

Volume I - 2018

EDITOR'S CORNER

The Risk Management Quarterly (RMQ) is the official journal of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and published several times a year.

RMQ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

This journal contains articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulation, as well as other relevant information of interest to risk managers. The articles are usually written by ***AHRMNY*** members, so the journal serves as an opportunity for members to showcase their writing talents.

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Article Requirements: Maximum article length 3,500 words; Photos should be high resolution JPEGs (at least 300 dpi); AHRMNY will not publish articles promoting products or services.

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SUBMIT AN ARTICLE

We are asking our readers to submit articles for future editions of the RMQ journal. We accept articles that focus on patient safety, environment or staff safety, risk management, claims management, insurance issues and other relevant topics.

The deadline for submission and consideration for the next journal is **August 31, 2018**

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PRESIDENT'S MESSAGE



The Board of Directors would like to take this opportunity to wish everyone a wonderful summer and to thank you for your support throughout the year. We have had a very successful year and are most grateful for all the support from our generous sponsors as well. To recap a few highlights, we started off our year with a webinar titled "Ransomware Attack! Before, During and After" by Betsy Baydala from the law firm of Kaufman, Borgeest and Ryan and Rosemarie White and Elizabeth Kirkpatrick from CareMount Medical.

We hosted our second Long Island Conference in Brookville, with presentations on Communication Factors in Malpractice Cases, Termination of the Physician Patient Relations and Resilience Solutions in Healthcare. Speakers included Dana Siegal and Penny Greenberg from CRICO, Alex Trinkoff and Dr. Victor Klein from Northwell Health and lastly Robert Perlman from Gallagher Continuum Solutions. Our evening event at Lenox Hill took place in March and covered topics on Sexual Harassment in the "Me Too Era" by Ruth Kraft and Mamie Stathatos-Fulgieri from the law firm Vigorito, Barker, Porter and Patterson and had an interactive session with Plaintiff attorney James Wilkens from Sullivan, Papain, Block, McGrath and Cannavo along with John Barker from Vigorito, Barker, Porter and Patterson.

Our Annual Conference, held on Friday, June 8th at the beautiful Andaz Hotel was a huge success. It was one of our largest attended programs with 174 attendees, 10 guest speakers and 11 exhibitors.

Thank you to the education committee for putting together an excellent program and our hard-working fundraising committee who assisted us in supporting our event.

I truly feel honored to serve as the President of this terrific organization. We are committed to being the New York central source of information and leader in healthcare risk management and patient safety.

We encourage all of you to get involved and promise it will be a rewarding experience. Please consider volunteering to work on one of our various committees. Stay tuned for information about upcoming educational programs.

Best regards,
Lesli Giglio, President
July 1, 2017 - June 30, 2018

Illustrating The Role of the ERM Committee in Risk and Opportunity Identification With A Proposal to Implement New Technology

By Caroline Bell, RN, BSN, JD, CPHRM, DFASHRM

Suppose the chief physician of your hospital system's family medicine department submits a proposal to implement the use of a digital health application (app) to monitor in real time the blood sugar levels for the pediatric and adult type I diabetes patient population. The chief physician explains that she intends to require all family medicine practitioners to use the app for every type I diabetes patient. She plans to implement the use of the app simultaneously with the new diabetes clinic that will be opened as a measure to address population health. What process is in place at your organization to identify each potential risk?

It will be difficult to conceptualize all of the risks and opportunities associated with the physician's digital health app proposal without a panoptic discussion in a committee-based forum. Organizations that have implemented a fully functioning Enterprise Risk Management (ERM) program, which includes an ERM committee structure and standardized processes, will have the greatest success identifying and managing each potential risk and opportunity.

Let's begin with a brief overview of ERM, then explore the mechanism by which the ERM committee can serve as a platform to generate comprehensive risk and opportunity identification.

ERM OVERVIEW

ERM is an organization-wide business model. According to the American Society for Healthcare Risk Management (ASHRM), "Enterprise risk management (ERM) in healthcare promotes a comprehensive framework for making risk management decisions which maximize value protection and creation by managing risk and uncertainty and their connections to total value."[1]

According to the Committee of Sponsoring Organizations of the Treadway Commissions (COSO), organizations that integrate ERM throughout the entity can realize benefits, such as:

- Increasing the range of opportunities
- Identifying and managing risk entity-wide
- Increasing positive outcomes and advantage while reducing negative surprises
- Reducing performance variability
- Improving resource deployment
- Enhancing enterprise resilience[2]

Contrast ERM with traditional risk management models, which are designed to preserve assets. COSO explains, "Enterprise risk management is not a function or department. It is the culture, capabilities, and practices that organizations integrate with strategy-setting and apply when they carry out that strategy, with a purpose of managing risk in creating, preserving, and realizing value."[3]

One of the key goals of ERM in healthcare is to shift from traditional risk management processes that focus on the downside of risk (loss), to a more proactive risk management program that focuses on the upside of risk (opportunity) and processes to timely identify and proactively manage risk before harm occurs.

The basic elements of a successful ERM Program may encompass:

- Goals that are consistent with the organization's mission, vision, values and strategic goals. The ERM goals facilitate establishing the organization's risk appetite and risk tolerance.
- A framework and supporting processes which provide the process to identify, analyze, evaluate, mitigate and monitor risk. One example is the ISO 31000 framework.
- A structure and function that supports the overall infrastructure for flow of information from the top down and bottom up, and across the organization. The ERM committee provides the infrastructure to accomplish organization-wide flow of information.
- A culture of accountability that extends from the governing board to frontline staff members. The organization's ERM program must be leadership-driven. Otherwise, it is destined to fail.

The organization's ERM committee structure and function can be one of the key drivers of the above listed success factors.

ERM COMMITTEE

The general structure of the ERM committee includes a working group and steering committee. Ultimately these committees report to the organization's governing board.

- ERM working group: "[T]he ERM working group reports to the steering committee and is the group charged with day-to-day activities."[4] Include in the committee membership representation from each clinical and non-clinical department. The Committee members may include both internal and ad hoc external experts. The general role of the ERM working group committee is to proactively identify, assess, evaluate and manage risk. Risk identification should generate from internal and external data, and through committee discussions regarding proposals for new building, procedures, technology, and so on. The scenario above, regarding the chief physician's proposal to implement the use of a digital health app in patient care, will be utilized as an example to discuss the ERM working group committee's role in risk and opportunity identification.
- ERM steering committee: This committee serves as the oversight committee to the ERM working group committee. In general, it functions to guide and review organization's ERM infrastructure, including establishing a framework and setting goals.[5]

Committee membership should include members of the c-suite and other executive leadership who collectively represent each clinical and non-clinical department within the organization.

The overall ERM committee function and processes extend beyond addressing only clinical/patient safety risks. It encompasses a variety of interrelated clinical, business, environmental, technology and people-centered risks. The eight fluid domains that have been adopted by ASHRM include:

- Clinical/Patient Safety
- Financial/Insurance
- Operational
- Strategic
- Legal/Regulatory
- Technology/Equipment
- Human Capital
- Hazard

The multi-risk domain process will be utilized as a guide for committee discussions to identify both threats (downside risk) and upside risk (opportunity) related to the scenario outlined in the beginning of this document. The process that will be described underscores the extent to which various risks associated with a single subject or event can be interrelated, and why it's important to include representation from all clinical and non-clinical departments in the committee membership.

This discussion is not comprehensive. Rather, it establishes a tone for the general thought process, discussion points, and it highlights certain ERM committee member experts who may be most useful under specific domains. Readers should consider the threats, opportunities, and internal and external experts within their own organization that would be pertinent to this process.

RISK DOMAINS

Clinical/Patient Safety Risk

Definition

The American Society for Healthcare Risk Management (ASHRM) has defined 'clinical/patient safety risk' management as, "Risks associated with the delivery of care to residents, patients and other healthcare customers. Clinical risks include: failure to follow evidence-based practices, medication errors, hospital acquired conditions (HAC), serious safety events (SSE), and others."[6]

Context

Threats

A variety of clinical risks may arise through the use of digital health apps. Informed consent, proper patient selection, proper provider selection, and quality of care concerns, are among the clinical/patient safety concerns.

For example, committee experts may explore informed consent-related concerns by discussing what informed consent means when care is supplemented through the use of digital health apps. The committee may consider how the use of technology may impact the informed consent process and generate risk. Clinicians should follow existing guidelines for informed consent and revise the process as necessary to conform with the unique nature of incorporating technology into patient care. There are multiple criteria related to informed consent that are applicable to this process including, but not limited to:

- Evaluating and documenting the patient's competence to understand and to decide, especially when pediatric patients are involved.
- Voluntary decision-making means the patient will not be coerced into using this technology. An alternative plan for obtaining and providing information from the patient to clinician should be in place for patients who do not want to engage in the process.
- Disclosure of material information is a key component of the consent process. The disclosure process should make clear what information will be shared with the patient's physician, how it will be shared, how the information will be used, and expectations by the patient and practitioner. It should be clear to the patient how the information gathered will be used in their treatment plan and publishing purposes, as applicable.
- The patient should expressly, in writing, authorize the plan. The plan should include when and how the patient should access the digital health app, and a process should be in place to follow-up with the patient to determine whether the patient has accessed the app at the designated time and whether the patient has been able to utilize the app as intended.

Quality of care issues may surface through improper patient selection. Patients who are not tech savvy or do not value the use of an app in their care will not be good candidates for use. The use of the app should be optional to preserve quality of care and optimal patient selection.

Opportunities

In terms of the upside of risk, and how the use of digital apps in patient care may drive value from the clinical/patient safety risk perspective, this technology has the potential to create an environment where patients receive care in real time. This may result in greater compliance and offer patients more control over their condition.

ERM Committee Member Experts

- Physician
- Physician office clinical staff
- Legal
- Medical staff office
- Patient safety
- Operations

Financial/Insurance Risk

Definition

The financial/insurance domain involves "Decisions that affect the financial sustainability of the organization, access to capital or external financial ratings through business relationshi relationships or the timing and recognition of revenue and expenses. Risks might include: costs associated with malpractice, litigation, and insurance, capital structure, credit and interest

fluctuations, foreign exchange, growth in programs and facilities, capital equipment, corporate compliance (fraud and abuse), accounts receivable, days of cash on hand, capitation contracts, billing and collection."[7]

Context

Threats

The use of digital health apps may present an insurance risk, especially related to professional liability claims in the context of 'standard of care' in a legal proceeding. Technology naturally changes the watchfulness, attention, caution and prudence that a reasonable person in the same or similar circumstances would exercise."[8] It's often a subjective issue upon which reasonable people can differ. If a person's actions do not meet the standard of care, then his/her acts or inactions fail to meet the duty of care. The medical industry defines 'standard of care' as, "A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness or clinical circumstance."[9]

According to the latter, digital health apps have the potential to change the standard of care. In broader terms, in the early 1990's open cholecystectomies were the standard of care for all patients who needed to have their gallbladder removed. Patients were hospitalized for several days, were on IV fluids and were not permitted to eat for several days. Then technology advanced and laparoscopic cholecystectomies became the standard of care. Technology is constantly evolving and new ways of enhancing the quality and efficiency of patient care are being adopted across the globe.

Keep in mind, when the use of a digital health app is considered 'experimental' it may amount to an exclusion on a commercial insurance policy.

Opportunities

Market share growth and competitive advantage may be realized through the use of digital health apps in patient care.

ERM Committee Experts

- Captive administrator
- Legal
- Billing
- Insurance broker (external expert who may be invited to a committee meeting to contribute to the conversation)
- Physician

Operational Risk

Definition

According to ASHRM, "The business of healthcare is the delivery of care that is safe, timely, effective, efficient, and patient-centered within diverse populations. Operational risks relate to those risks resulting from inadequate or failed internal processes, people or systems that affect business operations. Included are risks related to: adverse event management, credentialing and staffing, documentation, chain of command, and deviation from practice."[10] Operational risks may also refer to policies and procedures, and workflow.

Context

Threats

Operational risk can include the policies and mechanisms that are put in place to ensure safe usage of the app, and how the use of the digital app is protected from collateral threats. For example, risks can extend beyond the lack of direct security measures and hacks. In one case a cybersecurity start-up company pitched its software by showing to an outside organization how it worked within the network of a hospital that was a client.[11] The company never had permission to use its customer's data to provide presentations online and to other hospitals. In other words, the company selling security actually was giving outsiders an unauthorized look at information from inside its customer's system. Procedures should be in place to prevent this type of occurrence.

