Academy of Engineering and Institute of Medicine, 2005

Organizational Culture

- "Shared ***values*** (what is important) and ***beliefs*** (how things work) that interact with an organization's structures and control systems to produce behavioural norms (the way we do things around here)." Uttal, B., Fortune. 17 October 1983.

Errors in Radiation Therapy

- Staff and public exposures
- Misadministrations
  - Underdose
  - Overdose
  - Anatomical misses
- Magnitude
  - From few percent to lethal doses
  - From couple of millimeters to complete misses
- Regulatory
  - Nuclear Regulatory Commission
  - Errors that do not necessarily affect patients but have regulatory/legal consequences
- Sources
  - Staff
  - Software
  - Hardware
- Random
  - Affect one to few patients
- Systematic
  - Affect hundreds of patients
  - Potentially in a short period

Error spectrum

- Publicized – One side of the spectrum, usually large dosimetric errors – NY Times Articles
- Semi-publicized – RPC data
  - Approximately 20% of participating institutions fail the credentialing test at 7% or 4mm*
  - Approximately 30% fail at 5%*
- Unpublicized/unnoted – everyday occurrences
  - "Small" dosimetric errors and geographic misses
  - Suboptimal treatment plans (contouring and dose distributions)
  - Care coordination issues
  - Unnecessary treatment delays

*Molineu *et al, Credentialing results from IMRT irradiations of an anthropomorphic head and neck, Med Phys, 40, 2013.*

RPC Report

Credentialing results from IMRT irradiations of an anthropomorphic head and neck phantom

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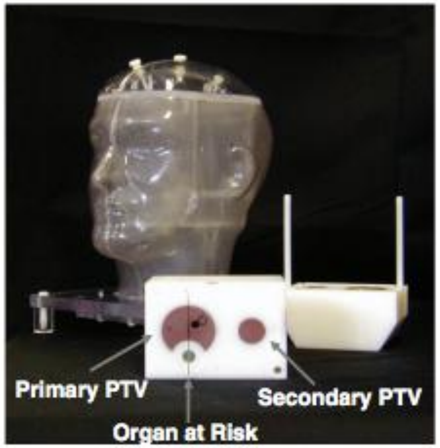
(Received 10 April 2012; revised 15 November 2012; accepted for publication 7 December 2012; published 8 January 2013)

Purpose: This study was performed to report and analyze the results of the Radiological Physics Center's head and neck intensity-modulated radiation therapy (IMRT) phantom irradiations done by institutions seeking to be credentialed for participation in clinical trials using intensity modulated radiation therapy.
Methods: The Radiological Physics Center's anthropomorphic head and neck phantom was sent to institutions seeking to participate in multi-institutional clinical trials. The phantom contained two planning target volume (PTV) structures and an organ at risk (OAR). Thermoluminescent dosimeters (TLD) and film dosimeters were imbedded in the PTV. Institutions were asked to image, plan, and treat the phantom as they would treat a patient. The treatment plan should cover at least 95% of the primary PTV with 6.6 Gy and at least 95% of the secondary PTV with 5.4 Gy. The plan should limit the dose to the OAR to less than 4.5 Gy. The passing criteria were ±7% for the TLD in the PTVs and a distance to agreement of 4 mm in the high dose gradient area between the PTV and the OAR. Pass rates for different delivery types, treatment planning systems (TPS), linear accelerators, and linear accelerator-planning system combinations were compared.
Results: The phantom was irradiated 1139 times by 763 institutions from 2001 through 2011. 929 (81.6%) of the irradiations passed the criteria. 156 (13.7%) irradiations failed only the TLD criteria, 21 (1.8%) failed only the film criteria, and 33 (2.9%) failed both sets of criteria. Only 69% of the irradiations passed a narrowed TLD criterion of ±5%. Varian-Elipse and TomoTherapy-HiArt combinations had the highest pass rates, ranging from 90% to 93%. Varian-Pinnacle[3], Varian-XiO, Siemens-Pinnacle[3], and Elekta-Pinnacle[3] combinations had pass rates that ranged from 66% to 81%.
Conclusions: The head and neck phantom is a useful credentialing tool for multi-institutional IMRT clinical trials. The most commonly represented linear accelerator-planning system combinations can all pass the phantom, though some combinations had higher passing percentages than others. Tightening the criteria would significantly reduce the number of institutions passing the credentialing criteria. Causes for failures include incorrect data entered into the TPS, inexact beam modeling, and software and hardware failures.
[http://dx.doi.org/10.1118/1.4773309]

