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INSIDE

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Patient Safety Improves with CUSP Approach

A health system in Maine is seeing good results with a safety program designed to unite frontline clinicians and provide specific tools to address hazards in the healthcare setting.

Northern Light Health in Brewer, ME, is using the Comprehensive Unit-based Safety Program (CUSP) to improve patient safety in several ways, from standardizing crash carts to preventing patient-to-patient assaults.

CUSP was developed by safety and quality researchers at the Johns Hopkins Armstrong Institute for Patient Safety and Quality and the Agency for Healthcare Research and Quality (AHRQ). *(See the story in this issue for more details on CUSP.)*

The CUSP approach was brought to Northern Light Health three years ago by Tim Dentry, then chief operating officer and now president and chief executive officer of the system. He learned the system in a previous role at Johns Hopkins, where the program is embedded in the system's culture.

CUSP was attractive to Northern Light Health leaders for its potential to improve the system's culture of safety, says **Jeffrey Parsons**, Esq., vice president for risk and patient safety.

"From a risk perspective, we struggled with the improvement side of things. Risk management is great after the fact, going in after the event with root cause analyses and finding out what went wrong, but the real goal is to go upstream and address the issues that gave rise to those harm events," Parsons explains.

> "RISK MANAGEMENT IS GREAT AFTER THE FACT ... BUT THE REAL GOAL IS TO GO UPSTREAM AND ADDRESS THE ISSUES THAT GAVE RISE TO THOSE HARM EVENTS."

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"One of the areas where we struggled was frontline engagement. This was a great solution to that because the frontline workers came up with what mattered to them and their patients."

Northern Light Health started using CUSP in two units at different hospitals, then deployed it system-wide the next year. This year, the health system is expanding CUSP in a broad range of departments.

At first, CUSP was used on a unit-specific basis, with an individual unit seeking safety improvements that could be implemented there, Parsons says. But as CUSP expanded, participants saw opportunities to develop safety improvements beyond their own units.

"They started seeing that if they reached out and included radiology, lab, or pharmacy, they could really address deeper root causes associated with the issue," Parsons says. "It's a nice, blended model that uses the unit-specific approach with CUSP but strategically and effectively bringing in a multidisciplinary approach."

Frontline Staff Empowered

CUSP emphasizes the frontline responsibility and accountability for patient safety, says **Navneet Marwaha**, MD, vice president and chief quality officer with Northern Light Health. The program emphasizes that frontline workers can most effectively identify hazards and develop solutions, she says.

"If you ask leaders to identify the problems across the system, chances are they are aware of only a small percentage. But the frontline staff know 100% of the problems they are facing because they do this work day in and day out. They develop the workarounds because the system doesn't provide support, or they don't have the right processes in place," she says. "CUSP tells them they are the experts in their work and the challenges they face, so they will find the solutions. The leader who is removed from the day-to-day work of the unit is unlikely to know what the right solution is."

One CUSP initiative involved standardizing crash carts in one Northern Light Health facility, Northern Light AR Gould Hospital in Presque Isle. A crash cart in the emergency department might be stocked and stationed differently than a crash cart in another unit. That could slow the response of staff in a cardiac or respiratory crisis, Marwaha says.

Staff realized they were losing valuable time looking for supplies, so they used the CUSP method to identify the hazards and develop a standard format for the crash carts no matter where they were located in the hospital. But the task was not simple.

EXECUTIVE SUMMARY

A health system in Maine is improving patient safety with the Comprehensive Unit-based Safety Program (CUSP). This approach emphasizes empowering frontline staff.

- Staff identify problems in their own units.
- Solutions may involve working with multiple disciplines in the hospital.
- An executive sponsor is an active member of the team.

"Everything we do in healthcare is complex and there rarely is a simple solution to any problem. By following the CUSP program, they realized that they needed to talk to central sterile processing, their colleagues on their different medical and surgical floors, and others," Marwaha explains. "It was not as simple as one unit deciding on a standard format and telling everyone else to do the same thing."

Addressing Patient Handoff

Success with that effort led to using CUSP to address the handoff and transport of patients diagnosed with high-risk infections, such as *Clostridioides difficile*. Hospital leaders realized the system needed a way to clearly identify those patients and communicate the risk to others as the patient moved between units or facilities.

Frontline staff worked with infection control practitioners and representatives from various units to develop an effective way to communicate a high infection risk when patients were moved in the system.

"For the teams that have tried it, CUSP has really broadened their knowledge about the interconnectedness and complexity involved with keeping our patients safe," Marwaha says. "It has broader implications for improving engagement and teamwork, which will further the mission of the organization. Northern Light's key strategic initiative now is to have CUSP unit-based safety teams at every member organization."

The goal is for each facility in the health system to staff half its units plus one more outpatient or nonclinical unit with a CUSP team.

"We are on the threshold of reaching a tipping point of becoming where this will be considered the way we do business and the way we do improvement and safety," Parsons says. "The next strategies will involve how we capture and celebrate all the successes of our CUSP teams rather than concentrating on the number of CUSP teams we have in motion. We want to celebrate the achievements as part of our culture."

Patient Violence Cited

Northern Light Health asked leaders at each facility to look for opportunities to improve patient safety with CUSP. Northern Light Acadia Hospital, a psychiatric facility in Bangor with a pediatric inpatient unit, highlighted the problem of patient-on-patient assault. Unlike patients in a typical acute care hospital, pediatric inpatients at Acadia Hospital spend most of their time together, ambulatory, and active, Marwaha explains.