Ensure that the app will perform the task that it is intended to do. Begin by researching whether the app does what it says it's going to do. One organization learned this the hard way. The New York attorney general's office settled with three separate health-related mobile app developers because they could have harmed patients by giving them wrong or misleading results. At least one of the apps claimed to measure vital signs and other key health indicators, but it was not backed by scientific testing, which could have caused significant harm.[12] Developers should be able to provide information about testing and provide disclaimers that their apps are not medical devices and are not approved by the FDA, when applicable.

The use of digital health apps and any technology that requires an overhaul of existing processes and procedures also requires a process to evaluate and revise workflows. Well-designed policies may be developed to guide proper use of the app, including patient management guidelines. Organizations should already have in place a new equipment/new procedure process. Follow those same procedures when adopting digital health apps into patient care. If not already done, incorporate a mock trial run of a patient encounter utilizing the technology before it is actually incorporated into patient care. Mock demonstrations are extremely effective in identifying gaps in the process that can be proactively addressed.

Opportunities

The upside of risk that the organization may experience is the technology has the ability to expand patient-centered care efforts. Practitioners will have the ability to receive information regarding the patient's blood glucose levels in real time and provide more timely and customized and patient-centric care.

ERM Committee Experts

- Operations
- Clinical experts
- Biomedical
- Committee members who are also members of the organization's policy and procedure committee
- Information technology

Strategic Risk

Definition

Strategic risks are those risks associated with the focus

and direction of the organization. Such risks may include competitive advantage, mergers/acquisitions/ divestitures, joint ventures, measures to adapt to changing times, health care reform, and other business arrangements.[13] Marketing messages should be consistent with the entity's mission, vision, and values. Strategic risks are measured by their applicability to the organization's mission, vision, values and strategic goals.

Context

Threats

The committee should consider how the use of the app furthers the organization's mission, vision, values and goals. For example, if the digital app is considered to be 'experimental' and the organization's mission and vision is conservative and does not support experimental endeavors, then it will probably not be approved for use at the board level.

Marketing efforts should not over-promise. Collaborate with marketing and corporate counsel to ensure that marketing materials are consistent with applicable rules and do not over-promise cures or chronic disease control.

Opportunities

Adopting digital health apps is a measure to adapt to changing times, and can provide a competitive edge. Align marketing messages associated with implementation and use of the app with the organization's mission, vision, and values.

ERM Committee Experts

- Marketing
- Operations

Legal/Regulatory Risk

Definition

Legal and regulatory risk relates to state and federal laws that impact hospital operations and the way care is delivered. It is not necessarily associated with medical malpractice/professional liability. According to ASHRM, "Risk within in this domain incorporates the failure to identify, manage and monitor legal, regulatory, and statutory mandates on a local, state and federal level. Such risks are generally associated with fraud and abuse, licensure, accreditation, product liability, management liability, Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoPs) and Conditions for Coverage (CfC), as well as issues related to intellectual property."[14]

Context

Threats

There are several potential legal/regulatory risks associated with the use of digital health apps in patient care.

The committee members may consider whether the use of the app may be considered experimental. If so, the IRB rules according to Title 45 of the Federal Code of Regulations may apply.

Committee members may also discuss whether the technology is considered a medical device according to the FDA which may answer the question whether the issue of harm may be considered according to product liability versus medical malpractice principles. Sometimes an event can cross both lines. Many organizations, such as the FDA, are working in collaboration with other entities to drive safe usage of digital health apps in patient care.

Within the past few years, the Federal Trade Commission (FTC) cracked down on several high-profile health-technology companies for deceptive marketing and claims, as well as delivering inaccurate results to patients. The FTC began to pay attention to the apps that lack scientific support to back up claims for products that purport to prevent or treat health or disease-related conditions. For example, a blood testing company claimed its technology was revolutionary, but investigators found serious deficiencies with its lab that posed serious health risks to patients.[15]

State law can also impact the delivery of care through the use of digital health apps. Although state laws have yet to specifically address this space, organizations should follow state laws that address privacy, security, telehealth, geographical boundaries to providing care from the practitioner licensure perspective, and other applicable rules.

Committee members may also consider the federal anti-kickback rules. These rules prohibit "the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business."[16] The committee members may require from the physician additional information regarding the relationship with the vendor and whether payment or gifts have been offered.

Opportunities

Value may be realized when the committee proactively prevents practices that may violate laws in the first place. This can save the organization millions of dollars in fines and legal expenses.

ERM Experts

- Legal
- Compliance
- Biomedical
- Billing
- Medical staff office
- Physician

Technology Risk

Definition

"This domain covers machines, hardware, equipment, devices and tools, but can also include techniques, systems and methods of organization. Healthcare has seen an explosion in the use of technology for clinical diagnosis and treatment, training and education, information storage and retrieval, and asset preservation."[17]

Context

Threats

Due diligence efforts would ensure that digital health apps would be provided through HIPAA compliant platforms and appropriate security measures would be in place. These include, but are not limited to the technology backbone and infrastructure to support the function, remote device integration with real-time data sharing, reporting and

cross data correlation; interoperability, data analytics and big data management, and privacy and security.

Opportunities

The upside of risk in this context includes taking proactive measures to prevent technology-associated risks and maximizing best practices in patient care through the use of technology.

ERM Committee Experts

- Information technology
- Compliance

Human Capital Risk

Definition

ASHRM explains,
This domain refers to the organization's workforce. This is an important issue in today's tight labor and economic markets. Included are risks associated with employee selection, retention, turnover, staffing, absenteeism, on-the-job work-related injuries (workers' compensation), work schedules and fatigue, productivity and compensation. Human capital associated risks may cover recruitments, retention, and termination of members of the medical staff and allied staff.[18]

Context

Threats

In the scenario, the chief physician of the family medicine department indicated that all physician's will be required to utilize the app with all applicable patients. Proper physician/employee selection for use of the app will be important. Some physicians and employees may not be comfortable with the technology. Sometimes, this can ultimately cause harm in the delivery of patient care.

Opportunities

On the other hand, the use of technology may be a driver for staff retention. There has been much discussion recently on the challenges healthcare organizations face regarding staff retention, especially regarding retaining the millennial workforce. Millennials tend to be tech savvy. One source reported that "only 28 percent of millennials feel their current organization is making full use of their skills.[19] Although this is only one factor related to millennial staff retention, one may surmise that they may be more content working in an environment that maximizes the use of innovative technology.

ERM Committee Experts

- Human resources
- Physician
- Clinical expert
- Frontline staff members

Hazard Risk

Definition

According to ASHRM, "This ERM domain covers assets and their value. Traditionally, insurable hazard risk has related to natural exposure and business interruption. Specific risks can also include risk related to: facility management, plant age, parking (lighting, location, and security), valuables, construction/renovation, earthquakes, windstorms, tornadoes, floods, fires."[20]

Context

Threats

Several hospitals have been victims of crypto-ransomware. The information technology systems of these attacks were infected with ransomware which encrypted files and made the system inoperable. The perpetrators demanded money to unlock the records and remove the malware.[21] The same type of threat could compromise the use of the app. The committee representative from the information technology department should take center stage on this portion of the discussion to describe the existing measures that are in place to prevent this type of occurrence. The committee as a whole may discuss which prevention measures or technology should be implemented to protect against this type of threat. The ERM steering committee will be responsible for allocating the resources necessary to implement such measures.

Opportunities

It may be wise for the committee to identify a team to conduct a proactive Failure Modes and Effects Analysis (FMEA) of the technology risks associated with the use of digital health apps in patient care. The findings of the FMEA will be valuable to consider for future plans to implement similar types of technology into patient care. This will ultimately save the organization time, money and resources.

ERM Committee Experts:

- Information technology
- Operations

NEXT STEPS

Once the ERM working group committee members have identified all potential risks, the next step is to analyze, evaluate, mitigate and monitor the risks. Committee members must be provided with the appropriate tools and guidelines to advance to the next steps in an expeditious, efficient and standardized manner. The ERM steering committee develops and guides these practices, and provides the resources necessary to complete ERM working group committee tasks.

CONCLUSION

Healthcare organizations that have implemented a fully functioning ERM programs benefit from accelerated processes to proactively identify and manage risk. An ERM infrastructure also provides a platform to maximize opportunities. The entity's ERM committee structure, when properly functioning, can advance the organization's successful achievement of ERM.

REFERENCES ON PAGE 31

ABOUT THE AUTHOR



Caroline has over 25 years of experience in the healthcare industry. She earned her Bachelor of Science in Nursing degree from Bowling Green State University and her Juris Doctor degree from Cleveland Marshall College of Law. As the founder and CEO of IERM (Integrated Enterprise Risk Management), she partners with health care leaders to achieve Enterprise Risk Management within their entity. Caroline has simplified the ERM process so that healthcare organizations can more easily integrate an effective, standardized and ongoing ERM infrastructure throughout their organization.

The Paradox of Prematurity
Why have improvements in the care of preterm infants led to more malpractice claims?

By Sean Maraynes

Advances in maternal fetal medicine and neonatology have dramatically increased survival rates for extremely premature infants, defined as infants born at fewer than 28 weeks gestation.[1] One would think that medical advances that increase survivability would tend to lower the frequency and severity of malpractice lawsuits. We will examine why, ironically, we've seen that medical advances related to the obstetrical and neonatal care of extremely premature infants have actually led to an uptick in high-exposure cases involving the birth of extremely premature infants. More importantly, this article will evaluate common plaintiff and defense strategies in malpractice actions involving extreme prematurity.

Backgrounds

One of the driving factors behind the increased survival of extremely premature infants has been the use of antenatal steroids. After a 1994 National Institutes of Health (NIH) recommendation regarding the administration of antenatal corticosteroids, The American Congress of Obstetricians and Gynecologists (ACOG) followed with its own endorsement, leading to the administration of a course of antenatal corticosteroids in 70–90 percent of women who delivered at fewer than 34 weeks gestation.[2] The use of antenatal steroids, coupled with the establishment of the modern neonatal intensive care unit, between the 1970s and 1990s, including the routine use of CPAP devices, mechanical ventilation and surfactant, has resulted in improved survival rates.[3]

Much has been written about societal costs associated with the delivery of extremely premature infants. A 2005 study found the annual societal economic burden associated with preterm birth in the United States to be least $26.2 billion, including special education services estimated at $1.1 billion.[4] However, the impact of increasing preterm survival rates on the frequency and severity of related medical malpractice actions is discussed less often. Nevertheless, we've seen a deluge of cases that involve defensible medical treatment that inexplicably results in a malpractice claim. The crux of the problem faced by medical providers and their defense counsel is this: Although the use of antenatal steroids, modern neonatal care and neuroprotective agents such as magnesium sulfate can sustain life and guard against cerebral palsy, they cannot make the fetal brain develop faster.

Litigation

The birth of an extremely premature infant with a poor neurodevelopmental prognosis creates an enticing opportunity for plaintiffs' attorneys. Clearly, the cognitive dysfunction found in many extremely premature infants constitutes a high-exposure injury. Additionally, the sheer number of medical decisions that must be made in the neonatal intensive care unit in order to keep the infant alive provides a plethora of opportunities for the plaintiffs' attorney to "Monday Morning Quarterback" the care rendered. These decisions in the intensive care unit can involve, among others, resuscitative efforts, ventilator settings, antibiotic coverage and decisions related to feeding. Given the fragility of extremely premature infants, and given the fact that nearly any medical intervention can potentially cause serious injury, the number and complexity of the treatment decisions in this setting provides opportunities for plaintiffs' attorneys.

Although every effort must be made to defend these claims on liability grounds, it can be challenging given that plaintiffs' experts attempt to link injuries sustained by extremely fragile premature infants to medical interventions. For instance, a plaintiff's expert may allege that an improper ventilator setting or use of a manual resuscitator caused an intraventricular bleed, a common occurrence in extremely premature infants. Given the seemingly endless potential for factual allegations that must be defended, in many cases the most viable defense theory is to focus on the science behind fetal brain development. This can provide a compelling causation defense as to why the infant's neurodevelopmental delays were not caused by medical treatment rendered, but rather by a brain that never had the chance to fully develop. For instance, a 26-week infant has one fifth of the brain volume of a 37-week infant. At 28 weeks, the cerebral cortex, perhaps the most important part of the brain in terms of cognitive function, has not fully formed, its neurons are not layered and its synapses remain unformed.

