Patient Safety

Brett Miller, M.S.
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Outline

- Simple Goal
- What can go wrong?
- What can't we control?
- What can we do?

Simple Goal

- Treat patients safely and as planned
- Treat the tumor, spare the normal tissue
- Simple process???

Steps in IMRT Process

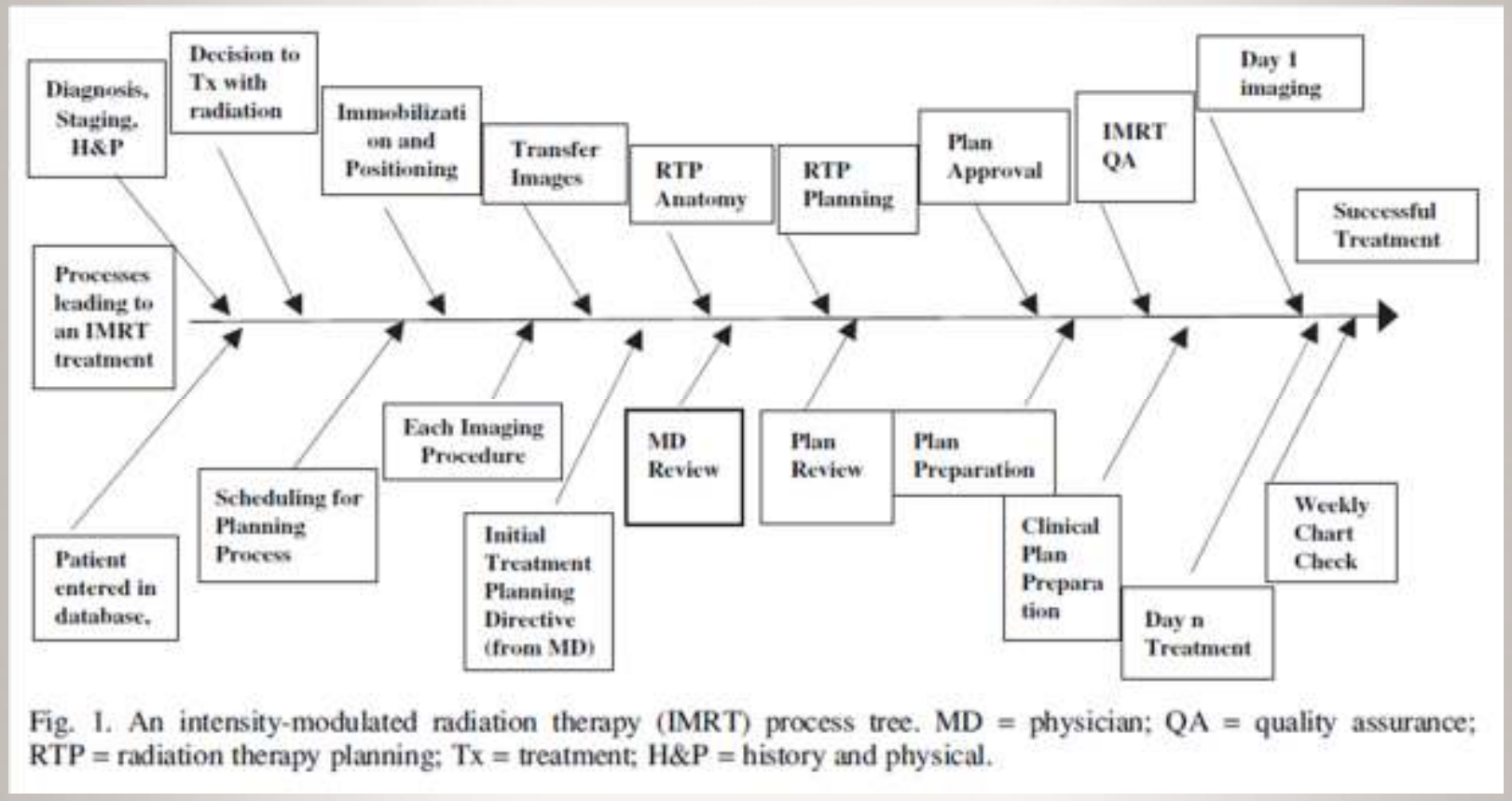


Fig. 1. An intensity-modulated radiation therapy (IMRT) process tree. MD = physician; QA = quality assurance; RTP = radiation therapy planning; Tx = treatment; H&P = history and physical.