That creates a risk of patient-on-patient violence among young people who can be vulnerable and also prone to physical interaction, she says. Using the CUSP model, the frontline staff at Acadia Hospital determined the common factor in many violent incidents was that staff did not know who was prone to violence and needed more attention.

The psychiatric technicians who spend the most time with the young psychiatric patients were not adequately conveying information at shift handoffs, Marwaha says. They needed to communicate more effectively about negative group and interpersonal dynamics among the patients.

Through CUSP, staff updated the 24-hour safety huddle report provided to all psychiatric technicians, administrators, and anyone helping on the pediatric unit. The improved report format provides information about patients experiencing problems with particular issues, like respecting boundaries or one group of patients not getting along with another group, alerting staff to patients who are at risk of assaulting others.

Executive Sponsor Is Key

A key benefit of the CUSP model is how it engages frontline staff across multiple disciplines. This includes an executive sponsor, who is an active member of the team, Parsons says.

"That has proven in multiple instances to be a huge part of the team's success. Sometimes, just the presence of the executive sponsor or the way that sponsor asks questions and supports the team indirectly provides the team a sense of empowerment and allows them to move forward," Parson says. "When there are true barriers, that person can step in and help. But what I've heard more often is the confidence and empowerment that the executive sponsor brings to the team. That has been critical."

At first, Parsons said he was uncomfortable with one aspect of CUSP, but since has learned to embrace it. In the beginning, he had a hard time letting the teams choose what topic they wanted to work on.

"As a risk manager, I know where the events are happening and what units are having less of this problem and more of that. That was hard at first because they would choose something to address and I knew there were other issues I might have chosen instead," Parsons says. "But

the front line knows. I may see data, but the front line knows what is important to the safety of the patients and happiness of the staff."

Parsons now focuses on providing useful information gleaned from the massive amounts of data collected by the health system to the frontline staff — data that can help them choose CUSP projects and guide those efforts, he says.

"We have to trust the process and provide these teams with as much information as we have related to these safety issues," he says. "We trust our staff to know what is important. They have not let us down."

Marwaha underscores the importance of frontline staff owning the process, although the participation of an executive sponsor also is crucial.

Staff may focus on seemingly small issues, not a grand patient safety initiative driven by tons of data and best practices, Marwaha notes. That is fine because they are addressing the issues they know have a real effect on patient care and safety every day, she says.

"What gets these teams really energized is tackling an issue and seeing that they are responsible for the improvement, that they own this area," Marwaha says. "It can be something as simple as how their utility room is stocked, whether they can find what they need. Or, it might be having a place to put extra beds and wheelchairs to keep the hallways clear, or having a necessary form in the same place in every unit so you can find it easily."

Once the teams know they have been trusted to address issues with their own solutions, their interest grows and they are eager to take on larger, more complex problems, she says.

Organizations adopting the CUSP approach should invest in a good understanding of improvement science and methodologies, Marwaha notes. It is common for an organization to throw a lot of effort and resources into an improvement initiative and see some initial good results — but a year or two later, everyone wonders why the improvement was not sustained.

That can happen with CUSP improvements if frontline staff are not educated on improvement science, Marwaha says. This includes how to define a problem, what is going to change, different hypotheses about contributions to the problem, and other structured ways of studying an issue.

"For organizations that commit to CUSP, there has to be a parallel commitment that we are ready to deploy this training and development of our staff to understand improvement science so they can go about in a scientifically structured manner and sustain the improvements they have made," she explains.

Marwaha notes it is important to provide staff protected time to do this work, instead of piling it on top of their duties and pulling them in different directions.

Do not be surprised if staff meet the introduction of CUSP with a roll of the eyes and a dismissal as just another flavor of the month in patient safety, Marwaha says. That reaction is understandable, but should be countered with an explanation that CUSP is different in its approach.

"When I hear that skepticism, I stress to them that this is just a structured way of doing our daily work. You're already doing this, but we want to make it more efficient," she says. "This approach can give structure to our work. A lot of the time our frontline staff feel like they are running around with a fire extinguisher all day putting out fires, but this can change their daily work from putting out fires to fire prevention." ■

SOURCES

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CUSP Provides Tools and Support for Improving Safety

The Comprehensive Unit-based Safety Program (CUSP) was developed by safety and quality researchers at the Johns Hopkins Armstrong Institute for Patient Safety and Quality and the Agency for Healthcare Research and Quality (AHRQ).

CUSP was developed to improve patient safety by providing tools and support for caregivers that can help them identify and address hazards, using these five steps:

- Educate staff in the science of safety;
- Identify issues;
- Engage executive leaders;
- Learn from problems;
- Develop tools for teamwork.

Johns Hopkins reports the program has been used to address patient falls, hospital-acquired infections (HAIs), medication administration errors, and specimen labeling errors, in addition to teamwork and communication issues. One project, called On the CUSP: Stop BSI, reduced central line-associated bloodstream infections (CLABSI) in 44 states by 40%. The project saved an estimated 500 lives. *(For more information on that project, see the journal report online at: https://bit.ly/2FixqZh.)*

The CUSP approach was piloted in more than 100 intensive care units in Michigan and showed promise for reducing HAIs. AHRQ cites these benefits from the CUSP program:

- Engaging frontline clinicians and leadership;
- Educating staff on the science of safety;
- Assessing the safety culture, including infection control policies;
- Creating regional consortia of stakeholders;
- Offering coaching, consultation, and technical assistance;
- Providing peer support;
- Creating educational materials, tools, and webinars;
- Collecting data and feedback to monitor performance;
- Engaging patients and families.