Plaintiffs' attorneys may argue that some extremely premature infants can develop in the extra-uterine environment and live totally normal lives; therefore, but for the negligence of the providers, their client would have developed normally. Complicating the defense of this argument is the fact that, oftentimes, extremely premature infants who have permanent neurodevelopmental delays had stormier neonatal courses. As such, more medical decisions are made in the neonatal intensive care unit and, as discussed above, each of these decisions can lead to a potential allegation of malpractice.

Mounting a Defense

One potential response to the question of why some extremely premature infants develop normally while

some do not is that in order for an extremely premature brain to continue to develop properly in an extra-uterine environment, conditions must be "ideal." Defense counsel must point to all the infant plaintiff's difficulties during the neonatal course – such as respiratory distress, infection or gastrointestinal problems – that were not caused by the medical providers but nevertheless led to increased stress on the infant and a decreased likelihood that the infant's brain would develop normally. Additionally, defense counsel must examine the quality of the intrauterine environment and point to complicating factors – such as intrauterine growth restriction or placental insufficiency – that would have made it less likely for the infant plaintiff to thrive once outside the womb.

In sum, when faced with the increasingly common claims involving extreme prematurity, it is helpful to assess the viability of the defense strategy from the outset, obtain experts who can support the theory and use the neuroscience regarding fetal brain development to respond to the plaintiff's efforts to link an infant's injuries to medical treatment as opposed to a tragic outcome that could not have been prevented by medical providers.

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ABOUT THE AUTHOR



Sean Maraynes is an associate at Wilson Elser Moskowitz Edelman & Dicker's White Plains Office who defends physicians, businesses and nonprofit organizations in lawsuits involving medical malpractice, catastrophic personal injury and wrongful death. Over the course of his career, he has served as lead counsel on 20 trials to verdict in New York State Supreme Court and has successfully resolved thousands of civil and criminal cases. Sean has represented physicians in nearly every medical specialty, including obstetrics, cardiothoracic surgery, neurosurgery and internal medicine specialties. Additionally, Sean routinely represents hospitals and businesses in lawsuits stemming from criminal conduct on their premises or by their employees.

TRAVELERS

Lessons Learned and the Importance of CMS Emergency Preparation Rules

By Stan Szpytek and Steve Wilder

The catastrophic life loss in a long-term care facility in Florida in the days following landfall of a major hurricane underscores the need for enhanced emergency preparedness capabilities in every type of health care facility. While it appears that the majority of health care providers impacted by two significant hurricanes to hit the United States in August and September of 2017 did not suffer significant losses, all of the hard lessons that will be revealed following the tragedy in Hollywood, Florida must be closely examined. New requirements of participation that will be enforced by CMS in November of 2017 will focus on emergency preparedness in a comprehensive manner that in many ways addresses the apparent failures that occurred during this disaster.

Here is an excerpt from CMS S&C 17-05-ALL that should resonate with skilled nursing facilities as well as the 16 other provider types that will be required to comply with new Emergency Preparedness regulations by November 15, 2017:

"On September 16, 2016, the final rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers was published (Federal Register Vol. 81, No. 180). This rule affects all 17 provider and supplier types eligible for participation in Medicare. The rule becomes effective on November 15, 2016. However, health care providers and suppliers affected by this rule have until November 15, 2017 to implement the new requirements and be in full compliance. Surveyors will begin evaluating the new requirements after November 15, 2017. Providers and suppliers found out of compliance with the new regulations will be cited for non-compliance and must follow standard procedures for correcting deficiencies (Centers for Medicaid and Medicare Services)*."*

These significant changes in emergency preparedness regulations for CMS regulated health care facilities have been on the horizon for many years. The highlights of the new regulations can be broken down into four specific areas of compliance that include the following:

- Development of an Emergency Plan based on a risk analysis using an "All Hazards" approach
- Policies and Procedures
- Communication Plan
- Training and Testing

Surveyors are in the process of being trained on the regulations, and new "E" tags have been developed to promote the enforcement of these requirements. It is critical for providers to understand the importance of these new requirements of participation, not only from a position of compliance, but also from a practical

perspective, as these rules have been designed to save lives. The creation and enforcement of the new requirements of participation will have a positive impact on emergency operations in health care facilities to help ensure that vulnerable lives are protected during emergencies and disasters.

Risk analysis is one of the significant elements of good emergency management practices and the new regulations. Without specific knowledge of the potential hazards and perils that can impact a long-term care facility, how can a provider truly be prepared? In addition to assessing the threats that may impact a facility both internally and externally, providers must also assess their capabilities and capacities to sustain operations during an adverse event to help ensure continuity of operations. CMS has not developed any special tools on how to conduct the risk assessment but has clearly stated that it must be a documented process that must be reviewed annually. There are a number of tools and resources available to address the risk assessment component of this process, including the use of tools that are publicly accessible and templates that are available for purchase along with the engagement of subject matter experts (SME) who can assist a facility with compliance requirements.

During the course of the required risk analysis process which also requires and assessment of capabilities and capacities, it is likely that a facility will identify areas of their operation that may be in need of enhancement to ensure safety and compliance. For example, many older health care facilities do not currently have their heating, ventilation, and air-conditioning (HVAC) equipment connected to an emergency power supply. In Hollywood, Florida, it appeared that while normal power was lost and the facility's emergency generator was running, some components of the facility were no on the emergency power circuit, subsequently leading to dangerous conditions for residents.

Across all facets of healthcare, the Incident Command System has become the recognized standard for emergency operations management, to the point that different facets of healthcare have specific Incident Command Systems. Hospitals have HICS (Hospital Incident Command System), Skilled Nursing facilities had NHICS (Nursing Home Incident Command System), and Assisted Living facilities have ALICS (Assisted Living Incident Command System). Each of these, while unique in their own right, offers common features, including enhanced span of control, assignment of responsibilities and accountabilities to qualified individuals, and, of critical importance, interoperability with community public safety agency. Any healthcare provider not using the respective form of the incident command for their environment is clearly behind the times and will have a hard time proving compliance with the new standards. Integration of the incident command system (ICS) into a health care facility's emergency management program will help promote an "All Hazards" approach to managing emergencies and disasters.

Developing an "All Hazards Plan" also means identifying hazards that are specific to the community or facility. It should be noted that the hazard vulnerability assessment (HVA) must be conducted at the local level, not at the corporate level. One client, with 180 locations around the nation, intended to perform one HVA and use it for all their locations. Certainly, this is an aberration of reality. The hazards that their communities in Florida face are clearly different than the hazards that their communities in Indiana face. The HVA has to be completed at the local level and be specific to the respective community. In addition, the HVA for each community should be reviewed with local public safety officials, and their input should be welcomed in developing the Emergency Operations Plan (EOP) that will be based on the HVA.

In addition to developing an "All Hazards" EOP, providers will be required to develop policies and procedures that not only support the plan but also support the facility's emergency management "program." In essence, the new regulations are focused on a programmatic approach to emergency management, not just a written plan. Once the EOP has been developed, additional policies and procedures will be needed to provide the necessary dimensions to help ensure program success. For example, if a facility's EOP states that it must provide three days of emergency drinking water for all residents and staff members on duty at the time of an adverse incident, a policy and procedures should be developed and maintained at the facility citing the procurement, storage, maintenance, security, and handling practices for the emergency water supply. Again, the requirement for the development of policy and procedures to support a facility's emergency management program will provide essential administrative and practical depth to the program.

Based on information that we know from the tragedy in Hollywood, Florida and the fact that a hospital was in extremely close proximity to the stricken long-term care facility, it is easy to surmise that major communications failures occurred both internally and externally. Effectively communicating during any type of emergency will always be a challenge. To have gravely ill and dying residents inside of a facility for any amount of time during emergency operations clearly equates to some type of communication problem. Failure to effectively communicate with emergency forces (utility companies, fire, EMS, law enforcement, hospital, etc.) could potentially lead to avoidable injuries and deaths.

The new CMS regulations require long term care providers, as well as all of the other 16 provider types affected by these new regulations, to develop and maintain comprehensive policies and procedures to effectively communicate with all stakeholders both internally and externally during an emergency or disaster. These stakeholders include, but are not limited to, other health care or "like" facilities, hospitals, health departments (local and state), emergency responders, residents, families, and responsible parties.

Subsequent to Hurricane Irma, Florida Governor Rick Scott set new emergency requirements for the state's nursing homes after several residents died at the facility in Hollywood, Florida. The emergency measures, which took effect on Saturday, September 23, bring nursing homes and assisted living facilities in line with emergency requirements at Florida's hospitals, the governor's office said. Facilities that fail to comply within 60 days are subject to $1,000-per-day fines and could have their licenses revoked.

These new measures mandate that nursing homes and assisted living in Florida have supplies and power to sustain operations for at least 96 hours after a power outage. Facilities must also have "ample resources, including a generator and the appropriate amount of fuel" to "maintain comfortable temperatures" over the same time frame. The requirements Governor Scott instituted in Florida only apply to that state.

Specific requirements for training and testing associated with a facility's Emergency Management Program are also part of the new regulations. Gone are the days of watching emergency preparedness videos and calling it training. For years, we have used the terms "education" and "training" interchangeably and synonymously. In reality, they mean two completely different things. When we have our employees watch videos, we are educating their minds. We give them knowledge: the ability to capture and later recall data or information. In other words, we give them information they need on what to do in an emergency. When we train them, we give them the hands-on skills needed to perform the tasks needed. Educating them gives them the knowledge; training them gives them the skills. In emergency preparedness, one without the other is useless. We educate the minds; we train the hands. And we MUST do both.

The new CMS regulations place additional requirements on providers to conduct comprehensive training with staff, including emergency procedures training upon hire. Additionally, facilities will be required to participate in "community-wide" drills on an annual basis. These are drills that involve the entire community, not just the facility. Providers will also need to conduct at least one tabletop exercise annually within the facility to exercise their EOP and better prepare their staff for emergencies and disasters. The specific requirements for training are quite detailed and must be carefully reviewed by long-term care providers to help ensure compliance.

What happened in Hollywood, Florida will take a great deal of time and comprehensive examination to fully understand. Until the investigation is complete and the findings are made public, we can only speculate. We know that a new day has dawned on emergency preparedness where health care providers must now place considerable emphasis on their emergency management programs to help ensure safety and compliance.

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R I S K Y B U S I N E S S

Root Cause Analyses – A to Z

By Pamela Monastero, MBA

WHEN COMMON SENSE IS UNCOMMON

A History Lesson:

This quarter's column is devoted to reviewing the efficacy of the root cause analysis (RCA) tool and its contributions to improving patient safety, quality of care and reduction of risk exposures. Prior to delving into a review of RCAs, a brief history of quality improvement initiatives in healthcare is in order. Before the term 'patient safety' became an official part of our vocabulary, the function of patient safety was performed, in part, by quality and risk management professionals. In illustration, quality improvement initiatives can be traced back as early as the 19th century, with the introduction of hand hygiene. More formal focus on quality in healthcare likely began in the mid-20th century. In fact, the Joint Commission on Accreditation of Hospitals (JCAH, now known as The Joint Commission or TJC) was established back in 1951 as a non-profit organization to provide voluntary accreditation to hospitals based on a rubric of defined minimum quality standards. Therefore, while the concept of improving outcomes and quality is not necessarily new, its evolution through the mid-20th to early 21st centuries is compelling.

Since the 20th century, population health issues such as poverty and poor living conditions are identified as contributory factors in high death rates. In the 1960's, the U.S. government responded, in part, vis-a-vis the introduction of the Medicare and Medicaid programs, originally entitled "Health Insurance for the Aged and Disabled" and, in the 1970's, utilization review (UR) was born in an effort to identify whether hospitals and medical personnel were providing appropriate clinical services that met 'conditions of participation.' Ultimately, the government recognized that the UR committees were ineffective and, thus, Professional Standards Review Organizations (PSROs) came into being. PSROs were a federally funded network of nonprofit physician-run organizations that were tasked with assessing the necessity, applicability and quality of healthcare services rendered.

