Texas Medical Board Continues Fight Against Practice of Telemedicine, Cites Patient Safety as Motivation

Last month, the Texas Medical Board (TMB) asked the 5th U.S. Circuit Court of Appeals to block a lawsuit challenging its recently instituted restrictions on the practice of telemedicine. Specifically, it wants the appeals court to overturn a federal district court's decision to let an antitrust case proceed against TMB by Teladoc, the nation's largest telehealth company, which provides around-the-clock access to medical care via telephone or interactive video for people experiencing nonemergency medical issues.

Texas regulators have spent years trying to rein in the practice of telemedicine, arguing that the practice degrades the quality of the physician-patient relationship and threatens patient safety. In April of 2015, TMB approved changes to its telemedicine rules that would prohibit the use of email, electronic text, chat, telephonic evaluation or consultation to establish a physician-patient relationship (see MEDICAL LIABILITY MONITOR, May 2015). Under the amended rules, which went into effect in June of 2015, physicians were prohibited from prescribing medications over the telephone to a patient they have never met face-to-face.

Lewisville, Texas-based Teladoc sued the TMB, arguing its new rules violate antitrust laws because it restricts the company's ability to compete, resulting in higher prices and reduced access to healthcare. U.S. District Judge Robert Pitman issued an injunction against the enforcement of TMB's new telemedicine rules in June of 2015 (see MEDICAL LIABILITY MONITOR, July 2015), indicating that Teladoc is likely to succeed in showing that the telemedicine rule revisions by TMB illegally limit competition by requiring a face-to-face visit before physicians are allowed to prescribe medication to patients.

In December, Judge Pitman officially rejected TMB's arguments for dismissing the case. "The medical board claims to be motivated by concerns about patient safety. However, they failed to produce evidence during their rulemaking process to support the position that telehealth poses a patient safety risk," said Adam Vandervoot, chief legal officer of Teladoc. "However, they failed to produce evidence during their rulemaking process to support the position that telehealth poses a patient safety risk. Additionally, the board offered no evidence of any harm done by telehealth during the federal court proceeding in opposition to Teladoc's request for an injunction."

Proponents of telemedicine argue the practice actually lowers malpractice risks because the majority of medical liability claims in primary care centers on communication barriers. Being available to patients by telephone and email 24 hours a day, seven days a week, significantly reduces those communication barriers. Research by the University of Texas Medical Branch Center for Telehealth Research & Policy shows that access to telemedicine reduces nonemergency emergency room visits by 50 percent, and telemedicine patients report satisfaction rates well above 90 percent.

Those arguing against the new Texas rules restricting telemedicine contend that the state already ranks 51 out of 51 states (including Washington, D.C.) for access to medical care, disproportionately harming rural, poor and low-income families. Telemedicine, they argue, is a commonsense way for Texas to address the strain on its health-care system and extend access to care to the state's underserved rural communities.

"Not only is telehealth the wave of the future, but Texas physicians have been treating patients without a prior in-person visit for decades," said Jason Gorevic, chief executive officer of Teladoc. "We are happy to be able to continue serving Texas citizens, employers and health plans by enabling them to access high-quality care in a cost-effective manner."
STUDY FINDS OPIOID PRESCRIBING GUIDELINES SIGNIFICANTLY DECREASES PRESCRIPTION RATES FOR MINOR, CHRONIC COMPLAINTS

Emergency medicine physicians at Temple University Hospital have found that an opioid prescribing guideline had an immediate and sustained impact on opioid prescribing rates for minor conditions and chronic noncancer pain in an acute care setting. The results of the study were published in the January 2016 Journal of Emergency Medicine.

The United States is in the midst of a crisis regarding the abuse of prescription drug opioids. According to the Centers for Disease Control and Prevention, the U.S. death rate from prescription opioid overdose now exceeds the combined death rates from heroin and cocaine.

Acute care settings are a major source of opioid prescriptions, often for minor conditions and chronic non-cancer pain. Emergency physicians have identified themselves as targets for patients who seek opioids for non-medical purposes. Given the difficulty in striking a balance that provides appropriate analgesia for patients without creating or exacerbating drug dependence, the U.S. Department of Health & Human Services recommends the synthesis of pain management guidelines and the creation of clinical decision support tools.