Huq et al, IJROBP, Vol 71, S1 ppS170-S173

Complexity of Radiation Therapy

- Many steps
- Many computer systems
- Complex technology
- Chaotic environment
- Increasingly complex interactions
- Many different people involved
- Beware of oversimplification of the process

People Involved in Radiotherapy Process

- Therapists
- Dosimetrists
- Physicists
- Physicians
- Nurses
- IT
- Administrators

Complexity of the Workspace

Complexity of the Workspace

Outline

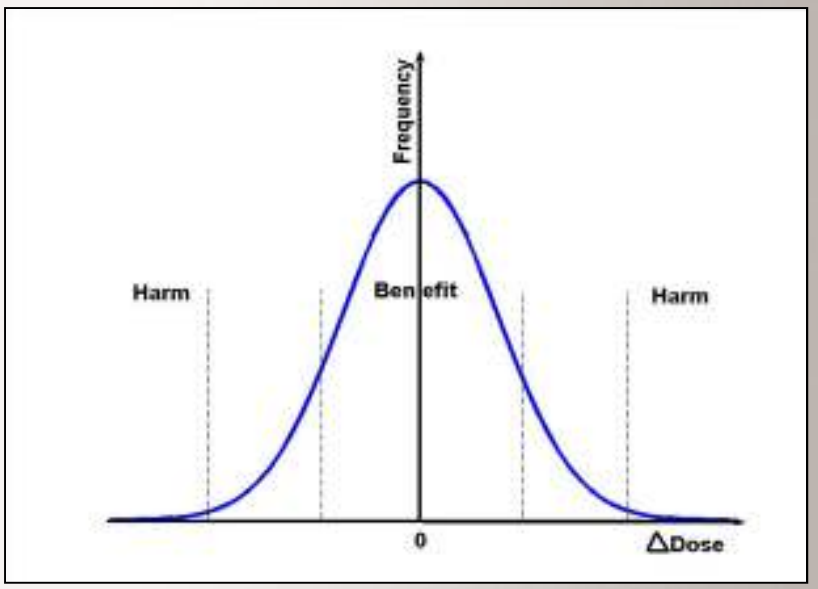
- Simple Goal – not really
- What can go wrong?
- What can't we control?
- What can we do?

What can go wrong?

- Error – an act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done
- *Incident – an unwanted or unexpected change from a normal system behavior, which causes, or has the potential to cause, an adverse effect to persons or equipment*

Consequences of an Incident/Error

- No effect on the safety or quality of treatment
- Erosion of quality
- A clinically significant adverse event

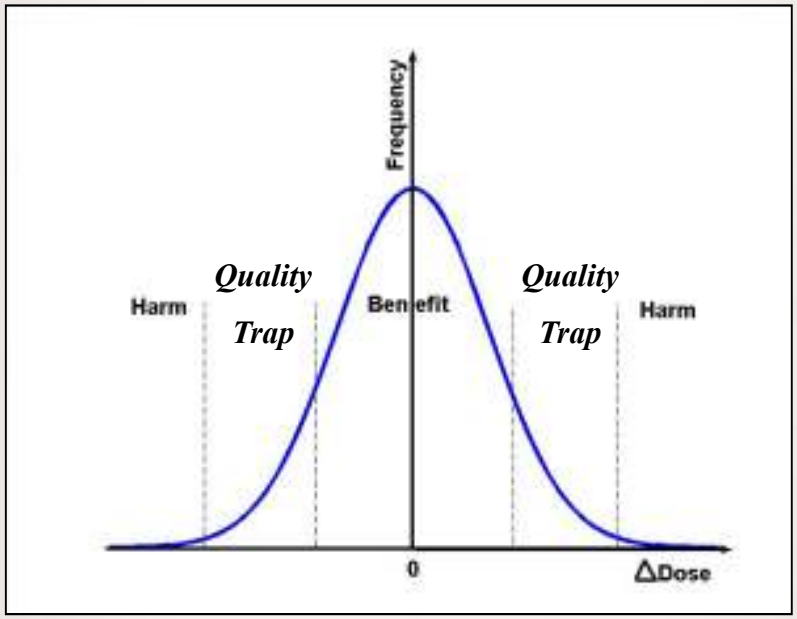


Deviation from optimum dose

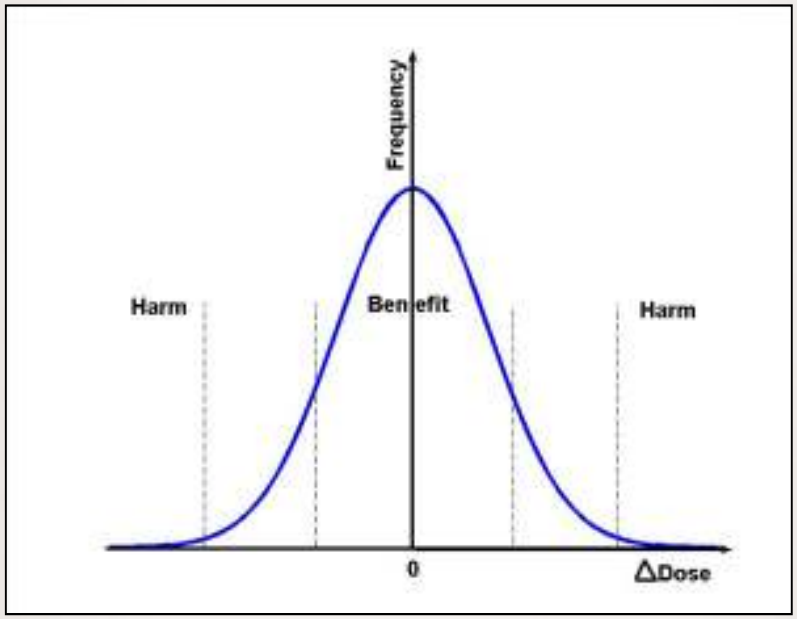
Peter Dunscombe, PhD, University of Alberta,
Tom Baker Cancer Center

What does going wrong mean?

