AHRMNY
The Association for Healthcare Risk Management of New York, Inc.

The Risk Management Quarterly

SPRING 2011

In This Issue

PRESIDENT'S MESSAGE

Greetings Members,

Our March 10 evening conference was very well attended and we enjoyed the warm, elegant atmosphere of the Harmonie Club. It was a great opportunity to meet new friends and catch up with old friends and colleagues at the cocktail hour and dinner. The presentation by Dr. Safyer was very interesting and thought provoking. We again thank all of our sponsors for their very generous support that allows us to get together in such comfortable venues.

I am excited to tell you about the upcoming educational opportunities that we will be offering in the next few months. The Education Committee has put together a very topical annual conference which includes Honored Guest Speaker, NYS Senator Kemp Hannon, Chairman of the Senate Health Committee addressing the legislative work of the Medicaid Redesign Team and with a Keynote address by Denis P. Whalen, Executive Vice President of HANYS, on the future issues with Medicaid but more significantly for our audience, addressing how these changes will impact NY's Malpractice Crisis. The conference will be June 10th at the NY Helmsley Hotel from 8am – 3:30pm. There will also be a Benchmarking presentation, a Creative Discharge Planning presentation and part one of a Risk Management panel. There will again be vendors exhibiting products you might find useful. Make sure you register for this enlightening program. On Friday August 12, 2011 AHRMNY will host a CPHRM preparatory course that will be held at Beth Israel Medical Center – Phillips Ambulatory Care Center, online registration will be available.

Our Public Relations Committee has been very active this winter and has made great advances on our website and you can now find our group on Linked-In. Plans are underway for AHRMNY's first webinar in the fall. So check out our website @ www.ahrmny.com. You can register for the June 10, 2011 conference while you are there and also renew your membership for the upcoming year.

We are proud to announce that our Membership is at an all time high of 282! Each year Alvin Safran, with the help of the membership committee, and Kisha seem to outdo the previous year through their strong efforts on membership drives.

The nominations committee worked hard vetting and preparing the slate for the expiring and open positions on the Board. We hope you all took the time to vote. The election results will be announced at the June 10th annual conference. We will be sorry to see Sam Senders, Judy Block and Lisa Bronikowski retiring from the Board of Directors. They have been a valuable asset and will be missed.

Our other committees Finance, Fundraising, and Bylaws, although not as visible, have been hard at work the year through. We encourage members as they renew their membership to think about the areas that interest them and join a committee. We always welcome new members and new ideas.

Last but never least our Publications Committee has again put together a Risk Management Quarterly packed with interesting articles and great columns. So sit back and relax with a beverage of your choice and prepare to be enlightened by the RMQ. It will be a great read.

Hope to see you June 10, 2011.
Peggy

EDITOR'S CORNER

The Risk Management Quarterly (RMQ), the official journal of the Association for Healthcare Risk Management of New York, Inc. is published four 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 regulations, 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.

For the official ***RMQ*** Author Guidelines visit our website http://www.ahrmny.com

Please forward any ideas or submissions for publication in the ***RMQ*** to "**Editors"**, via email with attachments to: ahrm@optimum.net

The deadline for submission and consideration for the next journal is **June 16, 2011.**

Reminder:
Maximum article length 3,500 words
Photo requirements: (high resolution JPEGs – at least 300 dpi)
AHRMNY will not publish those articles promoting products or services

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THE RISK MANAGEMENT QUARTERLY
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HEALTHCARE RISK MANAGEMENT WEEK
June 20-24. 2011

The theme for 2011's Healthcare Risk Management Week, June 20-24, is "Recognizing the Value of Risk Management."

In addition to promoting safe and trusted healthcare, this is an opportunity for AHRMNY members to communicate the value of risk management and heighten the awareness of the organizational value for today's healthcare risk manager.

See the national chapter's website at www.ashrm.org for communication tools and an educational webinar that supports Healthcare Risk Management Week.

IMPLEMENTATION OF THE FAMILY HEALTH CARE DECISIONS ACT: ONE YEAR LATER

By: Mathew C. Varughese & David Bohrer[1]

The Family Health Care Decisions Act (hereinafter "FHCDA") was enacted on March 16, 2010 after many years of legislative wrangling. The final result is a powerful new law that addresses how healthcare decisions, including decisions to withhold or withdraw life-sustaining treatment, are made for patients who lack decision-making capacity and who do not have a healthcare proxy.

Prior to the FHCDA, the law in New York was strikingly silent in addressing the unfortunate yet all too common scenario where a patient was incapable of making healthcare decisions and had not left any written instructions or designated a healthcare proxy to make decisions on the patient's behalf. Needless to say, this absence of law exacerbated an already emotionally taxing experience for family members and loved ones, as well as healthcare providers. The FHCDA fills this glaring legal gap.

A great challenge with any new sweeping healthcare law is implementation – applying the law to the healthcare setting. The FHCDA is no different. One year after enactment, the daunting challenge has been navigating the complexities and nuances of the FHCDA and reasonably applying the mandates, standards and requirements of the law at the point of care.

The critical and challenging first step in implementation is education. Lucidly, succinctly, continuously and frequently educating the relevant actors on the law is essential to appropriate implementation. The most common questions about the FHCDA have related to the decision-making standard imposed by the FHCDA, Order's Not to Resuscitate and its "place" within the FHCDA rubric, and how to deal with patient objections under the FHCDA. This article will tackle these questions as it relates to implementation of the law in the healthcare facility.

Decision Making Standards

Under the FHCDA, if an adult patient lacks capacity to make healthcare decisions, a surrogate has the legal authority to make any and all healthcare decisions on that patient's behalf.[2] However, for a provider, the analysis of implementing a healthcare decision does not end with this axiom. The surrogate must make such healthcare decisions based on legal standards articulated in the FHCDA.[3] Generally, the standard is "in accordance with the patient's wishes, including the patient's religious and moral beliefs."[4] If the patient's wishes are not reasonably known and cannot with reasonable diligence be ascertained, the decision must be made in accordance with the patient's best interests.[5] This sequence should not look too unfamiliar to the experienced healthcare provider. It is a similar standard enumerated in the Health Care Proxy statute.[6]

However, there are several differences in the standards that are to be applied to a surrogate decision under the FHCDA compared to an agent decision under the Proxy law. First, the FHCDA specifically defines what the patient's best interest must include, whereas, the Health Care Proxy law does not define a patient's best interest. Specifically, the FHCDA requires the provider to assess several points such as:

a) consideration of the dignity and uniqueness of every person;
b) the possibility and extent of preserving the patient's life;
c) the preservation, improvement or restoration of the patient's health or functioning;
d) the relief of the patient's suffering;
e) and any medical condition and such other concerns and values as a reasonable person in the patient's circumstances would wish to consider.[7]

The notion of a "patient's best interest" was a difficult idea to decipher prior to this law. It remains difficult, but there are helpful (and mandated) best interest standards. These standards appear onerous at first blush. However, careful study of the different requirements and thoughtful application quickly unlocks a host of important conversations and insights into a patient's particular situation. These standards can be seen as important "talking points" for providers to have among each other and potentially with family members. More importantly, it provides a blueprint for robust conversations and a sufficiently documented medical record. To be able to clearly and succinctly articulate all the aforementioned points empowers the provider and surrogate to communicate and come to the best decision for the patient.

Another critical difference between the standards for a surrogate versus the standards for an agent under a proxy is with respect to decisions to withhold or withdraw life sustaining treatment.[8] The FHCDA has created an additional level of scrutiny not seen with an agent under the Proxy Law. Under the FHCDA, the standard to apply differs depending on the patient's condition.

If the patient has an illness or injury which can be expected to cause death within six months whether or not treatment is provided; or the patient is permanently unconscious,[9] the standard is whether the treatment would be an extraordinary burden to the patient.[10] If the patient does not fall into either of these categories but, rather, is a patient that has an irreversible or incurable condition,[11] then the standard is much higher – the provision of treatment would involve such pain, suffering or other burden that it would be deemed inhumane.[12]

The next question is why have this additional level of scrutiny especially where it is absent in the proxy law? The FHCDA has delineated a person to now be legally authorized to make some of the most private, personal decisions for a person – healthcare decisions. Unlike an agent granted authority through proxy by the principal, the FHCDA allows these private decisions to be made even though that surrogate was not specifically chosen by the patient. As such, to protect from untoward decisions, one must follow this much more stringent standard.

Do Not Resuscitate

One of the most significant changes brought by the FHCDA involves Orders not to Resuscitate (hereinafter "DNR"). Before the FHCDA, Public Health Law Art. 29-B had been the law for DNR orders since 1987 and provided procedures for consent to and issuing DNR orders. Now Public Health Law Art. 29-CC applies to all healthcare decisions for patients of general hospitals and residents of nursing homes, including DNR orders.[13] Under the FHCDA, a DNR order is just one type of

decision to withhold or withdraw life-sustaining treatment. Specifically, in the definitions section of FHCDA, cardio-pulmonary resuscitation is presumed to be life-sustaining treatment.[14]

With that general presentation, what are the differences within the hospital setting? The question must be analyzed using two different settings: a) with a surrogate; and b) without a surrogate.

Under the old DNR law, there were four separate trigger points for ordering a DNR when the patient had a surrogate. They were:

a) Resuscitation would be medically futile;
b) Patient has a terminal condition causing death in one year;
c) Patient is permanently unconscious; or
d) Resuscitation would impose an extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of resuscitation for the patient.[15]

Under the new law, to implement a DNR order, you must fall under the previously indicated standards: either "extraordinary burden" or "inhumane" standard. For example, even if a patient is permanently unconscious or has a terminal condition causing death within six months, under the new law, to implement a DNR order, an assessment must be made to determine whether the treatment would be an extraordinary burden to the patient. This additional step was not required prior to the FHCDA. Furthermore, the new law does not cover medical futility.[16]

In a situation where there is no surrogate, under the old DNR law, the physician could order a DNR provided that the attending physician determines, in writing, that to a reasonable degree of medical certainty, resuscitation would be medically futile with a concurrence from a second physician.[17] Under the old law, medically futile was defined as when: "cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs."[18] The new law changes the parameters. A physician can withhold or withdraw life-sustaining treatment if the attending physician, with independent concurrence of a second physician designated by the hospital, determines to a reasonable degree of medical certainty that (i) life sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the provision of life sustaining treatment would violate accepted medical standards.[19]

Patient Objection

Another significant yet challenging aspect of implementing the FHCDA involves patient objection. If a patient objects to a) the determination of incapacity b) the choice of a surrogate or c) to a healthcare decision, the patient's objection prevails.[20] Thus, the FHCDA prioritizes a patient's objection. However, there are limited legal avenues to override the objection -- such as when providing emergency treatment. Additionally, under the FHCDA, a court can override an objection based on a determination that the patient lacks decisional capacity.[21]

The FHCDA inherently limits the need for judicial intervention with its clearly defined list of surrogates and a specific decision-making standard for treatment decisions. However, in the circumstances set forth above, litigation is still a necessary last resort for hospitals and nursing homes.

Risk managers must be mindful of the key issues that may ultimately impact litigation under the FHCDA in order to be prepared when these situations arise.

Of import, all efforts should be made to resolve conflicts without court intervention. On most occasions, family and/or provider intervention as well as ethics consults are beneficial in resolving conflicts early. However, when all avenues have been exhausted and the patient continues to object, the only remaining remedy is the court system.

The FHCDA permits a special proceeding by "any person connected with the case" in a court of competent jurisdiction.[22] The most common circumstance that has prompted a special proceeding under the FHCDA is when a patient objects to the performance of surgery. Many times this involves patients who have been diagnosed with advanced stage cancer and require the removal of an organ or extremity. In these "life over limb" situations, the facility is compelled to seek authority to perform surgery over the patient's objection.

An application of the FHCDA in these cases is not much different than it was under the common law. In fact, a court's analysis boils down to the same basic points: 1) whether the patient lacks decisional-capacity and 2) whether recommended treatment is in the patient's best interests. However, under the FHCDA, the standards are more clearly defined, providing guidance for both the facilities managing the patient's care and for courts who must decide the outcome.

