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

The Risk Management Quarterly

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A Message from AHRMNY's President

Dear AHRMNY members,

This has been a very exciting year thus far.

The fall webinar presented by Alice Vautour of the MRM Group and Shannon Grad of Connecticut Children's Medical Center concerning Risk Management and the Patient Experience was well attended and provided valuable insight into the interrelationship between the patient experience, risk management and positive outcomes.

Congratulations to the Education Committee lead by President-Elect Mary Steffany for producing the highly successful December 11, 2015, half day event, February 25th webinar and March 10th evening networking event. The morning half day presented at our longtime partner Beth Israel proved informative and entertaining. Topics covered included Human Factors, Errors and Patient Safety, as well as Electronic Medical Records and Medical Marijuana. The topics were timely and well-treated by our guest lecturers, Dena Goffman, M.D., Matthew Keris, Esq., Elizabeth Kase, Esq., and Hindi Mermelstein, M.D. The February 25th Webinar featuring Dr. John Stamatos and Paul Walker, Esq., discussing abuse of pain medications and the handling of these critical issues from a legal and medical standpoint was timely and valuable. Most recently, the evening networking event with keynote speaker Graham Billingham, M.D., Chief Medical Officer for Medical Protective Company, discussing health reform was timely and informative. Again, congratulations to Mary Steffany and the Education Committee on an extraordinary job.

ASHRM proved to be a wonderful showcase for AHRMNY. Congratulations to AHRMNY former president Mike Midgley on his successful election at the national organization and becoming ASHRM President-Elect Midgley. He will lead an organization featuring our own Dr. Victor Klein as a board member. Additionally, we congratulate AHRMNY Board Emeritus member Jose Guzman, Jr. on attaining DFASHRM status. Additionally, many of our members presented at ASHRM in Indianapolis in October.

Our membership committee under the stewardship of Naeem Holmes and Alvin Safran have once again expanded our membership and have worked on new and innovative ways to reach new potential members. Our membership drive is continuous and rolling.

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EDITOR'S CORNER

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

Click here for the official RMQ Author Guidelines

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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CALL FOR ARTICLE SUBMISSION

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

RMQ is published four times a year with a distribution of 300 copies per issue. Please forward any ideas or submissions for publication in the ***RMQ*** to "**Editors**", via email with attachments to: ahrmny@gmail.com.

The deadline for submission and consideration for the next journal is April 30, 2016.

MEMBERS AREA UNLEASHED

Access to the ***"Members Area"*** on the AHRMNY website is a benefit provided with all membership subscriptions. This area holds many items that members frequently request. With your username and login passcode, the following items are at your fingertip whenever you need them:

Member Directory
Contains current list of AHRMNY members

Member Information Editor
This section allows members to update their information that appears in the Member Directory

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Link to renew member dues

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The database by default is designed to renew one membership per transaction. If purchasing a group membership, pay group member dues first and then complete group member application and submit for processing

Seminar/Conference Handouts
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Member Spotlight Information Sheet
Form to complete and submit for inclusion in RMQ's Member Spotlight column

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The Court of Appeals Expands the Concept of "Duty" to Outsiders

By Elliott J. Zucker and Deirdre E. Tracey

On December 16, 2015, the Court of Appeals handed down a decision in which they forthrightly admitted to changing the common understanding of the scope of a physician's "duty." The case, Davis v. South Nassau Communities Hospital, 2015 N.Y. Slip. Op. 09229, has the potential to be quite dangerous and involved the question of what kind of duty a health care provider owes to someone outside of the normal patient-physician relationship.

This is not the first time the Court had addressed this question and some background is important to see the Court's shifting attitudes. In Tenuto v. Lederle Laboratories, 90 N.Y.2d 606, 687 N.E.2d 1300, 665 N.Y.S.2d 17 (1997), the Court had been confronted with a physician who had vaccinated his patient, a child, with the polio vaccine, but then neglected to tell the infant's parents of the dangers to themselves contracting polio, and the father did then go on to contract that disease. Although they were not his patients, the Court ruled that the physician nevertheless owed them a duty. In doing so, the Court discussed a number of factors, including the fact that the doctor knew or reasonably should have known that the parents would be relying on him for this service; that there existed a "special relationship" between either the physician and the injured non-patient *or* the patient and the non-patient; and that the service performed for the patient necessarily implicated the protection of household members who were foreseeably at risk of harm because of the performance of those medical services. Yet, the Court emphasized, this did not mean that the physician had a duty to the community at large.

The Court confirmed that latter point in McNulty v. City of New York, 100 N.Y.2d 227, 782 N.E.2d 162, 762 N.Y.S.2d 12 (2003). There, the defendants' patient was a woman being treated for infectious meningitis, while the plaintiff was that woman's friend. This friend apparently was in close contact with the patient, which led her to ask the defendants if she too should have any treatment for the disease. She was told that that would not be necessary, and then went on to contract meningitis herself. This time, the Court rejected the idea that the defendants owed any duty to this non-patient. They noted that the friend did not fall into the category of a "special relationship" with either the patient or the physician, and that the plaintiff's own injuries did not even directly arise from the defendants' treatment of her friend. The Court of Appeals indicated that they needed to be extremely careful in expanding a physician's recognized duty, and showed cognizance of the dangers of possibly making healthcare providers liable to such a broad number of potential plaintiffs.

Lower courts then followed the Court of Appeals' lead, as they must, and largely rejected efforts to expand the scope of a physician's duty. In a case handled by our office, for example, Candelario v. Teperman, 15 A.D.3d 204, 789 N.Y.S.2d 133 (1st Dept. 2005), the First Department addressed claims made by a daughter who was caring for her mother, who was in turn suffering from hepatitis C. The defendant physician in that case allegedly knew that the daughter was providing this care, yet failed to instruct her on precautions she should take against infection. The Appellate Division refused to impose liability, seizing on the McNulty idea that no recognized cause of action could exist unless there was a showing that it was the treatment itself that caused the injury.

In its new Davis decision, the Court of Appeals has now re-visited a medical provider's duty to third parties. There is an old adage that bad facts make for bad law, and the facts in Davis do necessarily give rise to a great deal of sympathy for the defendants. Here, the actual patient was an individual being treated in a hospital emergency room. While there, she was administered both an intravenous opioid narcotic painkiller, as well as a benzodiazepine drug well-known to cause sedation, unsteadiness and disorientation. The instructions for the narcotic specifically stated that its use impairs the ability to perform a number of tasks, including driving. The allegations in the case (the Court got to this case on an underlying motion to dismiss, and thus considered the factual averments as true) indicate that a mere hour and a half after receiving these medications, the patient was released from the emergency room, supposedly without any instructions or warnings about what she could or should do while still under the influence of these drugs. The patient then drove herself away from the hospital, and within twenty minutes had driven her car over a double yellow line and crashed into the plaintiff's automobile.

Interestingly, the Court of Appeals had dealt with a similar fact pattern once before, in Purdy v. Public Administrator of Westchester County, 72 N.Y.2d 1, 526 N.E.2d 4, 530 N.Y.S.2d 513 (1988). In that case, the plaintiff was also injured in an automobile accident, with the offending vehicle being driven by a resident of the defendant nursing home. The plaintiff claimed that the defendant had a duty to her, as a member of the general public, to either prevent its resident from driving (she had a medical history of fainting spells and blackouts) or to at least warn her of the dangers of driving. The Court disagreed, finding a lack of the requisite "special relationship." The Court was also clearly swayed by the particular facts of that case: this individual was a voluntary resident of the health care facility free to come and go at will, and there even existed a written contract that did not provide any means for the facility to control her conduct in non-emergency situations.

Yet there was also language in the Purdy decision that left open the possibility that the Court would not absolutely foreclose the idea of imposing a duty in a subsequent case, language the Court is now choosing to seize upon in deciding that a duty did in fact exist in this case, for the first time in essence creating a duty on the part of medical providers to the unquantifiable public at large.

A large part of the Court's decision in Davis is based on the consideration of public policy questions: Who is in the best position to protect against risk of harm? Who has the best capacity to bear the loss? Does "moral blame" attach to the alleged tortfeasor? What is the best policy for preventing future injuries? How does one prevent a proliferation of claims? What are the expectations of society, and more importantly, would reasonable people be expected to recognize the duty and agree it exists?

Applying those concepts to this case, the Court made its expansion of the concept of duty seem like a perfectly rational response to the fact that the defendants' administration of these drugs without allegedly warning the patient about the medications' disorienting impact did in reality create a peril to (at least) every other motorist in the patient's vicinity, and that the defendants were the *only* ones who could have provided that warning.

In ruling that a member of the public had a right to sue because of a duty the defendants had to warn their patient that the drugs they were administering impaired her ability to operate her automobile (the Court indicates in a footnote that its ruling on an expanded duty is in accord with what already exists in a number of other states), the Court also made a number of "observations" designed to limit the impact of its holding. First, it noted that the "cost" imposed on health care providers because of this expanded duty should be considered a small one. After all, the Court notes, complying with this duty requires nothing more than warning of the dangers of the drug that is being given, something the health care provider is supposed to be doing in any event. In other words, no additional obligation to warn is being imposed upon the physician or hospital. Rather, the only change is the scope of persons to whom the provider might be responsible if that obligation is not met. This leads the Court to its second point, which is that its decision is *not* about whether the patient should have been prevented from leaving the hospital in the first place, and is instead only about the "warning." Finally, the Court points out that its decision should not be construed as a type of slippery slope, and that while it is tempting to provide a form of relief to everyone who suffers an injury, the law in fact does not always do so.

The Court's decision in Davis was a 4-2 split. It was written by Judge Eugene Fahey, and joined by Chief Judge Jonathan Lippman, Judge Eugene Pigott and Judge Jenny Rivera. Judge Leslie Stein (joined by Judge Sheila Abdus-Salaam) wrote a surprisingly lengthy dissent, vociferously arguing against her fellow jurists for what she obviously deems a startling departure from past precedent, one based on what she classifies as a lack of rigorous intellectual analysis. The dissent would have kept the health care provider's duty confined to patients and a "readily definable third party of a definable class" to whom the provider affirmatively creates a risk.

The dissent disputes that the expanded duty is what parties or society expects. It suggests that since the obligation to warn already exists, expanding to whom the duty is owed in no way makes it more likely that the patient will heed the provider's warning. Judge Stein contends an expanded duty will actually interfere with the patient-physician relationship, making it less likely that the physician will put his or her patient's interests as paramount (i.e., medications should be administered solely on the patient's needs, and not on the potential impact the effects of the medication may have on the general public). She considers the expanded duty to be unworkable in any event, since injured members of the public at large will not be able to gain access to a patient's protected health care records. The dissent then expresses concern with the financial impact that this duty might have on malpractice premiums.

Much now remains to be seen. Will the lower courts heed the majority's efforts to confine the expanded duty they have created, or will all the dangers articulated by the dissent come to fruition? How will plaintiffs' attorneys try to expand the rationale behind the Court's ruling to fact patterns that involve more than failures to warn about the side effects of medications that result in harm to the general public? Will there be efforts to expand this ruling beyond the arena of health care providers and medical malpractice, particularly to the area of product liability law, where failure to warn claims are common? These are questions that will need to be monitored as the Davis ruling plays itself out in the years ahead.

In the interim, there are certain practices that should be emphasized that can alleviate concern about being drawn into an area where the law has now become less defined. In point of fact, this new ruling requires little new affirmative action on the part of health care practitioners. The Court's ruling, for example, does not require a broadcasting of warnings to the general public. And most physicians, as the Court notes, would already consider it part of their good and accepted medical practice to warn patients if any aspect of the care received had the potential to place "outsiders" in harm's way. The key here would thus seem to be documentation: making sure that medical records properly note that the "warnings" have in fact been given, and describing the content of those warnings in enough detail to establish that the patient has been told of any potential impact their care might foreseeably have on others once the patient leaves the office or facility. While there is obviously nothing that can stop a plaintiff from alleging a lack of warnings or instructions, contemporaneous notations can be highly effective in combatting such claims.