"CUSP is different from other change models because it combines behavioral elements — an emphasis on safety culture, teamwork, and communication — with clinical elements — the checklist of proven practices — to create a powerful tool for promoting the adoption of evidence-based practices to prevent HAIs," AHRQ states. *(More information is available at: https://bit.ly/2RbWEeb.)*

AHRQ cites these successful experiences with CUSP:

- 41% reduction in CLABSI in more than 1,000 intensive care units;
- 30% reduction in catheter-associated urinary tract infections (CAUTIs) in more than 700 hospital non-intensive care units;
- 54% reduction in CAUTI in more than 400 nursing homes;
- 25-40% reduction in surgical site infections.

Johns Hopkins offers extensive resources for CUSP online at: https://bit.ly/2FcZQDY. More information from AHRQ about CUSP is available online at: https://bit.ly/2R2Z4Mp. ■

Needlestick Injuries Increasing, but Not Always Taken Seriously

Needlestick injuries are on the rise after a long period of decline. Healthcare organizations may not be taking the risk of infection as seriously as they once did. A national expert on needlestick injuries is urging risk managers to reassess prevention programs and respond more aggressively when staff and physicians are injured.

The incidence of needlestick injuries fell sharply after national legislation passed in 2000 mandated risk reduction and response programs, says **Karen Daley**, PhD, RN, FAAN, former president of the American Nurses Association, who was herself a victim of an accidental needlestick that infected her with HIV. She is now a consultant in Cotuit, MA, serving on the board of several safety organizations and a company that has developed syringe technology addressing needlesticks.

Daley was one of the architects of the 2000 Needlestick Safety and Prevention Act (NSPA), the Occupational Health and Safety Administration bloodborne pathogens standard that requires the institution of safety measures in workplaces where there is occupational exposure to blood or other potentially infectious materials.

Data from the Exposure Prevention Information Network surveillance system (EPINet) shows that

after a sharp drop in accidental needlesticks after NSPA was enacted, needlesticks are on the rise again, almost at pre-2000 levels. From 1997 to 2000, the rate of needlestick injuries per 100 hospital beds per day, on average, was 34.825. That figured dropped to as low as 21.860 for 2010-2014, but it rose sharply in 2015-2019 to 31.040.

"We saw a couple of years where the immediate impact was significant, with about a 32% reduction in injuries, largely because the requirement to use safety devices was implicit within the law," Daley says. "Hospitals started adopting safer devices and making them accessible to the workers. Then, we saw a steady decline in injuries from year to year, until about 2010."

Injuries Taken Less Seriously

The rate of injuries plateaued for several years, then began rising in 2015. Daley says the increase is worrisome, and it is compounded by healthcare safety leaders taking the effects of needlesticks less seriously than in the past.

When the risk of needlesticks became a prominent issue in the healthcare community in the 1980s, the primary concern was the transmission of HIV. Now, the major concern after a needlestick injury is hepatitis B or hepatitis C. Healthcare organizations can follow guidelines from the Centers for Disease Control and Prevention to manage needlestick injuries, which may include post-exposure HIV prophylaxis.

Rates of seroconversion after a needlestick are low. But Daley says the potential effect of seroconversion can be quite high in terms of the personal costs to the worker and the costs to the employer.

Daley says that while it is good that there is less panic about the potential consequences of a needlestick than in years past, the normalization of needlesticks is leading to more injuries and less comprehensive treatment.

"There's a bit of complacency around the injures," she says. "We've had better drugs come out for things like HIV and hepatitis C, so workers are under the impression that it's not happening as much and it's not as serious when it does. I think hospital administrators are in the same space."

The reality is these injuries are increasing, especially in the operating room (OR). Needlestick injuries occur more in the OR because surgery involves a lot of sharps, but there is not as much needlestick prevention technology, she says.

Vaccine Administration Increases Risk

Most needlesticks involve suture needles and injection devices such as hollow-bore needles, Daley says. More than half of needlesticks currently involve devices without needlestick prevention technology.

"That's a significant concern, given how frequently injections are given in this country and how we are getting ready to administer a COVID-19 vaccine when that is available," she notes. "Flu season also is coming, and we're going to be challenged to provide more access points to get these vaccines. You need about 70% of the population to get the vaccine in order to have herd immunity, and that means about 230 million people in the United States."

That surge in injections increases the likelihood of more needlestick injuries, Daley says.

The approach to needlestick prevention and treatment has changed dramatically in the past 20 years, at least among some healthcare leaders and safety professionals. It is not uncommon to hear administrators and managers downplay the potential risk of a needlestick with comments about the low likelihood of disease transmission and the ability to treat any infection that does occur, she says.

But Daley speaks from experience when she says the person suffering the needlestick takes it very seriously. Or they should, if their organization has not downplayed the risks.

"It's a horrible experience because you're waiting potentially hours or days for the blood work on the source patient to come back. You don't know what you've been exposed to," Daley laments. "For administrators and C-suite leadership, there are places that are very diligent about responding to needlesticks. But in too many others, the complacency comes from thinking it is not as a big a problem as it used to be and doesn't need their attention and resources."