For example, by including "close friends" as potential surrogates, the law has increased the significance of preparation prior to petitioning the court for authority to compel surgery. It is incumbent on the patient's provider team to compile an accurate list of the names and addresses of all family members and "close friends" as defined by this statute.[23] This appears to be common-sense, but the last thing a court wants to hear is that there is a previously unknown potential surrogate that should be participating in that proceeding.

During a special proceeding under the FHCDA, the paramount question for the court is capacity. The FHCDA defines decisional-capacity as "the ability to understand and appreciate the nature and consequences of proposed healthcare, including the benefits and risks of and alternatives to proposed health care, and to reach an informed decision".[24] If the court does not find that the patient lacks capacity, it does not matter how important the recommended treatment is.

The initial determination of incapacity is made by the patient's attending physician.[25] Significantly, where the initial determination of incapacity is due to mental illness, the physician must be licensed to practice medicine in the State of New York and be either board-certified or board-eligible by the American Board of Psychiatry and Neurology.[26] For all practical purposes, it is more persuasive to have an experienced, board-certified psychiatrist available to testify as to a lack of capacity even if not required by this law.

In certain circumstances, initial determination of incapacity is subject to a concurring opinion.[27] Under the FHCDA, this need not be made by a physician. The concurring opinion can be made by a "health or social services practitioner."[28] However, as above, it is more persuasive to a court to have a board-certified psychiatrist confirm a finding of incapacity. Even if the criteria is met by having a non-physician concur, the court, when weighing the significant consequences of

overriding an objection, is bound to assess the concurring provider's experience level.

The law specifically requires both the initial and concurring provider to assess the cause and extent of the patient's incapacity.[29] These providers must also be of the opinion that the patient is not likely to regain decision-making capacity. This means that they must not be of the opinion that the patient's lack of capacity is acute. This provision may practically delay applications of this nature since it causes facilities to rule out a transient cause of the patient's incapacity.

Practically speaking, no matter what the circumstances are, the testimony of the patient whose capacity is at issue in a special proceeding will inevitably play a huge role in the court's decision. Many of these cases are difficult and are very close moral issues for the court to decide. On one hand, the court is often faced with the option of finding capacity, but in doing so must reject the undisputed testimony of a board-certified psychiatrist. On the other hand, the court must weigh the presumption that a patient is competent with the notion that the patient's insight is limited and that the treatment is in his/her best interests. In the end, the court will look to whether the patient has stated a rational explanation for her decision or objection, such as a religious objection, wanting to die, or fear of the operation. Lack of this type of evidence could arguably be seen as proof that the patient does not truly understand the nature and consequences of the recommended treatment.

The FHCDA also sets forth a specific decision-making standard for authorizing medical treatment for patients that lack decisional capacity and where there is no available surrogate.[30] In these situations, the approach to presenting recommended treatment to a court does not significantly change under the FHCDA compared to under the common law. The primary difference is distinguishing between major and routine medical treatment. Major medical treatment includes the use of general anesthesia, psychoactive medications under certain circumstances, and the use of physical restraints in non-emergent situations, significant risk, and a significant invasion to one's bodily integrity.[31] Routine medical treatment includes treatment for which health care providers do not ordinarily seek written consent, such as the administration of medication, the extraction of bodily fluids, or dental care with a local anesthetic.[32]

The law also provides specific guidance as to who should make these medical decisions. For major medical treatment, the law requires that the patient's attending consult with hospital staff directly responsible for the patient's care.[33] In a general hospital setting, at least one other physician must independently concur.[34] In a nursing home, a physician must independently concur with the recommended major medical treatment unless the treatment involves the use of non-emergent restraints.[35] Under those circumstances, "any health or social services practitioner employed by or otherwise formally affiliated with the facility" is permitted to concur. For routine medical treatment, an attending physician is authorized to make such determinations.[36]

One very important area of concern to health care providers and Risk Managers alike is what happens when the patient successfully completes the court-ordered medical treatment but now refuses further treatment. For this reason, the drafting of the court order following a special proceeding is an important aspect of the case that must not be overlooked. To ensure that the facility has as much discretion for future treatment, it is recommended that any order authorizing recommended treatment also include a clause for "all associated procedures". However, this "catch-all" will not provide a blank check for all future treatment. As such, during the special proceeding, it is critical for the physicians to include all foreseeable treatment so that it not necessary to run back to court every time the need arises.

Litigating special proceedings under the FHCDA are going to be few and far between. The law is designed in part to avoid such issues. However, one area where litigation cannot be avoided is where the patient maintains his/her objection.

Conclusion

The FHCDA is a robust body of law where application to real life situations has many layers. Every fact pattern that is presented to the Risk Manager illuminates different areas of this law. As such, successful implementation is hinged on regular communication with key actors within the organization and continued emphasis on education making implementation of the FHCDA in the healthcare setting a long, difficult, but exciting process.

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[1] **Mathew C. Varughese** is Assistant Counsel for Medical-Legal and Mental Health Affairs, Office of Legal Affairs, New York City Health and Hospitals Corporation (HHC). He has several years of in-house experience advising the corporation's various facilities on numerous legal issues ranging from patient privacy to informed consent. **David Bohrer** is a partner at McAloon & Friedman. He has over 10 years of experience representing hospitals and medical professionals in malpractice and healthcare litigation matters. The views and advice expressed in this article are purely those of the authors and do not necessarily reflect the opinions or policies of HHC.

[2] Public Health Law §2994-d[3][a][i].

[3] Public Health Law §2994-d[4],[5].

[4] Public Health Law §2994-d[4].

[5] Public Health Law §2994-d[4].

[6] PHL §2982[2]. Decision-making standard. After consultation with a licensed physician, registered nurse, licensed [fig 1] psychologist [fig 2] ,licensed master social worker, or a licensed clinical social worker, the agent shall make healthcare decisions: (a) in accordance with the principal's wishes, including the principal's religious and moral beliefs; or (b) if the principal's wishes are not reasonably known and cannot with reasonable diligence be ascertained, in accordance with the principal's best interests; provided, however, that if the principal's wishes regarding the administration of artificial nutrition and hydration are not reasonably known and cannot with reasonable diligence be ascertained, the agent shall not have the authority to make decisions regarding these measures.

[7] PHL §2994-d[4][ii]

[8] Similar to Surrogate Court Procedure Act 1750-b[4].

[9] This determination must be made by a physician with the independent concurrence of another physician. See PHL 2994-d[5][a][i].

[10] PHL §2994-d[5][a][i].

[11] This must be determined by an attending physician with the independent concurrence of another physician to a reasonable degree of medical certainty and in accord with accepted medical standards. See PHL 2994-d[5][a][ii].

[12] PHL 2994-d[5][a][ii].

[13] The old DNR law, 29-B is now amended and limited to DNR orders issued for a patient in a mental hygiene facility, will be governed by Article 29-B.

[14] PHL §2994-a[19].

[15] Previously cited as PHL 29-B.

[16] As of the date of this article, there has been talk of amending the FHCDA by adding "medical futility."

[17] Previously cited as PHL §2966.

[18] Previously cited as PHL §2961[12].

[19] PHL 2994-g[5]. This section does not apply to any treatment necessary to alleviate pain or discomfort.

[20] PHL 2994-c[6].

[21] Id.

[22] PHL §2994-r[1].

[23] PHL §2994-a[4].

[24] PHL2994-a[5].

[25] PHL 2994-c[2].

[26] PHL 2994-c[3][c].

[27] PHL 2994-c[3][a].

[28] Id.

[29] PHL 2994-c[2] and [3].

[30] PHL 2994-g.

[31] PHL 2994-g[4][a].

[32] PHL 2994-g[3][a].

[33] PHL 2994-g[4][b][i].

[34] PHL 2994-g[4][b][ii].

[35] PHL 2994-g[4][b][iii].

[36] PHL 2994-g[3][b].

LEGISLATIVE UPDATE

New York State Passes Major Medical Malpractice Reform

On March 31, 2011, the New York State Legislature passed the creation of a Medical Indemnity Fund (MIF) to pay for future medical costs in birth related neurological trauma injury lawsuits. The law is retroactive and will apply to all birth related neurological injury lawsuits where no judgment has been entered and no settlement agreement has been entered into before April 1, 2011.

Plaintiffs will still be required to file cases in and proceed through the courts and will still have to demonstrate provider negligence or causation.

The costs covered by the Fund include future medical and other necessary healthcare costs as they are actually incurred.

In advocating for the MIF, Greater New York Hospital Association (GNYHA) noted that the fact that cases involving neurologically impaired newborns are one of the principal drivers of high malpractice costs for hospitals and physicians, representing 35-50% of some hospitals' total coverage costs, and while devastating, these cases are often NOT the result of provider negligence.

Department of Health Regulatory Amendments

On December 17, 2010, the State of New York Department of Health (DOH) sent a letter to Chief Executive Officers to advise facilities of recent regulatory amendments (Sections 405 &755, Title 10NYCRR) that impact facility operations.

- **405.6(b)(7)(iii) Quality Assurance**- Standard amended to reduce from ten (10) years to five (5) years the credentialing look back period with regard to the professional misconduct / malpractice history for practitioners seeking clinical privileges. (effective 12/22/10)
- **405.7(b)(2)&(c)(2) Patient Rights**- Amended by statute for provision regarding patient rights and responsibilities to inform each patient of his or her right not to be discriminated against on account of age. (effective 12/22/10)
- **405.19(d)(1)(ii) Emergency Services**- For hospitals with fewer than 15,000 annual visits, the emergency service supervising or attending physician need not be present at all times and may now be available within 30 minutes as compared to 20 minutes previously required. (effective 12/22/10)
- **755.6(d) Free-Standing Ambulatory Surgery Centers-** State rule amended to allow post-surgical anesthesia assessments to be conducted by practitioner qualified to administer anesthesia. (effective 12/22/10)

AHRMNY Congratulates Bonnie

Bonnie Boone is the recipient of the

Peggy Cwik
Lifetime Achievement Award 2011*.

The Chicagoland Healthcare Risk Management Society (CHRMS) presented Bonnie with this honor in acknowledgment of:

- Positive recognition in the health care Risk Management profession at a local, state, national or international level
- Supports the profession of health care risk management through active interactions with other organizations
- Change agent within risk management by identifying, planning, coordinating new activities that assist other cognizant of the continuous changing role of health care risk management

Among her many achievements in the industry, nationally, Bonnie has been recognized as a Power Broker for Healthcare by Risk and Insurance Magazine in 2008 & 2009. Bonnie is an active member of AHRMNY, serves on the AHRMNY Board of Directors and is a Co-chairperson of the Fundraising Committee.

Congratulations!

WE WANT TO HEAR FROM YOU FOR THE SUMMER AND FALL EDITION

We are asking our readers to submit articles to appear in the summer and fall editions of ***The Risk Management Quarterly***. Submission of articles that focus on safe patient care practices, safe working environments, legal and financial updates in the health care arena are some of the topics we seek.

RMQ is published four times a year with a distribution of 200-300 copies per quarter.

Please forward any ideas or submissions for publication in the ***RMQ*** to "**Editors"**, via email with attachments to: AHRM@Optimum.net

LABORATORY EXPOSURE – A LEGAL PERSPECTIVE

By: Loretta A. Krez, Esq., Heather Laschewer, Esq. and Betsy Baydala, Esq.

In a typical hospital, thousands of specimens are analyzed in the laboratory each day.[1] The entire process of laboratory and pathology testing[2] is divided into three different phases – pre-analytic, analytic and post-analytic – with further subdivision within each phase. Given the multifaceted nature of the laboratory testing process, various policies must be in place to prevent errors during each phase.