In the 1980's the PSROs were deemed unsuccessful and Peer Review Organizations (PROs) were introduced in 1983. PROs introduced the concept of diagnostic-related groups (DRGs) e.g. prospective cost-per-case to assist in reducing unnecessary admissions and readmissions and to lower complications and mortality rates. What differentiated PROs from prior models is that the PROs were tasked with going beyond identifying problems and were given the authority to implement solutions, e.g. continued medical education requirements, disciplinary action, loss of Medicare billing privileges, etc.[1] In 1989, the Agency for Health Care Policy and Research (now known as Agency for Healthcare Research and Quality or AHRQ) was founded. AHRQ is a U.S. government agency that functions as a part of the Department of Health & Human Services (HHS) to support research to help improve the quality of health care.

At this point, it would be remiss not to mention that our own American Society for Healthcare Risk Management (ASHRM, originally entitled American Society for Hospital Risk Management) was established in 1980, mostly in response to the medical malpractice insurance crisis. ASHRM has always been historically focused on patient safety and improving the quality of care; this is illustrated in a statement by the second president of ASHRM (W. Ernest McCollum) in 1981 when he said "*Our challenge as hospital risk managers is to provide a safe and secure environment for patients, employees and visitors. Our job is to manage risk and assure quality despite the problems and increasing controls that we encounter. In the risk management profession, problems are opportunities, and all of our efforts are needed more than ever to formulate solutions. … As risk managers, we must keep in mind that our ultimate product is a safe environment in which the best possible patient care can be rendered at a reasonable cost.*" [2]

The 1990's—learning our "ABCs"—the introduction of the RCA tool in healthcare:

In the 1990's, the healthcare industry began to focus in earnest on improving the quality of healthcare in the US. In 1990, the National Committee for Quality Assurance (NCQA) was created. As the quality movement progressed, there was a focus on data driven quality initiatives, and introduction of additional programs and projects such as the 1994 National Surgery Quality Improvement Project (NSQIP) developed within the Veteran's Administration network and, from 1995 to 2000, introduction of the sentinel event policy by TJC, the founding of the Leapfrog group and, of course, the publishing of the iconic "*To Err is Human: Building a Safer Health System*" by the Institute of Medicine (IOM) which really brought patient safety to the forefront of the healthcare psyche.[3]

With the advent of the sentinel event policy by TJC, the concept of using RCAs (to identify 'root causes' of events and implement strategies to avoid recurrences of such events) was introduced to healthcare. As is the case with other tools used in healthcare, the RCA was adopted from the engineering sector, specifically from Toyota, whose founder, Sakichi Toyoda, is first credited with using the RCA tool—to ask the '5 Whys' to get to the 'root cause.'[4] Shortly after the introduction of the RCA methodology by TJC in the mid-1990's, the New York State Department of Health (NYSDOH NYPORTS—NY Patient Occurrence and Tracking System) required performance of RCAs by hospitals. Facilities in NYS utilize the NYSDOH RCA form, which is somewhat similar to the RCA format used by TJC. Other tools and methodologies to improve safety were also borrowed from industry, e.g. fishbone diagrams (to identify cause and effect), Failure Mode and Effect Analysis (to demonstrate workflow), Pareto charts (to perform data analysis) and, my favorite, James Reason's Swiss Cheese Models.[5]

To Err is Human is published, the patient safety movement is born and the RCA methodology reigns:

Following the publishing of *To Err is Human,* the patient safety movement began in full swing. Hallmarks include the establishment of the National Patient Safety Foundation (NPSF) in 1997, publishing of *Crossing the Quality Chasm: A New Health System for the 21st Century*[6] in 2001, creation of the John M. Eisenberg patient Safety and Quality Awards in 2002, launch of HospitalCompare.HHS.gov (to provide a public report of hospital outcome measures) in 2004 and TJC's issuance in 2004 of the first patient safety goals. In 2005, the *100,000 Lives Campaign* was introduced by the Institute for Healthcare Improvement (IHI) to promote patient safety/evidence-based medicine, and the World Health Organization (WHO) launched "Nine Patient Safety Solutions" and the Safe Surgery Checklist in 2007 and 2008, respectively. During this time, the use of RCAs proliferated as the standard tool to review adverse events to identify the '5 Whys' and to develop and implement risk reduction strategies and monitors to measure the success of those strategies.

The second decade of patient safety:

As we move through the second decade of the patient safety movement, more attention is focused on the prevention of adverse events vis-à-vis identification of close calls or near misses. Attention is being given to concepts of human factors engineering and recognition of the value of systems redesign vs. blaming individuals, as well as evolving into high reliability organizations (HROs) that are '*constantly preoccupied with the possibility of failure.*[7] In response to this focus on prevention, human factors engineering, systems based issues and becoming HROs, we have seen challenges to the traditional RCA methodology. In 2015, the IHI and NPSF introduced the concept of RCA^2, acknowledging that the "use of traditional RCAs has met with inconsistent success." [8] The methodology of the RCA^2 is to focus attention on preventing future harm and that prevention requires actions to be taken, with the result that "identification and implementation of sustainable systems-based improvements will make patient care safer in settings across the continuum of care. The approach is two-pronged: (1) to identify methodologies and techniques that will lead to more effective and efficient RCA^2; and (2) to provide tools to evaluate individual RCA^2 reviews so that significant flaws can be identified and remediated to achieve the ultimate objective of improving patient safety. The purpose of an RCA^2 review is to identify system vulnerabilities so that they can be eliminated or mitigated; the review is not to be used to focus on or address individual performance, since individual performance is a symptom of larger systems-based issues."[8]

The RCA^2 approach integrates human factors engineering (a subject profiled in this *Risky Business* column frequently over the past few years) to help ascertain the true "why" of an adverse event or close call. Effective RCAs focus on systems, not individuals, and veer away from the blame game. RCA^2 focuses on using an "explicit risk-based prioritization system to credibly and efficiently determine which hazards should be addressed first."[8] The major difference between this approach and traditional RCAs is the focus on learning and taking preventive actions vs. reactively responding after patient harm has been experienced or after a problem has been identified. Criticism of the traditional RCA approach is that that it is "not standardized or well defined and can result in the identification of corrective actions that are not effective—as demonstrated by the documented recurrence of the same or similar events in the same facility/organization after completion of an RCA." The RCA^2 methodology maintains that the underlying causes for this lack of effectiveness includes "lack of standardized and explicit processes and techniques to identify hazards and vulnerabilities and prioritize these, identify systems-based corrective actions, ensure timely execution of an RCA and formulation of effective sustainable improvements and corrective actions, ensure follow-through to implement recommendations, measure whether corrective actions were successful and to ensure that leadership at all levels participate in the process."[8]

Again, the traditional RCA tool tends to be linear in nature and the supposition that there is only one real root cause in and of itself is problematic, given the complex nature of health care delivery, the variables and moving parts. The RCA^2 methodology also explores reporting and timely feedback to the reporter and the associated vulnerabilities when reporters believe their concerns are not being addressed.

This column is not an exhaustive review of the RCA^2 methodology but is intended to provide an overview and highlights with insights from personal experience as a hospital-based risk manager for over three decades. RCA^2 methodology reviews: (a) the identification and classification of events (blameworthy events, risk-based prioritization of events, hazards and system vulnerabilities, close calls); (b) timing of review, interviews and team members; and (c) event review process—analysis and tools, actions, measuring action implementation and effectiveness, feedback, leadership/Board support, measuring effectiveness and sustainability of the RCA^2 process. The most important step in the RCA^2 process is the identification of actions to eliminate control system hazards or vulnerabilities as identified in the causal statements. Of course, leadership involvement and support is also essential to the success of any program.[8]

Of particular interest, the publication outlines the warning signs of an ineffective RCA^2 and these are:

1. There are no contributing factors identified, or the contributing factors lack supporting data or information.
2. One or more individuals are identified as causing the event; causal factors point to human error or blame.
3. No stronger or intermediate strength actions are identified.
4. Causal statements do not comply with the five rules of causation.
5. No corrective actions are identified, or the corrective actions do not appear to address the system vulnerabilities identified by the contributing factors.
6. Action follow-up is assigned to a group or committee and not to an individual.
7. Actions do not have completion dates or meaningful process and outcome measures.
8. The event review took longer than 45 days to complete.
9. There is little confidence that implementing and sustaining corrective action will significantly reduce the risk of future occurrences of similar events.

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The publication concludes with the following recommendations: (a) importance of leadership's active involvement and support in the process with a minimal annual look-back for effectiveness; (b) delineation of blameworthy events that should potentially be excluded from the RCA[2] review process; (c) utilization of a transparent, formal, explicit risk-based prioritization system to identify adverse events/close calls/system vulnerabilities; (d) timeliness of review (to commence within 72 hours of recognition of a review-worthy event); (e) RCA[2] team to consist of 4-6 people, with process and subject matter experts from all levels of the organization and a patient representative; the team should exclude individuals who were involved in the event but they should be interviewed for information; (f) working time into staff scheduling to allow participation in the RCA[2] process; (g) utilize interviewing techniques and tools (e.g. flow diagrams, cause and effect diagrams, five rules of causation, etc.) as defined in the publication); and (h) provision of feedback to involved staff, patients and their families regarding findings.[8]

In summation, we have been grappling with optimization of the RCA process for at least two decades now. We have consulted literature-based sources for best practices, have worked towards perfecting interview and investigation techniques, embraced analytic tools and have considered the integration of human factors engineering aspects into patient safety review processes. We have evolved towards systems redesign from blaming individuals, including the introduction of the concepts of Just Culture[9] and Zero Tolerance[10]. We have focused on improving collaboration and communication by integrating TeamSTEPPS[11] training and Crew Resource Management[12].

Looking forward:

More than likely, we can predict that the healthcare industry will continue to look towards aviation, manufacturing, transportation and other industries for tried-and-true tools in continuance of the quest for patient safety. One thing is certain--there is no magic bullet and the most integral component of patient safety lies in unequivocal and unwavering support from senior leadership who are *"constantly preoccupied with the possibility of failure."* [7] Focusing on organizational culture by addressing and eliminating significant, and sometimes intangible, barriers to patient safety—e.g. arrogance, ego, silos and "institutional ethnocentricity" can will yield exponential returns and bolster the efficacy of patient safety methodology, tools and concepts.

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Dear Risk Manager:

This column, which will appear regularly in the AHRMNY Risk Management Quarterly Journal (RMQ), is designed to support both the novice and seasoned risk manager by presenting brief *pearls of wisdom* based on the experiences of our colleagues. This column is based on the contributions of our constituent members, to whom we are grateful for sharing their experiences. We continue to encourage our members to submit their experiences anonymously for inclusion in this column. Please e-mail any suggestions to pamela.monastero@nyumc.org or mail to AHRMNY utilizing the RISKY BUSINESS form. The form permits confidentiality.

2018 ELECTION RESULTS

The annual election of AHRMNY's Officers and Directors was held May 8th-May 22nd, 2018. 21% of Membership participated and voted for the following candidates:

President-elect
Dylan Braverman

Treasurer
Robert Marshall

Secretary
Ruth Nayko

Reelected Board of Directors
Bonnie Boone
Michael Brendel
Linda Foy
CaraMia Hart
Victor Klein, MD
Robert Martin
Pamela Monastero
Carolyn Reinach Wolf

Newly Elected Board of Directors
Dawn Giunta
Michael Milchan

The Nominating Committee appointed a new Emeritus Board Member:

Diane Longo

The Nominating Committee also appointed three Emeritus Board Members to continue this honorable designation for another 2-year term:

Mike Midgley
Jonathan Rubin
Francine Thomas

The organization Bylaws were reviewed, voted and approved by AHRMNY voting members.

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AHRMNY Board appreciates the membership's participation in the annual election process. Please join us in congratulating our new and reelected Officers and Directors.

Eradicating Sexual Harassment in Healthcare

By Janet Walsh, RN MPA, ARM

In light of recent events, we are again publishing "Preventing Liability for Sexual Harassment by Creating a Culture of Civility". The article, written by Joan M. Gilbride, Esq., first appeared in the RMQ Vol. I 2017. Since publication, sexual harassment claims have quite literally exploded onto the front page of major newspapers and magazines, and has been a daily source of discussion on news channels and entertainment shows.