EXECUTIVE SUMMARY

Needlestick injuries are increasing. Healthcare workers and safety leaders have become complacent about needlestick injuries and the potential for infection.

- Needlestick injury episodes declined for several years but are now rising.
- Many needlesticks occur in the operating room.
- Flu vaccines — and a potential COVID-19 vaccine — will increase the risk.

Daley was an emergency room nurse when she suffered a needlestick injury on the job in 1998. She had drawn blood from a patient and was discarding the needle when she was stuck by a second needle that was wedged in the sharps disposal container. Daley tested positive for HIV and hepatitis C a few months later.

The emotional stress on the healthcare worker is worse if managers, administrators, and the organization downplay the incident, Daley says. They mean well by trying to reassure the worker the outcome is unlikely to be catastrophic, but that message should be balanced with an acknowledgment of how worrisome the incident is for the worker.

Some employers reassure the worker that drugs are available after exposure to pathogens, but Daley cautions this can turn into an insensitive dismissal of the worker's legitimate fears. Some post-exposure drugs are difficult to take, she says, and exposed workers will need support and follow-up by occupational health staff to help them cope with potential side effects.

Review Data, Seek Improvements

Risk managers also should engage workers after needlesticks to learn more about the incident and the aftermath. Seek insight about how the needlestick might have been prevented, but also how the hospital's response and follow-up care could improve, Daley suggests.

Hospitals and health systems should regularly review needlestick injuries, at least on an annual basis, to determine how, when, and where they are occurring. That review should be used to identify improved processes and devices that might reduce the incidence of needlesticks.

Daley says the attitude of immediate supervisors and the organization's overall culture can influence needlestick reporting.

"It's always a worry when a healthcare worker is giving an injection because we don't test every patient to know what they have. When you're stuck, your mind suddenly goes to wondering what is in that patient's blood," she explains. "Unfortunately, we know underreporting of needlesticks is still a big issue in healthcare, so all the complacency about how we have better drugs to treat HIV and these other diseases doesn't mean much if people don't report their injuries and get treatment." ■

SOURCE

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DOJ, OIG Changing Enforcement Policies for COVID-19 Era

The federal government's fraud and abuse enforcement priorities are shifting in response to COVID-19. Risk managers should be ready to adapt their compliance programs in response to the changing risks.

Federal authorities are prioritizing resources to focus on COVID-19-related issues, says **Melissa L. Jampol**, JD, an attorney with Epstein Becker Green in New York City. This new focus includes everything from personal protective equipment (PPE) scams, identity theft, and tax issues.

"Right now, they are focusing on low hanging fruit, such as the Paycheck Protection Plan going awry and somebody buying a Lamborghini," Jampol says. "But the enforcement efforts are going to go on for many years from now, in much the way we saw continuing enforcement after the 2008 financial crisis."

High Alert for Fraud

There will be an evolution of enforcement activities, says **Jennifer E. Michael**, JD, an attorney with Epstein Becker Green in Washington, DC, who previously worked with the Department of Health and Human Services Office of Inspector General (OIG). Prosecutors will be looking for relatively easily discovered crimes, like submitting lists of employees who do not actually work for the organization to receive more aid.

"There tends to be a lag in enforcement because the bad thing has to happen, then government has to learn that the bad thing happened through qui tam suits, data analytics, audits, or a variety of ways," Michael says. "Everyone is on high alert because there is so much money flowing so quickly. At the same time, OIG issued a message from leadership on minimizing burdens on providers, so OIG recognizes that right now there is a lot of confusion about what's okay."

Michael says there is some reasonable confusion about what is allowed, what is questionable,

and what is outright fraud. OIG has issued guidance stating that it is balancing those concerns while continuing with its mission to prevent fraud and misuse of funds.

"OIG is first going to make sure that the beneficiaries are not being harmed, but second that the federal resources aren't being pillaged," Michael says. "I think OIG will be cognizant of the need to investigate and pursue enforcement against things that aren't so egregious but are still fraudulent, for the deterrent effect. It's important to focus on compliance, and once the dust settles, to go back and look at how you expended your CARES [Coronavirus Aid, Relief, and Economic Security] Act funds."

If the lookback determines CARES Act funds were misused, or there was an overpayment from the government, the hospital or health system should devise an affirmative plan to repay those funds, Michael says. Do not wait for federal investigators to find the problem.

Overpayments can result from malicious intent, with healthcare organizations misrepresenting themselves on applications, but they also can happen through honest mistakes, Jampol says. Funds provided for PPE carry strict requirements, she notes, so risk managers should exercise tight control over the application process and the disbursal of those funds.

Guidance on Compliance

The Department of Justice issued new guidance for corporate compliance programs on June 1. Jampol says risk managers should study this publication closely. *(The Evaluation of Corporate Compliance Programs is available online at: https://bit.ly/3i9KOgM.)*

"It aids prosecutors in assessing the adequacy and effectiveness of compliance programs, helping them decide if you should receive monetary penalties or a monitor," she says. "Hopefully, you'll never end up on the criminal side of that, but it is equally as useful if you're looking at the administrative issues and civil liabilities. It gives you a direct window into what the Department of Justice is looking at."

The guidance emphasizes that companies must be flexible and adaptive with the compliance programs, Jampol notes. That can be difficult now because compliance programs often are one of the first to be cut when an organization faces financial challenges.