Studies have shown that errors occur more frequently in the pre-analytic and post-analytic phases compared to the analytic phase. However, errors in the analytic phase, such as misdiagnoses, can have devastating consequences and have garnered significant media attention. The following article will provide an overview of errors commonly observed throughout the three phases of laboratory testing and offer practical and legal suggestions for reducing these errors.

PRE-ANALYTIC PHASE

The pre-analytic phase encompasses the entire period before a specimen is analyzed in the laboratory. This phase starts with ordering a test, followed by identifying and preparing patients for testing, acquisitioning specimens, labeling and handling specimens, documenting information on tissue requisition forms and transporting specimens to the laboratory. Given that the majority of this phase occurs outside the laboratory, laboratory personnel have the least amount of control over this phase.

An error can instantly occur if an order is entered incorrectly into the hospital's laboratory computer system. A simple, but effective way to limit these errors is to implement policies requiring nursing to verify the accuracy of the orders entered in the computer before submitting specimens for testing.[3]

Correctly identifying a patient for testing is an obvious, but critical step in the pre-analytic phase. It ensures that laboratory results will reach the correct patient's medical record and, if necessary, appropriate treatment measures provided. Hospital patients are usually identified by wristbands. In a study performed by the College of American Pathologists (CAP), wristband errors were found 2.79% and 2.38% of the time in the first and second year of the study, respectively.[4] By far, the most frequent error was a missing wristband, which accounted for 71.6% of all errors. Other wristband errors included missing identification information (9.1%), illegible wristband (7.7%), erroneous identification information (6.8%), conflicting wristbands (3.7%) and the wrong wristband (1.1%). The study observed that lower error rates were associated with delaying testing until wristband errors were corrected and generating "discrepancy reports" that identified problems and were sent to nursing personnel for review. The study urged laboratories to incorporate the monitoring of wristband errors in their quality improvement programs.

An encouraging aspect of the study is that measures ensuring wristband accuracy are neither expensive nor require elaborate interventions. Hospitals and laboratories can achieve wristband accuracy by strengthening simple procedures already in place.

When pathology specimens are submitted to the laboratory they are accompanied by a requisition slip. Generally, requisition slips include the patient's identifying information, the type of specimen submitted, the exact anatomic site sampled, and the relevant clinical histories to guide the pathologist. If information on a requisition slip is insufficient or incorrect, a diagnostic error can result.

In a study that examined the adequacy of tissue requisition slips, pathologists reported that 0.73% of the time, the information provided on the requisition form was insufficient to render a diagnosis.[5] One study has shown that the most common deficiency found in requisition slips is the lack of clinical histories/diagnoses, which accounted for 40% of reported deficiencies.[6]

The pre-analytic phase also involves the critical step of obtaining a patient's specimen that is adequate for laboratory testing and correctly labeled and transported for testing. The University of California, Los Angeles (UCLA) Clinical Laboratories conducted a study to determine the frequency of blood specimen errors.[7] Specimen and requisition mismatch accounted for 6.3% of the errors, followed by unlabeled specimens (4.6%). Both of these errors are readily apparent upon the laboratory's receipt of these specimens. Policies should, therefore, be implemented to remedy these errors by immediately rejecting the specimen and obtaining a new specimen.

In the UCLA study, mislabeled specimens accounted for 1.0% of the total errors. However, the laboratory's ability to detect these errors is low and such errors are usually not discovered, if ever, until a clinician questions a highly atypical result given the patient's clinical history. The likelihood that a mislabeled specimen may go unrecognized is a significant concern and an area for continued surveillance and improvement in both hospitals and laboratories.

In addition to properly labeling and handling a specimen, it is crucial that the specimen is adequate for interpretation. If the pathologist is unable to interpret a specimen due to the quality of the specimen, the report must indicate that the specimen is "unsatisfactory" for interpretation so that the clinician can obtain a further sample. However, if the specimen is adequate for interpretation and the specimen is properly reported as benign, the pathologist would not have an obligation to request an additional specimen.

Thus, a pathologist may have a duty to the patient to request an additional specimen if it is deemed unsatisfactory. However, if a specimen is considered benign, a pathologist has no obligation to request further specimens if his or her interpretation of the specimen was within the standard of care.

ANALYTIC PHASE

The analytic phase of testing entails the routine analysis of laboratory specimens, which is a repetitive process with built-in quality controls. The testing process generally cannot advance to the next step if the quality control from the prior level is not met. Given these stringent controls, the analytic phase typically has the lowest error rates compared to the other two phases.[8]

However, errors during this phase are considerable and represent a significant amount of litigation against laboratories and pathologists. A common malpractice case concerns the pathologist's diagnosis of the wrong disease and the patient subsequently undergoing unnecessary treatment,[9] while another group of malpractice lawsuits concerns the failure of the pathologist to diagnose sometimes fatal diseases.[10] One study found that most misdiagnoses were attributed to sampling errors (either by selecting the wrong portions of tissue to freeze or failing to cut into frozen blocks deeply enough) and misinterpreting histologic frozen sections.[11] One study showed that sampling errors accounted for 68.0% of the errors, whereas misinterpreting samples accounted for 24.7% of the errors.[12]

Analytic errors have generated significant media attention. One of the more common headlines is a woman being told she had breast cancer, but later finding out, after undergoing a mastectomy and radiation, that she never had the disease.[13] Misdiagnoses have also caused alarming reactions from both patients and doctors. In one case, pursuant to the patient's last wishes, criminal charges were considered against a laboratory, a technician and the doctor in charge of the laboratory for fatally misdiagnosing cervical cancer in two patients' Pap smears.[14] In another case, a surgeon commenced a lawsuit against the pathologists and hospital seeking recovery for financial and emotional harm he allegedly suffered following a media campaign against him by his patient and her husband. The surgeon had performed an unnecessary mastectomy on the patient after the pathologist mistakenly concluded that the patient's biopsy was malignant.[15]

Reducing sampling errors is possible by sampling more than one area of gross tissue submitted for analysis (as long as there is enough tissue to do so). Moreover, diagnostic errors can be prevented by having an additional pathologist review the diagnosis before issuing the final report.[16] In one study, reviewing pathologists discovered discrepancies in the initial report in 6.7% of the cases reviewed.[17]

In Conti v. Albany Medical Center Hospital, the Court reaffirmed the value of a subsequent pathologist review. In Conti, the plaintiff alleged that her condition was mistakenly determined to be terminal, requiring improper treatment.[18] The two defendant pathologists had examined the patient's tissue samples following her brain surgery.[19] An associate pathologist initially reviewed the tissue samples and prepared an initial report. The tissue samples were then examined by a neuropathologist, who prepared a further report. In determining that the pathologists' were correct in their diagnosis of the patient, the Court referenced the hospital's policy regarding the examination of neurological specimens whereby the pathology department performed "routine processing" and expressed opinions in a "guarded manner," then forwarded the specimen to the neuropathology department for further analysis and an ultimate diagnosis.[20]

POST-ANALYTIC PHASE

The post-analytic phase is the actual reporting of laboratory test results and requires collaboration with laboratory and hospital personnel. The report is a laboratory's final product and the elements essential to a quality report include accuracy, timeliness and completeness.[21] Errors during this phase include incorrectly transmitting results, failing to report on ordered tests,[22] not reporting critical values fast enough, or failing to note critical results in the patient's chart.

In Hicks v. Ronald Fraser Clinic, the Court held that the sole function of the laboratory was to perform tests and report the results to the patient's physician for his or her evaluation.[23] In Hicks, the patient claimed that her private physician and the hospital's laboratory failed to diagnose her with lupus after she tested positive for syphilis after a routine serology blood test. The patient argued that the laboratory failed to consider testing for another disease such as lupus. However, the Court stated that lupus is not a disease that is diagnosable "based solely on laboratory results, but requires the evaluation of a physician based on medical history, physical examination, complaints, symptoms and laboratory test results." Given that the laboratory correctly performed its function by reporting an accurate test result, the Court held that any alleged failure to diagnose lupus was the responsibility of the patient's private physician.

As Hicks demonstrates, a diagnosis is commonly made after a physician thoroughly evaluates the patient's entire clinical history, which includes laboratory test results. As a result, if the laboratory properly reports on a patient's laboratory/pathology findings, any alleged misdiagnosis in the post-analytic phase is more likely to expose the patient's physician to a claim of malpractice rather than the laboratory. In Unger v. Stiber, a pathology report revealed an endometrial polyp and tissue that was insufficient for diagnosis.[24] The patient's physician reported that the lack of tissue was "reassuring." However, the patient was subsequently diagnosed with endometrial cancer. The Court held that the patient's physician departed from accepted standards of medical care in improperly interpreting the results of the pathology report.

CONCLUSION

As with all medical disciplines, it is necessary to continually evaluate and implement quality improvement measures to reduce errors during the laboratory testing process. The first step in any successful improvement program is to motivate the staff to become educated on measures that will improve patient safety and outcomes. Reducing errors is a step-by-step process that at first glance may seem overwhelming. Therefore, it is often best

best to start with the area that is the most problematic and work to implement improvements piecemeal. While working to improve patient safety, data-driven studies should be in place so that successes are documented and can be shown to encourage both the staff and the administration.

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[1] Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. Patient safety in the clinical laboratory. Arch Pathol Lab Med—Vol 130, November 2006: 1662-1668.

[2] For the remainder of this article, laboratory and pathology testing will be used interchangeably, unless otherwise explicitly noted.

[3] Novis, DA. Detecting and preventing the occurrence of errors in the practice of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-PROBES and Q-TRACKS programs. Clin Lab Med 24 (2004): 965-978.

[4] Howanitz PJ, Renner SW, Walsh MK. Continuous wristband monitoring over 2 years decreases identification errors. Arch Pathol Lab Med July 2002: 809-815. The College of American Pathologists (CAP) Q-Tracks program conducts studies to help evaluate and improve the quality of laboratory processes.

[5] Nakhleh RE, Gephardt G, Zarbo RJ. Necessity of clinical information in surgical pathology. Arch Pathol Lab Med 1999;123:615-9.

[6] Nakhleh RE, Zarbo RJ. Surgical pathology specimen identification and accessioning: a College of American Pathologists Q-Probes study of 1,004,115 cases from 417 institutions. Arch Pathol Lab Med 1996; 120:227-33.

[7] See note '1', supra.

[8] Howanitz PJ. Errors in laboratory medicine. Arch Pathol Lab Med—Vol 129, October 2005: 1252-1261.

[9] Catanese v. Furman, 27 A.D.3d 1050, 811 N.Y.S.2d 260 (4th Dept. 2006) (misdiagnosing the patient as suffering liposarcoma, a rare form of cancer; the patient underwent surgery to remove the mass and nerve in the patient's right leg was severed); Kremen v. Brower, 16 A.D.3d 156, 793 N.Y.S.2d 3 (1st Dept. 2005) (misdiagnosing the patient with breast cancer and undergoing an unnecessary bilateral mastectomy); Wert v. Lenox Hill Hospital, 151 A.D.2d 474, 542 N.Y.S.2d 264 (2nd Dept. 1989) (suffering mental anguish after a pathology report erroneously indicated that she had cancer); Modzelewski v. Kingsbrook Jewish Medical Center, 120 A.D.2d 498, 501 N.Y.S.2d 699 (2nd Dept. 1986) (misdiagnosing a spinal tissue sample as malignant, resulting in aggressive radiation treatment and surgery; the patient was subsequently diagnosed with a spinal cord disease from the radiation).

[10] Shapiro v. Good Samaritan Regional Hospital Medical Center, 55 A.D.3d 821, 865 N.Y.S.2d 680 (2nd Dept. 2008) (misdiagnosing spread of cancer in patient's mouth); Cummins v. Marchetti, 17 A.D.3d 1160, 794 N.Y.S.2d 552 (4th Dept. 2005) (failing to diagnose cervical cancer); Kaffka v. New York Hospital, 228 A.D.2d 332, 664 N.Y.S.2d 243 (1st Dept. 1996) (failing to diagnose breast cancer; however, causation was not established because at the time of the pathologist's examination, the patient's cancer had already metastasized to the bone and liver); McClurg v. State of New York, 204 A.D.2d 999, 613 N.Y.S.2d 71 (4th Dept. 1994) (failing to diagnose malignant melanoma); Roseman v. Goldberg, 181 A.D.2d 873, 581 N.Y.S.2d 854 (2nd Dept. 1992) (failing to diagnose cervical cancer on a series of Pap smears); Zarrelli v. Nathan Littauer Hospital, 176 A.D.2d 1181, 575 N.Y.S.2d 973 (3rd Dept. 1991) (failing to diagnose Hodgkin's disease).