About the Authors





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Risk Management Considerations with Prescription Drug Abuse

By Mike Midgley



INTRODUCTION: According to the Centers for Disease Control and Prevention (CDC), in the United States alone, 100 people die from drug overdoses every day, and 44 of those 100 deaths are caused by prescription drugs.[1] CDC has officially declared prescription drug abuse in the United States an epidemic. On September 4, 2015, CDC announced the launch of *Prescription Drug Overdose: Prevention for States*, a new program to help states end the ongoing prescription drug overdose epidemic. The *Prevention for States* program, as part of the U.S. Department of Health and Human Services' Opioid Initiative, will make a strong investment in 16 states, giving them the resources and expertise they need to help prevent overdose deaths related to prescription opioids. The program builds upon the infrastructure of CDC's Prevention Boost and Core Violence and Injury Prevention programs. Arizona, California, Illinois, Kentucky, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, and Wisconsin will be able to improve their ability to track the problem, work with insurers to help providers make informed prescribing decisions, and take action to combat this epidemic. In FY2015, CDC is committing $20 million to launch this program. Over the next four years, CDC plans to give the states annual awards between $750,000 and $1 million each year, subject to the availability of funds, to advance prevention. The focus is on (1) enhancing prescription drug monitoring programs (PDMPs), (2) putting prevention into action in communities nationwide and encouraging education of providers and patients about the risk of prescription drug overdose, (3) working with health systems, insurers, and professional providers to help them make informed decisions about prescribing pain medication and (4) responding to new and emerging drug overdose issues through innovative projects, including developing new surveillance systems or communications campaigns. States can also use the funding to better understand and respond to the increase in heroin overdose deaths and investigate the connection between prescription opioid abuse and heroin use.

Since 1999, the amount of prescription painkillers prescribed and sold in the U.S. has nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report.[2] In 2012, the Substance Abuse and Mental Services Administration (SAMHSA) estimated that among Americans 12 and older, 1.8 million started pain reliever use, 1.4 million started tranquilizers, and 166,000 started sedatives for non-medical purposes.[3] There is strong evidence that United States healthcare clinicians are overprescribing painkillers, leading to abuse and more overdose deaths.

Continued on next page

SAVE THIS DATE

AHRMNY'S

Annual Educational Conference

Friday, June 3rd, 2016
8:30 am – 3:30 pm
Holiday Inn West 57th Street

Program and registration details coming soon
http://ahrmny.com

TRAVELERS

PAID ADVERTISING

The CDC identified that 259 Million prescriptions for painkillers were written by clinicians in 2012.[4] This was enough for every adult in the United States to have a bottle of pills. While prescription pain medication will continue to be a key tool in managing some types of pain, certain clinicians will need greater education in pain management to mitigate overprescribing pain medication, particularly for chronic, non-cancer pain. There is little evidence that long-term opioid treatment improves chronic pain, function, and quality of life. Moreover, long-term use of opioid painkillers for chronic pain can be associated with abuse & overdose, particularly in higher doses.[5]

Although the problem remains a major concern, we have started to see some improvements. In 2012 we saw the first national drop in prescription overdose deaths since the 1990s, and it has essentially leveled off.[6] This drop in deaths mirrors a similar drop in painkiller prescribing rates across the country and provides hope to making even more progress in reversing the epidemic.[7]

Continued improvement with reducing prescription drug abuse will need to be championed by the prescribers. There is an opportunity for greater education of many prescribers. According to the Association of American Medical Colleges less than 1 in 4 of the 133 accredited medical schools in the country teach students about chronic pain management and most students receive less than 11 hours of pain management training in their entire 4 years of medical school.[8]

In a clinical study released in The Clinical Journal of Pain, June 2015, researchers at Johns Hopkins Bloomberg School of Public Health analyzed knowledge, attitudes and beliefs of physicians regarding prescription drug abuse.[9] Half of the 1,000 primary care doctors surveyed in 2014 in the US mistakenly believed that abuse-deterrent pills (those that can't be crushed and snorted or injected) are less addictive than standard narcotic painkillers. Thirty-three percent of the doctors also said they believed that most prescription drug abusers don't take pills by mouth, as intended. Research has shown, however, that the overwhelming majority do. Many fewer snort or inject prescription painkillers. All of the doctors surveyed believed that prescription drug abuse was at least a minor problem in their communities. More than half felt it was a "big" issue. Measures that could potentially reduce narcotic painkiller abuse were widely supported. Most physicians supported using patient contracts (98%), urine drug testing (90%), requiring prescribers to check a centralized database prior to prescribing opioids (88%), and instituting greater restrictions on the marketing and promotion of opioids (77-82%). This study indicates that prescribers are supporters of making the needed changes to mitigate the potential for abuse but the changes in practice will require extra dedication, time and resources.

The support for non-opioid options is also growing within many well respected organizations. The Join Commission recommends, "An individualized, multimodal treatment plan should be used to manage pain – upon assessment, the best approach may be to start with a non-narcotic."[10] CDC recommends, "Healthcare providers should only use opioids in carefully screened and monitored patients when non-opioid treatments are insufficient to manage pain."[11] The American Society of Anesthesiologists recommends, "a multimodal approach to pain management – often beginning with a local anesthetic where appropriate."[12]

CLINICAL MISSTEPS

There is no shortage of examples of criminal and civil cases involving clinicians inappropriately prescribing drugs.

Criminal Cases

It was alleged a Rancho Palas Verdes, California physician wrote prescriptions for powerful painkillers and muscle relaxants to an undercover agent who was showing him an X-ray of a dog, not his own. He was charged with twenty-one counts of illegally prescribing drugs with no legitimate medical need to undercover DEA agents. He allegedly wrote pain killer prescriptions without performing physical exams, taking vital signs or filling out medical charts.[13]

Former pain clinic doctor Gerald Klein was on trial in early September, 2015 and charged with first-degree murder after a 24 y/o patient died after taking a massive dose of a narcotic and an anti-anxiety drug. Dr. Klein had prescribed an excessive quantity of medication and the pharmacy filled it a day earlier at the Pain Clinic. The doctor gave up his medical license.[14]

Dr. Julio Gabriel Diaz, the infamous "Candy Man" is awaiting sentencing in California after being convicted in late August, 2015 by a Santa Ana jury for illegally prescribing patients dangerous amounts of narcotics that prosecutors believe led to twenty deaths. The jury determined Dr. Diaz knowingly distributed highly addictive sedatives and painkillers without a legitimate medical purpose. He was arrested in early 2012 on federal drug trafficking charges and pleaded guilty to illegally prescribing a controlled substance, failure to maintain proper security and storage, and two counts of illegally prescribing a narcotic. One patient overdosed and died after he was allegedly prescribed 2,087 pills in the six weeks leading up to his death.[15]

Dr. Stan Xuhui Li, an anesthesiologist from Hamilton, N.J., ran a pain management clinic one day each weekend in Queens, New York where he saw dozens of patients a day, posted a price list on the wall for drugs that included oxycodone and xanax and accepted payment primarily in cash. He was accused of overprescribing painkillers to two patients who later suffered fatal overdoses. Dr. Li was convicted of two counts of second-degree manslaughter and 200 of 211 other charges against him. Those charges included reckless endangerment, criminal sale of a prescription for a controlled substance and falsifying records. Dr. Lin allegedly prescribed drugs to patients who showed clear signs of addiction. He will serve a minimum 10 2/3 years and a maximum of 20 years in prison.[16]

Civil Cases

An Alabama jury awarded a widower $500,000 in 2012 after he sued his wife's family physician following her death due to an accidental overdose. She was prescribed narcotic pain medications combined with central nervous system depressants. The physician in this case, Dr. Larry Keithley, was found to have prescribed the deceased valium, xanax, xanaflex, hydrocodone and trileptal, along with demerol

and phenergan liquids. The claims involved Dr. Keithley's failure to meet the standard of care by prescribing liquid forms of high risk medications with no instructions for use.[17]

A Maine woman was awarded $1.9 million after it was determined her physician overprescribed methadone for pain treatment, which caused her to stop breathing and suffer brain damage. This patient of Dr. Steven Weisberger was being treated for chronic back pain. The claims included failure to prescribe the appropriate dosage of methadone. Approximately 48 hours after this patient was prescribed Methadone, her fiancé found her unresponsive in the middle of the night. She was eventually revived, but the resulting deprivation of oxygen resulted in brain damage that affected her ability to multitask and perform tasks that would allow her to work. Plaintiff's experts opined that the amount of methadone plaintiff was prescribed was eight times the amount recommended by experts in the field.[18]

In another case of alleged negligence, the patient was on an antidepressant, and according to the psychiatrist who was treating the patient, it was never discussed that the patient was simultaneously being treated by an orthopedist and was prescribed a narcotic. The patient threw himself down a flight of stairs and broke his neck in what was termed a "drug-induced haze." The patient's family sued the psychiatrist for negligence, and the case was later settled.[19] A tragic case in Utah involved a patient who shot his wife to death in a church parking lot. The woman's children sued the patient's physician, Dr. Hugo Rodier, and a nurse practitioner involved in the man's care, alleging a toxic combination of prescriptions led to the patient's deadly shooting attack on his wife. The physician's attorneys argued that the patient's children had no standing to sue because they had no patient relationship with the medical personnel. The Supreme Court of Utah ruled in favor of the children, finding that Dr. Rodier and his staff can be held liable for their patient's actions. The decision requires Utah physicians to consider all third parties who might be affected by a prescription decision. This includes unforeseeable, rare cases of a patient who reacts badly to a treatment regimen and harms others. The patient in this case was prescribed various psychotropic drugs, antidepressants and steroids and allegedly was not provided information on the side effects. Dr. Rodier allegedly failed to properly oversee this patient's medical visits or monitor a nurse practitioner's prescription decisions.[20]

In a similar case out of Massachusetts, the Supreme Judicial Court opined that a physician owes a duty of reasonable care to any individual foreseeably put at risk by the physician's failure to warn his or her patients. In this case, a seventy-five-year-old man lost consciousness while driving his car, causing him to veer off the road and kill a ten-year-old bystander. The patient suffered from serious illnesses including asbestosis, chronic bronchitis, emphysema, high blood pressure, and metastatic lung cancer and he was prescribed oxycodone, zaroxolyn, prednisone, flomax, potassium, paxil, oxazepam, and furosemide. Potential side effects include lightheadedness, drowsiness, dizziness, fainting, altered consciousness, and sedation. Although the physician in this case, Dr. Florio, warned his patient that he should not drive during his cancer treatment, he had later instructed him that it was safe to begin driving again. Allegedly, Dr. Florio never warned his patient about the side effects of any medications that he prescribed. The deceased child's family sued Dr. Florio on the theory that he negligently failed to warn his patient about the medications' known side effects. The MA high court held that a physician's duty of care includes the duty to warn patients of proposed treatment; this duty extends to parties foreseeably put at risk by the physician's failure to warn. In Massachusetts, physicians have a duty to inform based both on the nature of the physician-patient relationship and the foreseeability that an automobile accident injuring other parties might occur.[21]

Administrative Actions

An example of overprescribing abuse and administrative actions can be found in Washington. There were reportedly sixty complaints filed against Payette Clinic with the state Department of Health. Allegations included excessive controlled substances prescribing and the death of a high school senior who overdosed on oxycodone prescribed to another patient being treated at the clinic. DEA and the Washington State Department of Health charges against a Nurse Practitioner who worked at the clinic included unprofessional conduct. The state stripped her of her privileges to prescribe Schedule II drugs for two years. In order to get her privileges back, the commission ordered her to complete approved graduate-level coursework in pain management. At this clinic there was no policy about obtaining a patient's prior medical records before treating them, they did not have guidelines regarding the amount of opiates to be prescribed to patients nor did they have guidelines for identifying addiction in patients. The nurse practitioners reportedly used their discretion on whether to monitor patient usage with urinalyses and pill counts.[22]

COMMON ERRORS

There is no argument that healthcare providers are hard-working, dedicated professionals who are aware of basic pain management but they can become complacent and fail to do everything they can to prevent unintentional overdoses. Some of the most common errors associated with opioid prescribing for non-cancer pain treatment include (1) inadequate screening for safe and effective opioid use, (2) inability to monitor adherence, (3) improper selection of opioids, and (4) insufficient consideration of comorbid conditions.[23]

Inadequate Screening

The initial clinical assessment in managing patients with chronic non-cancer pain should involve establishing the diagnosis, medical necessity, and treatment goals.[24] This will include assessment for depression and tendency toward substance abuse dependence, assessment of the pain level and functional ability. A thorough assessment of the patient before prescribing any medication, much less an opioid, is always necessary. If the patient has a history of drug seeking or selling, consider close monitoring or follow up after discharge, as well as tight limits on the patient's prescription. If the patient is currently abusing substances, the provider should assess and treat the underlying condition as well as the substance abuse.

