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PEACE OF MIND | EXPERTISE | CHOICE | THE MEDPRO GROUP DIFFERENCE

Is that "Big Bang" a $2M Lawsuit ?

AAPM 8/2/2018

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AAPM – August 2, 2018

Today's speaker is Brenda Wehrle, BS, LHRM, CPHRM, Senior Patient Safety & Risk Consultant, MedPro Group (Brenda.Wehrle@medpro.com)

Brenda is an industry-recognized patient safety and risk management professional with more than 25 years of experience. Most recently, Brenda served as a corporate leader in clinical risk management. Her professional background also includes broad experience in community healthcare facilities, including acute care, long-term care, ambulatory surgery, behavioral health, and physician practices. These opportunities have afforded Brenda valuable insight into the challenges of providing healthcare in today's world and have provided her with extensive experience conducting site surveys, leading root cause analysis teams, developing innovative loss-prevention programs, and providing consultative risk management guidance.

Brenda also has been an instructor at the Florida Risk Management Institute and has presented training and educational sessions to introduce best practices at the national level. She has experience in infection control, patient and employee safety, quality, accreditation, and credentialing. As a TeamSTEPPS master trainer, Brenda helps healthcare leaders, providers, and staff use communication and teamwork strategies to improve working relationships, enhance patient safety, and reduce the risk of error.

Brenda earned a bachelor of science degree in medical microbiology from the University of Wisconsin. She is licensed as a healthcare risk manager in Florida, is a member of the American Society for Healthcare Risk Management (ASHRM), and has had her American Hospital Association certification as a professional risk manager (CPHRM) since 2004.

Presentation Objectives

At the end of this presentation the attendee will be able to:

- Describe trends that have increased risk incrementally in recent years in the practice of medical physics
- Explain proactive risk management strategies to simultaneously improve patient outcomes and reduce financial risk

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- Radiotherapy… is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death.

  Sir Liam Donaldson Chair, World Alliance for Patient Safety

Case Study #1

Patients sue St. Cloud cancer center, alleging negligent radiation therapy

- At least a dozen people allege they suffered injuries because of radiation errors at Coborn in St. Cloud.

Sandy Schwegman is one of seven former patients at Coborn Cancer Center in St. Cloud to file lawsuits for botched therapy plans. The move pained Schwegman, who spent a career as a hospital nurse.

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Patrick Malone & Associates

- **A series of articles in the New York Times in 2010 and 2011 exposed many sloppy and dangerous practices in the radiation therapy industry.** We have documented many of those in our own patient safety blog. Many of these bad practices, when they cause harm to a patient, justify a medical malpractice lawsuit.
- Examples include:
  - Poor technique in implanting brachytherapy radiation pellets in prostate cancer patients. An oncologist at the VA Hospital in Philadelphia was sanctioned for mistreating nearly 100 veterans.
  - Malpractice with stereotactic radiosurgery, with linear accelerators, which deliver powerful beams of radiation that are supposed to be finely targeted but often aren't aimed properly.
  - Unacceptable variations in doses delivered by Intensity Modulated Radiation Therapy, or I.M.R.T., a common form of machine-generated radiation

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Challenges facing healthcare

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Malpractice Refresher

Tort? Malpractice?

- The person making a tort claim in a law suit is known as the plaintiff; the tortfeasor is known as the defendant. In order to receive compensation, the plaintiff must prove that the defendant in some way caused the injury or damages suffered by the plaintiff.
- A tort claim is filed when an injured victim seeks compensation for personal or financial injury from the person who injured them. The injuries can be physical, emotional, psychological or even financial. "Tort" comes from the Latin word for wrong or injustice.
- Indemnity: a payment made to someone because of damage, loss, or injury

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What is…?

- ***Tort***: a wrongful act other than a breach of contract for which relief may be obtained in the form of damages or an injunction
- ***Medical malpractice*** is defined as any act or omission by a physician during treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury to the patient. Medical malpractice is a specific subset of tort law that deals with professional negligence

Professional Negligence

- The elements of negligence:
  - ✓ Duty
  - ✓ Breach
  - ✓ Causation
  - ✓ Damages

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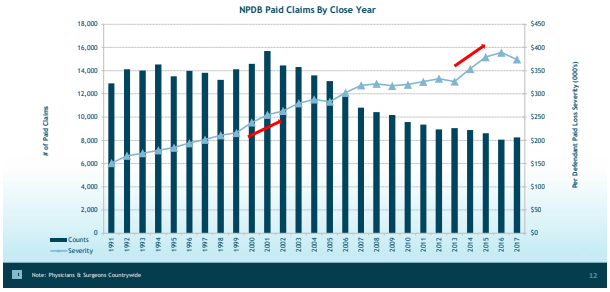
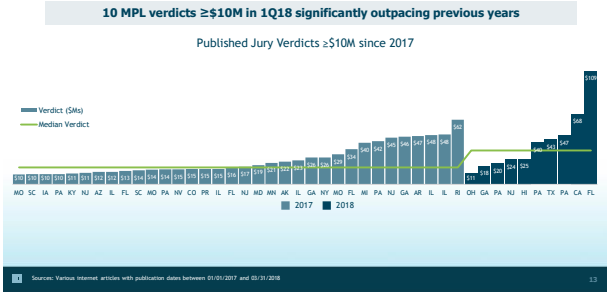
Data and Trends