[11] See note '3', supra.

[12] Id.

[13] Saul S. Prone to error: earliest steps to find cancer. The New York Times, July 19, 2010.

[14] Homicide charges are recommended in misread Pap tests. The New York Times, April 11, 1995.

[15] Megally v. LaPorta, 253 A.D.2d 35, 679 N.Y.S.2d 649

[16] In McClurg v. State of New York, 204 A.D.2d 999, 613 N.Y.S.2d 71 (4th Dept. 1994), a pathology report erroneously determined that the patient had a non-cancerous condition. The report was initialed by three physicians, two of whom were Board Certified Pathologists. Six years later, the patient was diagnosed with melanoma. A re-examination of the initial slides showed that the cancer was present six years earlier. In addition to claiming medical malpractice, the plaintiff alleged fraud against the physicians since "no two Board Certified Pathologists could have erroneously examined these slides, ruled out malignant melanoma and concurred in a diagnosis of 'granulomatous inflammation'." As such, it was plaintiff's argument that the pathologists initialed the report without having reviewed the slides. The Court dismissed the plaintiff's fraud claim on the ground that it was not separate and apart from the malpractice itself.

[17] See note '3', supra.

[18] 159 A.D.2d 772, 551 N.Y.S.2d 994 (3rd Dept. 1990).

[19] Id.

[20] See Moore v. Schlossman, 101 Misc.2d 182, 420 N.Y.S.2d 622 (New York County, 1979) (claiming that the laboratory was negligent in failing to have proper pathologists available to review non-negative slides).

[21] Nakhleh RE, Souers R, Ruby SG. Physician satisfaction with surgical pathology reports. Arch Pathol Lab Med November 2008: 1719-1722.

[22] In Cassidy v. County of Nassau, the plaintiff was not informed that surgical pathology from a hysterectomy revealed a viable fetus. 84 A.D.2d 742, 443 N.Y.S.2d 742 (2nd Dept. 1981).

[23] 169 A.D.2d 558, 565 N.Y.S.2d 484 (1st Dept. 1991)

[24] 18 Misc.3d 1125(A), 2008 WL 314181 (New York County, 2008)

Loretta A. Krez, a partner in the law firm of Kaufman Borgeest & Ryan, LLP specializes in the defense of all types of claims against health care providers including laboratories. She has authored articles on medical and legal issues and is a past contributor to the AHRMNY News publication.
Heather Laschewer, a senior associate in the law firm of Kaufman, Borgeest & Ryan, LLP handles the defense of all claims against healthcare professionals including laboratories.
Betsy Baydala is a former associate of Kaufman, Borgeest & Ryan, LLP.

DOCUMENTATION OF THE MEDICAL RECORD

HOW DOES THIS SUBJECT RELATE TO RISK MANAGEMENT, MEDICAL LIABILITY AND PATIENT SAFETY

By: Steven E. Pegalis

Every medical record must be complete, accurate and meaningful. An appropriate thought process should go into every significant medical decision. For the medical record to be meaningful, a knowledgeable person should be able to extrapolate from what is documented, the data and rationale for the thought process leading to each such decision.

As an attorney who represents plaintiffs in medical/ hospital liability cases I have been asked once again to submit to your Risk Management Quarterly an article. A prior submission that I co-authored with Paul Gluck, M.D. (a nationally recognized physician expert on patient safety) has basic definitions and principles that may help create a context.[i]

The representation of plaintiffs individually and collectively in medical/hospital liability cases can connect most meaningfully with a valid, moral, beneficial purpose if healthcare providers use the information learned from pending and prior suits as to what went wrong and link that information to a desire to avoid future suits by making care safer by preventing similar failures from occurring.

I hope the thoughts expressed in this article will promote in some way safer care.

Documentation: Some Basic Definitions and Concepts

The following is contained in a current Risk Management Handbook:

> **"The medical record is important as a tool of effective communication. It facilitates continuous performance improvement, supports reimbursement of services provided, and provides clinical data for research and education.**
>
> **The purpose of a medical record is to document the course of a patient's care and treatment. Documentation is the essence of the medical record, and risk management professionals have a vested interest in preserving the record and in enhancing the quality of documentation" [ii]**
>
> **"Documentation may be defined as the recording of pertinent facts and, observations about an individual's health history, including past and present illnesses, tests, treatments, and outcomes.. Documentation ... creates a legal record in the event of a claim ... Other purposes of documentation include;**
>
> **Planning and evaluating the patient's treatment;**
>
> **Facilitating communication among all care givers;**
>
> **Providing continuity of care for the patient;**
>
> **Providing evidence of care and treatment in legal actions and for reimbursement purposes;**
>
> **Meeting the standard of care. [iii]**

Just as everyone is for patient safety, everyone is also for good and proper documentation for all the right reasons. As with the subject of patient safety it is relatively easy to furnish definitions, principles and end point goals on the subject of documentation. It is, however, not easy to implement patient safety and not so. easy to actually create records consistent with both the letter and the spirit of these definitions and principles.

SOME ANECDOTAL COMMENTS

I was recently invited to participate in a seminar intended to aid New York State jurists with regard to their judicial duties related to medical liability cases. [iv]

Earlier in the program the jurists were given details concerning charting. For example, the JCAHO standard for documentation is that there must be a complete and accurate record. [v]

I was asked if in my view a failure to properly document would constitute an individual departure giving rise to liability.

My response was that in some instances a failure to document, for example a history of diabetes, might be an individual act of negligence, but often a superficial and/or sloppy note is not itself a departure from good and accepted care that independently will create liability. Rather, the inadequacy of the documentation can have important evidentiary implications in the disputed case.

When pressing a healthcare provider with regard to the inadequacy of his or her note I have often received the following responses: "You know I can't write a note and take care of the patient at the same time." and/or "You know I can't write an essay in the record". These answers invariably lead to the following questions: "Can we agree that when you completed what you were doing there was time and opportunity to write a proper note? Can we agree that writing a proper note is part of a process of taking care of a patient? Can we agree that while writing an

essay would be an inefficient waste of valuable time that making your note complete, accurate and meaningful is a valuable and necessary use of your time?"

In truth if the note really was superficial no excuse sounds good in court or in any other forum. The argument often made by defendants is that even if the healthcare provider was superficial with regard to his or her note that doesn't necessarily mean the actual care given was superficial. This argument usually has a very hollow ring to it.

If a frivolous case has been brought and the defense has true merit, the well documented, honest and contemporaneously made record is always the defendant's best friend.

Risk managers are realists. Inadequate and superficial records go hand in hand with frivolous defenses. Healthcare providers who have taken the time and effort to document a thoughtful and focused approach have usually delivered the quality care their patient was entitled to. Judges usually do not decide liability cases, but they do notice when the record is inadequate. Jurors who usually do decide liability cases intuitively connect to the evidentiary importance of the record that is or is not adequate.

A recent trial,[1] involved a young woman who had a second trimester fetal demise because of blood clots forming in the placenta. She was advised that she may have a "clotting problem" which may require follow-up with a hematologist. When consulting her primary care physician she advised the physician's assistant (PA) of this history which was documented in the record.

The PA then documented a plan to refer the patient to a hematologist to rule out a clotting disorder if blood clotting tests (PT and PTT) ordered by the PA would be abnormal. Was this plan to condition the hematology referral on abnormal test results discussed with and approved by the supervising attending physician? The record is silent in this regard. At trial, the physician maintained he was aware of and approved of the plan.

Several days later the PT and PTT along with other lab test data were reported back to the office. The supervising attending physician documented that he reviewed lab data including the PT/PTT which was within normal limits. Did the attending physician mentally connect normal lab data (including PT/PTT) with the plan not to make a hematology referral? The record is unclear. Was the attending physician being superficial and simply looking at lab data without connecting the results to focus on existing issues? The record is unclear. The physician maintained he was not superficial and was aware no referral was being made.

The PA advised the patient the tests results were normal and referral was not made. The patient assumed that she did not have a clotting problem requiring referral to a hematologist. Several months later the patient experienced a massive stroke caused by an existing active underlying clotting disorder which was identifiable with a proper hematologic work up. Appropriate anticoagulant treatment could and likely would have prevented the stroke.

Even though the defendant physician didn't know what the hematology work up should include nor did he know if an abnormal PT and PTT were prerequisites for a persistent active underlying clotting disorder, he maintained he knew and approved of the PA's plan not to make a referral.

At trial, defense counsel affirmatively argued to the jury that the record was well documented containing a rational and appropriate plan of management for the patient. In my summation reply I maintained that had the responsible attending physician focused on the issue and documented a note reflecting the thought process he claims occurred that the note would by necessity have read as follows:

> **"Even though my PA and I are not qualified to pre-condition a hematology referral on the presence or absence of abnormal PT/PTT tests I am nevertheless intentionally misleading my patient."**

My argument was that had there been documentation of a note that actually reflected a rational thought process for the decision concerning referral that documentation would have compelled the attending physician to think the patient's medical issue through in a logical manner. Therefore, the doctor wouldn't have written an illogical and unethical note.

The defense seemed preoccupied with the idea that we did "something" (ordered tests) and the test results were reviewed by the supervising physician. Accepting the idea that the physician intended no harm and must have understood his own limitations, the jurors accepted my suggestion that the gaps in documentation supported a conclusion that the physician was superficial in his oversight of the patient.

What is my point? In order to properly document the physician must think through the patient's issues. Proper documentation helps physicians do the right thing for their patient and avoid errors. Additionally, when an obviously very intelligent physician takes a position that is illogical, that will insult the intelligence of others (including jurors).

SHOULD THE MEDICAL RECORD ADMIT "FAULT"?

The following is contained in the Risk Management Handbook:

Verbiage

> **"Plaintiffs' attorneys look for gaps and inappropriate language to discredit or cast doubt on the credibility of medical records. Verbiage such as "unintentionally", "inadvertently" and "unexpectedly" is not appropriate, because it reflects a judgment that something untoward happened. Words such as "appeared," "apparently," and "seems to be" are not specific, and can be used by plaintiff's attorneys to cast doubt. Additionally, many words can have different meanings, and misuse might leave the author open to criticism. If it is necessary to use these words, then supplemental information is needed to provide clarity.**

It is also important not to, inadvertently or intentionally, imply that a fellow provider was negligent. Here are some ways to avoid raising a "red flag" for being drawn into a lawsuit with another provider:

- **Do not place blame for an unsatisfactory outcome.**
- **Empathize, don't apologize.**
- **Do not comment before having all the facts.**
- **Don't write in the medical record that someone was negligent.**
- **Do not prematurely document a corrective action plan.**
- **Discuss differences of opinion in a private environment away from patients.** [vii]

The same text notes that "documentation of patient care and events in the medical record is mandated by state and federal laws, accrediting organizations, professional organizations, and clinical standards of practice." The facts of an "incident" and how it resolved should be documented but it is suggested not to refer to the event as a "medical error. [viii]

CONCLUSION

Professionalism requires all healthcare providers to acknowledge that in healthcare, medical errors that injure patients sometimes occur. Reporting and analyzing medical mistakes *through quality assurance/performance improvement, risk management and patient safety programs* provide the basis for appropriate prevention and improvement strategies and *the judicial system offers avenues* for appropriate compensation for injured patients.[ix] Intelligent physicians and other healthcare providers know that appropriate documentation is best for their patients and incidentally (and importantly) best for them as well. If an error has occurred and the record is poorly documented, it is likely that the societal interest of promoting safety and compensating aggrieved individuals will be redressed through our legal system.