It is ideal to stratify patients into low, medium and high risk prior to initiating pain management treatment. This will help to prevent misuse and abuse. Patients with concurrent substance abuse and greater risk for abusing the prescription

opiates fall under the category of high risk. The patients who are categorized as high-risk must be monitored frequently with repeat assessment in conjunction with prescription drug monitoring programs, random urine drug testing, and random pill counts. In addition, these patients should be placed on low-dose opioids (and not on combination opioid therapy) and should be weaned off opioids if they develop any atypical behaviors. Risk assessments and validated tools can be used to stratify patients objectively. Examples are the Opioid Risk Tool and the Screener and Opioid Assessment for Patients with Pain.

Monitoring Adherence

Many patients prescribed opioids should be monitored for adherence and adverse effects. Monitoring for abuse is also highly recommended with high risk patients. Urine drug testing is one way to monitor. While patients may initially balk at this testing, the urine drug screen informs clinical decision making by prompting new conversations between clinician and patient.

There is fair evidence for the diagnostic accuracy of urine drug testing and that it serves to identify patients who are non-compliant or abusing prescription or illicit drugs. Clinicians will ensure full informed consent before prescribing opioids and determine methods to monitor adherence which may include urine drug testing. The urine test will reveal the presence of prescribed substances, pick up on non-prescribed substances and illicit drugs, uncover possible misuse/abuse and cross-reactivity risk. The screen will not tell the provider the amount of drug ingested or taken, when last dose was taken, source of the medication or absolute proof of misuse/abuse. If a patient is believed to be selling/diverting narcotics, and the patient's random urine test confirms no drug use of what is being prescribed or there has been a forgery or theft of prescriptions, then it is time to seriously consider discharging the patient.

Most evidence-based guidelines for prescribing opioids for chronic pain call for monitoring medication compliance with testing protocols that align with the risk level of the patients. For example, a low level risk patient could be tested within six months of therapy initiation and then yearly testing thereafter; a medium level risk patient could have testing at point of contact, two to three times yearly and confirmatory testing for inappropriate/unexplained results; and for the high risk patient, the testing frequency could be once per month and confirmatory testing for inappropriate/unexplained results.[25]

Improper Selection of Medications

Proper selection of medication for pain management for chronic non-cancer pain is no different than the selection for any other condition a patient might have requiring pharmacologic treatment. A careful assessment of risks and benefits as well as side effects is in order. Prescribing both long-acting and short – acting narcotics is typically a bad idea, especially for patients with comorbid respiratory disorders. It might be more appropriate to start with a single short-acting agent to determine adherence and tolerance. A trial of opioid therapy may be appropriate with monitoring on an ongoing basis. Clinicians must be careful to keep in mind that they are prescribing opioids as part of multimodal therapy.

Insufficient Consideration of Comorbid Conditions

Determination of underlying clinical pathology is the basis for diagnosis and recommendation of medical necessity for pain management regimens. Chronic pain is associated with a number of neuropathic conditions. All pain is not created equal and will not respond to the same types of treatment. As clinicians attempt to define the most appropriate treatment regimen for each person in pain, it is best to think in terms of categories of treatment. These categories include pharmacotherapy; interventional, invasive approaches; behavioral strategies; psychological support, lifestyle changes; complementary and alternative approaches; and physical medicine and rehabilitative approaches. Providers should be thinking of multimodal strategies that may include opioids as one appropriate consideration. If possible, they should be documenting a trial of non-narcotic medication and/or physical therapy before choosing to place the patient on a controlled substance. As with any other treatment plan a discussion of the goals, risk and benefits and obtaining the patients consent is very important.

RISK MITIGATION STRATEGIES

Clinical Guidelines

Consider a patient scenario where late in the day at an urgent care center, a young man enters the facility and identifies that he is on his way home to Germany but is in severe pain. He anticipated making it home to his local physician before seeking medical assistance, but has had increasing lower back pain and cannot continue his travel; especially sitting on an airplane for an extended period of time. He knows what the problem is, having been diagnosed with degenerative disc disease and having been provided pain treatment several times. He tells the clinician that if he can just obtain something to dull his pain, his return trip home would be possible and he can see his primary care provider in Germany. Valium and Vicodin are the only medications that have helped his pain in the past. He has no insurance coverage outside of Germany, so he only seeks the medication and he will be on his way. The physician is considering writing a prescription for a few pills, but she does not want to be inappropriately prescribing medications.

There is a benefit to having objective evidence based clinical guidelines in place for scenarios like this one. When formal evidence based guidelines are maintained as the focus of patient visit, it is usually not necessary to confront patients about their underlying motivations.

The clinician should be comfortable identifying what the standards are and explain why they have been formally adopted into practice. The clinician simply refers to the guidelines and states what is required before prescriptions for controlled medications are offered to the patient. If the patient has an issue with the guidelines than she/he has a problem with the clinical operation of the organization and not the prescriber.

The clinical guidelines for prescribing controlled substances will indicate that these medications will only be prescribed for one-time patients in non-emergency situations if specific conditions are met. These should include that the patient (1) presents a government issued

photo identification document or other identification document and Social Security Number and phone number (2) offers a complete clinical history and the contact information for their primary care provider and (3) undergoes an appropriate medical examination.

Signage

Another risk management practice is using controlled substances warning signage or printed notices given directly to the patient along with registration materials. This can be very helpful in discouraging some patients who are simply seeking narcotics, intending to fraudulently obtain them or use deceitful measures. These individuals may walk out when the likelihood of obtaining the prescription they desire appears remote. The content of the notice, depending on the state in which the clinic or facility is located, references the criminal statutes related to fraud or deceit in obtaining prescription medications and/or the state's Prescription Drug Monitoring Program. The notice should indicate active participation in these state drug monitoring programs.

Identifying Drug-Seeking Individuals

It is very important that clinicians learn how to spot the typical drug-seeking patient. Be consistent in assessments and be careful not to violate the Emergency Medical Treatment and Labor Act (EMTALA) in emergency departments. Where EMTALA applies, remember the clinicians will always need to conduct a medical screening examination to rule out an emergency medical condition. Once ruled out, the patient can be discharged to follow up with their primary care provider and/or at the pain clinic. Many drug seeking patients will use time pressure on clinicians. They will arrive to the office after-hours or shortly before closing. They may claim to be in a hurry to catch a plane or keep an appointment.[26] Some will attempt to direct the prescription writing. They may identify the drug they want prescribed, and know a great deal about pharmaceuticals. Many will know that there is higher resale value for brand names over generics. Some drug-seeking patients will claim allergies to non-opioid analgesics or anything but the requested medication.

There are other drug-seeking patients that claim ignorance of medications but consistently manipulate the choices to only one desired drug. Drug seekers may avoid appropriate medical evaluation as they resist undergoing comprehensive histories, physical examinations or diagnostic testing, especially urine drug screenings. They may not follow up on referrals to treat the underlying medical problem. Some will cancel or fail to show for any appointments made. Some do not follow through on recommended therapies or interventions. There are drug-seeking patients who will use intimidation to get narcotics. They can become demanding, disruptive, even threatening if their prescription for a controlled medication is not provided. Some may even claim suicidal intent if medication is not provided.

Many times drug-seeking patients demonstrate little accountability for their own medical history or prior care they received. Some may claim to have no primary care provider or claim their provider is retired or on vacation. Drug-seeking patients may refuse to grant permission to obtain old records or communicate with previous physicians. They can be vague or inconsistent about their medical history. Some may claim to have no health insurance, lost their prescription, forgot to pack medication on vacation or their medication was stolen. Many times the physical exam does not support prescription of opioids, as the symptoms, history and exam do not make medical sense. Discrepancies may exist between patient complaints and observable behavior. Once the clinician is aware the patient is deceptively seeking pain medication a critical conversation is needed to quickly assess the patient's rationale for this activity, determine the appropriate response, and follow up plan.

Chronic Pain Management and Informed Consent

Managing chronic pain can become more challenging than the management of an acute episode with short-term pain control. A shift is required from acute pain medicating to management for chronic pain, and a corresponding shift in clinician response is needed. Continuing on the same path of prescribing opioids over the long run is exactly the clinician behavior that has led to patient complaints of addiction, DEA and state investigations, sanctions from licensing boards, and various negligence claims. The transition to chronic pain management requires three new elements beyond the baseline history, physical exam, and diagnostic work-up. (1) The clinician wants to have a detailed and documented consent discussion about the risks, benefits, side effects, and alternatives to long-term opioid use. It is critical to have the patient provide an informed consent before proceeding with ongoing prescription of painkillers. It is the responsibility of the clinician to explain all of the risks associated with prescription painkillers and to ensure that the patient know how to go about using them in the proper manner. (2) A patient contract should be agreed to with stringent requirements for patient behavior to continue receiving the prescription and (3) Patient monitoring strategies should be documenting in the medical record.[27]

Controlled Substance Agreement

Formal contracts between patient and prescriber should be used when prescribing controlled substances for patients with chronic pain. This will be done in combination with the informed consent. A formal pain management agreement outlines the expectations of the provider and the responsibilities of the patient, including several key items. (1) baseline screening of urine/serum medication levels, (2) periodic unannounced urine/ serum toxicology screening, (3) medications to be used, including dosage(s) and frequency of refills, (4) a requirement that the patient receive medications from only one physician and use only one pharmacy, (5) frequency of office visits and (6) reasons for discontinuance of drug therapy (i.e. violation of agreement). These agreements are generally a great tool to enhance the communication between patient and prescriber.

"No Narcotics" Policy

Having a "No Narcotics" policy that prohibits clinicians from writing prescriptions for narcotics is not the prudent way to reduce drug-seeking activity. These policies typically do not assist the clinicians in prescribing practices; they actually inhibit clinicians in providing adequate care. If the organization adopts a strict "No Narcotics" policy it can be viewed as judgmental and not treating individual patients and their individual medical conditions. Patients with true

pain from burns, chest pain and COPD, for example, will be harmed. The best practice is to review individual patient's clinical presentation and diagnosis, assess old medical records if needed and treat patients after completing a thorough clinical assessment.

Flagging Patient's Medical Record

Some organizations have policies in place for flagging a patient's charts who they suspect of seeking drugs. The flags could create a problem as they appear discriminatory and could be used by plaintiff's counsel to discredit the clinicians if there happens to be an issue with a serious safety event with that particular patient. This can escalate a medical malpractice claim. In the emergency department all patients must get a medical screening exam to rule out an emergency medical condition under EMTALA, so a thorough assessment is always needed regardless of initial suspicions and patient track record. Pain assessment is part of ruling out the emergency medical condition. Also, any labeling in the medical records of a "drug seeker" or "frequent flier" are unprofessional and can be seen as discriminatory. These types of comments also must not be placed in the emergency department log.