"It's always true that you can't just establish a compliance program and let it run on autopilot, but especially now you have to pivot and think about where the risks are in this changing landscape," she says. "We had one client tell us that they threw out their compliance plan and developed an entirely new one because the original plan didn't work with all the new risks and changing environment that hit everyone this year."

Common Safeguards Identified in OIG Responses

The Department of Health and Human Services Office of Inspector General (OIG) has evaluated several proposed arrangements related to COVID-19 and identified safeguards that pose a low risk of fraud and abuse, says **Jennifer E. Michael**, JD, an attorney with Epstein Becker Green in Washington, DC.

Through several responses to proposed arrangements, OIG identified safeguards applicable to most situations that will make remuneration safe from enforcement under anti-kickback and civil monetary penalty rules, Michael says. She offers this summary:

- The arrangement is necessary because of COVID-19 and will exist only during the public health emergency.
- The remuneration is provided to a recipient who is financially needy.
- The remuneration consists of in-kind material or services required for the recipient to access medically necessary services.
- The healthcare organization does not advertise the remuneration and provides it only to established patients.
- A beneficiary's eligibility for assistance is not determined through a method related to the volume or value of federal healthcare program business.
- The arrangement is documented in a written agreement.
- The healthcare provider offers the remuneration to eligible providers on an equal basis.
- There is no requirement for the person or entity receiving the remuneration to refer patients to a particular individual or entity. The arrangement does not restrict the receiving person or entity's referrals. ■

Risk managers must shift priorities within their own departments, Michael says. They must be involved with overseeing the use of CARES Act funds, although there is no single right way to structure that oversight.

"Everyone is always asking if there is a compliance template they can use. The answer is no because every company is different. It depends on the size, the complexity, the types of funds you receive — numerous factors that influence how you manage risk and implement your compliance program," she says. "With COVID, for instance, there are additional payments for treating COVID patients. You want to make sure those billings are accurate, that you're not overbilling and submitting yourself to False Claims Act lawsuits. The same applies to the terms and conditions for CARES Act funds, but the OIG has some relatively new administrative authority with respect to grants and contracts."

Risk managers should assess what risks are present for the organization in light of these new conditions and pivot the compliance program accordingly, Michael says.

Traveling personnel represent another potential risk, Jampol notes. As physicians, nurses, and other healthcare workers travel to other facilities to aid in the response to COVID-19, hospitals must be careful to ensure compliance with credentialing and licensing requirements. There also is an added risk from having outsiders working in your healthcare facilities who may not follow the same processes and precautions, both clinical and compliance-related.

Michael notes that OIG is revising its work plan monthly. One new part of plan is a review of Medicare data on hospital use during the COVID-19 period. This is a signal that OIG is going to look at Medicare claims data to analyze the effects of COVID-19 on hospitalized Medicare beneficiaries and the hospital resources needed to care for them.

Jampol and Michael note that OIG is accepting inquiries regarding how it would apply its administrative enforcement authorities to arrangements made necessary by the healthcare community's response to COVID-19. OIG acknowledges that the federal Anti-Kickback Statute and the civil monetary penalty (CMP) prohibiting inducements to beneficiaries could apply to some of these arrangements.

OIG offers guidance on applying its administrative enforcement authorities to specific arrangements through the advisory opinion process. But it says this can be a time-consuming process, and healthcare organizations need faster response to COVID-19 arrangements.

Healthcare organizations can request guidance regarding OIG's administrative enforcement authorities by submitting questions to oigcompliancesuggestions@oig.hhs.gov. The responses are available online at: https://bit.ly/2ZvlZ7H.

"It's kind of like a mini-advisory opinion. It allows people to submit anonymously, which the advisory opinion process does not. You can describe your arrangement, and OIG will publicly post their response saying they think it is OK or not OK," Michael explains. "It does not offer all the protection an advisory opinion would. But because the Anti-Kickback Statute is an intent-based criminal statute, if you submit a question or there is one that is very similar to your arrangement and you follow the safeguards OIG outlines, someone is going to have a hard time proving you had the requisite intent to violate the statute."

The OIG advice on acceptable arrangements is updated regularly. Risk managers may find examples that fit closely with a situation they are facing in their own organizations, Jampol notes. For instance, one submission asks whether staff of a home health agency (HHA) may furnish free blood draws to assisted living facility residents who are federal beneficiaries but not clients of the HHA.

OIG responded that in "the unique circumstances resulting from the COVID-19 outbreak, we believe that these facts likely would present a low risk of fraud and abuse under the federal Anti-Kickback Statute and the Beneficiary Inducements CMP," as long as the blood draws are within the scope of practice of the HHA's staff, limited to the period subject to the COVID-19 declaration, and not contingent on referrals for any items or services that may be reimbursable in whole or in part by a federal healthcare program.

"In the future, we are going to see an accounting of where all the money went, and OIG is going to pursue a deterrent effect. After the 2008 financial crisis, the way OIG handled the Troubled Asset Relief Program is widely viewed as the model for how they are going to address this with COVID-19 funds," Jampol says. "Funds will be spent to help get through the crisis, but then there will be an accounting of where the money went." ■

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Focus on Individual Risks to Reduce Patient Falls

Fall prevention is a constant concern for hospitals and health systems, with great costs involved. It is important not to get stuck in the same old way of thinking when it comes to protecting patients. Take the time to re-evaluate your fall prevention program and look for new opportunities to improve this key aspect of patient safety.