- Unsafe = extreme compromise of quality.
- Let's not forget the patients caught in the "quality trap".



The Quality Trap



If you believe this distribution there must be patients who, due to departures from quality, receive treatments that do not result in obvious injuries but for whom the probability of the desired outcome is compromised.

Peter Dunscombe, PhD, University of Alberta,
Tom Baker Cancer Center

Contributing factors

- Lack of training, competence or experience
- Fatigue and stress/time pressure
- Poor design and documentation of procedures
- Over-reliance on automated procedures

Contributing factors (cont.)

- Poor communication and lack of teamwork
- Hierarchical departmental structure
- Staffing and skill levels
- Working environment
- Changes in the process

"Towards Safer Radiotherapy" www.ipem.ac.uk/docimages/2329.pdf

What we can't control

- Vendors
  - Increasing complexity of technology
- Regulatory agencies
  - NRC
  - State of Michigan – LARA

What can we do?

- Failure Mode and Effects Analysis
- Develop thorough QA policies and procedures
  - **Continually update**
- Review UMDC, CTB and product recalls
- Learn from experts in the field
- Learn from incidents in the field
- Staff
  - Educate staff/Learn from others
  - Provide with adequate tools, training and time
  - Maintain appropriate staffing levels
- Program Review
- Foster a Culture of Patient Safety

Failure Modes and Effects Analysis

- Process trees – helps to understand the steps in a process or procedure
- Fault trees – illustrates paths that can lead to errors
- Three categories:
  - O – probability that a specific cause will result in a failure mode
  - S – the severity of the effects from a specific failure mode
  - D – the probability that the effect from a failure mode will go undetected

Huq et al, IJROBP, Vol 71, S1 ppS170-S173

Failure Modes and Effects Analysis

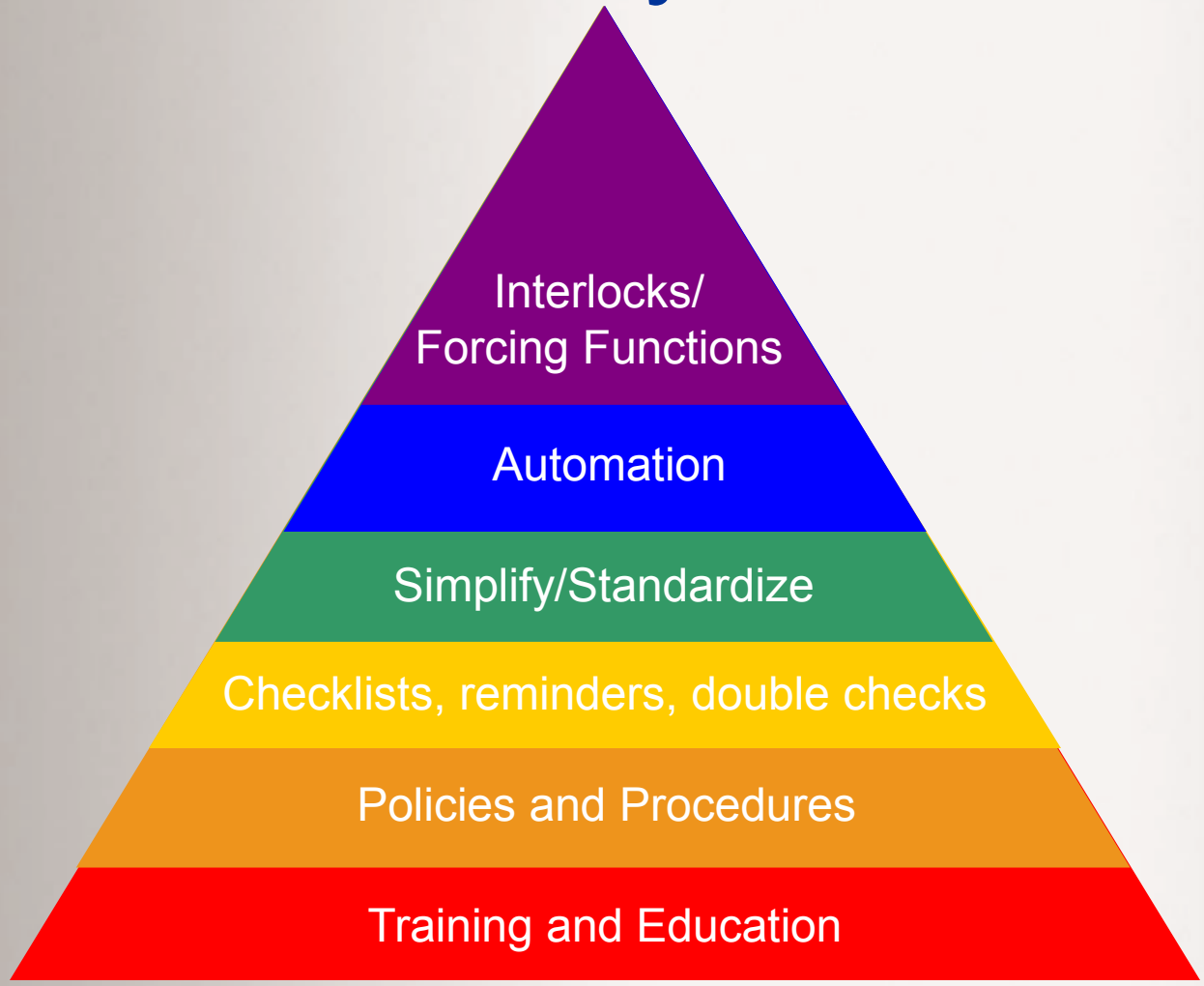
- Product of the three values is the *Risk Probability Number (RPN)*