Notifying other Hospitals of Drug-Seeking Patients

Some organizations have experienced a patient going "narcotic shopping," looking for any clinician that will provide a prescription for a narcotic. If there is a patient on a binge one night who has stopped by the emergency department or urgent care center looking for narcotics and the clinicians suspect he/she is going around town to other facilities seeking the same, and want to call the other facilities in the area to put them on notice, it's not a good idea due to confidentiality and privacy concerns. If the other facilities are covered under EMTALA, they will need to conduct a medical screening examination anyway.

Patient Termination

When all else fails, consider terminating the patient from the practice. This will be especially true when the patient has failed to abide by the pain contract. Sometimes it is very difficult for the clinician to do this because the clinician may have actually created the addiction with inappropriate prescribing. Consider for example, the patient who had a traumatic kidney injury and was medicated with Vicodin for three months and then the physician does not want to prescribe the medication any longer. This can create a very bad reaction from the patient, both physically and emotionally. The patient may need a referral to an addiction specialist. If termination is the only option, consider writing a letter to the patient stating objectively and reasonably why exactly they are being terminating from care. It might read they are being terminated because they have not been following the plan of care. The clinician will give an exact date when the patient is terminated. A thirty-day notice period is recommended. The clinician will need to make themselves available during that time. Refer the patient to another clinician if at all possible and provide resources if needed. Offer to send medical records to the patient and the next provider. Send the termination letter via certified mail with return request. Document very well in the medical record the entire chain of events.

PRESCRIPTION DRUG MONITORING PROGRAMS

Most states have adopted statewide electronic databases that collect designated information on controlled substances dispensed by pharmacies. Forty-nine states and D.C. have passed statutes establishing a program and provide authorized users access to that information. DC is in the process of adopting regulations, and Missouri has several bills pending in the state legislature that would enact a program.[28] The Prescription Drug Monitoring Programs (PDMPs) contain critical clinical data that can help (1) identify patients at risk for opioid-related overdoses, (2) inform providers of other medications the patient is receiving that may interact with those prescribed and (3) identify patients struggling with substance abuse. The information allows for a conversation with a patient about their risk for opioid dependence, overdose and death. The states that have enacted mandatory prescriber inquiry before the controlled substance is prescribed is the best approach. If it is voluntary, only partial compliance will be achieved.[29] PDMP requirements for data collection intervals widely vary throughout the US. The data collection interval is the time within which a dispenser of the medication is required to submit dispensing information to the state governed PDMP. This is the area where there has been the most change in the last year. Six states went from weekly reporting to daily. These states are Alabama, Arizona, Louisiana, Mississippi, Ohio, and Tennessee (effective January 1, 2016). Colorado and Michigan went from requiring reporting twice monthly to daily, and New Jersey went from reporting twice monthly to weekly. Indiana will go to daily reporting on January 1, 2016. Rhode Island and Pennsylvania recently went to reporting within seventy-two hours. Real time is only required in Oklahoma.[30]

Twenty-four states require prescribers and/or dispensers to access PDMP in certain circumstances. Thirteen states require certain authorized users to receive training or take some educational course before using or receiving data from PDMP. Most states offer optional training. Sixteen states provide by statute that practitioners have no obligation to access PDMP. Forty-five states allow interstate sharing of PDMP information. There is a great deal of variation throughout the US. What is needed is nation-wide mandated real time dispenser data entry requirements and mandated prescriber verification of PDMP every time when prescribing opioids and other key controlled substances. Then the timely entry and review of dispensing data, in "real time" maximizes the utility of the prescription history data. In addition, utilizing PDMP data for public health surveillance is a benefit and the system can be maintained to send proactive reports to authorized users to protect patients at the highest risk. In addition, each state must make the PDMP easy to use and a simple task to integrate into the clinical workflow. That is mostly still a work in progress across the US.[31]

PDMP Success Stories

There are several examples of success stories with PDMP's. For example, in New York physicians must consult the prescription monitoring program registry prior to prescribing any Schedule II, III, and IV controlled substance. New York law requires the submission of data in real time, meaning no later than twenty-four hours after the substance is delivered.

Prescribers and dispensers get direct, secure access to view dispensed controlled substance prescription histories. The system is available twenty-four hours a day, seven days a week. Accessible data includes all controlled substances dispensed in New York and reported by pharmacy dispenser for the past six months. It allows practitioners to better evaluate their patient's treatment plan and assess controlled substances to determine if there is the potential for abuse. In New York pharmacists are not required to consult the PDMP registry but many do. The penalty for not complying with entering in the prescription data within 24 hours is the same penalty as for any violation of the public health law in New York. After instituting universal PDMP in New York, the overall use of opioid prescriptions decreased 9.53% and multiple provider episodes decreased 74.8%. The major decrease in multiple providers is the big success in New York.[31]

Another example is the state of Tennessee. In 2012, Tennessee required prescribers to check the state's PDMP before prescribing painkillers and within a year they saw a thirty-six percent decline in patients' seeing multiple prescribers for the same drugs. Florida can be complimented on its success with their PDMP. After new regulations and enforcement activity, deaths from oxycodone overdose fell by over fifty percent from 2010 – 2012 when during the same period oxycodone prescribing fell by twenty-four percent. In addition, prescriptions for hydrocodone dropped by ten percent, as did methadone by ten percent and Xanax by eleven percent.[32]

From 2003 to 2010, prescription opioid overdose deaths in Florida doubled. The response in Florida involved action in early 2010 to begin regulating pain clinics by requiring them to register with the state. Drug Enforcement Agency (DEA) agents with assistance from federal, state, and local law enforcement partners began to work together in, what was deemed, "Operation Pill Nation." The agents were infiltrating rogue pain clinics by acting as undercover buyers of prescription drugs from clinicians in the so called "pill mills." They were arresting clinicians who were conspiring to distribute and dispense Schedule II narcotics, like oxycodone. In addition, several prescribers were charged with multiple counts of conspiracy and money laundering offenses.

The state developed and implemented new expanded regulations for pain clinics later in 2010. Raids continued through 2011 and then in July 2011 the Florida legislature restricted doctors from dispensing schedule II or III drugs and activated regional strike forces to address the emergency. This involved a statewide effort to reduce the supply of diverted prescription drugs through intelligence driven operations against the pill mills. Then in September 2011, the state required mandatory dispenser reporting to the newly established PDMP. In 2012 the state legislature expanded the regulations over wholesale drug distributors.

Florida efforts to curtail multiple providers prescribing narcotics is working. There has been a fifty-six percent decrease in multiple provider episodes since early 2012 to second quarter 2014. This was calculated for patients with five and over prescribers using five or more pharmacies and those with ten and over prescribers using ten or more pharmacies.[33] These results are very encouraging.

REGULATORY OVERSIGHT OF CONTROLLED SUBSTANCES

State and federal authority investigations and criminal prosecutions have increased over the years. It is very important to be aware of what laws are involved in prescription drug abuse cases. They include Federal and State Controlled Substance Acts, where drugs are listed, and State Medical Practice Acts and State Prescribing Authority Acts, that direct clinical practice in the states. It is critical to stay current on these laws as they are occasionally amended. The updates are not easy to learn about, access or even understand. Interpretation can be challenging.

Strategies to Manage an Investigation

An administrative investigation or criminal investigation could be initiated within a clinician's practice without their knowledge. It is key to know how to comply with the investigation from the DEA, the Office of the Inspector General (OIG) of The U.S. Department of Health and Human Services (HHS), state medical board agents, state narcotics agents, and the police. It may come to the authorities attention that there is a potential issue via reports of patients deaths from prescription drug overdoses, review of pharmacy patient records for signs of patient drug seeking behavior, review of doctors prescribing rates, tips from pharmaceutical distributors about doctors who order an unusual high amount of pain killers for dispensing, suspicion of drug diversion by the pharmacy, doctors, patients or even office staff, use of undercover informants seeking prescriptions, media reports about certain practitioners or citizen complaints to local law enforcement or medical boards.

The DEA and/or Medical Board agents or police personnel may raid the office or clinician's homes, they may serve search warrants, freeze bank accounts, confiscate files, medical records and computers, interview patients in search of witnesses who will testify against the physician. Agents can show up for an unannounced administrative inspection. Agents may call to talk about things that they have received reports of and innocuously ask for the providers help in the matter. They may get a subpoena to have the provider produce patient files and attend a meeting in a medical board office, or they may just show up and the provider gets arrested.

The outcome may include criminal charges, it could be a felony with a prison sentence, the charge could be unlawful sale and distribution of controlled substances or unsafe prescribing. The charge could be manslaughter or even murder if a patient died from complications from drugs prescribed. The provider could be arrested, hauled into court and charged in an indictment or criminal complaint, ordered to not practice medicine as a condition of release on bail. He/she could have to pay for a criminal defense attorney out of their own pocket, could be featured in the media, the medical board will initiate an accusation against them, their reputation takes a hit, they could be sued by the patient and survivors, they could be fired from the medical group, they could have their patients cut off from pharmacies, they could be in jail and lose their license or pay high fines.

When law enforcement agents show up in the office or clinic for an unannounced administrative investigation, they will typically arrive and expect immediate access to all prescription records for two years. The provider must keep prescription records on premises for inspection on demand. The agents will get a search warrant if the provider does not comply. If the records are available then it is best to give them to the agents for their review. If the records are off site for whatever reason, cooperate and tell the agents that the records will be transported to them. If the agents begin to ask questions it is not a good idea to answer anything that might be used in the investigation. If the agents ask the provider to sign any documents it is very important to know what is being requested. If agents ask for the provider to sign a document that simply states an understanding of their authority, that is reasonable, but it is not a good idea to sign anything that indicates anything about waiving rights or giving up any privilege, or acknowledging misconduct, or resolving an allegation, or doing anything that will threaten the providers ability to practice medicine. DEA Form 104 is the voluntary surrender of the DEA Certificate. Be careful not to sign this form because as soon as the provider signs it, their right to prescribe any controlled substance schedule II-V has been relinquished. There is no administrative review or appeal of a voluntary surrender.

CONCLUSION

Many positive policy changes, such as prescription drug monitoring programs in different states and other screening approaches for risk factors and behaviors for misuse and abuse, are making opioid therapy safer. However, we can do more. We know that the numbers of deaths due to unintentional overdose are beginning to decline. Nevertheless, more can be done. Providers must learn how to select patients for opioid therapy when indicated, and how to manage those patients on opioid therapy as safely and effectively as possible.

References listed on page 25

About the Author



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AHRMNY FALL HALF-DAY EDUCATIONAL CONFERENCE SUMMARY

December 11th, 2015 at Mount Sinai Beth Israel
Podell Auditorium

Mary Steffany and the Education Committee did an outstanding job with the AHRMNY Fall Half-Day Educational Conference. It was attended by 98 members at the Mount Sinai Beth Israel – Podell Auditorium on December 11, 2015. There were three education presentations which were well received.

Human Factors, Errors and Patient Safety Solutions was presented by Dena Goffman, MD, Associate Professor of Clinical Obstetrics and Gynecology and Women's Health, Montefiore Weiler Hospital. It was articulated that human factors research examines environmental, organizational and job factors of humans interacting with systems, as well as the physiological and psychological characteristics which influence behavior at work. There are "brain auto-corrects" where we see what we expect to see and therefore, we are programmed to miss both errors of repetition and errors of omission, both of which can be fatal in healthcare. With "accuracy of human observation" we see, interpret, prioritize and filter information constantly based on what our brain thinks is the most important! Then there is "discordant information" where color and shape are more important than text in determining how your brain "reads" a label or package and an incorrect medicine may be read as correct if the label and package color are the same as the "correct" medicine; this has resulted in multiple fatal occurrences nationally. A Key Takeaway is that "Human factors have become the 800 pound gorilla in the patient safety room…" A quote from Michael Leonard, Kaiser Permanente was stated, "…the inherent limitations of human memory, effects of stress and fatigue, the risks associated with distraction and interruptions and limited ability to multitask ensure that even skilled, experienced providers will make mistakes." Often the most effective way to improve safety is to simplify a process or system. Use human factors engineering to help develop stronger interventions when developing action plans. Lastly, a Just Culture will allow us to learn from error and prevent future errors. It was articulated that "A just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, "routine rule violations"), but has zero tolerance for reckless behavior… Frontline personnel feel comfortable disclosing errors-including their own-while maintaining professional accountability."