Temple University Hospital (TUH) and Temple University Hospital-Episcopal Campus (TUH-Episcopal) were among those that created a guideline for prescribing opioids in order to maximize safety and avoid misuse.

"Emergency physicians and other acute care providers can use various tools to promote the rational prescribing of dangerous opioid medications. In contrast to electronic prescription drug monitoring programs, which show promise but require significant infrastructure and regulation, an easily implemented guideline empowers physicians and protects patients from the well-documented dangers of opioid misuse." according to an expert. The retrospective observational study compared the rate of opioid prescriptions for dental, neck/back and chronic noncancer pain before and after adoption of the guideline in January 2013. The research team used data from 13,187 patients aged 18 years or older who met the diagnosis criteria and were discharged from the emergency departments at TUH and TUH-Episcopal.

The team also administered a survey to the faculty emergency medicine physicians who were practicing in the two emergency departments. Results showed the prescribing guideline had an immediate and sustained impact in reducing opioid prescribing rates for all age groups and for each of the three categories of complaints with a high degree of statistical significance. Also, 100 percent of physicians surveyed supported implementation of the voluntary guideline. Most (97 percent) felt the guideline had facilitated discussions with patients when opioids were being withheld and nearly three-quarters of respondents reported encountering less hostility from patients since adoption of the guideline.

"Emergency physicians and other acute care providers can use various tools to promote the rational prescribing of dangerous opioid medications," added del Portal. "In contrast to electronic prescription drug monitoring programs, which show promise but require significant infrastructure and regulation—and are as yet unavailable to prescribers in Pennsylvania—an easily implemented guideline empowers physicians and protects patients from the well-documented dangers of opioid misuse."

Other physicians contributing to the study include Robert M. McNamara, MD, Megan E. Healy, MD, and Wayne A. Satz, MD, from the Department of Emergency Medicine at the Lewis Katz School of Medicine.
CONGRESSIONAL REPUBLICANS GET PPACA REPEAL TO PRESIDENT’S DESK, PRESIDENT VETOES

A fter more than 50 attempts to repeal all or parts of the Patient Protection & Affordable Care Act (PPACA) of 2010, each one suffocating in the U.S. Senate at the hands of a filibuster, the Republican-controlled Congress last month passed the Restoring Americans’ Healthcare Freedom Reconciliation Act (RAHGRA), which would gut major budgetary provisions of PPACA as well as end federal funding of Planned Parenthood. President Barack Obama vetoed the legislation.

Because RAHGRA passed the Senate via a legislative process known as budget reconciliation, which only requires a simple majority to pass and cannot be filibustered, the Act’s content was restricted to budgetary concerns.

As such, the Act would not have repealed PPACA in its entirety. It is the first time legislation intended to damage PPACA has reached the President’s desk.

Instead of a full repeal, RAHGRA went after some of the key features of PPACA that are necessary to make the whole system work. The RAHGRA legislation would restrict the federal government from operating healthcare exchanges; phase-out funding for subsidies to help lower and middle-income individuals afford insurance through the healthcare exchanges; eliminate tax penalties for individuals who do not purchase health insurance and employers with 50 or more employees who do not provide insurance plans; eliminate taxes on medical devices and the so-called “Cadillac” on their most expensive healthcare plans; and phaseout the expansion of Medicaid over a two-year period.

The reconciliation process did not allow RAHGRA to offer a replacement for PPACA, but in February of 2015, U.S. Sen. Richard Burr, R-N.C., and Rep. Fred Upton introduced the Patient Choice, Affordability, Responsibility & Empowerment (Patient CARE) Act, which its authors offered as an alternative to PPACA and promise would reduce healthcare costs and increase access to care. The Patient CARE Act would repeal PPACA’s requirement on individuals and employers to purchase healthcare coverage, rescind the ability for children to remain on their parents’ insurance until age 26, defund the state and federal insurance markets launched under the PPACA, eliminate insurers’ obligation to cover preexisting conditions and reinstate annual limits of coverage.

In place of PPACA, the Patient CARE Act would offer tax credits to purchase health insurance for individuals earning up to 300 percent of the poverty line, create federal caps on noneconomic damages, limit attorney’s fees and fund the program via a new tax on Americans who receive health insurance coverage through their employer.