$$RPN = O * S * D$$

- The higher the RPN, the higher the risk
- TG-100 to define values for O, S and D

Huq et al, IJROBP, Vol 71, S1 ppS170-S173

Hierarchy of Effectiveness



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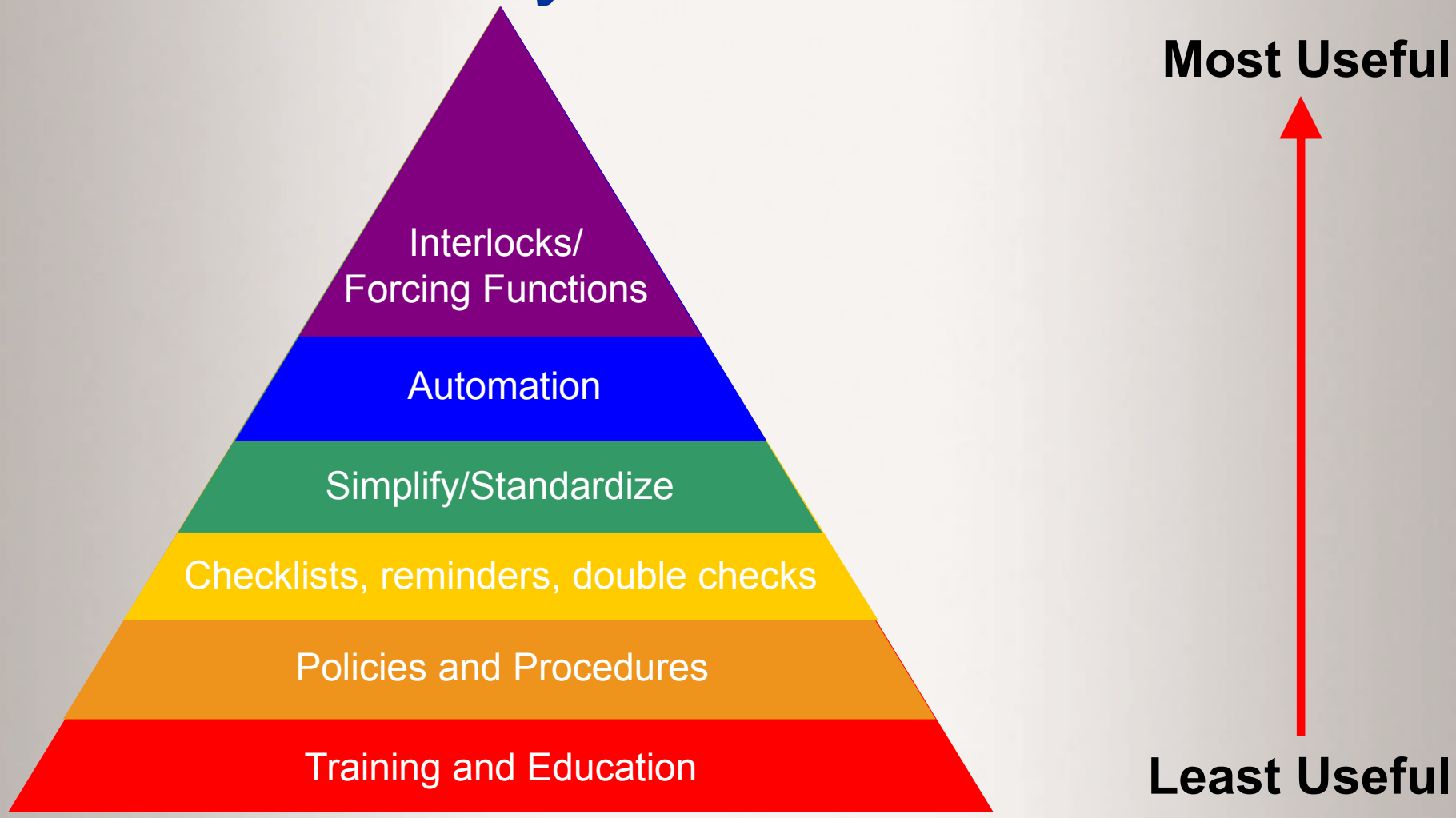
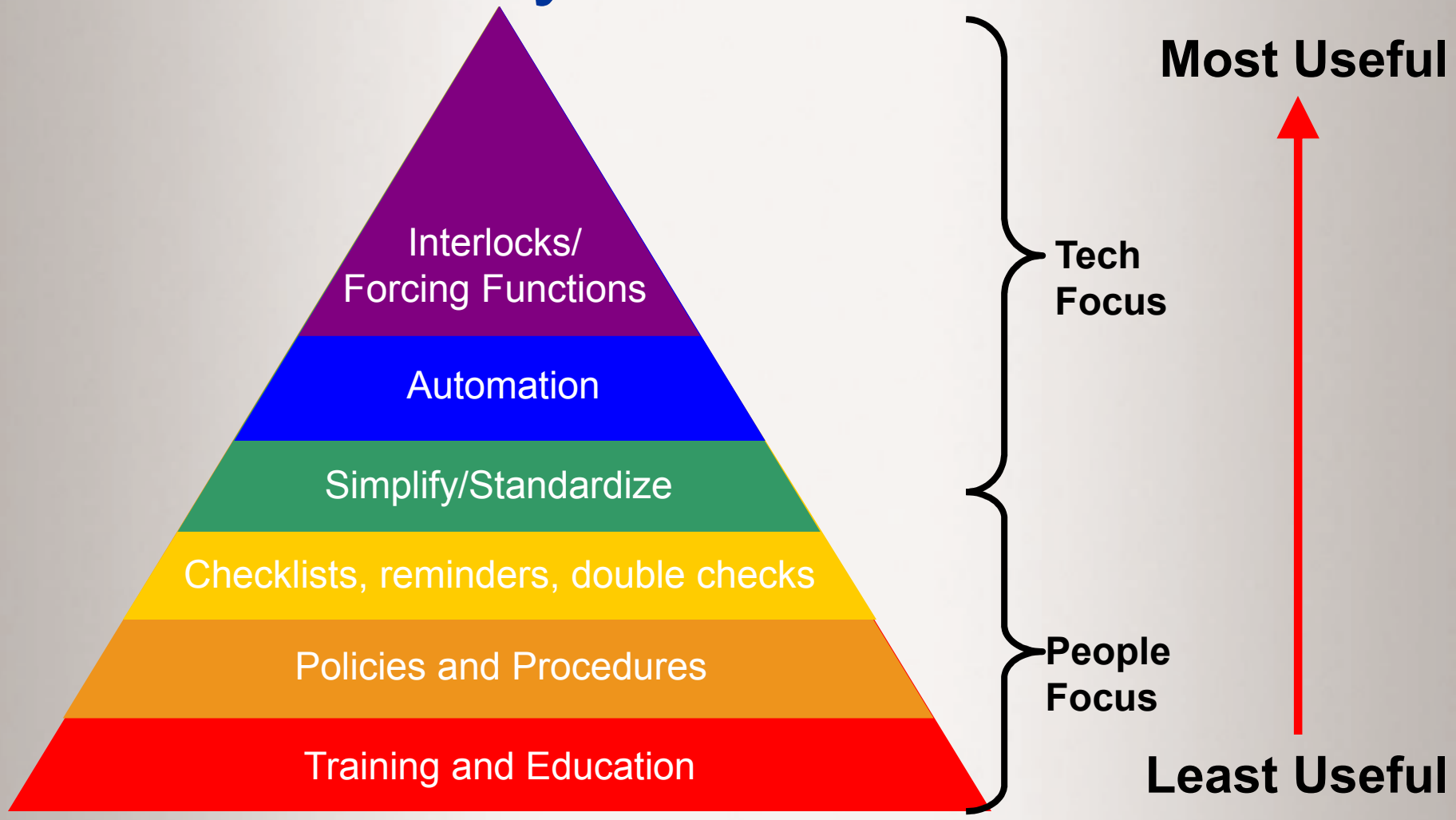
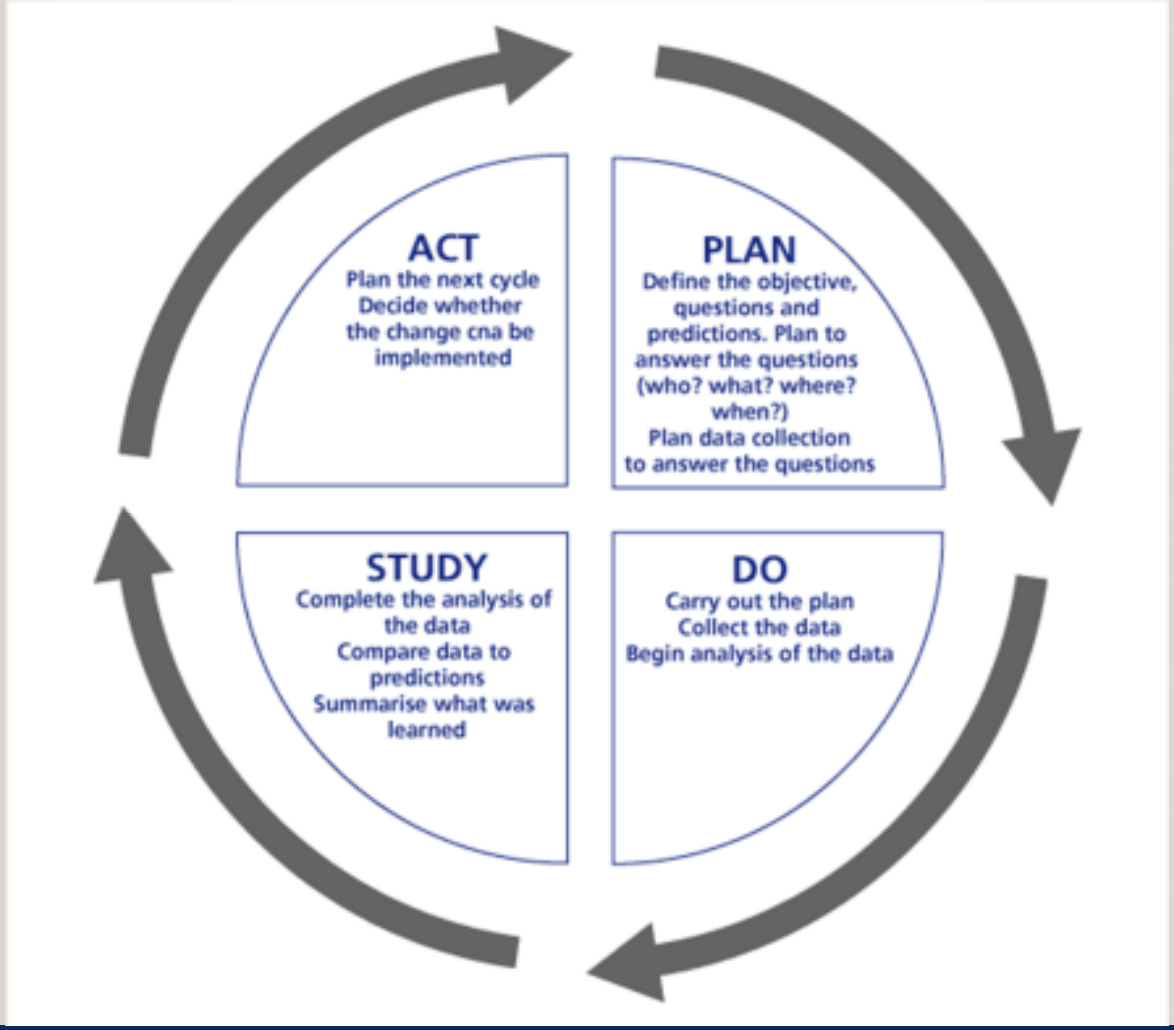