Key words: credentialing, clinical trials, IMRT QA, anthropomorphic phantom



Molineu et al, Med. Phys. 40 (2013)

RPC Data

- Pass rate at 7%/4mm – 81.6%
- Pass rate at 5% - 69%
- It indicates that the systems which have less local user input have significantly higher pass rates
  - Tomotherapy – no user input
  - Eclipse – Presumably golden beam data or the benefit of automodeling

TABLE II. Pass rate versus IMRT technique, treatment planning system, linear accelerator manufacturer, and linac-TPS combination.

			Criterion failed		
	Pass rate (%)	Attempts	Dose	DTA	Dose and DTA
IMRT technique					
Dynamic MLC	88	296	26	5	5
IMAT	86	103	11	0	3
Segmental	76	634	109	15	25
Solid attenuator	43	7	4	0	0
TomoTherapy	93	99	6	1	0
Treatment planning system					
Eclipse	88	387	30	8	7
Pinnacle[3]	75	425	84	8	13
TomoTherapy	93	99	6	1	0
XiO	76	137	19	4	10
Other	78	91	17	0	3
Linear accelerator manufacturer					
Elekta	67	130	37	4	2
Siemens	70	135	32	3	6
TomoTherapy	93	99	6	1	0
Varian	85	775	81	13	25
Linac-TPS combination					
Elekta-Pinnacle[3]	66	90	28	3	0
Siemens-Pinnacle[3]	67	76	21	0	4
TomoTherapy-HiArt	93	99	6	1	0
Varian-Eclipse	90	372	22	7	7
Varian-Pinnacle[3]	81	267	38	5	9
Varian-XiO	77	74	10	1	6

AAPM Task Group Reports

Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40

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(Received 24 February 2009; published 17 August 2009)

Accelerator beam data commissioning equipment and procedures: Report of the TG-106 of the Therapy Physics Committee of the AAPM

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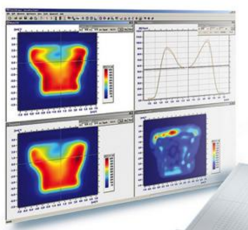
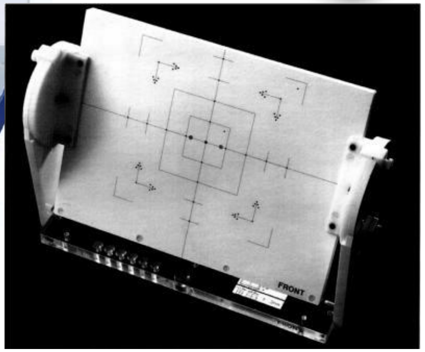
Task Group No. 210 - Conventional LINAC Acceptance Testing

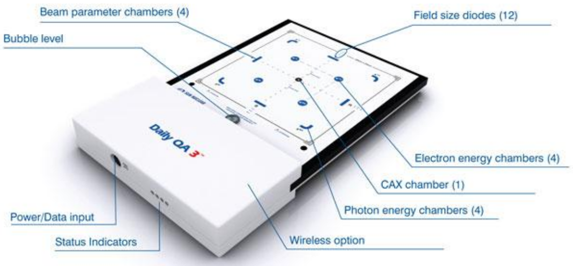
AAPM Members, Affiliates and Non-Member Affiliates - Login for access to additional information

Charge	1. Recommendations for (1) technical specifications that should be included in the purchase contract and (2) consideration of technical aspect of purchase contract. 2. To provide definition of performance specifications for major LINAC subsystems in ATP. 3. To make recommendations on the tests to be performed during the LINAC acceptance testing procedure (ATP, including beam matching and subsequent major repair/upgrades including testing methods that complement vendor-suggested measurements.
Bylaws:	Not Referenced. **Rules:** Not Referenced.
Approved Date(s)	Start: 10/4/2010 End: 12/31/2014

Commissioning Equipment







RPC tolerance for IMRT head and neck phantom irradiation is:

3%	a.	2%/2mm
12%	b.	3%/3mm
86%	c.	7%/4mm
0%	d.	2%
0%	e.	2mm

RPC tolerance for IMRT head and neck phantom irradiation is:

(a) 2%/2mm
(b) 3%/3mm
(c) 7%/4mm
(d) 2%
(e) 2mm

Answer: c – 7%/4mm

Ref: Molineu *et al*, *Credentialing results from IMRT irradiations of an anthropomorphic head and neck, Med Phys, 40, 2013.*

What are the obstacles

- Publicized (Catastrophic)
  - Ultimately a technical limitation
- Semi-publicized (Semi-catastrophic)
  - Ultimately a cultural limitation
- Unpublicized/unnoted – (unknown significance)
  - Technical and cultural limitation

End to End (E2E) Testing

- Designed to identify system dependencies and to ensure that the data integrity is maintained between various system components and (internal and external) systems.
- Two aspects:
  1) A holistic view/test of the overall process and integration
  2) An overall system test rather than testing of multiple individual components (unit tests)

End to End (E2E) Testing

- Where are the ends in RT?
  - For treatment delivery – Simulation orders to delivery record
- Who performs testing?
  - Ideally people responsible for individual tasks
- Is there a need for E2E with closed systems with standard data?
  - True closed systems do not exist. Even if they did exist – user testing still valuable.

End to End (E2E) Testing

- Focus is on system function and not on system capabilities – stressing the system is not the goal
- Demonstration of successful test is important. Do not fail the test and "fix" the problems without repeating the test
- Depending on the novelty of the system, initial failure is expected

Evidence based QM (us as a discipline)

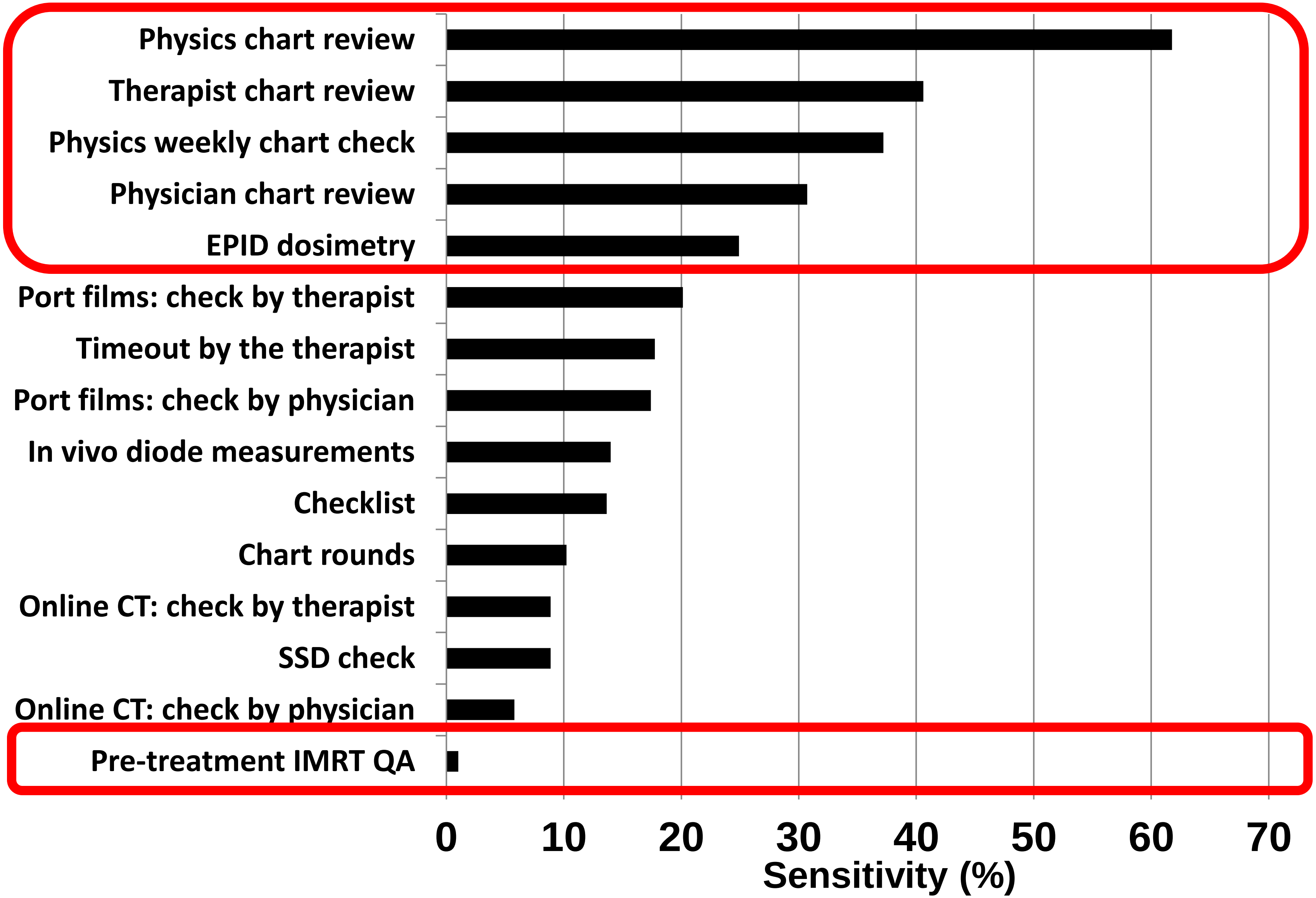
- It is difficult for individual clinics to prioritize their QA/QC/QM activities if the broader field and community is still struggling with what to prioritize
- Prioritization requires data
- Evidence based medicine is everywhere, QA/QC need to embrace the same approach