Electronic Medical Records: Litigation Nightmares was presented by Matthew P. Keris, Esq., Shareholder, Marshall Dennehey Warner Coleman & Goggin. Several cases were discussed that brought to light new areas of liability with the EMR. In Kolozsvari v. Doe, 943 N.E.2d 823 (Ind. Ct. App.2011) a patient was prescribed medications that twice generated EMR warnings to the pharmacists who in both instances, disregarded the warnings and gave the prescribed medications to the patient. In addition to giving the medications despite the warnings, the pharmacists did not inform the patient that warnings were generated and what the warnings indicated. The takeaways regarding automated warnings were that the court held that Indiana law recognized that the duty of care for pharmacists could include the duty to withhold or warn patients about the potentially significant adverse effects of prescription

medications. Other courts, when posed with a similar issue regarding EMR warnings, may take a similar approach and recognize that a failure to share or acknowledge EMR warnings is a factor in determining whether the healthcare standard of care has been breached. Are HCP's suffering from "warning fatigue" and ignoring them? Another case, Ortega v. Colorado Permanente Group, P.C., 265 P.3d 444 (Colo. 2011) – the court held that all of the plaintiff's EMR records from 1998 onward were relevant to the defendants for preparing an answer, asserting defenses, developing legal theories, planning discovery and determining trial witnesses and evidence. The Ortega case takeaways are that the Ortega decision illustrates that a patient's entire EMR will be relevant and accessible to a defendant health care provider in preparing a medical defense as long as it was accessible at the time of treatment. It may also create an expectation that health care providers who have access to a comprehensive EMR system are expected to review it in its entirety in providing care to a patient. What is a reasonable review of a medical history when you have everything?! Are HCP's reviewing other records? If not, why? What are the barriers? A third case involved 21st Century Version of "*Captain of the Ship*" Doctrine—Duty to Coordinate Care through EMR. Laskowski v. U.S. Dept. of Veterans Affairs, 918 F. Supp. 2d 301 (M.D. Pa. 2013) was a suit filed against Dept. of Veteran Affairs for the alleged mismanagement of a Iraq veteran's PTSD. Upon discharge, was receiving treatment through the VA medical system. Often, Mr. Laskowski's medication regimen was altered after mere telephone conversations without the benefit of an office visit, physical examination or review by a physician. At trial, both experts acknowledged that the care rendered to Mr. Laskowski required coordination of care through the electronic medical record. The Laskowski case takeaways are that the benefit of being able to monitor all care through the use of electronic medical records systems brings along the added responsibility to ensure that the total care be managed appropriately. As demonstrated in Laskowki, physicians may not only be held accountable for their part in caring for the patient, but, because electronic medical record systems allow review of what others are doing, they may be deemed responsible for failing to coordinate the total care of the patient.

Additionally, new EMR Theories of Liability were discussed. Corporate Negligence could include potential claims for the following: Failure to train staff to use system correctly; failure to enforce policies and procedures re: EMR use; and Permitting an unsafe/unreliable EMR system. New EMR Theories of Liability also include Individual Standard of Care Issues. The Individual Standard of Care Issues are:

- Failure to access complete EMR for critical prior medical history.
- Increased scrutiny on documentation standards and timing.
- Whether health care professionals are disregarding EMR warnings. Charting by exception-we are documenting less information and what information that is documented may be less than accurate.
- Reliance on others' documentation that may be incorrect or incomplete or overwhelming (too much information being captured).
- Depositions are hard to prepare for because all witnesses are using hard copy of the record which looks nothing like the computer screen.
- Failure to coordinate care through the use of the EMR system.

Medical Marijuana was presented by Elizabeth Kase, Esq., Partner, Abrams Fensterman Fensterman Eisman Formato Ferrara & Wolf and Hindi T. Mermelstein, MD, FAPM, Faculty Department of Psychiatry, New York University School of Medicine and Norwell Health System. New York State's Medical Marijuana Program launches in January 2016. The New York Compassionate Care Act (CSA) authorizes qualified patients, doctors and Registered Organizations to participate in New York's Medical Marijuana Program. There are stringent requirements for participation. A Registered Organization or "RO" is permitted by the state to grow and dispense medical marijuana. Each RO may open four (4) dispensaries and currently there are five (5) RO's. Practitioners must be registered with the NYSDOH to issue marijuana certification to patients. In order to obtain practitioner registration, practitioners must be licensed and practicing in New York; be qualified to treat a patient's "serious condition"; have completed a four (4) hour training course approved by the DOH; and be caring for patients for whom they are making a recommendation. In order for a patient to qualify for medical marijuana they must suffer from a "severe debilitating or life-threatening conditions" together with symptoms that are clinically associated with or are complication of such conditions. The "severe debilitating or life-threatening conditions" and symptoms are specified by the DOH. The patient must be registered with the New York State Department of Health and must receive a "certification" from a Physician on an approved form, which indicates that the Patient medically qualifies for medical marijuana and, in the professional opinion of the Physician, and based upon a review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marijuana for the serious condition. The forms of marijuana product that will be available include oil for sublingual administration, liquid extract for vaporization and capsule for ingestion. No whole flower products will be available and smoking of medical marijuana is not permitted. Only brands developed by ROs and approved by the State DOH may be recommended. Recommendations are restricted to a 30 day supply. Physicians may not receive, provide or dispense marijuana. Also, physicians may not issue a certification for himself/herself or a family member, employee or co-worker. Additionally, physicians may not examine patients at any location owned or operated by a RO. Federal protection for practitioners is cited in Conant v. Walters (United States District Court for the Northern District of California, September 7, 2000) which affirmed the right of physicians to recommend medical marijuana and states, "The government should be permanently enjoined from revoking any physician class member's DEA registration merely because the doctor makes a recommendation for the use of medical marijuana based on a sincere medical judgment and from initiating any investigation solely on that ground…whether or not the doctor anticipates that the patient will, in turn, use his or her recommendation to obtain marijuana in violation of federal law." State protection for practitioners is cited pursuant to the NY Public Health Law, 3369: "…practitioners… shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marijuana, or for any other action or conduct in accordance with this title."

With respect to marijuana in medical care, quality control and standards are needed. Research is needed to better determine when, whom and how. Lastly, best practices need to be developed.

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Risky Business

"When Common Sense is Uncommon"

By Pamela Monastero, MBA

WHAT ARE WE DOING?

16 Years of Patient Safety

It has been over 16 years since the iconic "To Err is Human[1]" report was published by the Institute of Medicine. It is widely speculated that this report served to launch the patient safety movement and sparked changes in how the healthcare industry is regulated, how facilities and providers are reimbursed and how we do business in general. Since then, voluminous literature has been published on the topic as well as the establishment of bona fide patient safety organizations. There is literature suggesting the many great strides made in improving the safety of our patients. A recent two-part New York Times[2] piece by David Bornstein explores important work done by hospitals to 'do no harm.' Mr. Bornstein cites efforts made in reducing hospital-acquired infections (e.g. hand hygiene, standardized bundles, pressure ulcer reduction through focuses on nutrition, hygiene and dehydration, sepsis protocols, falls prevention measures, etc.). Conversely, literature also suggests the opposite, identifying the significant patient safety work that still needs to be done despite the efforts over the past 16 years. Change is challenging and often occurs at a slower pace than we desire but it is happening! As healthcare professionals, we are often exposed to the dark side of medicine, focusing more on what went wrong, why and how to fix it. The skills and 'sixth sense' that innately enable us to be good at our jobs also tends to turn us into consummate skeptics. I am one such skeptic and, while I do think that wonderful things are happening in medicine, based on personal experience, I have to ask: *What are we doing?*

We continue to read about medical mishaps and astronomical malpractice settlements. These serve to reinforce the fact that medical errors do continue to occur. Medical malpractice plaintiffs, as well as patient safety advocates (many of whom have been victims of medical errors, either personally or via a family member) provide testimony that supports the struggle toward providing safer medical care. These stories are heartbreaking and, as someone who has dedicated her career to patient safety, I frequently find myself squirming in the audience when patients and their families relay incredible stories about preventable medical events. I feel shame, humiliation, anger and frustration that, 16 years later, we still cannot seem to get it right, despite our absolute best efforts. *What are we doing?*

In illustration, this is a true, personal history of several preventable medical errors that occurred within my own family with different providers at different facilities.

A Comedy of Errors

As a teenager in 1977, I was injured in an explosion in the Wall Street area. There was chaos and it appeared that most of the patients were transported to the closest hospital in the area. As we know, bringing multiple trauma victims to one emergency department (ED) is not the best strategy. At that time, patients were issued sequential medical record numbers (we all know that an assigned medical record number is only one digit away from a catastrophe, especially if diagnostic testing, procedures or blood transfusions are involved). The ED was overflowing with burn and other victims from the explosion and I felt fortunate that I suffered only a deep laceration to my left thumb (it was actually a little worse than that but I was blissfully unaware—the tendon was lacerated and bone was exposed). While in the ED, I overheard someone saying that I needed to be seen by a plastic surgeon. A few hours later a physician attempted to suture my thumb and I told him that I was supposed to wait for a plastic surgeon. Crisis averted (my very first risk management experience!), but it left me feeling frightened because the physician had not known about tendon injury.

In the late 1990's, my 80 year-old uncle needed surgery for a right carpal tunnel repair. While in the operating room holding area, the staff kept insisting that he was booked for a left sided procedure. The staff assumed that, because he was elderly, he was confused about laterality. We insisted that the surgeon's office be called and learned that there was a booking error--one of the surgeon's staff booked surgery for the wrong side. Crisis averted and surgery was performed on the correct side. Sadly, my uncle fell during this admission and fractured three ribs. Thankfully, he fully recovered and the rest of his admission was uneventful. While time out procedures in place today exist to prevent a recurrence of the 'almost wrong sided surgery,' sentinel events will occur if staff ignore checklists and time out procedures, take short cuts, or ignore what the patient/family communicate.

Fast forward to 2015:

My father was treated at a fabulous hospital ….one of New York City's finest. His health is fragile and he has survived to 82 years against all odds. The various providers who treat him are phenomenal. We have tremendous faith in them and they collaborate in his treatment, reading each other's notes, coordinating his care and responding quickly and compassionately when called. Despite this stellar medical care, Dad was the victim of several preventable medical errors (at least those that we are aware of). Thankfully, none of these medical errors resulted in a life threatening situation. What was most disheartening is that these errors occurred in a facility with abundant resources in terms of finances, equipment and staff. Here are some observations regarding the errors that we know occurred and the potential ones that I observed:

- Error #1: Dad needed a bone marrow aspiration to rule out leukemia. He is a big man at 6 feet tall, and weighing over 200 lbs. The exam table used to perform the procedure was very narrow; there was a serious risk that he could have fallen from this tiny table, especially if he had been left in the room alone without family present. Post-procedure, this very important specimen was 'lost' either in transit or misplaced in the laboratory, and we never did get results. Dad's oncologist was embarrassed and absolutely furious. We chose not to repeat this very painful procedure to obtain a second specimen (think about patient experience and how would this be scored in terms of HCAHPS[3]!).
- Error #2: Dad learned during a routine visit to his private physician, who is also faculty at the facility, that he needed admission for exacerbation of Chronic Obstructive Pulmonary Disease (COPD). Dad was admitted via the Emergency Department (ED) because there were no in-patient beds available. We stayed in the waiting room for hours until such time that the ED went on diversion and the waiting room was needed for fast track patients. Fortunately, Dad called at around 11:00 pm stating that he had finally gotten a room. The next morning, Dad called to relay that he had blisters on his forearm following administration of IV steroids. On arrival at 10:00 am, we asked that the wound care team be called to evaluate his arm, which was inflamed and blistered and resembled small pox lesions. The nursing staff stated that the doctor (resident) would come at 12:00 pm to evaluate Dad. After playing the 'risk manager' card to escalate his care and after speaking to various members of hospital administration, the wound care team was finally called to evaluate and treat Dad. The wound care team was fabulous but Dad's arm did remain scarred and discolored for over a year. (Think about patient experience and how would this be scored in terms of HCAHPS[3]!).
- Error #'s 3,4,5: The following occurred during a recent admission for a wedge resection for lung cancer: Dad was scored as a high risk for falls. Post-op he was attached to a chest tube for drainage. On the second post-op evening, Dad became confused, removed his gown and walked into the hallway. Of note, his was the window bed of a two-bed room. Although standard fall precautions were in place, the bed alarm had not been engaged. Fortunately, Dad did not fall, nor did he manage to disconnect the chest tube, both of which could have resulted in catastrophic outcomes (e.g. hip or other fracture, head bleed or pneumothorax, to name a few) and an extended hospital course, or worse!