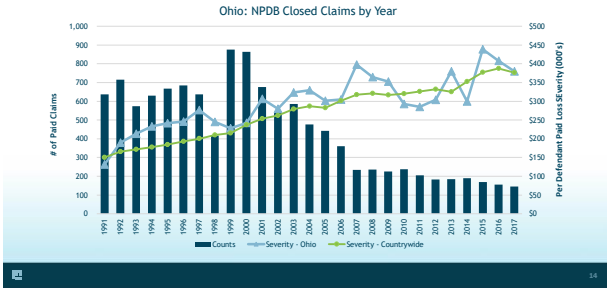
Storm clouds ahead? increasing severity…



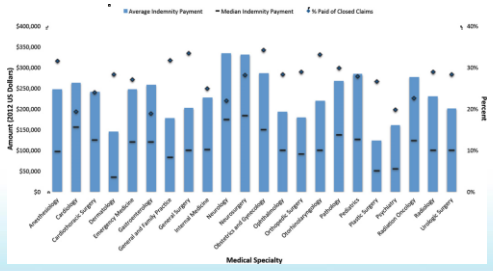
… illustrated by HCL jury verdicts ≥$10 million



State to State



- Characteristics of closed claims and indemnity payments by medical specialty, 1985–2012



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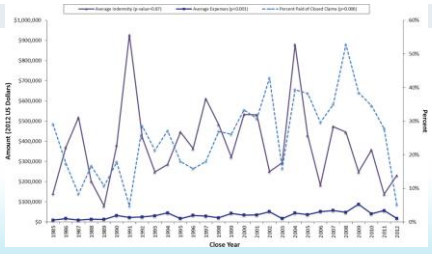
- Closed Radiation Oncology Claims



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- Pennsylvania Incident Data

Table 4. Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, February 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

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Case Study #2

Wrong hepatic lesion treated.

Stereotactic body radiation therapy (SBRT) treatment (50Gy in 5 fractions) was delivered to a benign liver hemangioma instead of the intended metastatic liver target.

A patient previously treated with SBRT for two liver metastases returned with a new lesion. The attending radiation oncologist and resident reviewed the imaging and made the decision to treat the new metastasis with SBRT. A simulation directive was performed by the resident complete with axial image snapshots from a diagnostic magnetic resonance (MR) scan as well as a contrast-enhanced computed tomography (CT) scan illustrating the lesion to be treated. After simulation, the gross tumor volume (GTV) contoured by the resident covered the wrong liver lesion. Treatment planning and quality assurance (QA) were completed based on that incorrect target. The error was not detected at the time of attending approval nor in peer-review rounds. Treatment was delivered to the benign liver hemangioma.

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Factors and Recommendations

Contributing factors in this case included:

- • Failure to accurately correlate target contouring with diagnostic imaging.
- • Hand-offs and extended workflow with multiple people interacting with the plan.
- • Safety-critical issue not identified in the review by the attending physician.
- • Safety-critical issue not identified in peer review, despite the prospective SBRT-specific peer review being performed.
- • Abbreviated treatment course.

Actions and Recommendations:

- • The clinic instituted a new policy and procedure which includes the explicit review of diagnostic images by the attending physician (with an accompanying checklist that is reviewed by others in the workflow).
- • The role of physician peer review (i.e. chart rounds) is well-recognized and is advocated in the American Society for Radiation Oncology (ASTRO) white paper[1] on this topic.
- • This case underscores the need for peer-review and suggests that for SBRT treatments it may take a special form with enhanced safety checks.
- • Other suggested actions include setting the isocenter at the time of simulation which may eliminate certain error pathways.

https://www.astro.org/uploadedFiles/_MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2016Q2Report.pdf