Example: QA\QC Check Effectivness

- An analysis of the effectiveness of common QA/QC checks
- IRB between Johns Hopkins University & Washington University
- Both institutions started incident learning systems (ILS) at the same time
- Data:
  - Incident reports: 2007-2011
  - 4,407 reports
  - 292 (7%) "high potential severity"

E.C. Ford, S. Terezakis, A. Souranis, K. Harris, MD, H. Gay, S. Mutic, Quality Control Quantification (QCQ): A tool to measure the value of quality control checks in radiation oncology, Int. J. Radiat. Oncol. Biol. Phys., 84(3), 263-269, (2012).

Common QA\QC checks

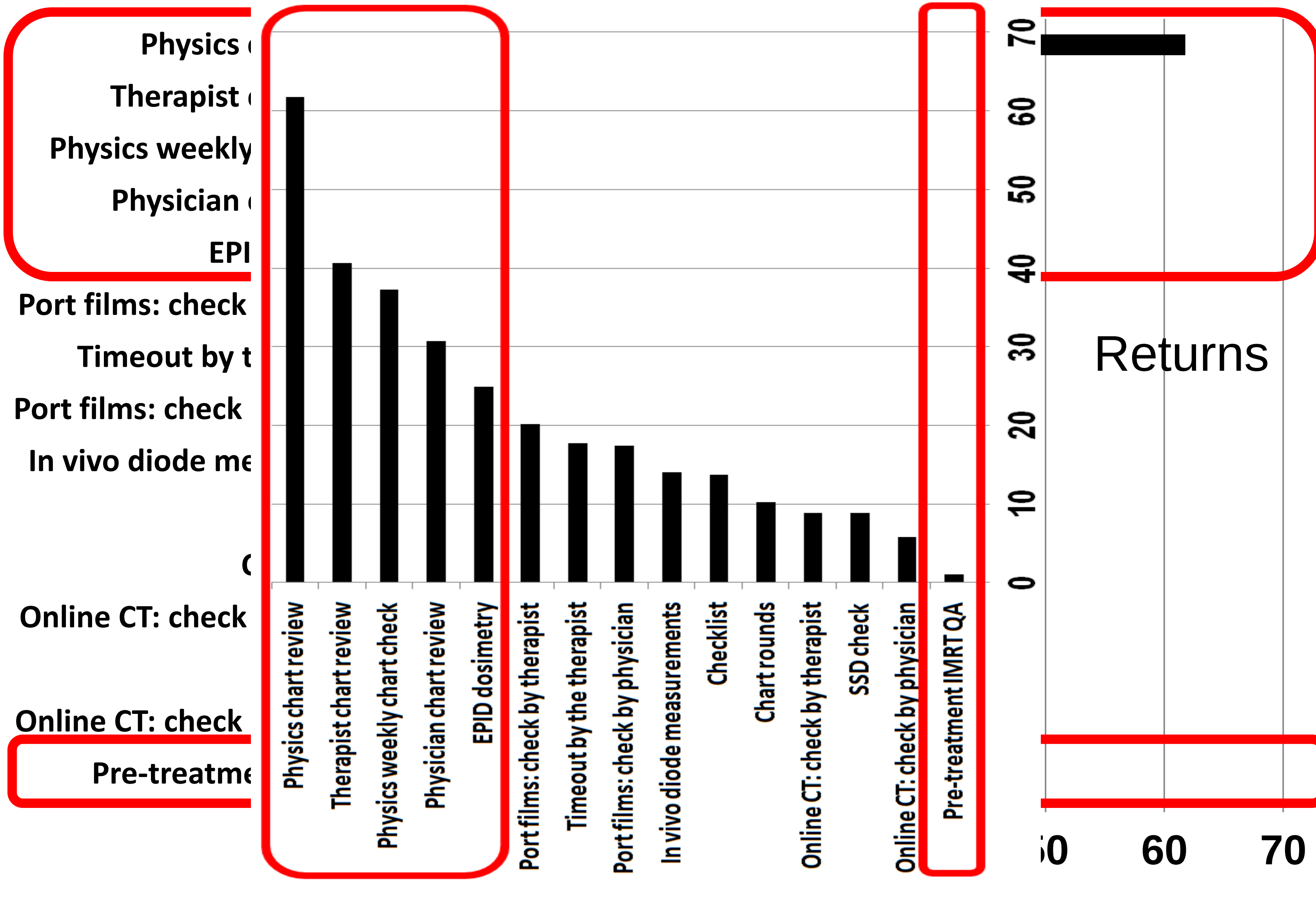


Literature Search

- pubmed.org search on:
  - (Quality Assurance) AND (Radiation Therapy) AND
    - (IMRT) Results: 463
    - (Chart Checks) Results: 7
    - (Chart Review) - Results: 34
- An order of magnitude difference

May 2013 Data

How would investors use this data?