  On post-op day #3, a Nurse Practitioner (NP) came to speak to Dad and the family. She stated that his INR was abnormal and that this would extend his admission. Some of what she said did not make sense and she appeared to be confused. The Registered Nurse assigned to Dad had a side discussion with the NP, alerting her to the fact that she was speaking to the wrong patient; the INR discussion was intended for Dad's roommate. Because I was distraught over Dad's diagnosis and was in "daughter mode," I failed to realize that the NP neglected to check patient identifiers prior to the discussion--she violated one of two sacred rules because she never checked two patient identifiers upon entering the room (the other sacred rule, of course, involves hand hygiene). One other issue, albeit a minor one, was that the surgeon told us that he removed a node from the lung and that it was negative. Later, we were advised by Dad's primary care physician, a pulmonologist, that no nodes were removed and that the specimen submitted was actually adipose tissue. Although this last item was not really a medical error, it could result in patients and family members losing confidence in the surgeon.

Even as a healthcare 'insider,' it is impossible to comprehend that these errors all occurred in one family, yet, they did -- *What are we doing?* Listed below are some very obvious theories as to why errors continue to occur. The fact that they are so basic almost makes it worse that we have not gotten it right yet:

1. My personal observation during Dad's wedge resection admission was that staff were very polite and attentive in those areas with higher nurse-to-patient ratios, e.g. the pre-surgical area, operating room, PACU and post-op critical care unit. Patient identifiers were always a high priority item. It was a bit of a different story when Dad got to the regular medical/surgical unit, where, although seemingly adequately staffed, we had to compete for his nurse's attention due to higher nurse-to-patient ratios. There was also a sense of complacency on the floors vs. the energy of the ORs, PACUs and critical care areas;
2. Frontline staff seemed to spend an inordinate amount of time at computers or in completing paperwork which detracted from bedside care;
3. Medicine in and of itself has gotten more complicated. For instance, there were over 1,453 new molecular entities (NMEs) approved as therapeutics in the USA as of 2013 as compared to a little over 400 in 1970. [4] And, although we are blessed with a plethora of medication and diagnostic tests (MRIs, MRAs, CT and PET scans, etc.) available to us, these also present additional opportunities for error, especially with respect to similarly named medications such as chemotherapy agents;
4. We tend to focus our energy and attention on high ticket items to help avoid sentinel events and undesirable outcomes. We implement great policies, procedures and checklists, we create rapid response teams to head off crises, we develop comprehensive infection prevention protocols, etc. That said, 'little things' matter and, when left unresolved, today's close call (or near miss) is tomorrow's sentinel event. Dad's lost specimen could have been an irretrievable biological. Dad's chemical burn could have become septic. Dad could have fallen with injury on two occasions. Dad could have suffered a horrible pneumothorax and, given his already diminished pulmonary status, died. Dad could have received incorrect treatment and medication due to the patient identifier issue, etc. These examples highlight the importance of diligence in addressing the 'little things.' Below is a description of an engineering study that focuses on the importance of addressing close calls or near misses.

H.W. Heinrich authored a book in 1931 called *Industrial Accident Prevention, A Scientific Approach*[5] that was written for industrial executives and safety engineers. He based it on seventeen years of insurance industry experience as it related to the engineering and inspection divisions. Not unlike healthcare (terms depicted here in italics), Heinrich outlines four fundamental principles of accident prevention: executive interest and support (*leadership*), cause-analysis (*comprehensive systematic analysis or root cause analyses*), application of a remedy (*corrective actions and monitors*) and executive enforcement of corrective practices (*accountability and Just Culture*[6]). While this writing was explored in more depth in the 2015 Vol II AHRMNY *Risk Management Quarterly*, (Close Call Identification)[7] a key point made by Heinrich is that "for every accident that causes a major injury, there are 29 accidents that cause minor injuries and 300 accidents that cause no injuries. Because many accidents have common root causes, identifying and addressing more common place accidents where there are no injuries helps to prevent accidents with injuries. It is claimed that Heinrich's work is the basis of behavior-based safety, which maintains that 95% of all workplace accidents are caused by unsafe acts."

Checklists

On the road to safer healthcare, we have implemented checklists and established basic protocols to assist in avoiding medical mistakes and injuries (e.g. checking two patient identifiers, falls precautions, labeling specimens in the presence of the patient, sign-offs for transport of specimens, smart pumps--especially those for high alert medications like steroids, etc.); these are not always followed. Whether this is a direct result of low staffing levels or fatigue, patient acuity, interruptions or distractions or advances of the technological age remains a source for speculation and further investigation. What we know is that staff do sometimes make mistakes, sometimes fail to follow basic rules or policies and sometimes take shortcuts and these can result in undesirable outcomes. While "checklists may seem like a ridiculously simple concept in a complex world, there is evidence that they work. Good checklists get the routine and obvious tasks out of your mind so you can instead focus on the hard stuff."[8,9,10] In the Spring 2012 edition of the AHRMNY *Risk Management Quarterly*[11], we reported on various patient safety projects that highlighted the use of forms and checklists, visual and audio reminders for staff, hand-off techniques, executive walk arounds and technology as methods employed to improve patient safety and quality outcomes. We highlighted the use of Quality Indicators (QI) and Patient Safety Indicators[12] (PSIs) by AHRQ, the Keystone project[13], the CUSP project,[14,15] the creation of a Patient Safety Professional programs[16] (PSPs), human factors and ergonomics[17,18] (HFEs), the QUASER study,[19] some of which provide tools and frameworks for patient safety. Yet, despite all of the projects and literature, we continue to lag behind other industries with patient safety being a relatively new concept to healthcare. *What are we doing?*

The first checklist: in 1935, the aviation industry commissioned the Boeing Model 299 for use in the US Army Air Corps. This model was significantly more complex than earlier aircraft. On October 30, 1935 the aircraft stalled during the climb because the captain did not release the elevator lock prior to take off; this resulted in a fatal stall that was attributed to "pilot error." The result was that one very experienced pilot was so preoccupied with the new technology and requirements of the airplane that he neglected to release a locking mechanism, resulting in the fiery crash. This event resulted in the creation of the first pilot's checklist—the premise being that if one of aviation's best pilots could make this error, it was a foregone conclusion that others would err as well. Aviation recognized that "in a complex high-pressure environment, experts always come up against two main difficulties: (1) it is easy to overlook routine matters under the strain of pressing immediate demands; and (2) people can lull themselves into skipping steps even when they remember them. When translated to the complexities inherent in medicine (equipment, tubing, medication, interruptions, etc.), human memory can become fallible especially under stress. It becomes easy to skip steps and not follow up on routine matters (e.g. making sure it is the correct patient or procedure, hand offs, equipment safety, etc.) Checklists make the minimum necessary steps explicit and verifiable. They can be applied to almost any situation and ensure that people are applying all the knowledge and expertise they have consistently well. They are a self-sustaining virtuous cycle that continue to improve over time. When simple checklists are in place and staff are given the freedom to act and adapt using their best judgment while meeting specified expectations, better results will follow. Checklists should leave room for judgment—they should remove the routine from the situation, allowing judgment for critical decision making.[20,21,22]

Checklists seem to work well in aviation (perhaps this is due to the hierarchical nature—the pilot is indisputably in charge) and because there may be more controllable variables (e.g. equipment vs. people, certainly not the weather!). Perhaps because of this, stronger systems can be put in place to reduce or prevent errors that can cause harm. In healthcare, control can be diluted for several reasons which serves to weaken systems. Control is affected by various issues: the number of variables (patients are unique), interruptions (clinical alarms, other staff, families, telephones, codes), hand offs (shift to shift, provider to provider, transport for diagnostic studies or treatment), multiple consultants (who is in charge, who is coordinating the care, who is dictating the care, entrepreneurs (attending physicians who work at several hospitals and are not familiar with policies) and human factors (assessments, judgment and opinions, fatigue, disruptive behavior). Patient care is often not as straightforward as - the **one** pilot who is in charge of the **one** plane, the **one** supervisor who is charge of the assembly line or the **one** manager who is in charge of the business division. Healthcare is perhaps complex for different reason and, until we can find ways to work through the clutter and complexity, and develop better controls, the 'human element' we will continue to struggle with variation and safety issues because *To Err is Human*.

References listed on page 25

Dear Risk Manager:

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

Smart Devices in the Operating Room: A Smart Choice?

By Jeffrey Hawkins and Jonathan Waldauer

Technology in the operating room continues to expand exponentially in terms of both surgical techniques, such as minimally invasive and video-assisted laparoscopic procedures, and assistive devices, such as robotics, computers, recording equipment, interfaces, and monitors.[1] In the most technologically advanced operating rooms, surgeons, anesthesiologists, nurses, and technicians have computers, keyboards, touch screens, and other user interfaces that allow for instant access to medical databases, patient records, and video conferencing.[2] In the event of complications, these assistive technologies facilitate immediate and direct interaction with off-site physicians and specialists, without the need for lengthy interruptions in the procedure and the possible contamination of the surgical field.

The Advent of Smart Devices

In addition to new medical technologies such as those described above, smart devices, ubiquitous in today's society, have made their debut in the surgical suite. For the purposes of this article, the term "smart devices" encompasses cell phones, laptops, and tablets. These devices can be used for videoconferencing, recording, accessing databases, and a host of other functions.

The use of smart devices in the operating room can advance and improve patient care, providing many of the benefits of technologically advanced operating rooms in a smaller, cheaper package. These applications are of particular significance in less-affluent community hospitals that cannot afford to upgrade their operating rooms with the newest and most advanced technologies. Nevertheless, their use raises a number of liability issues and leads to the question of whether the benefits are outweighed by the risks and, if so, whether there are preventive measures that can be put in place to contain costs while reaping the benefits.

Warnings and Restrictions

Some might argue that all smart devices should be banned in the operating room because they can distract those involved in surgery. One recent study found that operating room noise, which could be impacted by the use of cell phones, can decrease auditory processing and impact patient care.[3] In fact, the Association of periOperative Registered Nurses recommends that cell phones be banned in the operating room and left outside with an employee who monitors calls for emergent situations.[4] The American College of Surgeons also has considered similar restrictions, as cell phones have the potential to interfere with certain medical devices.[5] Their use should be monitored on this basis alone.

An across-the-board ban on smart-device use in operating rooms is likely unnecessary, and a more nuanced approach may be advisable. Banning all smart-device use only makes sense if the operating room is sufficiently technologically advanced to provide physicians and operating room staff the potential benefits provided by smart devices, such as accessing records, performing research, consulting others, recording, and videoconferencing. However, in many places such as those smaller, less-affluent community hospitals mentioned above, providing "smart" operating rooms may not be financially or logistically feasible. Further, even in a "smart" operating room, where the ability to use touch screens or recording equipment may be limited to one or two individuals, smart devices can provide additional interfaces. There is also the issue of enforceability of such a ban and whether liabilities will arise if staff members use smart devices in violation of facility policy.