Recommendations for Communication Failures

1. Establish robust procedures to communicate salient details of care to staff.
2. When special circumstances dictate departures from standard processes, prioritize extra communication to staff to ensure accurate treatment delivery.
3. When in doubt, ask for clarification.
4. Tackling communication failures begins with creating a culture of safety.
   a. Consider implementing the Agency for Healthcare Research and Quality's (AHRQ) Survey on Patient Safety Culture within your facility (if not already implemented organization wide).
   b. Make the results clear and easily accessible to every employee throughout the facility.
   c. Discuss and show your plans of action for improvements of the culture.
5. Educate staff and providers on human factors and its integral role in understanding errors.
   a. Identify champions or leaders (create a team within your facility that represents the roles involved, i.e. administration, physics, medicine, nursing).
   b. Train these individuals on AHRQ's TeamSTEPPS®
6. Consider the format of the message – this is central to securing good communication.
   a. Consider the role of briefings, huddles, debriefings and handoffs within your facility.[2]
   b. Develop and enhance individual providers' communication and teamwork skills.[2]
   c. Situational awareness, standardized language, closed-loop communication and shared mental models.[2]

https://www.astro.org/uploadedFiles/_MAIN_SITE/Patient_Care/Patient_Safety/RO-ILS/2016Q2Report.pdf

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- Know Yourself

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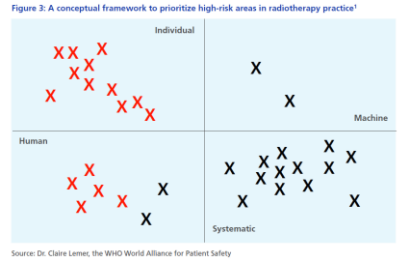
- Prioritization



6. Planning

Risks	Potential impact	Solutions
Incorrect calibration or incorrect output data generation	High	Equipment quality assurance External independent dosimetry comparison audits Protocols and sign-off procedures and audits
Incorrect physical data such as decay curves and tables of constants	High	Independent checks Planning protocols In vivo dosimetry
Faulty planning software Incorrectly commissioned planning software	High High	Commissioning Quality Assurance Sign-off procedures In vivo dosimetry
Misuse of planning software Erroneous monitor unit calculation	High High	Competency certification Manual check by independent professional In vivo dosimetry
Lack of independent cross-checking	High	Departmental policy
Incorrect treatment modalities and beam positioning Incorrect beam energy Incorrect beam size Incorrect normalizations Incorrect prescription point Incorrect inhomogeneity correction Incorrect use of bolus in calculation Wrongly sited blocks Poorly constructed blocks Wrong depth dose chart for wrong machine	High High High High Medium Medium High High High High	Planning protocol checklist Signature protocols and independent checking
Utilization of non-standard protocols	Medium	Standard protocol checklist

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Risks --- Where Do we Start?

Risk Management Techniques

- Culture
- Reporting Incidents and Near misses
- Analysis: Proactive and Reactive
  - Root Cause Analysis
  - FMEA
- Peer Review
  - Learning Systems
- Training on techniques and tools
- Communication
  - Literacy
  - Consent
  - Disclosure

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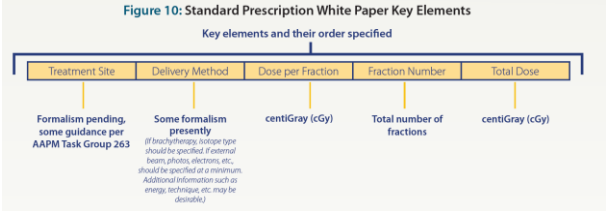
Culture

- Learning, progressive, punitive, high performing….
- HSOPS
- High Reliability
- Hierarchal / Collaborative
- Engaged
- Transparent
- TeamSTEPPS
  - Leadership
  - Communication
  - Situational Monitoring
  - Mutual Support

Training

- TeamSTEPPS
  - Huddles, debriefings, handoffs
  - Shared mental models
  - Closed loop communication
- Quality / Risk
  - Root Cause Analysis
  - HFMEA
- Competencies
- Human Factors
- Organizational Learning
- Patient Safety Organizations

"Standardizing dose prescriptions: An ASTRO white paper"



Incident reporting

- RO-ILS
  - Contribute to a national database and collectively improve the field of radiation oncology.
  - Track and review internal incidents, near misses, and unsafe conditions.
  - Receive Quarterly Aggregate Reports on events submitted throughout the country that include suggestions on how to prevent errors. See recent aggregate reports.
  - Receive bi-annual practice-specific reports on events submitted by your institution.

https://www.astro.org/RO-ILS.aspx

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SAMPLE REPORT CARD –
Q4 2016
October 1, 2016 – December 31, 2016

METRIC	PROVIDER HISTORICAL SUM	AGGREGATE HISTORICAL SUM
Total Number of Events	**150**	**2681**
Therapeutic Radiation Incidents	39	733
Other Safety Incidents	7	167
Near Miss	89	836
Unsafe Conditions	12	744
Operational/Process Improvement	3	201
Most Commonly Identified Workflow Step Where Event Occurred	**Treatment Delivery Including Imaging:** 47% (71/150)	**Treatment Planning:** 28% (756/2681)
Most Commonly Identified Workflow Step Where Event was Discovered	**On-Treatment QA:** 32% (48/150)	**Treatment Delivery Including Imaging:** 26% (706/2681)
Most Commonly Identified Treatment Technique	**3-D:** 41% (61/150)	**3-D:** 21% (560/2681)
Most Commonly Identified Dose Deviation for Therapeutic Radiation Incidents/Other Safety Incidents that Did Not Effect Multiple Patients	**≤5% Maximum Dose Deviation to Target:** 87% (34/39)	**≤5% Maximum Dose Deviation to Target:** 69% (352/512)