Current IMRT QA Paradigm

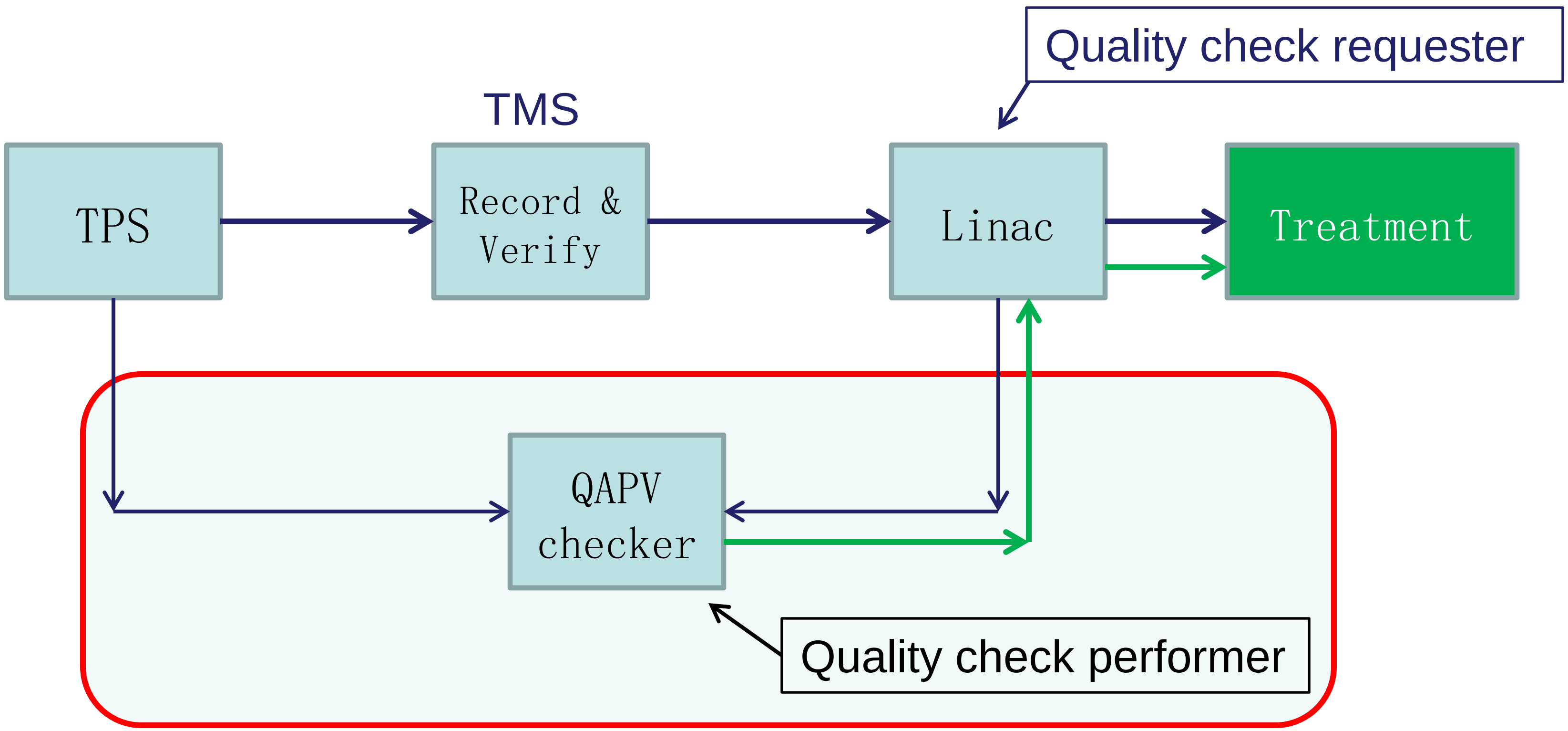
"We are pretty good at making sure that we can treat a phantom correctly at ~7:00 pm"

1. Transfer patient plan to a QA phantom
   - Dose recalculated (homogeneous) on phantom – any dose calculation errors would not be revealed
2. Perform QA prior to treatment
   - Subsequent data changes/corruption may result in systematic errors for all subsequent patients
3. The volume of data impossible to monitor and verify manually
   - Manual checks do reveal data changes/corruptions, but not reliably
4. The process too laborious with questionable benefits
   - A systematic analysis and redesign demonstrates possibility of a much more robust and automated process

IHE-RO (Integrating the Healthcare Enterprise in Radiation Oncology)

- IHE-RO is an ASTRO initiative that helps to ensure a safe, efficient radiation oncology practice by improving system to system connections
- IHE-RO was only setting standards until recently
- Quality Assurance Plan Veto (QAPV) is an IHE-RO initiative, in which they are proposing the framework called QAPV profile

QAPV profile framework



<u>QAPV checker</u>: Compares RT-plan (DICOM) from TPS and treatment parameters from Linac. If the **<u>plan passes</u>** the verification, proceed in **green direction**

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QAPV profile value

- IHE-RO QAPV (plan veto) profile
- Proposal for a software that would validate data sent to treatment machine every day
- Significant departure for IHE-RO as this is proposal of a new product and not simply integration work
- QAPV Cost\Benefit Analysis
  - Do the benefits of the QAPV justify introduction of another device
  - Quantify benefits of QAPV

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QAPV profile value

- Varian crated a 4DTC emulator with QCR (quality check requestor) functionality
- WU used electronic chart check infrastructure to create a QCP (quality check performer)
- WU used the ILS database to perform FMEA analysis of delivery process with and without QAPV