INDIANA FAILS TO RAISE MEDMAL DAMAGE CAP

A bill in the Indiana Senate that would have increased the state’s current cap on recoverable damages in medical malpractice cases by $400,000, to $1.65 million, then allow the cap to increase every four years based on the national inflation rate, died in committee last month. The Indiana cap restricts the amount of all recoverable damages, not just noneconomic damages.

Sen. Brent Steele, who sponsored the legislation, said he wants to protect the malpractice cap from court challenges. The current $1.25 million cap was set 17 years ago, and has never been adjusted for inflation.

“There is a real concern that this whole act is going to be declared unconstitutional due to the fact that it no longer addresses the legitimate damages of a claimant in an equitable fashion,” Steele told the Indianapolis Business Journal.

The Indiana Medical Association lobbied against raising the cap, arguing that the increase would drive-up costs for the state’s healthcare community. The Indiana Trial Lawyers Association supported raising the damage cap as a good start, but argued there should be no cap on recoverable damages.

NORCAL Mutual Insurance Co. completed its acquisition of FD Insurance (see MLM, December 2015), a Florida-domiciled medical malpractice insurer. The acquisition expands NORCAL’s national footprint and establishes Jacksonville, Fla., as the company’s new Southeast regional office.

The Centers for Medicare & Medicaid Services (CMS) has begun a three-year pilot project to improve assessment of infection control and prevent regulations in nursing homes, hospitals and during transitions of care. All surveys during the pilot will be educational surveys, meaning no citation will be issued. New surveyor tools and processes will be developed and tested during the pilot. Ten pilot surveys to be conducted in fiscal year 2016 will occur in nursing homes. Surveys in fiscal years 2017 and 2018 will be conducted in nursing homes and hospitals. It’s worth noting that, although no citations will be issued, if an immediate Jeopardy deficiency is noted, a referral to the CMS Regional Office will be made.

AXIS Healthcare has launched a new medical catastrophe (contagion) business interruption product for hospitals. The coverage protects medical entities in the U.S. and Canada against a loss of revenue caused by the outbreak of a contagious disease. The policy responds when the contagion directly results in any one of four triggers: a governmental quarantine of a hospital; if 25 percent or more of the medical personnel do not come to work; a 25 percent or more reduction in inpatient stays; or a 25 percent or more reduction in emergency room visits. The maximum length of coverage is limited to 12 months from the date the coverage is triggered.

A recently published Mayo Clinic study indicates that burnout among U.S. physicians is getting worse. An update from a three-year study evaluating burnout and work-life balance shows that American physicians are worse off today than they were three years earlier. These dimensions remained largely unchanged among U.S. workers in general, resulting in a widening gap between physicians and U.S. workers in other fields.
CANDIDATE MONITOR
FEBRUARY 2016 VOL. 41, NO 2

CAN AN INJURED THIRD PARTY SUE A HOSPITAL FOR MEDICAL MALPRACTICE?

by Michael C. Kiszek, Esq.

Consider the following scenario: A patient was given pain medication in a hospital emergency room which impairs the ability to operate a motor vehicle. The doctor who administers the medication discharges the patient from the hospital without advising her not to drive while on the medication. On the way home from the hospital, the patient, still under the influence of the pain medication, veers into oncoming traffic, causing an accident. Can an individual injured in that motor vehicle accident sue the doctor at the hospital who administered pain medication without informing the patient not to drive? The New York Court of Appeals recently said yes.

The case presented an interesting legal issue: can a third party, injured by a patient, sue a medical provider under the theory that the provider’s malpractice caused the injury, even thought the injured party had no special relationship with the medical providers? In a 4-2 decision, a New York Court of Appeals ruled that the claim in Davis was permissible.

Appellate Division affirmed the dismissal of the suit. The Appellate Division explained that there was no duty on the part of the defendant medical providers to prevent injuries to third parties. Davis then appealed to the state’s highest court, the Court of Appeals.

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The Court of Appeals ruled that the claim in Davis was permissible.