Endnotes

i. AHRMNY - The Risk Management Quarterly, Fall 2010, A Difficult and Challenging Role for Healthcare Risk Managers: Motivating Safe Care. Paul A. Gluck, M.D. and Steven E. Pegalis, J.D., pp. 9-11.

ii. Jossey-Bass - Risk Management Handbook, For Health Care Organizations - 5th Ed. - 2006; Chapter 10 - Documentation and the Medical Record by Sandra K. Johnson, Leilani Kicklicuter and Pamela J. Para, p. 269.

iii. Ibid - p. 270.

iv. New York State Judicial Institute: "29010 Medicine For Judges."

v. Ibid - Footnote #2, pp. 273-274.

vi. Trajkovic v. Bollhofer, Supreme Court Suffolk County. Jury verdict for plaintiff on June 1, 2010. Case now settled.

vii. Ibid – Footnote #2, p. 280.

viii. Ibid - p. 283.

ix. Medical Professionalism in the New Millennium: A Physician Charter. Ann. Intern. Med. 2002; 136: 243-246.

Mr. Pegalis is a plaintiff's medical malpractice trial attorney for over 40 years. He has a J.D. degree from New York Law School where he is currently a member of the Board of Trustees and is an adjunct professor teaching Medical Malpractice. He has written and lectured on the subject of Patient Safety.

EVENING CONFERENCE SUMMARY

Health Care Reform: A View from The Bronx
March 10, 2011 – The Harmonie Club

Once again this educational event was a big success. The evening at the Harmonie Club began with cocktails and networking, followed by a delicious dinner. The speaker was Steven M. Safyer, M.D., President and Chief Executive Officer of Montefiore Medical Center. Dr. Safyer reminded us that the idea of healthcare reform is not a new one and took us through a historic timeline of presidents who saw and see health care as a right. The message in the past as in the present is that public health is emerging. Dr. Safyer then transitioned to the foundation of the Healthcare Reform today and identified the health care facilities utilized by the legislation as the model for the reform. We were reminded of the deep divides which stand in the way of meaningful reform along with the opportunities to change the current model of care and payment with the economic challenges currently facing the nation.

Dr. Safyer discussed his view of Healthcare Reform based on the demographics of the Bronx County. The challenges identified included matters of the professional liability arena to the financial and health challenges of the population served by Montefiore Medical Center. Specifically, Dr. Safyer discussed the obesity 'epidemic' or challenge, of the nation as a whole, and how it translates to the population of the Bronx. Evidence of this epidemic translates to co morbid conditions such as diabetes which has significant impact on the adult population of the Bronx but has managed to penetrate to the pediatric population.

Dr. Safyer shared the Montefiore model for Care Management Organization (CMO) and vision of a Bronx Accountable Care Organization (ACO.) Dr. Safyer noted that Montefiore Medical Center 'today' encompasses the characteristics of those healthcare facilities utilized by the legislative body to define Healthcare Reform. Montefiore 'today' is an academic medical center; functions as an integrated delivery system; and demonstrates commitment to the community it serves. As well, the mission and vision of Montefiore Medical Center includes quality care and patient safety, disease management, and partnerships. Overall the presentation was well received.

Certified Professional in Healthcare Risk Management (CPHRM) Examination Preparation Course

FRIDAY, AUGUST 12, 2011 9:00AM – 6:00 PM

In coordination with ASHRM, The Association for Healthcare Risk Management of New York, Inc. is offering a CPHRM Examination Preparation Course. The Certified Professional in Healthcare Risk Management (CPHRM™) is a professional designation based on a solid assessment of a broad range of risk management skills. This course is designed as a one-day educational program to help candidates prepare to take the CPHRM examination. The cost for all attendees is $35.00 which includes training course, handouts, breakfast and lunch)

Location: Beth Israel Medical Center
Phillips Ambulatory Care Center
2nd Floor Auditorium
10 Union Square East-NY NY 10003

Agenda:

9:00	Registration & Breakfast
9:15	Program
12:30	Lunch (provided)
6:00	Adjourn

Faculty Roster: Joyce Benton, RN, MSA, ARM, DFASHRM, CPHRM
Monica Berry, BSN, JD, DFASHRM, CPHRM

ABOUT THE CPHRM EXAM

Who is the certifying body?

The CPHRM certification is awarded by the American Hospital Association's Certification Center. The certification is for three years. Re-certification is based on re-passing the national examination or completing 45 clock hours of approved continuing education credits in Healthcare Risk Management Education.

How do I take the exam?

The CPHRM examination is administered by Applied Measurement Professionals (AMP) at testing centers throughout the country. Copies of the CPHRM Candidate Handbook and Application can be obtained online at www.aha.org/aha/Certification-Center/CPHRM or by phone from AMP at (913) 541-0400.

How much does the examination cost?

The cost for the examination for ASHRM members is $275. The cost for non-members is $425.
There is a $100 fee to reschedule the exam.

Are there any references or study guides?

Participants in this program may want to use the Risk Management Handbook for Healthcare Organizations, 5th Edition, and the CPHRM Exam Preparation Guide as study aids. They are available online via the ASHRM Store at www.ashrmstore.org or (800) 242-2626 weekdays.

REGISTRATION:

COMPLETE FORM AND MAIL WITH PAYMENT TO: AHRMNY, PO BOX 4200, GRAND CENTRAL STATION, NY NY 10163

Name: _____

Title: _____

Organization: _____

Address: _____

_____

Phone: _____ Email: _____

PLEASE CONTACT KISHA SAPPINGTON WITH QUESTIONS ABOUT THE CPHRM EXAM
TEL: 973-641-5311 AHRM@OPTIMUM.NET
FAX: 347-402-2953

Risky Business

"When Common Sense is Uncommon"

By: Pamela Monastero, MBA

Dear Risk Manager:

This column, which will appear regularly in the AHRMNY Newsletter, is designed to assist 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@nychhc.org or mail to AHRMNY utilizing the RISKY BUSINESS form which can be found on our website at AHRMNY.org. The form permits confidentiality.

COMMON SENSE TIPS FOR STAFF:

This quarter's column focuses on preventive maintenance issues that may impact patient care and present risk management challenges and financial exposures.

As risk managers, we focus not only on the clinical environment, but we devote time to analyzing exposures in the physical environment of our respective facilities. We put faith in the processes that we have in place which are designed to review the physical environment for Joint Commission on-site surveys and the occasional (hopefully!) surveys from NYSDOH or CMS on environmental issues. Physical environment issues tend to be low hanging fruit for regulatory bodies.

We have committees where the "responsible" parties report on their activities and preventive maintenance, e.g. biomedical engineering, facilities management, housekeeping, infection control, construction and interim life safety, etc. Risk management involvement in these areas varies by facility but the liability exposures remain the same. Given the current fiscal crisis facing most health care facilities, preventive maintenance programs may not always be a priority due to staffing and financial reasons which increases risk exposure and presents inherent patient safety issues.

Tips & Tools:

1. Get out of the office and walk around your facility; conduct your own "environmental rounds." Risk managers see the world differently and can offer proactive risk reduction recommendations that others may miss. Example: (a) Do the patient areas look clean and well maintained, e.g. patient or visitor chairs that are old or dirty...how many incident reports have you seen where the chair breaks when someone sits on it in a patient room or waiting area? (b) Is broken equipment and furniture stored in closets in patient care areas? (c) Taken as a whole, does the facility look well maintained or poorly maintained (are windows and air conditioner/heating vents clean, is upholstery clean? From an infection control perspective, if there are curtains/drapes on windows and between patient beds, how often are they laundered?, etc.).

2. Meet with your operating room and biomed staff periodically. Is equipment outdated? Are servicing parts no longer available? When certain equipment is upgraded, are components upgraded as well? Example: (a) One hospital had different operating room tables (purchased at different points in time) and it was discovered that arm boards were falling off of the tables during surgery because they were inadequate fits for the tables. (b) One hospital had warming blankets in the recovery room that were so old that replacement parts were no longer available (temperature reading was inaccurate and patient was burned).

3. Meet with your Engineering/Facilities Management director to ascertain what constitutes the facilitiy's preventive maintenance. You may be surprised at what you discover—in some facilities, "preventive" maintenance translates into "we fix it when it breaks." If long term plans are in place to replace existing equipment or facility issues, are there any interim life safety issues and how are they being addressed (e.g. is equipment being rented, can interim cost-effective fixes be implemented until the longer term projects are accomplished to ensure patient comfort and safety?). Example: in one hospital, stretcher malfunctions resulted in falls; the issue identified was that the screws used to hold up side rails were installed many years prior and they were stripped down.

4. Monitors. We are accustomed to clinical monitors but what "monitors" are in place in non-clinical areas such as housekeeping and engineering? How do they prioritize their projects? Do they quantify data and develop action plans based on their data (e.g. do they maintain logs or electronic systems to monitor work, requests, problems, etc.?). Example: in one facility, the number of falls increased when the floor wax product was changed.

Tools, Resources and Literature:

"The Hospital Built Environment" Chapter 6. What is the Research Base for the Hospital Built Enviornment?
www.ahrq.gov/qual/hospbuilt/hospenv2.htm

American Society for Healthcare Engineering, ASHE.org

PUNITIVE DAMAGES AWARDS IN CLAIMS AGAINST NURSING HOMES

By: Joshua R. Cohen, Esq.

"My view you know, is that the ultimate destination of all nursing is the nursing of the sick in their own homes … But no use to talk about the year 2000." **Florence Nightingale, June 1867**

The frequency of punitive damage awards in nursing home negligence claims has risen sharply in the past few years. In the last year, there have been multi-million dollar awards for punitive damages in actions against nursing facilities in several states including $100 million in Florida,[1] $50 million in New Mexico,[2] $28 million in California,[3] and $3.5 million in Pennsylvania.[4] In December, 2009, a Brooklyn jury rendered the first punitive damages award against a New York nursing home in the amount of $15 million.[5] This award was in addition to compensatory damages, also in the millions. It is expected that this precedent of seeking and obtaining punitive damages on top of compensatory payments, will continue to expand as more plaintiffs' attorneys employ a new model of litigation against nursing homes, incorporating allegations of corporate greed to sustain and inflate claims for punitive damages.

This article will discuss plaintiffs' attorneys' use of punitive damages as a financial weapon of mass destruction against nursing homes and long-term care facilities, seeking to force unfair settlements or recover unjust verdicts. It will explore new strategies to avoid or deflate such claims and will illustrate techniques to utilize when defending these institutions before a jury.

Background

In the 1800's, nursing care was part of domestic life and provided in the home. Care of the elderly was mostly given by the family. Those without family or wealth were often relegated to the Almshouse for the poor. With society becoming more urban, and the birth of the nuclear family, more and more of the sick and elderly were consigned to the already overburdened poorhouses. With the passage of the Social Security Act of 1935, more funding became available to the elderly, thus starting the growth of the nursing home industry. Thereafter, the passage of Medicare and Medicaid in 1965 brought a significant increase in funding to help care for the elderly and poor. Between 1960 and 1976, the number of nursing homes grew by 140 percent, and the number of nursing beds increased by 300 percent. Consequently, nursing home industry revenues rose by 2,000 percent.

By the year 2000, nursing homes had become a $100 billion industry paid for largely by Medicare and Medicaid. More nursing homes were privately owned by corporations, some controlling hundreds of homes in many states with revenues over a billion dollars. Nursing homes being operated for profit set up the scenario for plaintiffs' attorneys to argue that corporate greed resulted in poor quality of care, leading to injuries. Using a large corporation's balance sheet as a backdrop, plaintiffs' attorneys started seeking large punitive damage awards commensurate with corporate revenues.

Before the 1990's, there were relatively few lawsuits against nursing homes. Most residents of nursing homes are elderly with no income, and have significant pre-existing medical conditions. Claims for bedsores, fractured hips and even wrongful death were considered of limited value by most plaintiffs' attorneys and therefore, very few cases were brought.