The most progressive approach to fall prevention involves taking a holistic approach to the patient and focuses on an individual's risk factors, says **Daniel Devine**, MD, board certified in internal and geriatric medicine, practicing with Devine Concierge Medicine in Wayne, PA.

"In geriatric medicine, we're moving more toward environmental issues and physical activity as a way of preventing falls. We're looking at the whole person, everything from the shoes they wear and their activities, trying to sign them up for things like tai chi if they are cognitively intact," Devine says. "Vitamin D supplementation has been shown to help. We continue to look at the medications a patient is on."

There is an emphasis on "de-prescribing" as a means of limiting the medications a patient is on, because falls often are tied to low blood pressure or low blood sugar caused by prescription drugs, Devine says.

"Particularly for risk managers, it can be useful to review the use of psychotropic medications monthly or bi-monthly. Psychotropic medications are very highly related to falls, pretty glaring red flags for increased fall risks," he explains. "Make sure you know who is on these medications and that these patients are being properly assessed to see if they are still necessary. If you can, do a dose reduction."

Devine also advises simply watching patients walk around and meet regularly with physical therapists to assess fall risks. There is no population-based intervention for reducing falls because falls are so multifactorial that it takes deep study into each patient to find solutions, he says.

"Part of the way we look at falls is seeing the actual incident as just the tip of the iceberg. We have to look underneath to see what actually caused the fall," Devine says. "It can be easy to think of all patients at risk of falls as one category of patients and then apply the same fall prevention strategies to them across the board. It is much more effective to look at each patient and determine what makes that particular person at risk for falling and address those issues."

Devine says there is a lot of room for improvement with how hospitals and health systems address fall prevention. Part of the problem is the time constraints of modern medicine. A good geriatric assessment and discussion with the patient and family members takes about half an hour, he says.

"The regular 15-minute office visit or a quick visit in a nursing home makes it difficult to get into that," Devine says. "Time is the most valuable commodity, and giving a patient time to express what is happening to themselves and what may influence their risk of falling is a difficult thing for most healthcare professionals." ■

SOURCE

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Evidence of Race Disparities in ED Could Support Negligence Claims

If plaintiffs allege they received poor care in an emergency department (ED) because of their race, there is plenty of potentially admissible research that demonstrates it is indeed possible.

"It's important for the defense to consider evidence in the literature that the plaintiff attorney could use against the defendant," says **Jay M. Brenner**, MD, FACEP, medical director of the community ED at State University of New York Upstate Medical University in Syracuse.

People of Black or Latin American descent coming to the ED with cardiac symptoms were less likely to be admitted to specialized cardiology units than white patients, according to the authors of a study.[1] "Frontline clinicians have a unique vantage point to identify and characterize inequities in care," says **Regan H. Marsh**, MD, MPH, one of the study's authors and an assistant professor of emergency medicine at Brigham and Women's Hospital in Boston.

Marsh and colleagues decided to conduct the study because of a worrisome trend they observed in their own ED. They noticed Black and Latinx patients diagnosed with heart failure were frequently admitted to the general

medicine service, as opposed to the cardiology service. "Our objective was to identify potential inequities in care and differential access to care," Marsh says.

Researchers analyzed 1,967 cases of heart failure patients who presented to the ED. The study was not designed to identify malpractice risks. "However, any time patients experience disparities in care, or challenges in access to care, based on race, ethnicity, or gender, it can lead to worse outcomes and greater legal risk," Marsh says.

Black and Hispanic pediatric patients were less likely to be classified as urgent or immediate than white pediatric patients, and also were less likely to be admitted to the hospital, according to the authors an analysis of 78,471 ED visits.[2] "There's an incomplete understanding of disparities in emergency care for children across racial and ethnic groups," says **Xingyu Zhang**, PhD, the study's lead author and research assistant professor at the University of Michigan School of Nursing.

If the plaintiff in a malpractice lawsuit is Black or Hispanic, relevant studies could be used to support allegations not only of negligent care, but of negligent care due to racial bias. "Bringing up such papers would be a shrewd strategy to inflame the jury, even if allegations of racial bias were logically refuted," says **Daniel Pallin**, MD, MPH, former research director in the department of emergency medicine at Brigham and Women's Hospital in Boston.

Admissibility would depend on the judge and the jurisdiction. "Inconsistency from judge to judge makes admissibility hard to rule out," Pallin adds.

The plaintiff lawyer could use the research to paint a picture of racial bias leading to a poor outcome. Brenner says the ED defense team should consider these questions:

- Was there a delay in care because of undertriaging?
- Was there a missed opportunity to give treatment for myocardial infarction or hospitalization for heart failure?
- Was there a missed antidote or a paucity of analgesia offered?
- Was insufficient attention to follow-up and prescribing given with a seizure patient?
- Were antibiotics not prescribed for an infection?

"These are all potential situations that the plaintiff attorney could exploit in a malpractice case," Brenner explains. Here are some examples of findings that could be used to support allegations of racial bias in an ED claim:

- White patients are more likely than Black patients to receive thrombolysis treatment for myocardial infarction.[3]
- Black pediatric patients are more likely to receive an urgent triage score.[4]
- Black patients are more likely than white patients to present to the ED with breakthrough seizures because of missed anticonvulsant medications.[5]
- White pediatric patients are more likely than Black and Hispanic pediatric patients to receive antibiotics for viral upper respiratory infections.[6]
- White patients are more likely to be hospitalized for heart failure than Black patients.[7]

To refute allegations of racial bias, the defense attorney could ask ED providers about their typical practices. "They would have to show that the care rendered was the same regardless of race," Brenner reports.