As this aspect of medicine evolves, lawsuits will raise issues of new "standards of care" based on the benefits of smart devices in the operating room. A plaintiff may argue, for example, that it would be a deviation from the standard of care for an anesthesiologist not to electronically research the most recent dosage charts during surgery, and for a surgeon not to send a photo of an unforeseen complication to solicit advice from a colleague during an intra-operative consult. Plaintiffs could also argue that health care providers were distracted during a procedure by improper use of smart devices. Therefore, to ensure that patients receive the best possible care and to avoid potential liabilities, it is beneficial for facilities to establish specific guidelines for the use of smart devices in the operating room.

Guidelines for Use

One of the first guidelines adopted could be a prohibition against the direct use of smart devices by those scrubbed and involved in the operative field. Cell phones, laptops, and tablets, like anything exposed to unsterile human or surface contact or carried around in a pocket or purse, can be colonized with bacteria, including but not limited to influenza, E. coli, MRSA, and C. diff.[6]

A second guideline could be a complete ban on the personal use of smart devices during procedures. This rule mainly applies to medical providers in the operating room who are not directly involved in the operative field, such as the anesthesiologist or circulating nurse. This issue is already being litigated. In one case, a Dallas anesthesiologist, sued for malpractice, acknowledged at his deposition that he routinely checked social media sites on his iPad, read electronic books, and even browsed the Internet during procedures.[7] He went so far as to post on his Facebook account *during the surgery at issue* a picture of the patient's vital signs with the caption, "Just sittin here watching the tube on Christmas morning. Ho ho ho." One can imagine the benefit plaintiff's counsel obtained when he discovered this posting. Even if it may not be considered a departure from the standard of care, the jury reaction to such a posting may significantly impact the perception of the physician.

A third guideline could be to designate one individual assigned to the operating room to be responsible for the use of the smart devices. The individual would be permitted to research issues as they arise, take photographs if necessary, respond to procedure-related messages, and arrange for phone calls and videoconferencing.

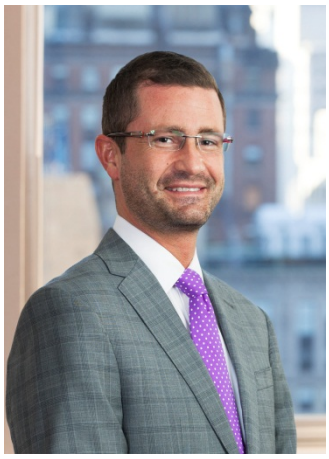
It is imperative that hospitals and ambulatory surgery centers have guidelines governing the use of smart devices in the operating room. As the Dallas anesthesiology case shows,

social media is becoming a larger and perhaps unavoidable aspect of medical malpractice cases. Plaintiffs are not the only parties at risk through the use of information gathered from their online lives. Well-informed plaintiffs' lawyers have already begun to investigate, through deposition questioning and other means, physicians' cell phone data usage and text logs as well as their Internet presence. It follows that clear liability issues are raised by treatment providers' use of Facebook, Twitter, and other social media sites, particularly in the operating room. This is without even addressing the privacy and HIPAA concerns raised by such communications and postings – an issue beyond the scope of this article.

Smart devices are everywhere. They provide unquestionable benefits to society – the ability to instant message, videoconference, record audio and video, and access databases, among countless others. However, they also can divert our attention from our primary tasks at hand and, as such, it behooves hospitals and surgical centers to establish guidelines and policies that ensures that their medical professionals and staff use smart devices in productive ways. Remember smart devices are smart. Time stamps, email communications, texts, search histories, cataloguing, and other electronic documentation can tell a story without the exchange of a single word.

References listed on page 26

About the Authors

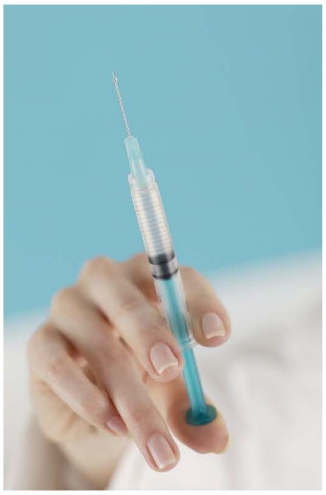


Jeffrey Hawkins is an associate in Wilson Elser's New York City office. Jeff defends physicians, hospitals, and other healthcare providers against high exposure medical malpractice claims. He is involved in all stages of litigation, including drafting and arguing motions, taking and defending depositions, court appearances, fact and expert witness interviews, trial preparation, case development, legal research, fact investigation, and lawsuit evaluation.

Jonathan Waldauer was an associate at Wilson Elser when the article was written.

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- FEE: $60/pp (light continental breakfast and lunch included in fee)
  - Continuing education for this activity is pending. See final announcement for details.
- SPEAKERS:
  - Kim New, JD, BSN, RN, Institutional Diversion Education
  - Katrina Hansen, MPH, New Hampshire Department of Health & Human Services-Div of Public Health Services
  - Laura Taylor, PhD, MCHES, New Jersey Department of Health-Communicable Disease Service
  - Barbara Montana, MD, MPH, FACP, New Jersey Department of Health-Communicable Disease Service
  - Mitch Sobel, BS Pharm, MAS FASHP, St. Joseph's Healthcare System
  - Stefanie Mozgai, BA, RN, CPM, New Jersey Department of Health-Health Facilities, Evaluation & Licensing
  - Jillian Scott, RN, MSN, New Jersey State Nurses Association
- REGISTRATION: https://goo.gl/t9DJtF

Questions? Contact Laura Taylor, PhD, MCHES at laura.taylor@doh.nj.gov

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Doreen DeVito, RN, CPHRM
Regional Risk Manager
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Doreen DeVito has served for more than 30 years as a critical care nurse. From 2008-2013 she held position as Director of Quality/Risk Management for outpatient practice at Advantage Care Physicians (formerly Staten Island Physician Practice). Since 2013, Doreen holds the position as Regional Risk Manager overseeing nine (9) outpatient sites in Staten Island and Manhattan. She is a current member of AHRMNY and obtained CPHRM designation on November 1, 2014.



Mary K. Steffany
RN, MA, ARM, CPHRM, FASHRM
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Zurich

Mary Steffany recently applied for FASHRM designation through The American Society of Healthcare Risk Management (ASHRM) on July 28, 2015. On October 26, 2015, ASHRM approved Mary's application and awarded her with FASHRM designation. Mary is the Chairperson of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) Education Committee and also serves as President-elect. Mary will begin her term as President on July 1, 2016.



Lesli Giglio, RN MPA CPHRM, CPPS
Director, Regulatory Affairs, Risk Management & Privacy Officer
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Lesli Giglio was recently awarded the Certified Professional in Patient Safety designation by the National Patient Safety Foundation. This certification is provided to health care professionals who meet competency requirements in patient safety and human factors engineering and who demonstrate the ability to apply this knowledge to effectively plan and implement patient safety initiatives. Lesli holds the Officer Secretary position with The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and also Chairs the Fundraising Committee.



Bonnie Boone
Senior Vice President
Marsh USA, New York

Bonnie was honored in 2008 as a Business Insurance Woman to Watch. This year in Celebration of Business Insurance's 10th anniversary of awards, she received the Impact Award for exceptional contributions to diversity and inclusion in the industry. Bonnie is a current member and Board of Director of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and also serves as a regular member of AHRMNY's Education Committee.



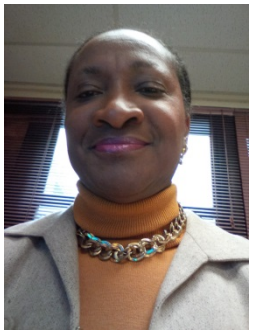
Jonathan D. Rubin, Esq.
Partner
Kaufman Borgeest & Ryan LLP

Jonathan Rubin spoke on Legal Issues Relating to Treating Dangerous Patients at the Connecticut Society for Healthcare Risk Management (CSHRM) meeting in Cromwell, CT on December 1, 2015. The Presentation covered the duty to warm, relevant and recent Connecticut cases and statutes, New York's SAFE Act and other topical issues and news impacting mental health care providers.



Tiffany Wickes-DeMillio, RN CPHRM, LNC
Risk Manager
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Tiffany Wickes-DeMillio was awarded the Certified Professional in Healthcare Risk Management certificate in October of 2015. She currently works as the Risk Manager at St. Francis Hospital where she assisted in the development of an Electronic Incident Reporting System. She obtained her certification as a Legal Nurse Consultant in June of 2000 from Hofstra University and will be graduating from Adelphi University with a Masters in Business Administration specializing in Healthcare Administration in May of 2016. Tiffany is a current member of AHRMNY and also serves as a member of the Fundraising Committee.



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How High is the Risk to Your Organization? Risk Management and Medical Marijuana

By Yulian Shtern, Esq., Elizabeth Kase, Esq., Hindi Mermelstein, M.D., and Carolyn Reinach Wolf, Esq.

Abstract

Marijuana, cannabis sativa, is a pharmacologically active plant that can alleviate a number of distressing symptoms caused by a wide variety of serious medical conditions. Its use, even when legalized by state law, is fraught with legal and medical challenges. The New York Compassionate Care Act ("CCA") regulates the distribution and use of medical marijuana for New York State physicians, health care providers, institutions, and patients. In this article we will present an overview of the law, its risks, liabilities and applications from both the legal and medical perspective.

Introduction

New York's medical marijuana program went into effect earlier this year. It is considered by many to be the most restrictive marijuana program in the United States. The CCA governs various aspects of medical marijuana use, cultivation, dispensing and consumption. New York's CCA also establishes guidelines on the dosages and strengths of medical marijuana, the qualifying symptoms and conditions, and requirements for physicians to become eligible to certify patients for medical marijuana consumption.

In addition to New York's regulatory restrictions, practitioners, risk-managers and institutions must also navigate through the contradictory Federal legal system. Notwithstanding the legalization of marijuana in 23 states and its growing acceptance among the medical community, the Federal Government still categorizes marijuana as a Schedule I controlled substance. This means that the production, sale or use of marijuana, whether recreationally or medically, will violate the Federal Controlled Substances Act of 1970.[1] Though Federal prosecutions have been few and far between, this legal dichotomy can add to the risk management and compliance concerns for many health care providers and institutions.

While the demand from the patient community remains high, to date few patients have obtained medical marijuana in New York State. The complexities of implementation of the CCA have contributed to the hesitation of medical practitioners, health care providers and institutions to participate. This creates a *de facto* situation that threatens access to treatment for the very patients the law sought to help. With the growing acceptance and presence of marijuana in medicine, it is imperative for providers, risk managers and hospital management to identify and address the various risk areas and liabilities associated with medical marijuana.

The Medicine of Medical Marijuana

Marijuana contains more than 60 pharmacologically active substances. They interface with receptors located throughout the body with the highest concentration of receptors contained in the brain and spinal cord. The clinical effect depends on which active element of the plant is prevalent in a particular strain. For example the euphoria that is associated with marijuana is related to the THC9 component. Accordingly, the potency of medical marijuana is measured based on the ratio of THC9 to cannabinoid components. An individual's response to any form of marijuana is dependent on several factors including the specific preparation, dose, patient characteristics and total treatment regimen.



As with all biologically active agents, there can be adverse effects. Like alcohol, marijuana commonly produces mild cognitive impairment and affects judgment. Many patients may be taking other medications such as pain medicines or muscle relaxants that can amplify these effects and increase the risk of machine operated accidents. Marijuana can also acutely affect blood pressure and cardiac function, which for medically compromised populations, can increase the risk of hazardous conditions. Chronic use of marijuana can have more severe sequelae such as the neurocognitive effect of amotivation. The pulmonary damage from smoking marijuana, common in recreational use, may supersede that of tobacco cigarettes. Therefore, the New York medical marijuana program does not permit smoking marijuana products. In vulnerable populations, including the young or those at high risk for developing serious psychiatric illnesses, the use of marijuana can alter brain function, hasten the onset of illness and may affect overall outcomes.