The Court stated that a third party, injured by an impaired patient, can sue a physician for failing to warn the patient that medications will impair the patient’s driving ability. Writing for the majority, Justice Eugene Fahey explained that the doctor in this case "by taking the affirmative step of administering the medication ... without warning Walsh about the disorienting effect of those drugs a peril affecting every motorist in Walsh's vicinity," Justice Fahey went on to explain that the doctor and hospital were the only ones in a position to warn Walsh.

It is noted that both the Medical Society of the State of New York and the American Medical Association filed an amicus curiae brief opposing the Court's decision. They argued that such a ruling would open the floodgates and expose medical providers to a practically limitless number of lawsuits. According to Justice Fahey, however, physicians already had a duty to warn their patients about the dangerous side effects of medications they are being given and, therefore, this ruling does not impose any additional obligation on physicians.

Michael C. Kiszek is an associate at Stark & Stark, a law firm with offices in New York, New Jersey and Pennsylvania.

PENN INSURANCE DEPT. APPROVES MMC OF NC TO ASSUME POLICIES FROM HPX

Medical Mutual Insurance Co. of North Carolina, a provider of medical professional liability insurance in the Southeast, and Healthcare Providers Insurance Exchange (HPX), an insurer of medical professional liability in the Mid-Atlantic area, signed a definitive agreement under which Medical Mutual will acquire the rights, title, interests in and the policies of HPX. Last month, the Pennsylvania Department of Insurance approved the transfer of HPX’s estimated $30 million of medical malpractice insurance policies to the North Carolina company. The deal grows Medical Mutual’s insured count by 20 percent.

Joining Medical Mutual advances HPX as the leading brand for medical professional liability insurance in the Mid-Atlantic and preserves the physician-owned, customer-centricity of HPX’s insurance platform," said Tom Gaudioso, HPX vice chairman and CEO. "With so much insurance M&A focused on cost, this transaction is unique because it is precipitated by a strategy to build worth and unlock value for our current and future members. Through an intense and diligent search, we found Medical Mutual to be the most symbiotic and synergistic partner. There is an obvious fit between HPX and Medical Mutual that will be apparent to our policyholders as we deliver tangible benefits that will ensure their long-term success.

"The addition of HPX policyholders to Medical Mutual will provide benefits to both sides," said Dale Jenkins, Medical Mutual CEO. "The partnership expands Medical Mutual’s geographic footprint into the Mid-Atlantic States and continues the HPX legacy of providing outstanding service, products and resources to policyholders. Medical Mutual and HPX share a culture and philosophy focused on serving physician members."

Medical Mutual offered employment to a majority of the HPX employees upon completion of the deal. "We are delighted to welcome a very experienced and talented team of HPX professionals, in addition to their clients, agents and brokers to Medical Mutual," Jenkins said. "As we continue to witness the expansion and growth of regional physician practices throughout the country, we are excited to work with their agents and brokers to build upon the HPX franchise and expand the reach of Medical Mutual into the Mid-Atlantic region."
AS HEALTHCARE COSTS RISE IN 2016, CAN WE EXPECT PHYSICIANS’ MEDICAL PROFESSIONAL LIABILITY RISKS TO INCREASE AS WELL?

by Jeffrey D. Brunken

A report from the Commonwealth Fund—a private foundation dedicated to promoting a high-performing healthcare system that achieves better access, improved quality and greater efficiency—showed that 25 percent of Americans have a high health cost burden relative to their incomes. This report was based on a survey of Americans who have private health insurance and who are mainly covered by employer-sponsored health plans.

This 25 percent of Americans were not enrolled in the lowest-cost bronze plans purchased from state Health Insurance Marketplace. They were presumably insured through employer-provided plans that typically have lower-deductible and co-pay provisions than the state marketplace options.

So what does this problem have to do with physician liability risks? One could argue that consumers who bear a higher out-of-pocket cost for healthcare will have higher expectations. Any dissatisfaction could lead to malpractice suits. If that happens, it is unfair to the physician. But it points to the fact that most patients view their physician as the face of the healthcare system. Those patients who struggle to pay will likely make no distinction between the healthcare provider and the healthcare insurance and system behind it. Patients having difficulty paying for healthcare may also become a collection problem for the physicians. Higher deductibles and co-pays are the trend among employer-sponsored health plans. The result will be a higher number of patients struggling with the increased burden. Any risk the physicians already have with collection efforts will only be compounded if there is any level of patient dissatisfaction. It’s no surprise that among those surveyed, adults with low incomes struggled the most, the Commonwealth Fund reported. More than half of all adults with low incomes had high health-cost burdens, the report showed.