Character witnesses attesting to nondiscriminatory behavior could help the defense. An ED nurse could testify to a long period of observation of the defendant in the ED, and never once witnessing discriminatory behavior. "It could help if they could testify to only seeing equal, consistent compassion without regard to race or ethnicity," Brenner suggests.

The ED medical director or ED nurse manager could be brought in as witnesses as to whether the defendant had received any other patient complaints alleging discrimination. "This could be helpful to the defense if there were none — and helpful to the plaintiff if there were," Brenner adds. ■

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HEALTHCARE RISK MANAGEMENT™

CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **What is one key feature of the Comprehensive Unit-based Safety Program (CUSP) used at Northern Light Health?**

   a. It emphasizes the frontline responsibility and accountability for patient safety.
   b. It emphasizes C-suite executives are most responsible for developing solutions to patient safety issues.
   c. The program focuses exclusively on long-range goals and systemwide problems.
   d. The program focuses only on clinical issues.

2. **In the Northern Light Health system, who determines what issue a CUSP team will address?**

   a. The risk manager and quality improvement director
   b. A management team appointed by the chief executive officer
   c. The director of the department
   d. The CUSP team

3. **According to data from the Exposure Prevention Information Network surveillance system, what is the trend for the rate of needlestick injuries per 100 hospital beds on an average daily census?**

   a. It rose sharply in 2015-2019.
   b. It fell sharply in 2015-2019.
   c. It rose only slightly in 2015-2019.
   d. It fell only slightly in 2015-2019.

4. **Which is true regarding the opinions offered by the Department of Health and Human Services Office of Inspector General in response to potential COVID-19 arrangements submitted by healthcare organizations?**

   a. The responses do not offer all the protection of an advisory opinion.
   b. The responses carry the same weight and authority of an advisory opinion.
   c. The responses apply only to the healthcare organization submitting the arrangement.
   d. The responses do not offer specific guidance regarding safeguards.

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Appellate Court Affirms $10.3 Million Verdict in Cerebral Palsy Birth Suit

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News: During a pregnant patient's hospitalization, nurses failed to notify a doctor of fetal distress signs, leading to permanent injuries. The baby was born with the umbilical cord wrapped around his neck after an emergency cesarean section. This caused the baby's oxygen level to drop for an extended time, resulting in permanent brain damage. A trial court found the care providers were negligent and awarded the plaintiff $10.3 million.

A three-judge appellate panel upheld the decision, finding sufficient evidence the nurses' failure to notify the physician caused the baby's cerebral palsy because the nurses waited more than 30 minutes to inform the physician that the fetal heart rate had been dropping.

Background: In October 2014, a patient was hospitalized due to complications that led to the premature birth of her son. Throughout the hospitalization, the baby's heart rate slowed multiple times. The physician ordered the nurses to continuously monitor the baby's heart rate. For the first few days of hospitalization, no abnormalities with the heart rate were registered. However, on the third day, the baby's heart rate dropped below baseline on three separate occasions. On the first instance, the nurses noted an abnormally low heart rate for two minutes. Shortly thereafter, the heart rate dropped again for approximately seven minutes. Later, the baby's heart rate declined for the third time, reaching levels the nurses deemed "dangerous." After this last drop, the baby's heart rate never reached normal levels and continued to decrease.

Approximately 30 minutes after the first drop was detected, nurses could not detect a heartbeat. Despite these emergency circumstances, the nurses waited another six minutes before calling the physician. The physician arrived at the hospital approximately 20 minutes later and performed an emergency cesarean section to deliver the baby. When the baby was delivered, the physician noted the umbilical cord had been wrapped around the baby's neck, depriving the brain of blood and oxygen.

> DESPITE THESE EMERGENCY CIRCUMSTANCES, THE NURSES WAITED ANOTHER SIX MINUTES BEFORE CALLING THE PHYSICIAN.

The baby was airlifted to a nearby hospital, where he spent a month in the critical care unit and was subsequently diagnosed with cerebral palsy. The extent of the brain injuries caused by the lack of oxygen and blood to his brain is so severe that the child will require permanent, 24-hour care for the remainder of his life.

The patient filed a medical malpractice lawsuit against the hospital, arguing the nurses breached their duty of care by failing to timely notify the physician when the baby's heart rate dropped rather than waiting until the heart rate was undetectable. The jury found in favor of the patient and awarded $10.3 million: $9 million in future healthcare expenses while the child was a minor, $1.2 million in future healthcare expenses for the child as an adult, and $62,000 in past expenses.

The defendant hospital filed an appeal on multiple grounds, arguing there was insufficient evidence to

support causation, the court erred in calculating the child's life expectancy, the trial court erroneously excluded expert testimony, and the final judgment disregarded the jury's findings and was not supported by the weight of the evidence. The appellate court rejected these arguments and affirmed the trial court's decisions.

What this means to you: This case revealed multiple important issues on appeal relevant to medical malpractice cases generally. These issues can be divided into three general groups: issues about causation, issues about periodic payment, and issues about the exclusion of witnesses.