Hierarchy of Effectiveness



Policies and Procedures



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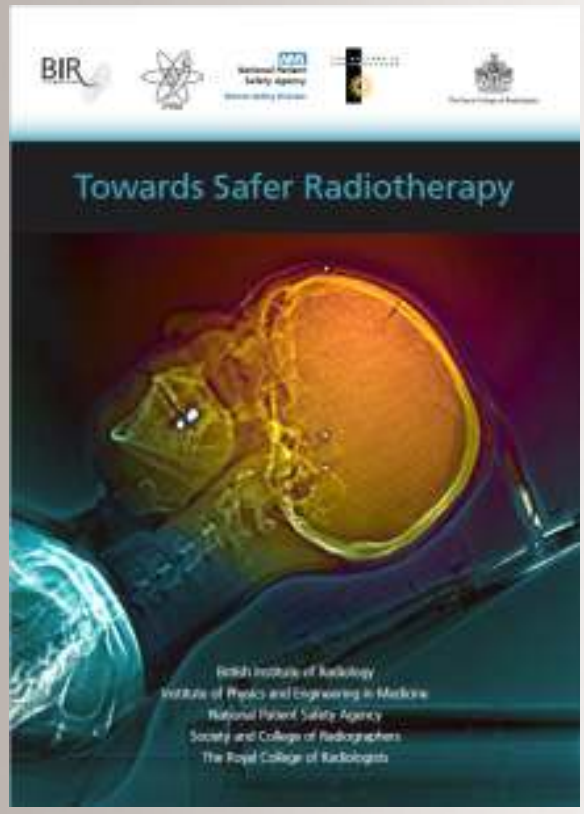
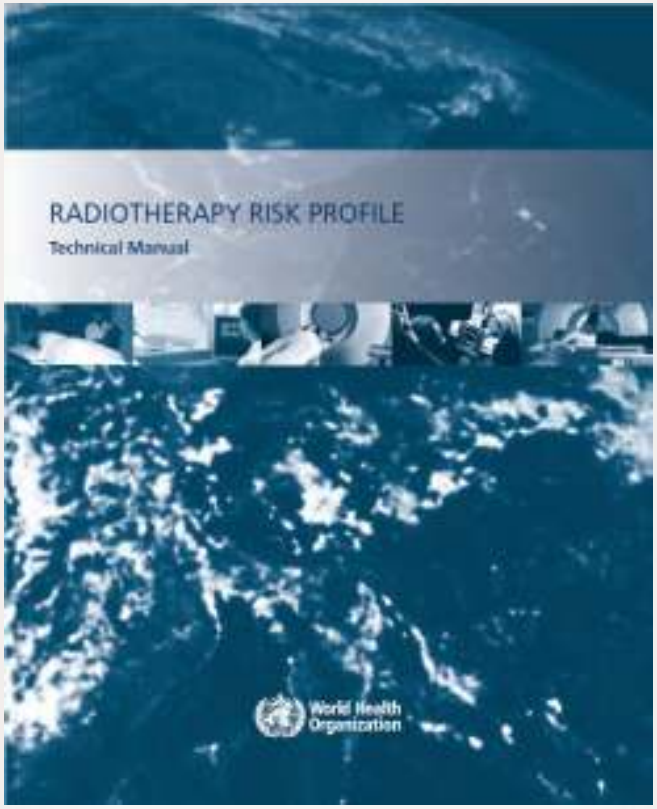
Review notices from vendors