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DiICOM RT plan parameter	O	S	D		RPN	
			Without QAPV	With QAPV	Without QAPV	With QAPV
Patient Identification information	6	9	2	1	108	54
Plan Identification information	8	5	7	4	280	160
Number of Fractions Planned	8	9	4	4	288	288
Number of Beams	2	6	6	4	72	48
Beam Dose Specification Point	1	2	9	9	18	18
Beam Meterset	6	9	6	2	324	108
Institution Name	3	7	9	9	189	189
Treatment Machine Name	6	8	6	2	288	96
Beam Type	1	8	2	2	16	16
Radiation Type	1	9	3	2	27	18
High dose technique type	4	9	4	4	144	144
Treatment Delivery Type	2	4	5	5	40	40
Wedges	4	9	7	2	252	72
Number of Control Points	1	5	4	1	20	5
Nominal Beam Energy	5	7	5	1	175	35
RT Beam Limiting Device Type	5	8	5	1	200	40
Leaf/Jaw Positions	3	8	7	3	168	72
Gantry Angle	1	7	5	1	35	7
Beam Limiting Device Angle	3	6	5	1	90	18
Patient Support Angle	3	5	3	3	45	45
Isocenter Position	6	9	4	2	216	108
Cumulative Meterset Weight	2	5	9	1	90	10

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The main focus of IHE-RO is:

4%	a.	Dosimetric testing
5%	b.	Clinical trials
2%	c.	Institutional credentialing
87%	d.	System integration testing
3%	e.	Maintenance of certification

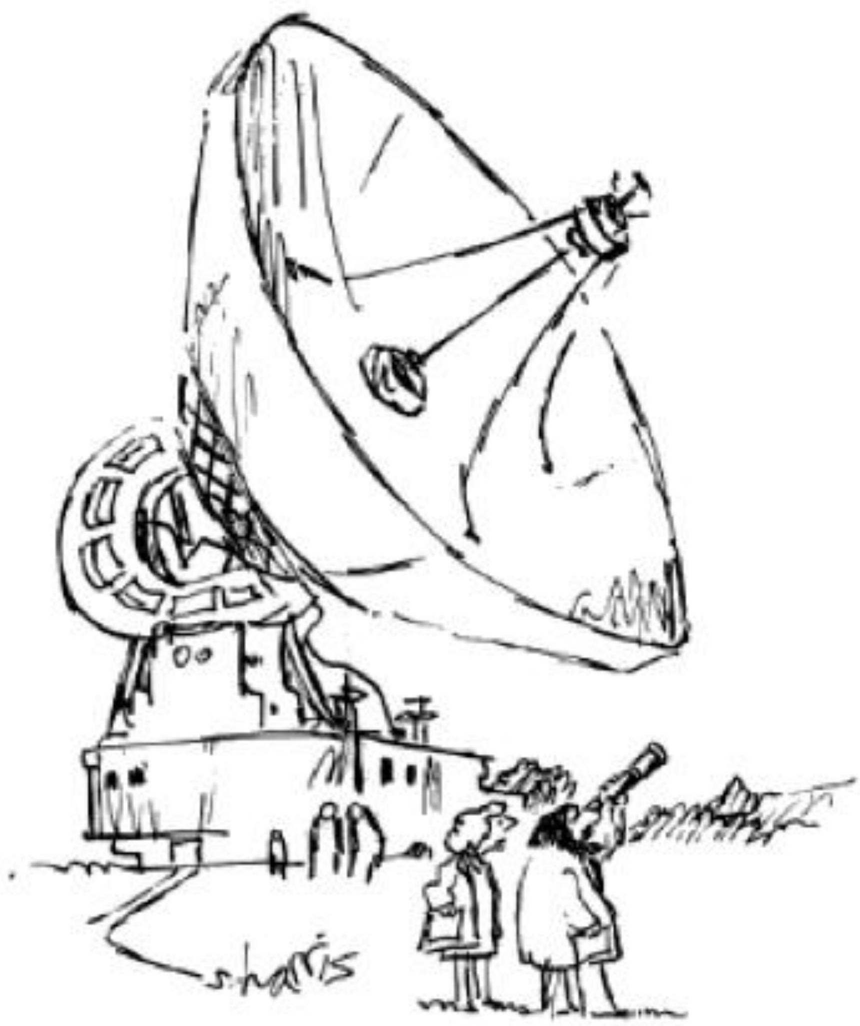
The main focus of IHE-RO is:

(a) Dosimetric testing
(b) Clinical trials
(c) Institutional credentialing
(d) System integration testing
(e) Maintenance of certification

Answer: d - System integration testing

Ref: Noel *et al* Int J Radiation Oncol Biol Phys, Vol. 88, 2014

Thank you!



"Just checking."