Unfortunately, sexual harassment is not isolated to industries outside of healthcare. At least 3,085 employees at general medical and surgical hospitals filed claims of sexual harassment with the EEOC between fiscal years 1995 and 2016, according to a *BuzzFeed News* investigation. During this 21-year period 170,000 claims were filed. Women filed 83 percent of claims, while 15 percent were filed by men. Listed in **Table 1.** are the areas in healthcare identified by the EEOC as receiving complaints.[1]

Table 1

Area	# Complaints Filed
General medical and surgical hospitals	3,085
Other miscellaneous ambulatory health care services	1,911
Nursing care facilities	1,530
Medical laboratories	436
Physician offices (excluding mental health specialists)	382
Home healthcare services	314
Direct health and medical insurance carriers	254
Offices of other miscellaneous healthcare practitioners	140
Specialty hospitals	81
Psychiatric and substance abuse hospitals	73
Ambulance services	51
Other outpatient care centers	50

The EEOC noted that claims it receives are often filed by individuals who previously tried other channels of reporting harassment.[2] So, what did or did not happen within the organization(s) that these claims reached the EEOC? We could speculate on any number of reasons why, but that would take an in-depth analysis and another article. The main concern right now is to support the healthcare community to do all in its power to eradicate this problem.

It should be no surprise that this issue is not isolated to the U.S. The Royal Australasian College of Surgeons published a report in 2015 on this subject. The following is a statement from the College President and Vice President.[3]

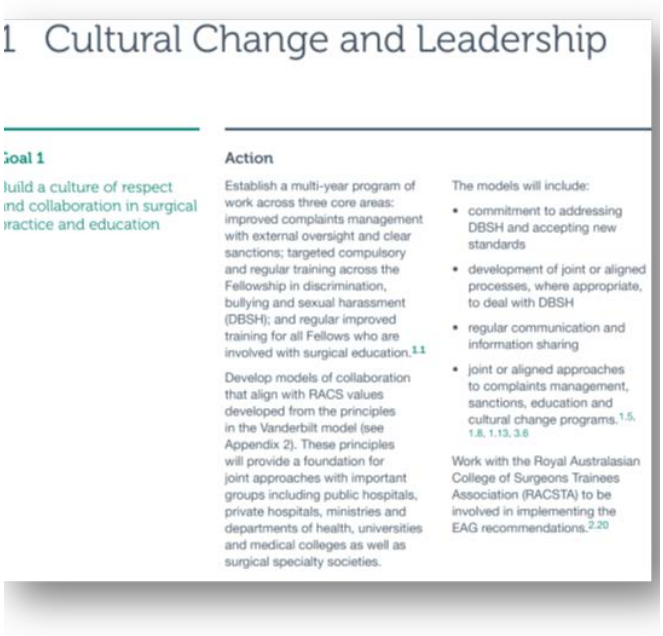
"Drawing on the experiences of our own Fellows, Trainees and International Medical Graduates", the EAG research revealed widespread discrimination, bullying and sexual harassment in the practice of surgery. These behaviours are bad for individuals, impair teams and put patient care and patient safety at risk.

The Expert Advisory Group (EAG) that carried out the research for this report provided the following statement.[4]

"...there must be a profound shift in the culture of surgery and an unwavering commitment to achieving this. Long-established traditions that have been inherited and have normalised unprofessional, and sometimes illegal, behaviours must be relinquished. Gender inequity must be addressed. Discrimination, bullying and sexual harassment must become problems of the past..."

Three key areas the EAG highlight as needing to be addressed include: (a) cultural change and leadership; (b) surgical education; (c) complaints management. Each area has specific goals and an action plan for each goal (**Exhibit 1.**).[5]

Exhibit 1



1 Cultural Change and Leadership

Goal 1	Action	
Build a culture of respect and collaboration in surgical practice and education	Establish a multi-year program of work across three core areas: improved complaints management with external oversight and clear sanctions; targeted compulsory and regular training across the Fellowship in discrimination, bullying and sexual harassment (DBSH); and regular improved training for all Fellows who are involved with surgical education.[1.1]	The models will include: • commitment to addressing DBSH and accepting new standards • development of joint or aligned processes, where appropriate, to deal with DBSH • regular communication and information sharing • joint or aligned approaches to complaints management, sanctions, education and cultural change programs.[1.5, 1.8, 1.13, 3.6]
	Develop models of collaboration that align with RACS values developed from the principles in the Vanderbilt model (see Appendix 2). These principles will provide a foundation for joint approaches with important groups including public hospitals, private hospitals, ministries and departments of health, universities and medical colleges as well as surgical specialty societies.	Work with the Royal Australasian College of Surgeons Trainees Association (RACSTA) to be involved in implementing the EAG recommendations.[2.20]

The College notes that this is a multi-year project with no exact deadline for completion.[6] The aim is to take small, methodical steps to eradicate this problem by building a positive, healthy environment for both staff and patients.

".....Patient safety should be the absolute and common priority in the workplace. Teams work together effectively respecting the skills, experience and contribution of each member. The success of work-based teams is measured by the safety of the workplace and the educational environment and by the extent to which all team members recognize that what they achieve together is more valuable than anything they can achieve on their own....."[7]

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Preventing Liability for Sexual Harassment by Creating a Culture of Civility

By Joan M. Gilbride

Given the close quarters, intense pressures and at times informality of communication surrounding the provision of medical care, it is no wonder that healthcare facilities can be breeding grounds for harassment and sexual misconduct allegations and claims. Unlike an office setting, a hospital environment exposes patients and co-workers as potential victims of harassment, which not only often leads to lawsuits, but also negative publicity, legal fees and all types of complications and complexities. To avoid this quagmire, it is important that risk managers are aware of potential liability and ways to foster a safe working environment at a healthcare facility.

The seriousness of preventing sexual harassment and sexual misconduct grabbed the public's attention when earlier this year, a shocking news story reported a Mt. Sinai emergency room doctor was indicted for sexual assault of a patient. In graphic detail, the reporter described the sexual assault alleged by a patient who was sedated, but aware that she was being violated by a physician, and incapable of reacting. The type of sexual misconduct described by this patient is a nightmare for the patient and the hospital and, thankfully, happens rarely. To prevent this type of conduct and less egregious variations, it is crucial that employers implement training programs to promote an environment that encourages civility, peer reporting and clear avenues for complaining of sexual harassment and sexual misconduct in the healthcare profession.

As a first step, the employer must be aware of the risks before deciding which tactics would be most effective in preventing liability and determine whether its workplace culture needs to be transformed.

Risk Factors for Sexual Harassment and Sexual Misconduct

In June 2016, the United States Equal Employment Opportunity Commission (EEOC) Select Task Force on the Study of Harassment in the Workplace (the "Task Force") released a report. In its report, the Task Force identified factors that increase the likelihood of harassment in a workplace, which include characteristics typical of healthcare environments, such as: "high value" employees, significant power disparities, and decentralized workplaces.[2] Based on these factors, hospitals and healthcare facilities are extremely susceptible to allegations of a hostile work environment based upon harassment and indeed, to unknowingly allowing such circumstances to develop. The Task Force also noted that in addition to the expected legal and financial implications of sexual harassment, harassed employees were found to be less productive, and employers often suffered reputational damage and risked losing patients.[3]

Understanding Potential Liability for Healthcare Facilities

In egregious events of sexual misconduct (like the case of the emergency room doctor at Mt. Sinai), under New York law, healthcare facilities face risks to the extent that the conduct was foreseeable. A hospital may be able to defend successfully against liability for a doctor's outrageous or near criminal behavior, but not against a hostile work environment that breeds such behavior. It is essential that healthcare facilities implement procedures to prevent harassment and successfully defend against allegations of harassment regardless of the legal risks.

A hospital's duty to protect patients and visitors as a caretaker is governed by a standard of foreseeability.[4] New York courts have limited the duty to protect persons lawfully present on a hospital's premises from the reasonably foreseeable criminal or tortious acts of third persons.[5] For example, a New York hospital faced potential liability when a male nursing assistant allegedly sexually assaulted a female patient while preparing her for a surgical procedure. The court found in favor of the hospital and held that plaintiffs failed to show the hospital knew or should have known of the assailant's propensity for the conduct that caused plaintiff's injury. In a decision rendered by the Appellate Division, First Department, the court found that it was not reasonably foreseeable that a hospital's independent contractor would sexually assault a patient while conducting her vaginal sonogram, and the patient therefore was not entitled to recover on her negligent supervision claim against the hospital. In that case, the court considered the sufficiency of the independent contractor's background check on its employee and examined whether the hospital was on notice of the independent contractor's employee's potential for violence or sexual abuse.[6] The hospital was lucky that its independent contractor thoroughly vetted its employee and plaintiff failed to rebut the lack of reasonable foreseeability based on the background check. Although the court found in favor of the healthcare facility in these cases where patients sued, when a hospital is sued as an employer by its own employee, it is less likely to avoid liability.

In *Salamon v. Our Lady of Victory Hosp.*, a former employee attempted to hold the hospital liable for conduct of a doctor on staff.[7] The hospital argued it was not liable as a matter of law for the harassing conduct of a doctor who was not an employee, but an independent contractor. Id. The federal district court in *Salamon* denied the hospital's motion for summary judgment, finding the Second Circuit had not definitively ruled on the question of whether an employer can be liable for a non-employee's harassing conduct.[8] The court recognized, however, that the Second Circuit limited any potential liability for non-employees to "instances in which the employer provided no reasonable avenue of complaint or knew of the harassment but did nothing about it."[9] Thus, an employer could be exposed to liability for even a non-employee's conduct if the employer does not have a complaint procedure in

place. As such, not implementing a complaint procedure or failing to educate your employees about an existing procedure can exponentially increase risk.

Harassment often involves multiple missteps by more than one employee. A recent case[10] involved allegations of harassment against a nurse's colleague where one long term pediatric nurse alleged she was harassed by another long term nursing employee; the harassment included late night phone calls, adjusting the plaintiff's label on her underwear and discussing plaintiff's medical history with other employees.[11] In addition, plaintiff claimed that she suffered harassment from her treating physician, a surgeon who worked at the same facility[12] and made comments to her while at work that she perceived as references to her personal medical history. For instance, her physician referenced the movie *40 Year Old Virgin,* teased plaintiff about getting pregnant when she mentioned taking vacation to visit a male friend, and made comments about her not having children. Plaintiff also alleged that she complained to human resources about the harassment, but nothing was done. In the Complaint, plaintiff implicates several actors who allegedly contributed to her damages: a fellow nurse, a doctor, and human resources staff. The court denied the hospital's motion to dismiss as to negligent retention and supervision, hostile work environment, sexual harassment, and disability discrimination.

Another scenario which has potential for posing great risk to healthcare facilities is relationships that might occur between interns and residents in medical teaching facilities. If the facility allows or empowers a resident in his or her second year of postgraduate residency (PGY2) to supervise and direct a first year postgraduate student (PGY1), the facility may be liable for sexual harassment based on PGY2's behavior. It is not hard to imagine two postgraduate students dating, but if a PGY2 uses his or her supervisory position to persuade the PGY1 to go on a date, this can pose serious risk for the hospital. Environments where supervisors do not constantly observe their subordinates, and are not trained to spot troubling inappropriate behavior, are more likely to breed a culture of acquiescence rather than a culture of civility. Managers and supervisors are the heart of an employer's prevention system.

Implementing Solutions[13]

Regardless of the legal outcome, the defendants will be forced to pay substantial legal fees and the incident can have lasting effects on the hospital's reputation. Accordingly, preventative measures are in everyone's best interest. As noted previously, to create a culture in which employees believe that the organization will not tolerate harassment, managers and supervisors must receive clear messages of accountability. Compliance training translates those expectations into concrete actions that managers and supervisors are expected to take – either to prevent harassment or to stop and remedy harassment once it occurs. Employers should begin by taking complaints of sexual harassment and misconduct made against their current employees very seriously and evaluating current employees to ensure employees who demonstrate a propensity toward such misconduct are not retained.

Compliance training provides managers and supervisors with easy-to-understand and realistic methods for dealing with harassment that they observe, that is reported to them, or of which they have knowledge or information. This includes practical suggestions on how to respond to different levels and types of offensive behavior, and clear instructions on how to report harassing behavior up the chain of command. Training should also stress the affirmative duties of supervisors to respond to harassing behavior, even in the absence of a complaint. This training should be tailored to the specific worksite, organization, and/or industry, so that the examples used are helpful to managers and supervisors.