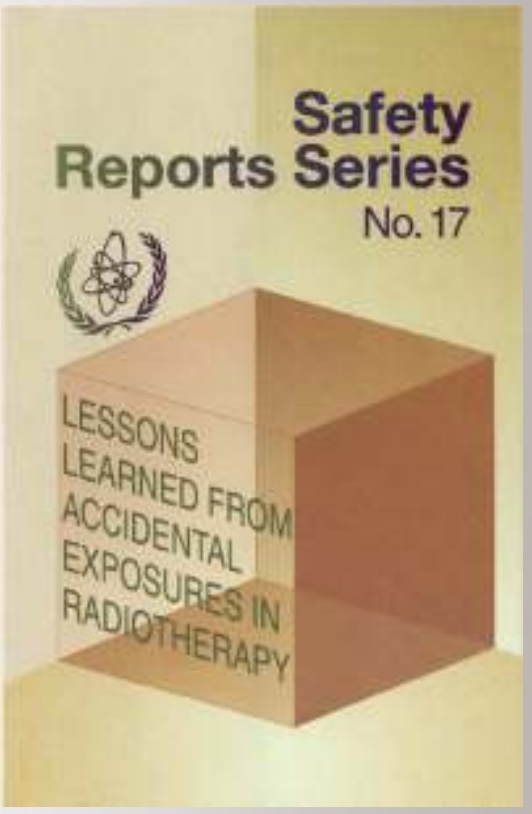
URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Potential Detachment of Gantry Center Throat Cover
Commercial Name of Affected Product:	Varian High-Energy Clinac® linear accelerator (H14, H27, H29)
Reference / FSCA Identifier:	CP-03412
Date of Notification:	***2011-05-24***
Type of Action:	Notification and Correction
Details on Affected Devices:	Refer to appendix page.

Sources of Information







Sources of Information

- www.ipem.ac.uk/docimages/2329.pdf
- www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf
- http://www-pub.iaea.org/MTCD/publications/PDF/Pub1084_web.pdf

Sources of Information

January 23, 2010

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

January 26, 2010

THE RADIATION BOOM

As Technology Surges, Radiation Safeguards Lag

By WALT BOGDANICH

February 24, 2010

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ

December 28, 2010

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO

January 27, 2010

THE RADIATION BOOM

Case Studies: When Medical Radiation Goes Awry

By WALT BOGDANICH

February 10, 2010

F.D.A. to Increase Oversight of Medical Radiation

By WALT BOGDANICH and REBECCA R. RUIZ

Sources of information

- **R**adiation **O**ncology **S**afety **I**nformation **S**ystem
- Established in 2001 under the auspices of ESTRO
- Voluntary web based safety information system for radiotherapy
- Annual Meeting in Dublin, Ireland
- http://www.rosis.info/

IAEA | Radiation Protection of Patients (RPOP)

Search RPoP: GO

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Radiotherapy

- Standards
- Accident Prevention
- Radiation Safety in Brachytherapy
- Radiation Safety in External Beam Radiotherapy
- Radiation Safety in Endovascular Brachytherapy

Radiotherapy, the treatment of disease using ionizing radiation, is mainly associated with cancer treatment but is - to a limited extent - also used for the treatment of some non-malignant diseases. In external beam radiotherapy, radiation beams originating externally to the patient are directed towards the treatment site. These beams are usually created through the use of a linear accelerator or a cobalt unit. In brachytherapy, small and encapsulated radioactive sources are placed directly into or near the volume to be treated. Endovascular brachytherapy, finally, is used for prevention of restenosis in arteries following coronary arterial angioplasty.