Higher healthcare costs can also impact patients’ compliance with physician-care recommendations. The same survey suggests that high out-of-pocket payments have negative effects on many patients’ willingness to seek needed healthcare and fill their prescriptions. That means the health conditions of these patients could suffer, which may drive up their healthcare costs. Unhealthy patients present higher-risk scenarios for the physician providing care. The survey also highlighted the troubling level of confusion healthcare consumers have about which services were free and which ones one would count toward their deductibles. This could result in patients skipping preventive care visits, leading to an unhealthy patient population and high-risk healthcare scenarios.

Physician practices now must collect larger sums from patients. In essence, doctors and their staff members are becoming debt collectors, a factor that can further strain physician-patient relations and, again, raise the chance of a medical malpractice lawsuit.

Another survey found similar results, but offered even grimmer news. In a poll conducted by The New York Times and the Kaiser Family Foundation, 20 percent of people under age 65 had health insurance but reported having trouble paying medical bills in the past year. Among those with such problems, 63 percent used up all or most of their savings, 42 percent took on an extra job or more work hours; 14 percent moved or took in roommates; and 11 percent turned to charity, the Times reported.

For physicians, this news may mean that increased healthcare costs may lead to greater patient dissatisfaction, as a report last year from the Deloitte Center for Health Care Solutions showed.

At a conference last fall, one of the speakers warned insurers that when patients pay for their own care, such as those in these two surveys, their expectations about quality rise. “To the extent that patients are unhappy with their healthcare experience and pay out of their pocket, the likelihood of a lawsuit rises,” we were told.

What’s more, physician practices now must collect larger sums from patients. In essence, doctors and their staff members are becoming debt collectors, a factor that can further strain physician-patient relations and, again, raise the chance of a medical malpractice lawsuit.

In the Times article about the survey, Margaret Sanger-Katz reported: “We found that medical bills don’t just keep people from filling prescriptions and scheduling doctors’ visits. They can also prompt deep financial and personal sacrifices, affecting their housing, employment, credit and daily lives.”

As we have often seen, deep financial problems commonly drive patients to file lawsuits.

Having said all that about one potential risk, there is one more liability risk that physicians must address this year if they haven’t

CONTINUED ON PAGE 7
MISSION SENATE PASSES TIGHTER GUIDELINES FOR EXPERT TESTIMONY, MISSOURI SUPREME COURT REVISITS NONECONOMIC DAMAGE CAPS

Last month, the Missouri Senate passed SB 591, which would align the state's standards for providing expert witness testimony to those of the updated Daubert Standard, which has been adopted by the federal court system and a majority of other states.

The Daubert Standard is a rule of evidence that allows judges to act as gatekeepers so juries are not subjected to irrelevant or unreliable testimony. SB 591 does not affect the standards used for admitting expert testimony in cases assigned to probate court, juvenile court or family court, or in actions involving divorce, marriage, adoption, child support orders or protective orders.

"Missouri's unfair and outdated civil judicial system has forced businesses and job creators out of the state," said Senate Leader Ron Richard. "I believe by addressing some basic, commonsense reforms, we are building a better business environment and improving our state's litigation climate."

SB 591 sponsor Sen. Mike Parson said updating to the Daubert Standard will help improve the reliability of expert testimony.

"We need a commonsense basic standard to ensure that judges act as gatekeepers so juries are given reliable, factual evidence," said Sen. Mike Parson. "Expert witnesses have the ability to significantly influence the outcome of cases. If someone says they are an expert, they better be a qualified expert. The bill clarifies the standard and adds certainty, consistency and fairness for trustworthy testimony."

SB 591 now moves to the Missouri House of Representatives for consideration.

In related news, the Missouri Supreme Court is hearing a case that could determine whether wrongful death should fall under the state's law that limits how much can be received in noneconomic damages in medical malpractice lawsuits.

The case involves the family of Shannon Dodson, who died in 2011 after heart surgery at Mercy Hospital in St. Louis, Missouri. Their lawyer argued that capping damages is unconstitutional as they serve to compensate for other forms of harm besides medical fees, lost earnings or other measurable economic damages.