The EEOC encourages strong anti-harassment policies that provide a clear explanation of prohibited conduct and assurance of protection from retaliation. Compliance training is essential, but focusing on steps to avoid legal liability may fall short of preventing a hostile work environment and a culture of harassment. The EEOC recommends creating a culture of civility by training with specific goals in mind as a "holistic effort" to prevent harassment, which should also include accountability and leading by example.

The goals of training should be to educate employees and supervisors, to ensure that employees understand what is considered harassment in the workplace and empower supervisors by creating procedures for complaint follow-up. Understanding what is not appropriate is the first step towards preventing a volatile work environment or changing an already toxic one. The EEOC also suggests that trainings educate employees about the external consequences (including reputational harm) of conduct that rises to the level of illegal harassment. A senior leader's attendance at the training is the strongest expression of support. As an alternative, a video of a senior leader introducing the training could be shown, or a memo from leadership sent prior to the training. Trainings should be interactive and take place at least every other year to demonstrate the employer's commitment to preventing harassment. Also, the trainings should evolve to ensure they are relevant and grab employees' attention with new content.

The EEOC Task force recommends "bystander intervention training" and "civility training" given that incivility is a harbinger of a hostile work environment.[14] This type of training focuses on what employees and

supervisors should do, rather than what they should not do. The training alone, however, is not enough. The employers who are most successful in preventing harassment have taken other steps to convince employees that they will not be tolerant of sexual harassment. The EEOC suggests that prior to training, employers should provide their employees with avenues for complaints (such as a hotline).

A proactive employer that is focused on creating an environment of civility through adequate training and leadership will reduce the likelihood of sexual harassment and sexual misconduct in the workplace. These strategies not only make the workplace safer, but lower the possibility of flagrant sexual misconduct as well as liability and the economic and intangible impact on an employer's business.

REFERENCES ON PAGE 32

ABOUT THE AUTHOR



Joan is the managing partner of KBR's national Employment Law Practices Team. Her practice focuses on the representation of management in employment litigation and complex commercial litigation which includes insurance coverage litigation and professional liability defense. Practicing law since 1987, Joan has obtained extensive pre-trial, trial, and appellate experience in both individual and class actions in federal and state courts throughout the country. She has been admitted to practice on a *pro hac vice* basis in numerous states and often manages complex litigation on a national basis. Joan has tried many cases to verdict over the past 26 years and has been involved in media-intensive class action litigation. She litigates and arbitrates before administrative agencies as well and is well-versed in ADR proceedings.

Oceanus RRG was put into liquidation, what should we learn from this?

By Phalanx Healthcare Solutions

South Carolina Department of Insurance has formally executed the liquidation order effective September 21, 2017 after adverse development in the malpractice insurer's claims reserves. Simply put, Oceanus no longer has the assets to meet their claim obligations.

Oceanus, as recently as 2013, was the sixth largest writer of physician malpractice liability in New York but in 2016 their premium volume decreased by over 40%. This decrease coupled with an increase in claim reserves due to adverse loss development reduced their policyholders' surplus (net assets) to negative $6M and placed the company in extreme financial distress (per the Oceanus June 30, 2017 statutory statement).

What is most unsettling about this is that providers who are currently insured with, or that have purchased "tail" coverage with Oceanus, may be personally responsible for existing or future claims made against them. Providers paid hard earned dollars to a company that may be unable to uphold their responsibility to their insureds.

Frequently Asked Questions about the Oceanus Insurance RRG Liquidation (source: oceanusinsurance.com):

1. What is a liquidation proceeding?

Liquidation is a type of receivership and is similar to bankruptcy. The South Carolina Insurance Code authorizes the Director of the South Carolina Department of Insurance, in his or her capacity as Liquidator, to liquidate the insurance company. The Liquidation Order directs the Liquidator, to (i) take possession of and safeguard the property of the insurer, (ii) conduct the insurer's business, and (iii) take such steps needed to liquidate (wind-up the affairs of) the business of the insurer under the supervision of the Court and as the Court may direct.

2. What happens to my coverage under my Oceanus policy?

All policies in effect at the time of the issuance of the Liquidation Order continue only for the lesser of: 1) 30 days from the date of entry of the Liquidation Order (10/21/17 at 11:59 p.m. EDT) 2) the expiration of the policy coverage 3) the date the coverage has been replaced with equivalent insurance with another insurer or otherwise terminated the policy or 4) the Liquidator has effected a transfer of the policy obligation pursuant to Item (8) of subsection (a) of Section 38-27-400.

3. When should I replace my coverage?

Immediately

4. Will I be issued a refund for my premium?

No

5. Is there Guaranty Association Coverage to Pay Claims?

No

6. Will my claims be paid in full by the liquidator?

No. It is too early to estimate what amount of policyholder claims will be paid. The amount will be pro rata based on all assets liquidated compared to the valuation of all policyholder related claim liabilities.

7. What happens if I have, or want to bring, a lawsuit against Oceanus?

No action at law or equity may be brought against Oceanus or the Liquidator, whether in South Carolina or elsewhere, nor shall any such existing actions be maintained or further prosecuted after issuance of the Liquidation Order.

8. Whom can I contact if I have a question regarding Oceanus and/or the Liquidation Proceeding?

Email Claimant Services at:
ClaimantServices@oceanusinsurance.com
You can also call Claimant Services at 305-952-3533. Oceanus home office remains at: Oceanus Insurance Company, a Risk Retention Group in Liquidation 20200 West Dixie Highway, Suite 1208 Aventura, Fl. 33180.

As you can see from the FAQ's, the insured is placed in an extremely difficult position with little recourse even though they upheld their end of the insuring agreement by paying the premium due. Before purchasing malpractice insurance (or any insurance for that matter), a provider must consider the following criteria and confirm an Insurer's financial strength and stability:

- **A high A.M. Best rating:** A.M. Best is the preeminent rating agency for insurance companies. This rating provides an unbiased view of an insurance company's operations and standing in the industry. Companies rated A ("Excellent") are considered by A.M. Best to have "an excellent ability to meet their ongoing insurance obligations". The majority of hospitals require that physicians be insured by a company with an A.M. Best rating of A- or higher to grant hospital privileges.

- **A large policyholder's surplus:** Policyholder's surplus on your mortgage, you have equity. The larger the surplus the better. Companies with a large surplus are better able to adapt to the ever-changing dynamics of the healthcare environment, withstand challenging business cycles, and develop new products and services without reneging on these services when they run into problems.

- **Consistent income generation:** The ability to consistently generate income year after year is another good indicator of financial health. If your insurer loses money in multiple years, this detracts from its equity and can affect whether they can meet their liabilities—including your malpractice claims.

- **Stable investment philosophy**: Your insurance company should have a conservative investment philosophy and should not have risky investments or a history of making bad investments. A company that invests in secure, fixed income securities such as government debt or safe corporate debt should be at the core of any insurance company investment philosophy.

- **Longevity**: Your insurance company should have a record of withstanding the test of time through many business cycles. A company with more than 30 years in the medical professional liability market has proven its ability to withstand market cycles and routinely pay claims and deliver services to its policyholders.

New York is a challenging malpractice market and the Medical Society of the State of New York has identified other malpractice insurers that are in serious financial jeopardy (with one insurer having a policyholders' surplus of negative $354M). New York State's Department of Financial Services has cautioned that circumstances under which certain insurers are currently operating could deteriorate further should Governor Andrew Cuomo sign legislation that would lengthen the statute of limitations for certain types of medical malpractice claims.

Phalanx Healthcare Solutions is a New York based medical malpractice insurance consultant specializing in insurance and reinsurance solutions for physicians, physician organizations, and healthcare systems. For more information, visit our web site at www.phalanxllc.com.

END

MEMBER SPOTLIGHT

Join us in congratulating the following AHRMNY members for volunteering to share their achievements featured in this edition's MEMBER Spotlight

Betsy D. Baydala, Esq. - Kaufman, Borgeest & Ryan, LLP



Betsy Baydala was promoted to Partner at the law firm of Kaufman Borgeest & Ryan in March 2018. Betsy focuses her practice in the fields of cyber liability, medical malpractice, and healthcare law. She is a Certified Information Privacy Professional/United States (CIPP/US) and handles healthcare related cyber liability matters. Betsy has counseled healthcare clients on cyber issues and is well versed in breach response measures and regulatory investigations.

Betsy represents major metropolitan medical centers and healthcare professionals in numerous medical specialties. She handles all aspects of litigation and has tried cases to verdict. Betsy will be co-presenting a program entitled: "Cyber Risk: It's Patient Safety - Clinical, Legal and Insurance Perspectives" at ASHRM's Annual Conference.

Mike Midgley RN, JD, MPH, CPHRM, DFASHRM - Swiss Re Corporate Solutions



Mike Midgley, Vice President Healthcare Risk Engineering participated in a panel discussion on healthcare cybersecurity at the 25th Annual Cayman Captive Forum on November 30th, 2017. The panel focused on managing cyber/privacy exposure in an Enterprise Risk Management (ERM) Program. The discussion included how some of the nation's leading healthcare institutions identify the critical cybersecurity issues within their organizations, and work to protect their systems and create value through targeted risk management initiatives. The panel members shared the investments their organizations have made across disciplines- risk management, finance, IT, marketing, and crisis management- to detect cybersecurity exposures, and establish best practices to control them. Mike explained how to conduct an ERM risk assessment to prioritize opportunities for protecting the organization from cyber threats.

Jose. L. Guzman, Jr., RN, MS, CPHRM, DFASHRM - Hudson Insurance Group



Hudson Insurance Group's Vice President of Risk Management, Jose Guzman collaborated with Covery's Tracy Melina, to present a program entitled: "Managing Risk for an Aging Population" at the American Society for Healthcare Risk Management's (ASHRM) Annual Conference and Exhibition in Seattle, Washington, October 15-18, 2017.

MEMBER SPOTLIGHT

Francine Thomas, MA, BSN, RN, CPHRM, FASHRM - Hudson Insurance Group

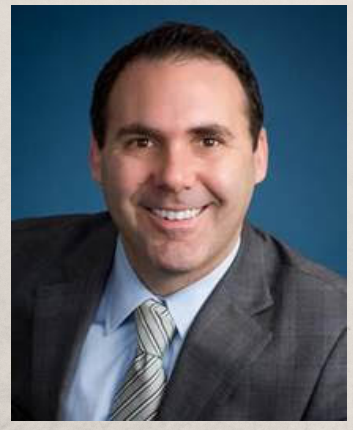


Francine Thomas is a Risk Manager on Hudson Insurance Group's healthcare team.

During the 2017 ASHRM Annual Conference, Francine Thomas was awarded the Fellow of the American Society for Health Care Risk Management (FASHRM).

Francine is currently an Emeritus member on the AHRMNY Board of Directors and Is currently serving on the ASHRM Chapter Leadership Task Force to develop and implement plans to create a mutually beneficial and supportive relationship between ASHRM and its affiliated chapters.

Dylan C. Braverman, Esq., Partner - Vigorito Barker Patterson Nichols & Porter, LLP



AHRMNY President-Elect Dylan Braverman has recently accepted a partnership at Vigorito, Barker, Patterson, Nichols & Porter, LLP. Dylan is also a recent graduate of the New York State Firefighter 1 Academy, qualifying him as a full interior/ exterior firefighter in the state of New York. After many years in downtown New York, Dylan will now practice out of the Valhalla office, while also splitting time at the office adjacent to Grand Central Station. In addition to serving as a trial partner and Member of the Chappaqua Fire Department, Dylan is the President-Elect of AHRMNY and chairs its Educational and Nomination Committee.

Jonathan D. Rubin, Esq., Senior Partner - Kaufman Borgeest & Ryan, LLP
Marianne J Walker, RN, JD, CPHRM - Greater Hudson Valley Health System





Jonathan D. Rubin, Esq., Marianne J. Walker, RN, JD, and Patricia Bomba, MD presented "Best Practices and Strategies for Improving End-of-Life Care" at the AHRMNY 2018 Annual Educational Conference in New York City on June 8th, 2018.

The session discussed the current state of end-of-life care in America and key recommendations to ensure individual preferences for care are honored near the end of life. The session also reviewed lesson learned from New York's MOLST program, a founding member of National POLST Paradigm. Jonathan and Marianne how EMOLST improves quality and patient safety, ensures accessibility and achieves the quadruple aim.