Originating in Florida, and then spreading to other states, plaintiffs' attorneys formulated a new model for recovering large awards against nursing homes by focusing on their administration as well as care giving. Plaintiffs' attorneys would look at corporate balance sheets, profit statements and staffing budgets in addition to the medical chart. Instead of painting the nursing home as negligent by solely attacking the care to the individual patient, plaintiffs' attorneys zeroed in on the corporation's fiscal decisions, claiming they compromised patient care. They argued vociferously that the large corporations controlling individual homes put profits before patients. Plaintiffs' attorneys contended that by cutting one nurse's aide per shift, per floor, per home, for over a hundred centers, it netted the corporation millions of dollars in profit, all to the detriment of the patients.

Juries became inflamed and began awarding punitive damages. Concurrently, the compensatory awards rose dramatically, indicating a punitive element as well. The sick and elderly confined to nursing homes, traditionally ignored by most plaintiffs' attorneys in the past, started attracting more litigation interest because of the potential for multi-million dollar recoveries. Plaintiffs' attorneys began advertising targeted to those potential clients with nursing home claims. By 1998, one out of four Medicaid dollars spent on nursing homes in Florida went to tort litigation. In 2003, even the Florida branch of the AARP, which fights for the elderly, supported caps in nursing homes claims.

Present Day

New York's first punitive damage award in a nursing home case was in December, 2009. In Danzy v. Brooklyn Queens Nursing Home, plaintiff alleged that the decedent sustained more than 20 bedsores and became severely dehydrated during a 10 month stay at the nursing home, losing almost 100 pounds. Plaintiff's counsel claimed that his client was restrained to prevent wandering, but he was left unattended for long periods of time. Plaintiff called a document examiner who testified that about 100 entries in the chart with regard to skin checks had been altered. A Kings County jury awarded $3.5 million for pain and suffering and $15 million in punitive damages.

This Danzy case illustrates the triumvirate of plaintiffs' punitive damages claims against nursing homes; a significant injury and obvious change in the habitus of the plaintiff; understaffing allegedly as the result of cost cuts to increase profits; and alteration of the medical chart showing fraud or deceit.

> ***"It is as expedient that a wicked man be punished as that a sick man be cured by a physician; for all chastisement is a kind of medicine."*** **Plato**

In New York, to recover punitive damages in a tort action a plaintiff must show conduct that amounts to recklessness, gross negligence and callous indifference to a patient's rights.[6] However, Public Health Law §2801-d gives patients of residential health care facilities a private cause of action for deprivation of a right or benefit. The statute expressly provides for recovery of punitive damages. It states:

> In addition, where the deprivation of any such right or benefit is found to have been willful or in reckless disregard of the lawful rights of the patient, punitive damages may be assessed.[7]

Plaintiffs in claims against nursing homes can assert both traditional tort causes of action and a claim under Public Health Law §2801-d.[8] One trial court decision has already stated that the standard for proof for punitive damages under Public Health Law §2801-d(2) appears to be a "less stringent standard than that under the law governing medical malpractice."[9]

As residential care facilities are highly regulated, the "lawful rights" of patients in these facilities are vast. For example, New York regulations require a nursing home to make "every reasonable effort" to prevent patients from developing bedsores. The statute states in pertinent part, as follows:

> (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility shall ensure that:
> (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable despite every reasonable effort to prevent them; and
> (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.[10]

Thus, bedsore cases are a prime target of plaintiffs' attorneys seeking to recover punitive damages. Similar provisions apply to accidents, nutrition and hydration.

The Defense

The best defense is controlled by the nursing homes themselves. Obviously, preventing an injury will avoid litigation, however, not all injuries are preventable. Notably, Christopher Reeve who presumably received the best nursing care, died from an infection caused by a bedsore. However, nursing homes can control the documentation and evidence that will be used to prosecute or defend them in litigation. By the time an action is commenced, all of the facts and evidence that a jury will hear has already been created. It is well known that better documentation reflects positively on the care at issue. Similarly, poor documentation conveys substandard care and negatively impacts the defense. Therefore, the best way to avoid litigation or defend a nursing home if a lawsuit is commenced starts on the day of the patient's admission.

Likewise, nursing homes control the maintenance of the documentation and evidence. As previously noted, alteration or spoliation of evidence will not only make an action more difficult to defend, but often results in dramatically higher compensatory awards. Further, spoliation of evidence may cause the jury to conclude there was reckless or willful conduct, resulting in punitive damages. All staff must be trained on the importance of maintaining the integrity of the chart, and to follow proper procedures to avoid the loss or destruction of documents.

With the emergence of electronic discovery (e-discovery) in state court actions, nursing homes and their parent corporations will be subjected to litigation holds that also encompass electronic records and data. Failure to comply with litigation holds often results in severe sanctions, including the striking of an answer. If the case does proceed to trial, a jury may draw the most negative inference from the loss or destruction of evidence, likely resulting in not only an inflated award and significant punitive damages.

Once a facility recognizes that there may be litigation over a severe incident or complication it should take steps secure the appropriate documentation and evidence. If the incident involves a specific piece of equipment, such as a wheelchair, walker or bedside rails, the object should be identified and secured if practical. If the equipment is essential to the continued operation of the facility, other methods of preservation such as photography or independent examination of the equipment should be considered.

After a lawsuit is commenced, the nursing home must work closely with defense counsel in assessing and defending the claims asserted. Early identification of the patient care issues, documentation deficiencies and staff involved should be conducted. Any potential violations of regulations or policies must be identified and addressed as they will form the basis of a claim for punitive damages.

In addition to patient care issues, corporate decision making will likely be targeted, particularly where budgeting and staffing issues are involved. Any cost cutting measures, such as a reduction in staffing, will be used by plaintiffs' attorneys to argue corporate greed and the need to punish the facility. The documentation supporting these decisions, such as memos and e-mails, can show a deliberative process wherein patient care was a priority and thoroughly addressed, which will help defend against claims or avoid punitive damages. However, if the documentation appears to put profits over patients, obviously an inflamed verdict with punitive damages is more likely.

Conclusion

Punitive damage awards in claims against nursing homes have risen sharply over the past few years and are likely to continue. Plaintiffs' attorneys have focused on corporate balance sheets and facility administration to portray nursing homes as unsympathetic corporate conglomerates seeking to put profit over patient care. Given federal and state cutbacks in funding, nursing homes must cut costs to maintain financial viability. This concern with remaining profitable sometimes results in less than optimal treatment for nursing home patients, most of whom are sick and elderly. Plaintiffs' attorneys are taking advantage of this, and are framing this as corporate greed and indifference to a fragile population resulting in sympathy for the patient and anger towards the large corporation.

Through better documentation in not only the patient's chart, but the records pertaining to corporate decision making and administration, nursing homes can defend the care rendered and can diffuse claims of corporate greed. Improved strategies in creating and preserving the evidence that will be used to prosecute and defend nursing home cases will avoid claims of altered records and spoliation, which are often used to inflame juries. All claims must be aggressively investigated and those lacking merit must be vigorously and thoughtfully defended to negate the impact of adverse facts. This strategy will help prevent a jury finding of willful or reckless conduct, thus deflating the predicate for an award for punitive damages.

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[1] Jackson v. Trans Healthcare, Polk County, Florida, July, 2010.
[2] Selk v. ResCare, Inc., New Mexico, December, 2009. Reduced by trial court to $10.8 million.
[3] Tanner v. Colonial Health care, Sacramento California, May, 2010.
[4] Blango v. Hillcrest Convalescent Home, Philadelphia, Pennsylvania, March, 2010.
[5] Danzy v. Brooklyn Queens Nursing Home, Brooklyn, New York, December, 2009.
[6] Randi A.J. v. Long Island Surgi-Center, 46 A.D.3d 74 (2d Dep't. 2007).
[7] PHL §2801-d(2).
[8] Kash v. Jewish Home and Infirmary of Rochester, 61 A.D.3d (4th Dept. 2009).
[9] Osborne ex rel. Osborne v. Rivington House – The Nicholas A. Rango Health Care Facility, 19 Misc.3d 1132(A) (N.Y. Sup. 2008).
[10] YCRR 415.12. The Code of Federal Regulations contains a similar provision. 42 CFR 483.25.

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EMERGING HEALTHCARE TECHNOLOGY

By Dylan C. Braverman, Esq.

Emerging medical technology saves lives. Period. However, every break-out medical advancement must be equally met with forward thinking risk management to ensure that the advancement is being properly and most effectively utilized to assist in patient care.

While radiological imaging has been utilized for a long time, the practice is becoming more precise and efficient due to new technology. At the same time, the effects of radiation are becoming a 'hot topic' – not least of all due to extensive recent media coverage.

My column this issue focuses on helping risk managers guard against heretofore rare claims of radiation over-exposure. We also invite you to read the wonderful companion piece written by Christopher E. DiGiacinto, Esq. and Leslie A. Wheelin, Esq., partners at Kaufman Borgeest and Ryan, LLP, entitled, "Strategies for Defending Malpractice Claims Against Radiologists in an Era of A Heightened Duty to Report." The article will similarly help risk managers implement guidelines and protocols to protect against unnecessary claims against their facility's Radiological Department.

How you can help
Should you have any suggestions or questions regarding this column; or topics of interest for future emerging technology columns please e-mail any suggestions to dbraverman@blawpc.com and/or contact AHRMNY Publication Committee "Editors" at ahrm@optimum.net

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THE MEDIA SEEDS THE POSSIBILITY OF "EXOTIC" RADIATION CLAIMS AGAINST MEDICAL PROVIDERS

On April 25, 2011 the New York Times published an article entitled Thyroid *Fears Aside, That X-ray's Worth It*,[1] written by Jane E. Brody. Ms. Brody, the Personal Health columnist for The New York Times who joined the paper in 1965 after completing degrees in biochemistry and science writing, was surprised at the stream of panicked emails she received in response to an episode of Dr. Mehmet Oz's popular television show- *"The Dr. Oz Show."* Dr. Oz cited thyroid cancer as, "the fastest-growing cancer in women," and cited the harmful effects of radiation from sources like dental X-rays and mammograms.

This is not the first time that the New York Times sounded the alarm regarding the deleterious effects of X-ray radiation. There has been a concerted effort to report on this subject, including another recent article published on April 12, 2011 entitled, "Bad X-rays Found Again at a Brooklyn Hospital." The article focused on the recent statement by Claudia Hutton, a spokeswoman for the New York State Department of Health, that regulators suspected premature babies were being subjected to over-radiation at a Brooklyn hospital. This was even after that same hospital was cited in 2007 for providing whole body X-rays when only chest examinations were ordered.

Is This the Next Litigation Gold Rush?

Ms. Brody should not have been surprised. The plaintiff's bar has done everything it can to foster this fear. Even cursory research on the Internet shows plaintiff's firms stirring the pot and looking for potential clients to bring, "radiation poisoning" lawsuits. The media, when not focusing on the potential for radiation Armageddon stemming from the tragic events in Japan, is helping to feed the panic. Dr. Oz informed his legion of viewers that patients who undergo more than five X-rays a year have a whopping "fourfold greater risk of developing thyroid cancer." As a result, he recommended the use of a lead shield when getting a dental X-ray or mammogram. This was amplified by a guest gynecological cancer specialist on Dr. Oz's show, who informed the audience that she would refuse routine dental X-rays.

Even voices of reason can be contrived to spread alarm. Dr. Leonard Wartofsky, a thyroid cancer specialist at Washington Hospital Center in the District of Columbia, stated in an interview, "The doses associated with mammography have been well studied *and well calibrated*. *As long as it is done with modern equipment*, women should not be concerned. That

degree of radiation is not consequential." I add emphasis to that statement for a reason. In addition to attacking the frequency of the radiological studies, there is the potential for the intensity of the study to be criticized. Even more, allegedly aggrieved claimants can attack the medical machinery used for the studies.