"Placing a limit on damages disregards the tremendous suffering that patients and their families undergo due to the irresponsible actions of doctors and other medical staff," said Charles James, an attorney in St. Peters, Mo., whose firm specializes in personal injury law. "Hospitals and physicians should be held accountable for their actions so that they do not repeat them."

Dodson's family was awarded $9 million in noneconomic damages in December 2013. However, a trial court reduced the amount to $350,000 per state laws. Gov. Jay Nixon signed a bill capping such damages in medical malpractice cases in 2015. The new law comes after the Missouri Supreme Court's 2012 ruling that deems limits on noneconomic damages unconstitutional.

The court invalidated the previous caps that had been in place since 2005.

The Dodson case raises the issue of whether the limits on damages should remain in a wrongful death case. The family's attorney argued that while there is a precedent in common law for medical malpractice awards involving personal injury, the limits do not apply to wrongful death cases. He said there should be different policies in wrongful death and personal injury suits. Supreme Court Judges questioned whether it makes sense to only restrict damages in personal injury cases in which the patient survives but not in wrongful death cases.

CJ&D RELEASES NEW BRIEFING BOOK: MEDICAL MALPRACTICE BY THE NUMBERS

The Center for Justice & Democracy (CJ&D) at New York Law School recently released its newly updated briefing book, Medical Malpractice: By the Numbers. The book is the fifth update since CJ&D first began compiling the latest statistics and research on issues related to medical malpractice. It is a fully-sourced volume that has expanded to 128 pages with nearly 600 footnotes linking to original sources. Principal authors are Emily Gottlieb, CJ&D's deputy director for law and policy, and Joanna Doroshow, CJ&D executive director.

Topics include medical malpractice litigation, healthcare costs and defensive medicine, physician supply and access to healthcare, medical malpractice insurance, patient safety and special problems for veterans and military families.

Among the many new research findings in this volume are:

* Medical malpractice cases constitute only three percent of tort cases. Explains researchers from the National Center for State Courts, "Although medical malpractice and product liability cases often generate a great deal of attention and criticism, they comprise only five percent of tort caseloads (less than one percent of the total civil caseload)." Of medical malpractice cases, very few—only 3 to 9 percent—are resolved by juries.
* While hundreds of thousands of patients die from medical errors each year, making this the third leading cause of death in America (not to mention causing huge numbers of serious injuries), only 8,551 medical malpractice payments were made on behalf of physicians in 2014, and only 5,288 disciplinary actions were taken "that restricted, suspended, revoked or denied physicians' clinical privileges or membership in a health care entity.'
* Among doctors still listed as eligible to bill Medicare as of March 2013 were "147 who had received a final adverse action from a state medical board for crimes against persons, financial crimes, and other types of felonies."
* Diagnostic medical errors, which most people experience at least once in their life, are almost twice as likely to result in death compared to other medical errors.
* In half of all surgical procedures, there is some sort of medication error or drug adverse event. Surgeons with the highest complication rates perform surgeries every day—a problem many hospitals fail to track.
* Robots used in minimally invasive surgeries "were involved in 144 patient deaths, 1,391 patient injuries and 8,061 device malfunctions."

"Although hundreds of thousands of patients die each year due to medical errors, very few medical claims are paid to compensate injured patients," Doroshow said. "It is not easy for someone who has lost a leg, their eyepatch or a child to continue hearing from medical lobbies that they—the few patients who file claims—are the problem, as opposed to the medical negligence that caused these tragedies. We have an enormous patient safety problem in this nation, and the last thing we should do is try to solve it by increasing the obstacles sick and injured patients face in the already difficult process of bringing a case against a negligent healthcare institution."
SENATE COMMITTEE RELEASES REPORT FOLLOWING YEARLONG INVESTIGATION OF OUTBREAKS IN WASHINGTON STATE, NATIONWIDE

Last month, the U.S. Senate's Health, Education, Labor & Pensions HELP Committee—which has jurisdiction over the nation's healthcare programs, schools, employment and retirement programs—released a new report: Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients. The report is the result of a yearlong investigation into the cause of and response to outbreaks of antibiotic-resistant infections linked to medical devices called duodenoscopes at Virginia Mason Medical Center and other hospitals nationwide.