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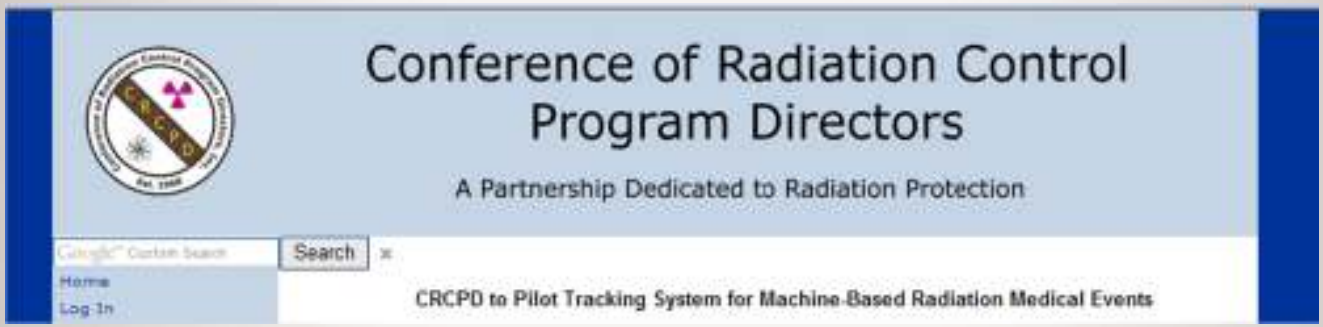
Henry Ford Health System

"SAFRON (Safety in Radiation Oncology) is a global safety reporting system being developed for radiotherapy. The system aims to enable reporting and learning from accidents / incidents and near incidents; integrate with existing systems while complementing national and mandatory systems; and integrate retrospective reporting and prospective risk analysis."

https://rpop.iaea.org/RPOP/RPoP/Content/ArchivedNews/recent-issues-radiation-risks.htm



In the process of staffing a Committee that would:

- Develop a definition of reportable events to include radiation therapy using linear accelerators and e-brachytherapy technology, as well as high dose diagnostic procedures such as computed tomography (CT) and fluoroscopy.
- Develop/maintain a format and mechanism for state programs to provide the committee with details of reportable events.
- Review submitted reports for completeness and accuracy, and develop notices to the state programs when necessary.
- Oversee the development and maintenance of a CRCPD database of reportable events.
- Prepare an annual summary report for the CRCPD Board and the *Newsbrief*.
- Provide a verbal report at the Annual Meeting.

http://www.crcpd.org/

What can we do?

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Staff Education

- Periodic Review of updated Policies and Procedures
- Just-in-time training
- In-service for new equipment, technology and procedures

Staffing Levels – ACR recommendations

Academic/CCC Comprehensive Cancer Center or main teaching hospital of a medical school

H1 Hospital based; 600 or more patients

H2 Hospital based; 201-599 patients

H3 Hospital based; 200 or fewer patients

F1 Freestanding; 600 or more patients

F2 Freestanding; 201-599 patients

F3 Freestanding; 200 or fewer patients

	ALL ACR ACCREDITED FACILITIES	ACADEMIC / CCC	H1	H2	H3	F1	F2	F3
New patients/ radiation oncologist	208	213	253	221	151	248	221	141
New patients/ Physicist	278	196	220	292	153	378	340	226
New patients/ FTE dosimetrist	262	296	348	279	192	287	257	198
New patients/ FTE therapist	71	72	67	75	51	81	73	58
FTE therapist/ Rx machine	3.3	4.1	2	3.4	3	3.9	3.3	2.5
New patients/ Rx machines	187	287	206	241	146	321	258	134

Program Audit/Review

- RPC/RDC
  - OSLD
  - Site visits
- Peer Review/Self Audit
- External Audit
- ACR Accreditation

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Culture of Patient Safety: What we need to do

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality

Culture of Patient Safety

- **Start at the top**
  - Every process needs a leader who must lead by example
  - Everyone, including the leader, must look at their work with a critical eye
- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality

Culture of Patient Safety

- Start at the top
- **Work as a Team**
  - **Therapist, Dosimetrist, Physicist, Physician, Nurse IT Professionals, Administrators**
  - **Remove Hierarchy**
  - **Anyone on the team can prevent an error**
  - **Everyone member of the team needs to have the appropriate tools, training and time to do their job correctly**
  - **Communication; Flow of Information**
- Accountability not blame
- Policies and Procedures
- Measurement of Quality

Culture of Patient Safety

- Start at the top
- Work as a Team
- **Accountability not blame**
  - **Talk about errors as a learning experience**
  - **Must be a non-punitive, nurturing environment**
- Policies and Procedures
- Measurement of Quality

Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- **Policies and Procedures**
  - **Clear, consistent and thorough**
  - **Willingness to delay a treatment if not safe**
  - **Continually updated and modified with feedback from staff and monitoring of variance**
  - **Review of incidents when policies are not followed**
- Measurement of Quality

Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures
- **Measurement of Quality**
  - **Error Analysis and Variance Reporting**
  - **Key Quality Indicators**

How can we reduce errors?

- Simplify the human interface
- Improve human performance
  - Establish and maintain (continually update) clear and thorough Policies and Procedures
  - Education – professional meetings and reports, training,
  - Make sure staff has the necessary tools, training and time
  - Error reporting and analysis
- Establish a Culture of Patient Safety

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Thank You