Armed with this news, opportunistic plaintiff attorneys will likely have no trouble matching up with patients who have undergone radiographic testing and feel that they are damaged as a result. While medical malpractice law in New York requires a plaintiff to prove a causal link between a departure from the good and accepted practice of medicine and an injury, there sadly will likely be no shortage of medical experts willing to testify that an array of cancers can be and are caused by excessive radiation exposure due to improper frequency or intensity. Indeed, the very same New York Times article that recommended patients undergo X-rays despite the purported risks conceded that, in theory, the cumulative effects of low-dosage radiation could add up to a cancer risk. Under New York law, this may be enough to get the issue to the jury- especially in plaintiff friendly venues and the current appellate trends.

It goes without saying that this scenario can lead to frivolous claims and unwarranted litigation exposure. For example, it is believed that while there has been a confirmed rise in diagnosed thyroid cancer, this is due to advancements in diagnostic technology and not as a result of radiation overexposure.[1] Swedish studies also confirm that when precise medical records are kept, there is no connection between radiological studies and thyroid cancer. Finally, there is the possibility the radiation was introduced to the patient sometime in the past, and that other risk factors contributed to the cause of cancer. This is, of course, a small consolation because in many medical malpractice lawsuits the defense has science on its side, but for plaintiff the lure of pure emotion. So, as long as the plaintiffs' bar can get these claims to the jury, there is a potential for a verdict despite strong scientific evidence that there was no malpractice.

Even more, as repeatedly reported on by the New York Times and adopted by plaintiffs nationwide; radiologists, technologists and administrators have been caught being lax in regards to preventing unnecessary radiation exposure. In those instances, claimants will have no problem convincing a jury of a medical departure, and then need only prey on pre-conceived notions of the horrors of radiation exposure in order to get a jury award.

Technologist Liability

Plaintiff's firms, including Beasley, Allen, Crow Methvin, Portis & Miles, P.C., have dedicated pages on their websites, describing "disturbing reports" that X-ray technicians do not know how to properly use the machinery. This results in allegedly hazardous doses of radiation. The damage to the patient is left to the reader's imagination (where it is likely worse than the actual real-life result).

Yet, technologists in New York are subject to light regulation. In fact, even the American Society of Radiologic Technologists has lobbied Congress to pass a bill to establish minimum educational and certification requirements nationwide for occupations in medical imaging and radiation therapy. In New York state, technologists must be licensed and prove they have passed a professional examination. There were, however, no continuing education requirements and regulators usually let hospitals choose when to discipline their technologists. This has turned out to be a rare event, as New York health officials have not disciplined any of the 20,000 or so licensed technologists for work-related problems.

In contrast to the disjointed nature of this profession nationally, standards of care regarding radiation exposure during imaging and therapy is widely available. Facilities must ensure that their radiology departments are acting according to the most up-to-date standard of care regarding radiation exposure. Any failure to do so can result in unwanted litigation. It is especially important that technologists are educated and monitored. This is vital, as the technologist has the least amount of education and training, yet is the professional who directly applies the radiation to the patient. Moreover, Quality Assurance reviews and discipline should be well-documented.

Avoiding Being a Target

With the probability increasing that a radiation-related claim can be filed against hospitals and physicians, the goal is to implement a firewall to defeat these claims. Of course, proper protocols regarding radiation levels and charting must be implemented. The best defense is usually a good offense, and these cases appear to perpetuate that rule. Documented compliance with industry radiation guidelines will protect against claims of excessive radioactive intensity or frequency, as will documented evidence that all radiographic equipment is up to date, tested and maintained.

The 900-pound gorilla in the room here, as in most instances where potential litigation is involved, is the need to practice precise and accurate charting. For example, one radiologist at the Brooklyn hospital cited for over-radiation of premature infants claimed that technologists were sometimes instructed at bedside by physicians to include additional areas of interest in the chest X-ray. Had this been charted properly, then potential claims of over-exposure would be difficult to assert. However, since it was not charted, the assumption favors the claim that rogue technologists over-radiated premature infants. That is not a good fact pattern if you are defending a claim before a New York jury.

Additionally, the radiographic intensity must be well documented in patient charts so there can be no question that the radiation levels met standards. It is recommended that proper protective equipment, such as baby shields or lead thyroid collars be used. The practice of the use of this equipment should also be well-documented in patient charts.

The risks, alternatives and benefits of all radiological examination should be clear, and patients should be required to affirm that they have read and understood what he or she agreed to. For example, patients can be advised that under many circumstances an MRI or an ultrasound examination is an option. In litigation, patients often explain that they did not fully understand the consent form, or that they were compromised due to a medical

emergency. However, in many instances of radiographic study, there is no current medical emergency, and the consent should be written clearly so there is no question that the patient understood what he or she agreed to.

While technology upgrades are expensive, many facilities are moving towards digital equipment that delivers less radiation. On the other hand, a new scanning device favored by many dentists called a cone-beam CT scanner may emit 4 to 30 times as much radiation as a conventional X-ray. While dentists prefer the 3-D images, the risk of potential claims should be considered. Indeed, this technology was subject to a scathing article published by the New York Times on November 22, 2010 that even went so far as to suggest that dentists were seduced by slick promotions by the manufacturer into using this possibly dangerous equipment. In essence, the article suggested that this equipment is used to save dentists time and to maximize profits, in spite of the potential for cancer. The bottom line is that risk managers now have to consider the radiation dosage when looking to upgrade or purchase new equipment.

Even if the best equipment is being used, employees must be properly trained to ensure that all radiological examinations are carried out to reduce radiation exposure to the least amount necessary. As set forth above, the radiology technologist must receive proper training and monitoring. This technologist must ensure the least patients receive the least amount of radiation exposure necessary, and should be subjected to continuing education on the latest standard of care. The completion of this continuing education should be well-documented.

Finally, employees should be taught that Quality Assurance is a key to best practices. Attending physicians, residents, nursing staff, radiologists and technologists should be vigilant in monitoring that all standards of care are met. They should be encouraged to report any deviation, so that a culture of deviated care is not institutionalized.

Conclusion

With proper precautions, risk managers can guard against a tidal wave of claims arising from alleged radiation overexposure. As with any advanced technology, this is an area that the plaintiffs bar will attempt to prey upon. That should not stop medical providers from optimizing care to their patients. Indeed, medical providers must proactively make certain that the best practices are employed and that advanced standards are met to guard against unwarranted radiation exposure. This must be well-charted and documented. Taking these precautions may be the best defense against a possible onslaught of exotic radiation over-exposure claims.

[1]See *Fears Aside, That X-ray's Worth It*, Jane E. Brody, *New York Times*, April 25, 2011 *citing The Journal of American Medical Association.*

STRATEGIES FOR DEFENDING MALPRACTICE CLAIMS AGAINST RADIOLOGISTS IN AN ERA OF HEIGHTENED DUTY TO REPORT

By: Christopher E. DiGiacinto, Esq., and Leslie A. Wheelin, Esq.

I. Introduction

While New York Courts have not spoken directly on the issue of a radiologist's duty to report findings, a survey of cases from other jurisdictions including those referencing the relevant Guideline from the American College of Radiology ("ACR") provide valuable insight for proactive claim avoidance strategy. More specifically, recent decisions from several jurisdictions suggest that in certain circumstances radiologists are more likely to be bound by a duty to report directly to patients rather than just reporting to a referring physician or third party. The ACR Practice Guideline for Communication of Diagnostic Imaging Findings is purposely vague as to when direct reporting to patients is required. Its recommendations, however, underscore both the ethical responsibility of radiologists to report unexpected findings directly to patients along with wide deference to their judgment as to the circumstances where such reporting is required. It appears that the best defense to avoid malpractice claims altogether would be to encourage and facilitate direct reporting of results to patients whenever possible while recognizing that certain clinical situations may make this practice very difficult to follow in every circumstance.

II. Discussion

a. In circumstances involving outpatient referrals, radiologists have been held to a duty to inform patients directly of significant findings

In Williams v. Le, 662 S.E.2d 73, 77 (Va. 2008) the Supreme Court of Virginia reversed a defense verdict for a radiologist and remanded the case for a new trial holding that a particular jury instruction on superseding and intervening causes was not appropriate under the circumstances presented by the facts in the case which involved the sufficiency of a radiologist's communication to a primary care provider.

In Williams, the deceased plaintiff, was examined by her primary care physician, Dr. Paul McClain, for pain in her right calf and leg and Dr. McClain ordered a Doppler ultrasound to be performed on her calf. The sonogram which was performed by a technician at Tysons Corner Diagnostic Imaging Center, showed a deep vein thrombosis in her right lower leg.[1] The technician, Megan Murphy sent the images to defendant, Dr. Le, who reviewed the sonogram and confirmed Ms. Murphy's findings.[2] Ms. Murphy told Dr. Le that she informed Williams that there was a "positive finding" and that she should see her doctor as soon as possible.[3] Dr. Le telephoned Dr. McClain to report his findings but reached an automatic telephone system. Dr. Le spoke to an operator, was put on hold, and

eventually "lost confidence" that he would get in touch with Williams' physician.[4]

He therefore prepared a "wet read" of his findings, drew a picture of Williams' leg, depicting the location of the blood clots and placed the wet read in the "wet read" box, which was sent by facsimile to the Dr. McClain.[5] The results, however, were not examined by Dr. McClain and were entered into Williams' medical records as "non-urgent." Williams died several days later from a pulmonary embolism.[6]

The Virginia Supreme Court reversed the defense verdict setting forth the law that should have been relied upon by the jury: "an intervening cause does not operate to exempt a defendant from liability if that cause is put into operation on the defendant's wrongful act or omission." Applying this standard, the Virginia Supreme Court went a step further in explaining its decision by holding: "(o)n the question of causation, the evidence proved without contradiction that the communication problems in this case were begun and put in motion by Dr. Le's failure to make direct contact with Dr. McClain, a member of his team, *or Williams* . . . on this record, it cannot be said that Dr. Le's alleged negligence was not contributing 'in the slightest degree' to the death of Williams."[7] (*emphasis added*).

The Arizona Supreme Court extended the duty to report in an even more attenuated set of facts. For example, in Stanley v. McCarver, 92 P.3d 849, 856 208 Ariz. 219 (2004), the Arizona Supreme Court affirmed the portion of the appellate court's opinion which imposed a duty on the defendant radiologist to report to a non-patient he examined for a pre-employment screening and remanded the case for further proceedings.

In Stanley, the defendant radiologist, Dr. Robert McCarver, contracted with Osborn, Nelson & Carr portable X-Ray, Inc. ("ONC") to interpret x-rays. The plaintiff's prospective employer, Mesa Christian Care ("MCC") hired ONC to conduct tuberculosis screenings of potential employees.[8] Dr. McCarver evaluated a chest x-ray of the plaintiff, a prospective Mesa employee and prepared a report which noted abnormalities in the plaintiff's x-ray. He forwarded the report to ONC, who, in turn forwarded it to MCC. While it was MCC's company policy to notify prospective employees directly of any abnormal findings, it failed to do so in this instance. Ten months later, the plaintiff was diagnosed with lung cancer.

While the apparent absence of a doctor-patient relationship and existence of MCC's contractual duty to report would make establishing a duty for the radiologist to report under these circumstances unfathomable, the Court held that the relationship between a radiologist retained for pre-employment screening purposes only still owed a legal obligation to act for the benefit of the examinee. Specifically, the Court held: "Although there was no traditional doctor-patient relationship between the parties, Dr. McCarver did agree, for consideration, to interpret Ms. Stanley's confidential medical record, her x-ray, and accurately report her results to ONC."[9]

Accordingly, the Court found Dr. McCarver liable to the plaintiff, holding that "the absence of a formal doctor-patient relationship does not necessarily insulate a doctor from liability."[10]

Chief Justice Jones' dissent explained the clear issues with the majority opinion:

> Dr. McCarver did nothing more than evaluate Ms. Stanley's pre-employment x-ray at the request of a prospective employer relative to an informed hiring decision. He did not see Ms. Stanley and was never approached by her for medical treatment. No physician-patient relationship existed, nor was there any particular relationship between the two. Nevertheless, *the majority holds the doctor undertook a duty of care toward Ms. Stanley, the breach of which could subject the doctor to liability in tort for a medical condition that was not caused by the negligence of the doctor*."[11] (emphasis added)

Justice Jones' dissenting opinion in Stanley demonstrates that recent decisions from different jurisdictions appear to hold radiologists to a higher standard than afforded by tort law. The practical question becomes how far must radiologists go in their examinations and reporting? Both cases involve different questions of duty. In Williams, the court's holding suggests that Dr. Le was required to do more than report his findings to the decedent's physician, but ensure that his findings were actually reviewed and comprehended by the primary care physician. Thus, Dr. Le was required to do his own job, and, in addition, he was required to assume the duties of the decedent's primary care physician, clearly beyond his reasonable expectations.