The investigation demonstrates that duodenoscopes spread life-threatening, antibiotic-resistant infections, including superbug infections, among patients in a number of hospitals throughout the United States and Europe in 2013 and 2014. It documents a systemic and unacceptably slow response to growing evidence that duodenoscopes could not be reliably decontaminated between patient use, and makes clear that the Food & Drug Administration current system to monitor medical device safety is unable to effectively identify device problems when they occur, which poses an unacceptable risk to patients.

"Unfortunately, this investigation makes clear that current policies for monitoring medical device safety put patients at risk, and in this case, allowed tragedies to occur that could have, and should have, been prevented." The report recommends a series of legislative and regulatory changes to ensure the FDA is able to effectively monitor and evaluate the postmarketing safety of medical devices, including:

- Calling on the Food & Drug Administration to evaluate whether repairs to closed-channel duodenoscopes are necessary to prevent the spread of infections, and if so, requiring manufacturers to implement those repairs through a phased recall.
- Requiring that unique device identifiers (UDI) be included in medical data to allow the Food & Drug Administration to more quickly identify risks associated with a given device.
- Strengthening the Food & Drug Administration guidance regarding clearance of modified medical devices by manufacturers.

WILL MEDICAL PROFESSIONAL LIABILITY RISKS INCREASE IN 2016?

CONTINUED FROM PAGE 5

already. That is the threat of cyber hacking. We saw last year that health insurers were hacked with what seemed like relative ease, and that each time, millions of patient records were breached. If health insurers' information systems can be hacked, what's to stop cyber thieves from hacking into a physician's office system and stealing patient records? And, note that cyber criminals place a higher value on patients' medical records than credit card data.

In 2014, Reuters reported that medical record data is worth 10 times more than credit card data on the black-market. Hackers collect names, birth dates, policy numbers, diagnosis codes and billing information, all of which allows them to make fake identification cards that can be used to buy medical equipment or drugs they can resell.

Here, the lesson for physicians is make sure your IT systems are protected against hacking and check that your liability policy covers you in case of a loss. Addressing liability risks should be a priority each year, so don't let this year be any different.

Jeff Brunken is president of The MGIS Companies, which for more than 45 years has provided specialized group disability and medical professional liability insurance policies as well as healthcare practice improvement ancillary products and services to more than 10,000 physician groups, 900,000 group members and 300,000 physicians nationwide. More information can be found at www.mgis.com.

MAMMOGRAPHY: MAKING A SAFE PROCEDURE EVEN SAFER

CONTINUED FROM PAGE 8

In addition, tomosynthesis, which provides 3D-like views, may also lessen exposure from diagnostic workups if early evidence of reduced false-positives holds up in larger studies.

"Early evidence suggests that tomosynthesis may be a promising tool for women with dense breasts that may reduce false positives," said Christopher Lee, associate professor of radiology at the University of Washington School of Medicine, who contributed to the study.

However, to reduce radiation exposure, it is important that tomosynthesis be used with synthetic 2D views instead of being done in addition to 2D digital mammography, Lee said. Otherwise, radiation exposure from the screening exam, and radiation-induced breast cancer risk, is more than doubled. The synthetic 2D images, however, are currently not widely used.

The authors emphasize that mammograms are safe and their benefits overwhelmingly exceed the radiation risk. They hope this study will help open a conversation between women and their providers.

"Women need to have a dialogue with their primary care providers about when to start screening, when to stop screening and how often to screen based on their personal values and the potential benefits and harms associated with each scenario," said Lee. "It's really an important step."
MAMMOGRAPHY: MAKING A SAFE PROCEDURE EVEN SAFER

In a comprehensive modeling study, researchers from UC Davis and other institutions have found that breast cancer screening with digital mammography poses only a small risk of radiation-induced breast cancer for most women. However, the research showed increased risk for women with large breasts or breast implants, who must often receive extra screening views, increasing their radiation exposure.

The study also showed that biennial, rather than annual, screening mammograms, as well as beginning at age 50 instead of 40 or 45, make these procedures safer for all women. The study, published in Annals of Internal Medicine, was one of several that helped in development of revised mammography screening guidelines from the U.S. Preventive Services Task Force, published in the same issue of the journal.