EHR in Malpractice Litigation: How "Cloning" and The Audit Trail Can Lead to Unnecessary Claims

By Santosh N. Chitalia and Jonathan D. Rubin

As of 2016, 95% of hospitals and 60% of office-based physicians participating in the Centers for Medicare & Medicaid Services (CMS) Electronic Heath Record Incentive Program had demonstrated *meaningful use*[1] of certified health information technology (*i.e.* use of the electronic health record).[2] These statistics demonstrate the fact that the EHR is no longer a novel idea, but rather is common practice and here to stay.

The benefits of the electronic health record (EHR) are well-known. The EHR facilitates ease of access to clinical information, including, but not limited to, patient demographics, past medical history, laboratory test results, and medications.[3] This enables a physician seeing a patient for the first time (*e.g.* a specialist in a multi-practice medical group) to access the patient's pertinent medical data at the click of a button rather than having to obtain the patient's paper chart and comb through pages of medical records, thus increasing efficiency and reducing time and labor. The EHR also permits physicians to order testing and prescriptions electronically thereby limiting mistakes due to illegible handwriting and preventing the ordering of duplicate medications from another different doctor.[4] The EHR further issues warnings about potential improper drug interactions as well as other reminders and alerts that may be of significance to the physician. Medical providers are not the sole beneficiaries of the EHR. Many EHR systems promote patient participation and engagement by permitting patients to access and review their medical records anytime through patient portals.[5]

For all that the EHR improves upon the paper record, like any technological advance, it is not without its drawbacks. Physicians have made various complaints about the EHR, including *inter alia* that the EHR is time-consuming[6]; impairs relationships with patients[7]; and, lacks interoperability platforms to share information with other outside medical practices[8]. Physicians also complain that drop-down menus do not always provide options that are appropriate for a particular patient and there is insufficient area to create a narrative. This last complaint was previously an issue in a medical malpractice claim[9] and we can expect more malpractice claims involving the EHR in the coming years due to the EHR's various shortcomings.

Due to the relatively recent implementation of the EHR, there has not yet been substantial medical malpractice litigation directly involving issues with the EHR.[10] Most cases settle before trial and few cases, if any, have reached the appellate level (at least in New York). Yet, two issues with the EHR have come into focus as potentially leading to malpractice claims and litigation: "cloning" of records and time-stamped entries. This article discusses these issues and how they have led, or could lead, to litigation.

"Cloning" – Copy and Paste

One of the biggest issues that has arisen with the advent of the EHR is the ability for medical providers to copy and paste portions of prior notes into subsequent notes, also known as "cloning".[11] A recent study published in the Journal of American Medical Association found that when reviewing thousands of progress notes from 460 clinicians at the University of California San Francisco, only 18% of the notes were entered manually. 46% of the notes were copied and 36% were imported.[12] Notably, residents were found to copy and paste more than both hospitalists and medical students, although hospitalists were found to copy more text.[13] However, these findings are nothing new. In a study of notes published in the Journal of American Medical Informatics Association in 2009, it was found that 54% of the information in progress notes and 78% in sign out notes contained information duplicated from previous notes.[14] Moreover, a study in 2008 found that 90% of physicians in the study reported that they had used the copy and paste function in progress notes.[15]

When seeing several patients in one day, it is expected that physicians will take advantage of measures that will save time and energy. Re-typing or filling out of categories in the EHR which may remain the same as a prior progress note (*e.g.* past medical/surgical history and medications) is time-consuming and can be avoided by simply cloning information from prior notes. This may be especially useful when seeing the same patient shortly after the last visit, or during a hospital admission when other medical professionals saw the patient earlier in the day.

There are also instances when an EHR system prepopulates certain portions of prior notes into the next note.[16] Indeed, this author previously encountered a physician in a medical malpractice action who testified in deposition that the past medical history and prior diagnoses sections from earlier notes were automatically included in subsequent notes. The physician made no attempt to modify the autopopulated portions of the note. This did not affect the overall issues in this specific malpractice case, but can shine an unfavorable light on the physician as it may present the physician as being lazy and uninterested.[17]

There are multiple other dangers that arise from copying and pasting portions from prior notes. For one, copy and pasted material can create lengthy notes (also

known as "note bloat"), with only a very small portion of the note containing new information. This can make it difficult for another physician subsequently reviewing the chart to determine whether there is new or updated pertinent information, potentially leading to unnecessary delays in care and treatment and possible missed information. Moreover, while copying and pasting a prior medical history may not be too risky, copying and pasting findings from a prior physical examination and/or laboratory and test results is dangerous as a patient's condition can change from day to day.[18] For instance, in a patient receiving Warfarin therapy for treatment of atrial fibrillation, if a physician notes in the EHR that the patient's PT/INR was normal on one visit and then copies that portion of the note on subsequent visits without checking updated laboratory results, the physician could be opening him/herself up to liability if the patient were to clot or stroke.

In early 2015, the Medical Director of The Doctors Company, David B. Troxel, M.D., disclosed the amount of EHR-related claims the company had closed from 2007 through the first two quarters of 2014.[19] 13% of the claims attributable to EHR-user factors were due to copy and paste and prepopulating.[20] Dr. Troxel provided an illustrative example of a cloning claim where a previous note contained an error which was copied and pasted into the next note and into subsequent notes thereafter.

Following a trip abroad, a toddler experienced fever, rash, and fussiness. The physician considered a possible bug bite or flu and provided antibiotics and flu medication. The physician noted in the EHR that there was no TB exposure, but failed to note that the toddler had traveled to a country where tuberculosis was prevalent. The physician proceeded to clone this note into subsequent visit notes. Two weeks later, the toddler was diagnosed with tuberculosis meningitis and had suffered from permanent and severe cognitive defects due to the delay in diagnosis and lack of treatment.[21]

In another example presented by Mag Mutual Insurance Company, following an emergency department visit, a patient with atrial fibrillation and potential heart disease was to follow with his primary care physician for a stress test.[22] At the next PCP visit, the physician did not perform a stress test and did not diagnose the patient with cardiac disease. The patient had high blood pressure for which the physician prescribed medication. The plan was for the patient to call the PCP or go to the ER if symptoms worsened and to maintain a healthy diet. Thephysician thereafter copied and pasted this assessment and plan for office visits over the next two years. The physician never administered a stress test or performed a cardiopulmonary work-up, despite the patient intermittently complaining of shortness of breath. The physician apparently told the patient to see a cardiologist, but it was not noted in the plan. Rather, the plan was cloned from prior notes. The patient subsequently expired and the cause of death was noted as cardiac-respiratory arrest, chronic obstructive pulmonary disease, and cardiac arrhythmia. The physician was sued and the case settled for "a high-dollar amount."

In each of the examples discussed above, the physicians copied portions of notes from prior notes without providing new and updated information. The physicians relied on old information to continue the treatment in place while the medical conditions of each of their patients declined, leading to significant injury and/or death. The plaintiffs thereafter commenced lawsuits alleging that the physicians committed medical malpractice. While the cases did not solely turn on the copy and pasting of records, the cloning certainly played a role and likely affected the integrity of the notes in the EHR as well as that of the physicians.

When a lay jury cannot fully trust the medical chart, it can spell serious trouble for the defendant-medical professional driving potential verdict values into the multi-millions.[23] That is the case even if the issues with the EHR do not directly relate to the allegations of malpractice. In one case, a judge went so far as to dismiss the EHR as exculpatory evidence, stating that the record was not be believed as it contained "plagiarism" characterized as cut and paste.[24]

Healthcare professionals and medical facilities should also be aware that cloning also has other negative effects outside of being sued for malpractice. Cloning records can lead to charges of fraud by the CMS, who will then deny payment for services.[25] Also, there are some who believe that cloning is considered "clinical plagiarism"[26] and have even led to the firing of medical professionals.[27] Thus, while there may be some benefit to copying portions of prior records to save time, the practice should be done with caution.

Time-Stamped EHR and Audit Trails

The timing of an evaluation or visit by a physician or nurse may be imperative where the allegations in the case center on the failure to timely examine, provide treatment, medication, and/or testing to a patient. Prior to the EHR, physicians and nurses would typically date and time a progress note in a patient's chart at the time of writing the note. However, if the medical provider did not author the note until sometime after he/she saw the patient, the time reflected on the note could be hours after the patient was actually seen. If the medical provider did not specify the time he/she actually saw the patient, then the timing of the visit may become a major disputed issue in the case.[28]

The EHR can assist in resolving this potential issue under the right set of circumstances. That is, if it is a physician's custom and practice to log on to the EHR system when seeing a patient (possibly to look at the patient's medical history and any previously entered notes, test results, etc.) then the audit trail (the EHR's metadata) will typically provide a time stamp of when the physician saw this particular patient. Audit trails and metadata

record when the physician logged into the system and how long he/she remained in the system.[29] While the physician could technically create a note on the examination of the patient later in the day, the audit trail/metadata will provide evidence (pursuant to the physician's custom and practice) of the time the physician actually saw the patient. This can assist in reducing claims related to the timeliness of tasks, such as examinations and testing. Of course, this issue can only be rectified if it is in fact the physician's practice to log into the EHR when seeing patients. If not, then the physician will face an uphill battle to prove the time he/she saw or treated a patient if the physician did not log into the EHR until later in the day when entering the note.[30]

Yet, the ability of audit trails to track log ins/outs to the system generates a new set of problems for healthcare professionals and facilities. For instance, if the defense of a malpractice suit is predicated on the ambiguity of whether something did or did not occur (*e.g.* physician never became aware of the patient's symptoms) then metadata showing a log in by that physician into the EHR is clearly unfavorable to the defense. That is because if the physician logged into the system, he/she would be expected to have learned of the patient's symptoms, assuming they were in fact noted in the EHR.

Another problem occurs when a medical provider, such as a nurse, enters that he/she completed a certain task (*e.g.* administering medication; turning and positioning) without having yet done so. The nurse may make the entry in order to complete the note ahead of time with every intention of completing the task at some point later. Yet, the audit trail and EHR will track when the nurse actually made the entry. What may seem like a time-saving measure to the nurse at the time of the entry could damage an otherwise defensible case. Even if the forward-charted note was inconsequential to the malpractice issues in the case, it can impact a defendant's credibility.[31] The sense of impropriety has led to settlements prior to trial in order to avoid potential blowback from a lay jury.[32]

The above shows that the existence of metadata and audit trails can be a double-edged sword. Medical professionals must keep in mind that the EHR can track auser's every move, including editing, printing, and when an individual returns to a note well after the note was signed off.[33] Many EHR systems will make a notation when a prior note was "reviewed" which, while not improper by itself, can raise questions about the reason for returning to the note, especially if the note was "reviewed" after an adverse result, or after the commencement of a lawsuit.[34] Furthermore, contrary to paper records, if one wants to edit a mistake or add to a note, the audit trail will record the time of the amendment and/or addition. The EHR will likely also time stamp the edit. In paper records, unless the medical professional specifically noted the date and time of the amendment, it would be impossible to know by simply looking at the note when the note was modified. Although improper pursuant to CMS guidelines, this ambiguity provided some mild protection in malpractice suits when a medical professional attempted to edit a note after an adverse result.[35] However, in the age of the EHR and audit trails, this protection is nonexistent. Any attempt at amending a note will be tracked and professionals can find themselves in significant trouble if an attempt to edit was made after an unfavorable outcome.

It is important to note that while metadata and audit trails can assist in authenticating the EHR, there is an indication that audit trails may also be able to be manipulated and altered. 45 C.F.R. § 170.304 (s)(2) and (3) prohibits the alteration of audit trails created by the EHR. Yet, in a December 2013 survey conducted of 900 hospitals, the Department of Health and Human Services' Inspector General's Office found that 44% of responding hospitals reported having the ability to delete their audit logs; 33% could disable the audit logs; and, 11% could edit the logs.[36] It is possible that since this survey was conducted approximately four years ago, electronic record systems have improved in preventing alterations to the audit trail, however, audit trails may still be able to be manipulated once copied onto a spreadsheet or other document.[37] The ability to alter the audit trail calls the integrity of the EHR into question.[38]

Of note, metadata and audit trails have been generally found to be discoverable in New York.[39] However, defense counsel should be prepared to object to such demands and even force plaintiffs to make motions, if the demands are unduly burdensome, expensive, and appear to be requested solely for the use of a fishing expedition.

