Is that “Big Bang” a $2M Lawsuit?

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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. Her professional background includes broad experience in community healthcare facilities, including acute care, long-term care, ambulatory surgery, behavioral health, and physician practices. These opportunities have offered Brenda significant 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’s 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.
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.

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 500 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
**Challenges facing healthcare**

- Changing delivery platform
- Changing reimbursement
- Changing workforce
- Continued advances in technology, genetics, etc.
- Greater focus on consumerism
- Continued consolidation

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**Malpractice Refresher**

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**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
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

Data and Trends
Storm clouds ahead? increasing severity...

... illustrated by HCL jury verdicts ≥$10 million

State to State

Note: Physicians & Surgeons Countrywide

Published Jury Verdicts ≥$10M since 2017

Verdict ($Ms) Median Verdict

10 MPL verdicts ≥$10M in 1Q18 significantly outpacing previous years

Published Jury Verdicts ≥$10M since 2017

Ohio: NPDB Closed Claims by Year

Ohio: NPDB Closed Claims by Year
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.

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 paper¹ 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.

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. In doubt, ask for clarification.
4. Tackling communication failures begins with creating a culture of safety.
   - Consider implementing the Agency for Healthcare Research and Quality’s (AHRQ) Survey on Patient Safety Culture. When the facility is not already implemented, advocate on behalf of your facility.
   - Make the results clear and easily accessible to every employee throughout the facility.
   - Disclose 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.
   - Identify champions or leaders (create a team within your facility that represents the roles involved, i.e. administration, physics, medicine, nursing).
   - Train these individuals on AHRQ’s TeamSTEPPS®
6. Consider the format of the message – this is central to securing good communication.
   - Consider the role of briefings, huddles, debriefings and handoffs within your facility².
   - Develop and enhance individual providers’ communication and teamwork skills.
   - Situational awareness, standardized language, closed-loop communication and shared mental models.

References:

Know Yourself

Prioritization

Figure 3: A conceptual framework to prioritize high-risk areas in radiotherapy practice.

Source: Dr. Clare Lows, the WHO World Alliance for Patient Safety.
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
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”

Figure 10: Standard Prescription White Paper Key Elements

<table>
<thead>
<tr>
<th>Key elements and their order specified</th>
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</thead>
<tbody>
<tr>
<td>Treatment Site</td>
</tr>
<tr>
<td>Formulation pending, some guidance per AAPM Task Group 264</td>
</tr>
</tbody>
</table>

“Culture eats strategy for breakfast”
- Peter Drucker
**Incident reporting**

- 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](https://www.astro.org/RO-ILS.aspx).
- Receive biannual practice-specific reports on events submitted by your institution.

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**Incident learning**

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.
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

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

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

Human Error

Skill-based Error
Slip of Action
Memory Lapse
Rule-based
Knowledge-based

Mistake
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

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 behavior

- **Unintentional blindness**
  - Also known as perceptual 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.

Rank Order of Error Reduction Strategies

<table>
<thead>
<tr>
<th>Most Effective</th>
<th>Least Effective</th>
</tr>
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<tbody>
<tr>
<td>Forcing Functions &amp; Constraints</td>
<td>Education &amp; Information</td>
</tr>
<tr>
<td>Automation &amp; Computerization</td>
<td>Policies &amp; Procedures</td>
</tr>
<tr>
<td>Standardization &amp; Protocols</td>
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Communication
- Literacy
- Participation
- Communication
- Provider to Provider
- Provider to Patient
- Team
- Informed Consent
- Critical Values
- Disclosure

"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
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

Results

- Increased staff fundamental safety knowledge
- Enhanced Peer Review
- Reduced frequency of State reported medical events
- Improved AHRQ culture of safety grade over time

“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

https://hbr.org/2011/04/strategies-for-learning-from-failure
References

1. WHO Radiotherapy Risk Profile - https://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf
2. Patient safety in an environment of rapidly advancing technology in radiation therapy. Joshi Department of Oncology, Queen's University, Kingston, Department of Medical Physics, Cancer Centre of South East Ontario, Kingston General Hospital, Kingston, Ontario, Canada - https://www.ncbi.nlm.nih.gov/pubmed/24872602
3. Improving patient safety in radiation therapy through error reporting and analysis - Findlay Medical Exposures Group, Radiation Assessments Department, PHE Centre for Radiation, Chemical and Environmental Hazards, Chilton, Didcot, Oxon OX11 0RQ, UK - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4165825/

Questions, comments, insights...

Thank You!