"For most women, the risks are very low," said Diana Miglioretti, professor of Biostatistics at UC Davis School of Medicine, senior investigator at Group Health Research Institute in Seattle and first author on the study. "The one group I worry about is women with very large breasts who choose to be screened annually from ages 40 to 74. Most screening mammograms are two views per breast. Some women with large breasts need more than four views for a complete screening examination, increasing their exposure to ionizing radiation. In addition, the dose per view increases with compressed breast thickness, further increasing exposure." The international team of researchers modeled the lifetime risk of women developing radiation-induced breast cancer from digital screening mammography and dying from the disease compared to the number of breast cancer deaths prevented by early detection. They found that biennial screening of 100,000 women, from ages 50 to 74, prevents 627 deaths. The radiation exposure from these screening exams, and any subsequent diagnostic workups, can cause 27 breast cancer cases and four breast cancer deaths. Annual screening from ages 40 to 74 increases these risks five-fold, leading to 100 additional radiation-induced breast cancers and 12 additional breast cancer deaths compared with biennial screening from ages 50 to 74.

Unfortunately, the risks associated with screening mammography increased when the team focused on women with larger breasts, who received 2.3 times more radiation than women with smaller breasts. These larger doses put them at risk for approximately 57 cases of breast cancer and 10 radiation-induced breast cancer deaths (per 100,000 women screened biennially, ages 50 to 74). Though not specifically addressed in the study, women with breast implants may also be at higher risk because they receive twice as many screening mammography views, doubling their radiation exposure and radiation-induced breast cancer risk.

In addition, the study found that false positives, which may require follow-up diagnostic mammograms and associated radiation, increased breast cancer risk. However, again, the risk varied with different groups.

"For the average woman, having an additional workup for an abnormal screening result offers very small additional radiation exposure. But for some women who have additional mammography views and an image-guided biopsy, the additional workup can account for a quarter of their annual radiation exposure from mammography." To project these risks, the team used two different simulation models. The probability of additional workups, and types of workups, were based on estimates from the Breast Cancer Surveillance Consortium, a collaboration of six breast imaging registries across the U.S., which contains the nation's largest collection of breast imaging information. Radiation doses were based on estimates from the American College of Radiology Imaging Network Digital Mammography Imaging Screening Study, a large clinical trial that compared digital to film screening mammography.

From there, they used the preferred published model of breast cancer risk from radiation exposure to project the number of radiation-induced breast cancers. The study modeled eight screening scenarios that differed by starting age and screening interval: annual or biennial screening from ages 40 to 74, 45 to 74, or 50 to 74; and two hybrid strategies: annual starting at age 40 or 45 and biennial from age 50 to 74. For most women, biennial mammograms starting at age 50 may be the best choice.

"For the majority of women, screening mammography is very safe," Miglioretti said. "And if you screen every other year between 50 and 74, that makes it safest." While the study identifies women with large breasts at higher risk of radiation-induced cancer, new technologies may help mitigate that danger. For example, larger detectors can image women with very large breasts with fewer views and less radiation.

"For the average woman, having an additional workup for an abnormal screening result offers very small additional radiation exposure," Miglioretti said. "But for some women who have additional mammography views and an image-guided biopsy, the additional workup can account for a quarter of their annual radiation exposure from mammography."

To project these risks, the team used two different simulation models. The probability of additional workups, and types of workups, were based on estimates from the Breast Cancer Surveillance Consortium, a collaboration of six breast imaging registries across the U.S., which contains the nation's largest collection of breast imaging information. Radiation doses were based on estimates from the American College of Radiology Imaging Network Digital Mammography Imaging Screening Study, a large clinical trial that compared digital to film screening mammography.

From there, they used the preferred published model of breast cancer risk from radiation exposure to project the number of radiation-induced breast cancers. The study modeled eight screening scenarios that differed by starting age and screening interval: annual or biennial screening from ages 40 to 74, 45 to 74, or 50 to 74; and two hybrid strategies: annual starting at age 40 or 45 and biennial from age 50 to 74. For most women, biennial mammograms starting at age 50 may be the best choice.

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