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Incident learning

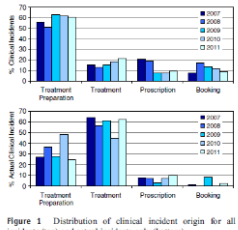

Figure 1 Distribution of clinical incident origin for all incidents (top) and actual incidents only (bottom).

- Results demonstrate that effective use of an incident learning system will strongly encourage the reporting of incidents, whether or not they directly impact a patient, and serve as a proactive means of enhancing safety and quality.

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WHO Incident project

The incidents were recorded according to the following categories:

- Description
- Direct cause(s)
- Contributing factors
- Stage of the treatment process during which the incident happened
- Reported impact or outcome
- Corrective actions and prevention of future incidents

http://www.who.int/patientsafety/implementation/IMPS_summary-report.pdf

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Analysis

- Proactive -HFMEA
- Reactive- Root Cause Analysis
- Data definitions
- Trends and significance
- Quality Assurance
- Case Reviews
- Peer Review

- Domains
  - Equipment
  - Assessment
  - Information Management
  - Communication
  - Environment
  - Leadership
  - Human Factors

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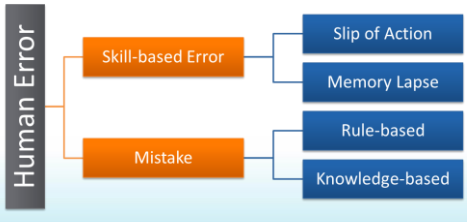
Human Error



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Human factor as a cause of human error

- Stress
- Fatigue
- Time-Compression
- Distractions
- Hierarchy
- Autonomy in practice, resulting in variation in process
- Ineffective teamwork and communication
- Bias

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Common terminology in RCAs

Hindsight Bias
- Tendency to believe, after hearing an outcome, that it could have been foreseen or prevented

Latent Failure
- Errors made by people who are removed in time and space. These errors often relate to design, organization or training for a system

Active Failure
- Error with immediate consequence, usually made by frontline staff

Performance shaping factors: Job vs. Individual
- Attributes in a system, technology, or environment and a person's internal characteristics that affect the likelihood of error or at risk behaviors

Unintentional blindness
- Also known as perceptional blindness, this is the phenomenon of not being able to see things that are actually there. May be due to no internal frame of reference or the result of mental focus or inattention that causes a distraction.

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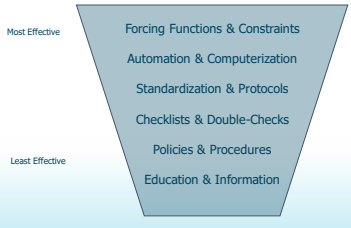
Rank Order of Error Reduction Strategies



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Communication

- Literacy
- Participation
- Communication
  - Provider to Provider
  - Provider to Patient
  - Team
- Informed Consent
- Critical Values
- Disclosure

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"Journey toward High Reliability"

A case example

Elements of High Reliability Organizations

- Preoccupied with failure
- Reluctance to simplify
- Sensitive to operations
- Commitment to resilience
- Deference to expertise

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Journey Toward High Reliability: A Comprehensive Safety Program to Improve Quality of Care and Safety Culture in a Large, Multisite Radiation Oncology Department

1. The Implementation of a Comprehensive Quality and Safety Educational Curriculum
2. The Development of a Hard-Stop policy to Systematically Standardize Patient Safety Checks before Administering RT
3. Enhancement of Peer Review Through an Automated Electronic System
4. Increases Leadership Oversight and Reinforcement
5. Implemented an Electronic Condition Reporting System
6. Routine Assessment of Serious Events and Incidents

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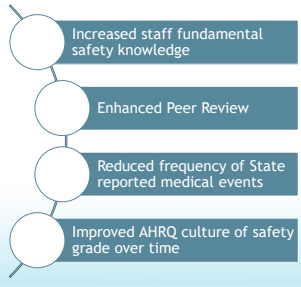
Results



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"This common worry should be replaced by a new paradigm—one that recognizes the inevitability of failure in today's complex work organizations. Those that catch, correct, and learn from failure before others do will succeed. Those that wallow in the blame game will not."

Amy C. Edmondson , Harvard Business Review

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Questions , comments, insights…

Thank You!

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