Takeaways

Cloning may be an efficient tool when re-stating facts that have not changed, such as past medical history or certain patient demographics, but it can be dangerous when copying test results, vital signs, essentially anything that can be different the next hour or day. If a medical professional should clone prior portions of notes, it is recommended to 1) ensure that the information to be copied has not changed; and, 2) specifically state the date and time of the note from which the copied portion was obtained. This will, at the very least, show that the medical professional acknowledges that the information is copied and will prevent from "clinical plagiarism". This can also assist physicians subsequently reading the note to quickly locate the new or updated information.

Prior to the implementation of the EHR, the timing of when an action occurred (*e.g.* treatment visit) was frequently an issue in malpractice suits. When the EHR is used appropriately, audit trails dispose of that problem. That is, if a medical professional logs into the EHR each time he/she treats a patient, then the audit trail will have an entry for when that professional logged in. The timing

of the treatment will not become an issue. However, that the audit trail tracks any use of the EHR is a both a blessing and a curse. Importantly, medical professionals must avoid the temptation to forward-chart the completion of tasks that have not yet been completed. Also, medical professionals must remember that any use of the EHR is tracked, and thus, any attempt to view or amend notes following an adverse result or commencement of a lawsuit, can shine a negative light on that professional.

With the vast majority of hospitals and medical facilities, as well as a growing number of private physicians, implementing the EHR, we can expect the number of medical malpractice lawsuits involving issues with the EHR to increase. In addition to cloning of records and issues caused by audit trails, other drawbacks of EHR may contribute to the rise of such suits, such as physicians ignoring incessant alerts and inadequate progress notes due to lack of options in drop-down menus. The EHR is now the common practice for documenting notes and recording interaction and will continue to evolve with further technological advances. Indeed, there is now word that Amazon and Apple are seeking to create their own EHR platforms.[40] As the EHR is here to stay, medical professionals must do their best to keep up with the ever-changing EHR landscape so as to avoid any potential legal liability.

REFERENCES ON PAGE 32

ABOUT THE AUTHORS



Santosh is currently the Director of Corporate Compliance and Risk Management at National Health Care Associates, Inc., a long-term and rehabilitation care company with 40 affiliated facilities across the northeast. As part of his role at National, Santosh oversees litigation commenced against the facilities. He also ensures that the facilities are in compliance with state and federal regulations. Prior to joining National, Santosh was an associate at Kaufman Borgeest & Ryan, LLP where he focused his work on the defense of medical and long-term care facilities and professionals. Santosh is also a member of AHRMNY's Publications Committee.



Jonathan D. Rubin is a senior partner with Kaufman Borgeest & Ryan LLP in New York City. His practice areas include Medical Malpractice Defense, Long Term Care and Nursing Home Defense, Health Care, Products Liability Defense and General Liability Defense Litigation. Mr. Rubin represents hospitals, nursing homes, physicians and health care professionals in civil litigation matters in state and federal courts. He is a former President of The Association for Healthcare Risk Management of New York, Inc. and a member of the New York State Bar Health Law section.

#MeToo Goes Viral
Healthcare Perspectives

By Hon. Ruth Bogatyrow Kraft, Mamie Stathatos-Fulgieri, Esq., and Krista Schlueck, Esq.

In recent months, the sexual harassment virus has assailed a multitude of industries with the same effect as an influenza epidemic. Healthcare organizations are by no means immune from such allegations and conduct. Society has reinforced a sexualized portrayal of those in the healthcare industry, especially nurses, and this may contribute to the conduct experienced in the workplace. From their portrayal in movies to Halloween costumes, at times nurses are seen in a sexualized manner rather than a professional one. Problems regarding sexual harassment are not limited to nurses, but extend to the rest of the healthcare profession as well.

Approximately 50% of female nurses, physicians, and medical students have reported experiencing sexual harassment. In 2016, one third of female physician-scientists reported having experienced sexual harassment during their career. In 2017, two-thirds of nurses, both men and women, stressed that harassment was an issue in the healthcare field. Furthermore, according to an analysis of charges filed with the EEOC, from 2005-2015 the Health Care and Social Assistance category had the fourth highest instance of complaints at 11.48%.

What is Sexual Harassment?

Actionable sexual harassment ranges from creating a hostile or offensive working environment to unwelcome sexual advances and requests for sexual favors. Victims and harassers are not limited to one gender and they can both be of the same sex. Harassment is illegal when it is so frequent or severe that it creates a hostile or offensive work environment or when it results in an adverse employment decision. The harasser can be the victim's supervisor, a supervisor in another area, a co-worker, or someone who is not an employee of the employer, such as a client, patient, or customer.

Harassment is not limited to physical actions. Verbal acts, such as offensive teasing, joking, or suggestive remarks or sounds, may also be considered sexual harassment, as well as whistling, catcalls, or inappropriate emails, letters, memos, or telephone calls. Non-verbal sexual harassment may include sexual gestures, winking, leering, looking inappropriately at a person's body, blocking a person's path, or giving personal and unwanted gifts.

Who is at Risk?

Healthcare workers are particularly at risk for experiencing instances of sexual harassment for several reasons, the first of which is the complex power dynamics in large institutions such as hospitals. These facilities have multiple departments, multiple supervisors, and multiple levels of authority that provide the perfect environment for instances of sexual harassment to occur. Those in power can use their position to manipulate subordinates, and due to the complex nature of authority in these institutions, reporting such instances may be a challenge.

Healthcare workers are equally at risk for experiencing instances of sexual harassment by patients. These workers may be spat on, hit, or grabbed by patients. Patients may also expose themselves, make inappropriate comments, or engage in other forms of harassment. Patients may respond adversely to medication or have illnesses such as dementia that make them unable to understand that their actions are inappropriate. While there is no way to prevent all inappropriate conduct, especially in instances where the patient is cognitively impaired, all healthcare facilities have a duty to protect their employees.

Who is Liable?

Once aware of an instance of harassment by a patient, a healthcare entity is liable if the conduct continues and no action is taken. Healthcare entities should take the following steps to address harassment by patients: (1) have a policy and procedure specifically addressing harassment by third parties and patients; (2) provide training on how an employee should respond if sexually harassed; and (3) if an employee alleges harassment by a patient, the entity should investigate and take affirmative steps to end the harassment.

In the nursing industry, instances of sexual harassment are often underreported. Many nurses attempt to ignore instances of sexual harassment or may not deal with the problem immediately. In certain instances, nurses may fear reporting harassment at the risk of experiencing retaliation, especially in instances where the harassers are their superiors. Federal and state laws are in place to protect nurses from harassment by patients but the problem continues to exist nonetheless.

Litigation Outcomes

On several occasions, instances of sexual harassment in the healthcare industry have intertwined with the legal field. For example, in 2009, a nurse from a hospital in New York was awarded $15million following years of sexual harassment by her superior, a physician. This harassment escalated and resulted in two violent attacks on the nurse in 2001. Despite complaining to her supervisors, no action was taken even though the doctor was previously sanctioned by the state medical board for what they called moral unfitness to practice medicine. In 2017, the Second Circuit Court of Appeals upheld a district court verdict that found the Connecticut Hospital liable for sexual harassment of a dental assistant, who alleged that she had been repeatedly harassed and physically touched by a dentist over a period of months.

Sexual harassment in the workplace can severely impact several companies. Taking action to prevent occurrences of sexual harassment benefits the well-being of both employees and employers. A sexual harassment complaint can cost a Fortune 500 company approximately $6.7 million in costs as a result of absenteeism, turnover, and decreased productivity and morale.

The Civil Rights Act-Title VII

Title VII makes it unlawful to fail or refuse to hire or to discharge any individual or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's race, color, sex, or national origin. In order to establish that sexual harassment is actionable under Title VII, certain conditions must be satisfied. First, the alleged victim must belong to a class or group protected under Title VII. Second, the alleged victim must be subjected to unwelcome sexual harassment. Third, the sexual harassment in question must be shown to have been based on the alleged victim's sex.

Hostile environment harassment occurs when the alleged victim demonstrates that the conduct of a sexual nature was sufficiently severe or pervasive as to have the effect of unreasonably interfering with work. Fellow employees can create the hostile environment. Conduct that is merely offensive to the victim is not enough. It must be shown that the discriminatory conduct was so severe or pervasive to create an objectively hostile or abusive working environment.

The Supreme Court rejected the requirement that hostile environment claims could only be substantiated by demonstrating that the complaining party's psychological well-being had been adversely affected.[1] The Supreme Court and federal courts have held that the mere utterance of an epithet which merely engenders offensive feelings or amounts to normal job stress does not violate Title VII. Simple teasing, offhand comments, and isolated incidents, unless extremely serious do not constitute a Title VII violation.[2]

An employer may be directly liable for hostile environment harassment if the employer knew or should have known that the sexual harassment was occurring

and then failed to take immediate and appropriate corrective action. An employer may be vicariously liable for wrongful actions of its employees regardless of whether or not the employer knew or should have known of the sexual harassment. However, the Supreme Court will permit the organization to avoid liability provided that two criteria have first been satisfied: (1) the employer exercised reasonable care to prevent and promptly correct any sexually harassing behavior and (2) the complaining party unreasonably failed to take advantage of any preventative or corrective opportunities provided by the employer or to otherwise avoid harm.

To establish the liability of an employer in instances of quid pro quo harassment, the Supreme Court has required the complaining party to establish four facts. First, the employer must have acted with malice or reckless indifference to the employee's Title VII rights. Second, the supervisory person representing the employer must have committed the violation. Third, the supervisory person must have been working within the scope of his or her employment. Finally, the supervisor's action must not be contrary to the employer's good faith efforts to comply with Title VII.

Organizational Responsibilities

Employers are required to take responsible care to prevent sexual harassment and take reasonable care to promptly correct sexual harassment once it occurs. Employers can affirmatively raise the subject amongst their employees and express strong disapproval for occurrences of sexual harassment. Additionally, employers should develop appropriate sanctions and inform employees of their right to raise issues of harassment under Title VII.

Policies established by employers should include several key elements. All policies should be clearly written, comprehensive statements of the employer's zero tolerance sexual harassment by anyone in the workplace. Assurances should be included that employees who make complaints and witnesses who provide information will receive protection from retaliation. Additionally, assurances should be made that the employer will protect confidentiality to the extent possible and will take immediate and appropriate corrective action if harassment is found.

Moreover, employer policies should create practices whereby an employee who has been harassed should be provided with options for notification and access. Options open to employees should include: (1) consulting union representatives, human resources personnel, or legal counsel; (2) following the employer's complaint process; (3) filing a charge with a state fair employment agency or the U.S. Equal Employment Opportunity Commission; or (4) commencing civil litigation in the federal or state courts of record.

Employee Responsibilities

Employees must recognize that consensual behavior is not sexual harassment and is not actionable under Title VII. Employees must be clear about saying 'no' and objecting to instances of sexual harassment. Employees should also document every incident of sexual harassment including the date, time, description, and witnesses. A formal complaint should be made to the appropriate supervisor in writing and the complaint should outline exactly what has occurred. The employee should provide evidence or a supporting statement of witnesses as appropriate. Furthermore, the employer should then create a written record that contains copies of all such document.

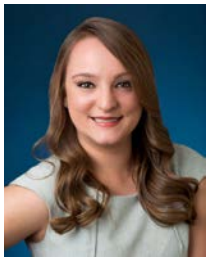
Conclusion

The prevalence of sexual harassment can be reduced through proper workplace policies and effective handling of reported occurrences, demonstrating organizational commitment to integrity and ethical stewardship. Healthcare entities have the potential to alter the dialogue, thereby eradicating inappropriate conduct by giving all allegations due consideration, irrespective of the identity and status of the complainant. Preventing sexual harassment is the obligation of both organizations and individuals. The axiom of "primum non nocere" first do no harm, spoken in the patient care context, is equally applicable to the obligation to provide a safe and harassment free environment for all stakeholders in healthcare.

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ABOUT THE AUTHORS





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AHRMNY hosted a cocktail reception during ASHRM's Annual Conference in Seattle, Washington on October 17th 2017 at the Purple Café & Wine Bar

Featured are a few photos of the enjoyable gathering



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