If a physician determines that a patient can benefit from medical marijuana, completing the required New York State forms with the patient can serve as a springboard to an enhanced discussion regarding the newly available products. Good assessment, shared treatment planning and decisions making, careful follow up and documentation are the tenets of good medical care and are applicable to this area as well.

The CCA limits access to medical marijuana to those patients who are diagnosed with severe, debilitating or life threatening conditions as defined by New York State law. At present, they include cancer, HIV positivity or AIDS, amyolateral sclerosis, Parkinson's disease, Huntington's disease, multiple sclerosis, damage to the spinal cord resulting in intractable spasticity (confirmed), epilepsy, inflammatory bowel disease, and neuropathy. In addition, the patient must suffer from cachexia (wasting syndrome), pain (severe or chronic), nausea (severe), seizures, or muscle spasms (severe or persistent). While the CCA limits provider registration to only those physicians who treat such conditions, in practice, patients who suffer from such conditions and symptoms are usually under the care of a wide variety of practitioners in a wide variety of specialties.

The Lack of Education and Training Resources Available

Traditionally physicians and other health care providers have had little, if any, training regarding cannabis and the endocannabinoid system. There is also a gap in the reference material available to physicians on this subject. The lack of education and resources impedes the ability of practitioners to gain comfort in recommending medical marijuana. Practitioners are also generally unfamiliar with the pharmacology, indications, contraindications, and potential drug interactions of marijuana use.

The void in education and resources concerning marijuana is somewhat attributable to the lack of research conducted due to marijuana's classification as an illicit substance under Federal law. Since the enactment of the Comprehensive Drug Abuse Prevent and Control Act in 1970, the Federal Government has classified marijuana as a Schedule I controlled substance, which in turn placed extraordinary burdens on efforts to research marijuana. These burdens exist even to this day. Prospective marijuana researchers must receive approval from four Federal administrative entities: the Food and Drug Administration ("FDA"), the National Institute of Drug Abuse ("NIDA"), the Department of Health and Human Services ("HHS") and the Drug Enforcement Agency ("DEA").[2] This restrictive process of obtaining Federal approval has deterred and even prevented research into marijuana.

Within the past decade, there has been a growing body of research from around the world reflecting increased acceptance of marijuana in medicine, with a few of the studies included in standard medical literature. Such research has expanded the educational resources available to physicians who recommend medical marijuana in the United States. However, such research has its limitations, as it is based on observations made from foreign grown strains of marijuana or restricted federally produced plant-products, which may have differing effects from marijuana products available in New York. In addition, such research has not made its way into mainstream medical educational training courses or reference books. Thus, the education and resources for physicians who may recommend marijuana remains limited.

To address this fundamental limitation, New York State mandates physicians who wish to participate in the medical marijuana program to complete a specific state-sanctioned educational course. The mandatory educational course is four hours in duration and its content includes the pharmacology of marijuana, contraindications, side effects, adverse reactions, overdose prevention, drug interactions, dosing, routes of administration, risks and benefits, warnings and precautions, and abuse and dependence. While this requirement helps to ensure that physicians who certify patients are well-educated on medical marijuana, other professionals who may treat the same patient are under no legal obligation to complete similar training. Accordingly, such practitioners may lack adequate expertise to understand how marijuana can affect the patient and their recommended treatment plan.

Standards of Care and Professional Liability Issues

The integration of marijuana into the field of medicine raises serious professional liability questions. What degree of negligence liability does a hospital and/or a physician face for adverse patient outcomes that stem from the medical use of marijuana? What steps can be taken to mitigate liability? How will your current professional liability insurance carriers react to your medical marijuana policies? Do you have a duty to notify your carriers? Will your carriers cover any marijuana related incidents or will they disclaim coverage due to marijuana's legal status? Do you need supplemental or gap insurance coverage?

The answers to these questions are unclear as medical marijuana programs around the nation are relatively new and there have been few professional liability cases decided on the topic. In addition, there is little to no guidance as to the accepted standards of medical care, a key component in analyzing a medical malpractice action, with respect to medical marijuana.

While "the jury is still out" as to the accepted standards of care, there are certain guidelines that can be deduced from existing medical and legal literature. For instance, medical literature suggests that a practitioner who recommends marijuana simply to accede to patient demands does not comport with ethical and medical standards of care:

> [s]imply acceding to patient demands for a treatment on the basis of popular advocacy, without comprehensive knowledge of an agent, does not adhere to the ethical standards of medical practice... [and] any recommended therapy requires proof of concept by sound scientific study that attests to both efficacy and safety.[3]

In addition, it is a criminal offense in New York and certain other states to recommend medical marijuana with reasonable grounds to know that a patient has no medical need for it or will not be using it to treat a qualifying serious medical condition.[4] Such an offense is punishable as a felony and can lead to negligence *per se* liability.

We can also look to cases and standards of care established in other states, which have a relatively longer history of sanctioned medical marijuana use. For instance, the Medical Board of California issued a press release, setting forth accepted medical standards when recommending marijuana.[5] The Medical Board stated that these accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication and include the following factors: (1) history and an appropriate prior examination of the patient; (2) development of a treatment plan with objectives; (3) provision of appropriate consent including discussion of side effects; (4) periodic review of the treatment's efficacy; (5) consultation, as necessary; and (6) proper record keeping and maintenance thereof that supports the decision to recommend the use of marijuana for medical purposes.[6]



Forms of Medicinal Cannabis

Risk managers and hospital executives would be wise to address these issues with their liability insurance carriers and review their insurance contracts carefully. Several liability insurance companies in the United States have already included exclusionary language in their contracts or their policies and procedures, specifically excluding "non-FDA approved medications or devices."[7] To address this lack of coverage, several companies have explored offering a supplemental or gap insurance policy specifically covering marijuana related professional liability. These issues and potential solutions should be explored to avoid gaps in coverage.

Insurance Eligibility and Reimbursement Issues

It is clear that Medicare, Medicaid and most health insurance companies have refused to pay for the costs of medical marijuana. Marijuana's status as a Schedule I substance makes it medically unnecessary by definition and thus non-reimbursable by third-party payors. In furtherance of this long-standing policy, New York and several other states enacted statutory provisions allowing insurers to freely refuse to provide coverage for medical marijuana.[8]

However, it is unclear whether any other items or services associated with a medical marijuana certification or recommendation will also be excluded from reimbursement. If a patient comes in for an office visit and subsequently receives a recommendation by his or her treating physician, can the hospital or physician bill for the evaluation? What if a physician orders laboratory tests for a patient using medical marijuana to monitor how the patient is responding to marijuana? Do the laboratory tests become excluded from coverage?

Hospitals and providers will have to determine whether certifying patients for medical marijuana use will jeopardize their ability to seek reimbursement from third-party payors and their continued eligibility to participate in government programs and grants.

Regulatory Compliance and Enforcement Risks

Physicians and institutions may not be comfortable with the medical marijuana program. Marijuana has been culturally treated as taboo in the United States and remains a Schedule I controlled substance. Physicians cannot legally "prescribe" marijuana, but, rather may only "recommend" it with guidelines as to type, potency and dosing. However, the dispensaries and the New York State Department of Health exercise considerable control over the products that are ultimately developed and dispensed to end-users. The marijuana products in New York may be inconsistent, as they are separately produced by five different companies and without the FDA-like quality control standards in place. New York State has also issued strict adverse event reporting rules for physicians, adding to the other regulatory burdens.

Marijuana's status as an illicit drug under Federal law raises potential risk areas for an organization's compliance efforts. Hospitals are required to certify compliance with all Federal and state law during various events, particularly when submitting claims for reimbursement to Medicare or Medicaid[9] or in its cost reports. In addition, hospitals must adhere to strict requirements to maintain their DEA and other narcotics licenses. Hospital risk managers, compliance personnel and attorneys will need to scrutinize whether the hospital's participation in a medical marijuana program will impact its compliance efforts.

It is unclear whether institutions will receive the same protection as physicians for "recommending" marijuana. In 1996, following the enactment of the first medical marijuana program in California, the Federal Government threatened that it would prosecute physicians for participating in the program with penalties including revocation of their DEA licenses and denial of participation in Medicare and Medicaid.[10] In response to this declaration, several physicians filed a lawsuit in U.S. District Court in the Northern District of California.[11] In *Conant v. Walters*, these physicians successfully argued that the physicians' recommendations are protected by the First Amendment to the United States Constitution. The Court recognized the significance of the doctor-patient relationship and the need under the First Amendment to protect physicians' opinions with respect to the care and treatment required for a particular patient. In furtherance of this First Amendment right, the Court prohibited the Federal Government from prosecuting physicians solely for the expression of their medical opinions.

While the *Conant v. Walters* decision protects physicians' opinions, it does not offer a blanket protection from the Federal Government. Following the *Conant v. Walters* decision, the Federal Government successfully prosecuted patients and other individuals involved in the medical marijuana industry.[12] Under President Barack Obama's administration, Federal enforcement against marijuana program participants has decreased.[13] The United States Attorney General's office issued several policy memos, essentially requiring Federal prosecutors to prioritize their resources and to avoid investigating individuals and entities that follow the strong and effective regulatory and enforcement systems implemented under state law.

To date, there have not been any significant enforcement efforts against hospitals that participated in a state's medical marijuana program. However, significant risks of enforcement can arise, depending on the degree that the hospital participates in such a program, the hospital's compliance with the respective state regulatory enforcement scheme and the safeguards that the hospital puts in place. Such risks include enforcement actions from the DEA and the Centers for Medicare and Medicaid Services for non-compliance with regulatory and legal requirements.

Conclusion

We anticipate that as the research and support for the legalization of marijuana progresses, the political and legal atmosphere will also adapt to alleviate some of the risk areas identified in this article. In March of 2015, Congress made initial steps to solve some of these problems, when Senators Corey Booker (D-NJ), Rand Paul (R-KY) and Kirsten Gillibrand (D-NY) co-sponsored the Compassionate Access, Research Expansion and Respect States (CARERS) Act of 2015. The CARERS Act was a monumental bi-partisan bill that would, among other things, reclassify marijuana from Schedule I to Schedule II, allowing for its prescription and use under Federal Law. While the CARERS Act was not enacted into law, it showed promising support from members of the Democratic and Republican parties, giving hope to patients and providers around the nation. While we wait for the inevitable reconciliation between Federal and state law, it is an opportune time to become more educated about the legal and medical issues surrounding medical marijuana.

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President's Message Continued……

Congratulations to Lesli Giglio and Gehan Soliman on tremendous success with the fundraising committee. Their tireless efforts make it possible for AHRMNY to produce our programs at a reasonable cost. We also appreciate the efforts of our Treasurer, Rob Marshall and Assistant Treasurer Dylan Braverman for their efforts to make sure our finances are maintained in a professional manner.

The Publications Committee under Linda Foy and Ruth Nayko continue to put out a product that is well regarded at the national level and continues lead in quality peer reviewed articles on cutting edge topics important to the risk management community. The "Risky Business" column and "Member Spotlight" have proven to be popular additions.

The nominating committee has been working to prepare for elections later this spring.

We look forward to a terrific annual meeting at our new venue, the Holiday Inn Midtown located at 57th Street between 9th and 10th Avenues. Mary Steffany and the Education Committee have been hard at work producing what will be an exceptional event featuring group events and four break-out sessions on June 3, 2016. We look forward to seeing you there!

I wish to thank the board and emeritus members, as well as the membership, for your support and involvement during my term.

Best Regards,

Robert D. Martin
President
2015-2016

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