In an even more drastic set of circumstances in Stanley, Dr. McCarver was required to ensure that his findings were reported to an individual to whom he owed no duty. He was only contractually obligated to his own employer to report findings of abnormalities. The plaintiff's potential employer was obligated by company policy to report the abnormalities to the plaintiff. And again, Dr. McCarver reported the abnormalities to his employer, who, in turn reported the findings to the plaintiff's potential employer, the party that ultimately failed to report to the plaintiff when it was company policy to do so. According to the Court's majority decision in Stanley, Dr. McCarver was expected to go beyond his role in the chain of communication and contact MCC, and then Ms. Stanley, to ensure that MCC followed its internal policies.

b. In circumstances involving in-patient hospital referrals, radiologists are more likely to be held to a duty merely to inform attending physicians of significant findings

For example, in Jenoff v. Gleason, 215 N.J.Super. 349, 521 A.2d 1323 (1987), the Superior Court of New Jersey reversed the trial court's dismissal of claims against a defendant radiologist where the trial court improperly found plaintiff failed to provide evidence of a breach of duty or any accepted medical standards. The Superior Court disagreed with the trial court's position that the proper method of communicating a radiologist's findings was a matter requiring expert testimony.[12]

In Jenoff, plaintiff was hospitalized on September 13, 1980 for a surgical procedure on her wrist and chest x-rays were ordered because of a general Hospital policy concerning administration of anesthesia.[13] Chest x-rays

were taken on September 14 and 15, read by the defendant radiologist, Dr. Peck on the day they were taken and reports were prepared indicating a finding of a two centimeter nodule within the left lower lobe of the lung suggesting possible bronchogenic neoplasm (lung tumor).[14] Dr. Peck's first report recommended tomography for further delineation and his second report recommended appropriate follow up exams. Dr. Peck did not communicate his findings to plaintiff's treating physicians other than by preparation of the reports.[15] The reports were typed and arrived at the nurses' station on the floor where plaintiff was hospitalized on September 17, 1980, after she had been discharged. A nurse reviewing the x-ray findings on behalf of plaintiff's employer's workers compensation insurer in November 1980 became alarmed at the findings, alerted plaintiff's primary physicians, and plaintiff was ultimately informed of the presence of a lung tumor in December 1980.[16]

In its decision, the Superior Court in Jenoff concluded that communication of an unusual finding in an x-ray, so that it may be beneficially utilized, is as important as the finding itself and indirect service may provide justification for the absence of direct communication with the patient, but that does not in any way justify failure of communication with the primary care physician.[17] The Court went on to note that the exigencies of the medical situation may call for different levels of response and in certain situations direct contact with the treating physician is necessary beyond communication through administrative personnel.[18] The Court also noted that the fact that there was no expert testimony as to what standard of care applied was not necessary as "modes of communication are not so peculiarly within the expertise and knowledge of the medical profession as to necessitate expert testimony."[19] It was perhaps not insignificant that one of the defendants, Dr. Gleason, had testified in plaintiff's case that in his experience where there was an unusual or unexpected finding "it would be fairly standard procedure" for the radiologist to call him and they would review the film."[20] The Court noted that since the critical information was never provided to the treating physician at all, the trier of fact should be permitted to pass on the issue of adequacy of the radiologist's communication without the need for expert commentary.[21]

In Courteau v. Dodd, 299 Ark. 380, 773 S.W.2d 436 (1989), the Supreme Court of Arkansas affirmed the lower Court's dismissal of claims against the defendant radiologist via summary judgment where the sufficiency of plaintiff's expert affidavit was called into question. In Courteau, the injured plaintiff suffered a spinal cord injury following a diving accident and was hospitalized following surgery.[22] While a patient at the North Little Rock Memorial Hospital, the infant's breathing tube became dislodged, his breathing became hampered and he suffered a heart attack and massive brain damage. A daily requisition form for a chest x-ray noted "chest portable, recumbent and intubation".[23] Defendant Dodd, a radiologist, indicated the chest film was taken at 6:35 a.m. and he read it between 7:15 a.m. and 8:30 a.m. Dr. Dodd then dictated notes which indicated that "the endotracheal tube is not visualized and may have been removed."[24] This note was transcribed and printed at 10:37 a.m. after the infant had suffered the heart attack.

The Appellate Court in Courteau held that the plaintiff's expert was not qualified to express an opinion about how Dr. Dodd should have reacted to the x-ray given the instructions in the requisition. More specifically, the Court held that the expert's affidavit "contained nothing about his having knowledge as to how a radiologist in a community like North Little Rock should have interpreted the July 5, requisition."[25] In Corteau, the Court did not agree with plaintiff's argument that the "mode" of communication should not require expert testimony and differentiated cases like Jenoff where the discovery of a lung tumor by a radiologist is clearly an item to be communicated to a treating physician and patient, and a layperson could determine that failure to communicate in those circumstances could be characterized as negligence.[26] In Corteau the Appellate Court held instead that "the jurors here would have had the task of interpreting the term 'intubation' and determining the action, if any, it required under the community standard made applicable by the statute".[27]

c. ACR General Diagnostic Radiology Practice Guideline for Communication of Diagnostic Imaging Findings is not determinative of the standard of care

Indeed, the current preamble to the ACR Practice Guideline for Communication of Diagnostic Imaging Findings states:

> These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care.[28]

Notwithstanding the above, the Guideline for Communication of Diagnostic Imaging Studies ("Guideline") simultaneously explains the need for standardization of reporting formats and content as well as the fact that "various factors and circumstances unique to a clinical scenario may influence the methods of communication between interpreting physicians and referring clinicians."[29] The recommendations in the Guideline set forth the format for imaging reports as well as the difference between preliminary and final reports. In many ways these recommendations appear to serve as a strong reference and logical cornerstone for good practice. They also appear to stop short, however, in setting forth any bright line requirements even in circumstances where emergent or non-routine clinical situations present themselves. In such circumstances the Guideline recommends only that "the interpreting physician expedite the delivery of a diagnostic imaging report (preliminary or final) in a manner that reasonable ensures timely receipt of findings."[30]

The Guideline goes on to discuss the difference created by the circumstance involving the self-referred and third-party referred patient. Significantly, the Guideline notes on the one hand that "regardless of the source of the referral, the interpreting physician has an ethical responsibility to ensure communication of unexpected or serious findings to the patient".[31] The Guideline then goes on to defer to the physician's judgment on this point indicating "(t)herefore in certain situations the interpreting physician may feel it is appropriate to communicate the findings directly to the patient."[32]

Given the above, it should be of no surprise that no reported cases evidence successful reliance on the Guideline as being determinative of the standard of care for reporting of unexpected or abnormal results. Indeed, in one reported case Thomas v. Alford, 230 S.W.3d 853, (Tex. 2007), a radiology expert's misplaced reliance on the ACR Guideline as being determinative of the standard of care proved to be fatal to plaintiff's claim against the defendant radiologist.

In Thomas v. Alford, the Texas Court of Appeals in 2007 affirmed the lower Court's decision that dismissed claims against a radiologist based on the sufficiency of plaintiff's expert's Affidavit. In Thomas, plaintiffs claimed that the defendant radiologist, Dr. Malone failed to communicate the findings of a neoplastic nodule seen on a CT scan in March 2002 to plaintiff's family practice physician Dr. Alford.[33] Plaintiff's expert radiologist's report cited to the ACR Guideline indicating that the reporting guideline required that unexpected abnormal findings should be "directly communicated" to the referring physician.[34] According to the decision, plaintiff's radiology expert further opined in his report that "my own practice" is to telephone the referring physician and document this in the report.[35]

The Court of Appeals in Thomas found fault with the expert's report since "it is not apparent from the report whether the guideline referred to is (1) the standard of care for what any prudent radiologist would do under the same or similar circumstances; or alternatively, (2) a higher standard to which board certified radiologists should aspire.[36] The Court also found fault with the fact that the report did not state that the guideline required telephoning the referring physician to meet the standard but only that the expert viewed the guideline as imposing that requirement.[37]

d. In certain circumstances direct patient reporting is not possible

A March 2009 article in the American Journal of Roentgenology concluded that the time had come for direct reporting of all outpatient results directly to patients.[38] The article posited that radiologists owed a duty to their patients and the best and most complete manner to discharge that duty was for "direct communication of radiologic findings between the radiologist or radiology imaging facility and the patient on who a radiologic examination has been performed..."[39]

The caveat reported in the above-referenced article that "direct patient communication of radiologic results of in-patient examinations presents hurdles that do not exist with outpatients"[40] may not ultimately serve to insulate radiologists. Indeed some Courts as in the Williams and Stanley matters cited above, appear willing to apportion liability where none was previously contemplated.

Direct reporting to patients would also appear to be hampered where teleradiology services are used to provide off hour remote reviewing for in-patient imaging. Indeed, as more facilities begin to rely on teleradiology services, it is likely that there will be a greater need for more detailed verification of the reporting between the interpreting physician and the attending physician to ensure that an examinee ultimately receives information concerning a report of abnormal findings. Indeed, since the Court in the above-mentioned Stanley matter appeared willing to assign a duty to a radiologist in a very attenuated circumstance, it is easy to believe that other courts may also choose to extend this duty in previously unimagined circumstances perhaps even to radiologists who provide reviews for in-patients, or to those who provide such reviews via teleradiology services.

III. Conclusion

While the prevailing case law and ACR Guideline on this issue do not set forth a bright line standard applicable to all clinical circumstances, it appears that the best way to for radiologists to prevent against malpractice claims, at least those concerning outpatient radiologic exams, is to develop and facilitate means by which results can be reported directly to patients. For the reasons discussed above, the same cannot yet be said for reporting of in-patient radiologic exams. Developing a consistent reliable means of recording that the results were received and acknowledged by the party to whom they were sent is equally important to the prevention of such claims, especially where direct patient reporting is not possible.

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[1] Id., at 76
[2] Id.
[3] Id.
[4] Id.
[5] Id.
[6] Id.
[7] Id., at 77
[8] 92 P.3d 849, 856
[9] Id., at 853
[10] Id., at 856
[11] Id., at 858
[12] 215 N.J.Super. 349, 352
[13] Id., at 353
[14] Id.
[15] Id.
[16] Id.
[17] Id., at 357
[18] Id.
[19] Id.
[20] Id., at 355
[21] Id., at 357
[22] 299 Ark. 380, 381
[23] Id., at 382
[24] Id.
[25] Id., at 386
[26] Id., at 387
[27] Id.
[28] American College of Radiology Diagnostic Radiology Practice Guideline for Communication of Diagnostic Imaging Studies, Preamble, Revised 2010 (Res. 11).
[29] Id., at Sec. I.
[30] Id., at Sec. II, C, 2.
[31] Id., at Sec. III, B.
[32] Id.
[33] 230 S.W.3d 853,855
[34] Id., at 859
[35] Id.
[36] Id., at 860
[37] Id.
[38] Berlin, L., Communicating Results of All Outpatient Radiologic Examinations Directly to Patients: The Time Has Come *AJR 2009*; 192:571-573
[39] Id., at 573
[40] Id.

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