First, the defendant care provider attempted to challenge the court's finding of a breach of duty by arguing the trial court failed to consider existing factors that may have contributed or caused the patient's injuries. Specifically, the defendant care provider noted that due to the mother's age and high blood sugar levels, the pregnancy was considered "at risk." Additionally, the mother suffered from a urinary tract infection that remained untreated during her pregnancy. The defendant care provider also noted the patient missed several routine checkups throughout the pregnancy, which may have revealed potential problems sufficiently in advance, and the patient's membranes had ruptured prematurely, leading to her hospitalization. Tests conducted after delivery also revealed the patient's placenta had torn away from the uterine wall, the umbilical cord was inflamed and twisted (which may have resulted in less oxygen delivered to the fetus), and the patient suffered from chronic infection resulting in amniotic fluid infection.

According to the defendant care provider, these conditions may have caused or contributed to the child's injuries. However, the appellate court found these arguments unmeritorious because the expert witnesses stated the child's injuries could not have been caused by anything other than acute asphyxia from the umbilical cord wrapping tightly around the child's neck. This determination confirms the importance of expert witnesses, as courts do not have the necessary medical knowledge to determine such factual issues. Expert testimony is critical in evaluating issues about causation. Arguing against the weight of expert testimony is impossible, absent other, more compelling expert testimony.

In fact, the appellate court stated "even if the evidence did raise other possible causes of the injury, the experts negated them as possible causes." Because medical malpractice cases require a certain level of specialized knowledge due to their nature, it is clear how evidence provided by laboratory results and other testing must be interpreted by a competent witness, in most cases a physician, to draw an accurate conclusion as to its meaning. In this matter, the defendant hospital attempted to challenge the experts' conclusion by presenting evidence that may or may not show possible alternative causes of the injury.

However, without an expert's opinion supporting the defendant's position, the evidence did not carry any weight in the court's decision. This case involved nurses' duty to provide the standard of care to patients. Despite the multiple complications that occurred during the mother's pregnancy and the possible reasons for the anoxia suffered by the fetus, timely intervention by the physician is key to mitigating the damage anoxia can cause. Fetal monitoring in a hospital during labor is dependent on the interpretation of the monitoring strips. Obstetrical nurses are trained to interpret fetal monitoring strips. The American College of Obstetricians and Gynecologists provides specific guidelines that identify which abnormalities noted on the monitoring strips must be immediately brought to the attention of the physician. Decelerations or slowing of the fetal heart are not all abnormal. As contractions occur, uterine pressure on the umbilical cord can occur, but should immediately recover once the uterus begins to relax. When a deceleration occurs between contractions or lasts for an extended period, a physician must be notified immediately.

This standard applied to this case demonstrates the nurses' hesitance to make the call was a failure to provide the standard of care and a breach of the nurses' duty. Reasons for this are varied, but there are two common circumstances that stand out. First is simply the lack of knowledge seen when untrained nurses have to float to areas of the hospital with which they are not familiar. The second occurs when a nurse has experienced hesitance, resistance, or even bullying or disrespect from the physician the nurse needs to call. It is the responsibility of hospital administrators to ensure neither scenario occurs. Seconds count when a fetus is deprived of oxygen, and no reasonable nurse delays informing the physician. Anything less is negligence on the part of the nurse.

In the second major issue, the defendant care provider argued the trial court erred in denying the award be paid in periodic payments and in its interpretation of the periodic payment law. To this point, the defendant argued the court failed

to charge the jury with the question of the patient's life expectancy, which was a controlling issue of fact. However, the appellate court confirmed that trial courts have significant discretion and should give such instructions "as shall be proper to enable the jury to render a verdict." In this case, the trial court did not abuse its discretion because the question of life expectancy was not cited by the periodic payment statute, and the defendants did not provide any evidence of the question being addressed by other courts in applying the statute.

Lastly, the defendant care provider argued the trial court abused its discretion in excluding witness testimony about the insurance payments the plaintiff could receive under the Affordable Care Act (ACA). However, the appellate court ruled this exclusion was proper because under an established legal principle — the collateral source rule — a negligent party may not mention or obtain benefit from the payments the injured party will receive from external sources. Here, although the patient would receive payments under the ACA, those payments are irrelevant for the purpose of calculating the damages owed by the defendant. Admitting such evidence would have been a clear violation of this legal principle. ■

REFERENCE

Decided on July 30, 2020, in the Texas Court of Appeals for the Thirteenth District, Case Number 13-18-00362-CV.

Incorrect Intubation Results in Brain Damage, $16 Million Award

News: In February 2016, a child fell from playground equipment and struck her head. After her father brought her to an Indian Health Services-operated medical center, staff intubated her incorrectly, resulting in lack of oxygen to the brain and permanent brain injury. Because of this, the child's brain will never develop past the capacity of a toddler. The child also will require life-long assistance, as well as physical and developmental therapy. The award of $16 million compensates the family for the injuries as well as for the cost of treatment they will incur throughout the child's life.

Background: In February 2016, a healthy six-year-old girl fell off playground equipment, hitting her head and face on a hard surface. The child suffered a head injury that required immediate medical attention. Her father rushed her to a federally funded hospital where she was seen and evaluated by nurses and the on-call emergency department (ED) physician.

Immediately after seeing the patient, the physician ordered a CT scan and performed a rapid-sequence intubation, administering Ativan, ketamine, and succinylcholine. However, the endotracheal tube was placed improperly. The medication related to the intubation also was administered improperly, depriving the child of oxygen and causing severe anoxic brain damage.

Additionally, no X-rays were taken after the first intubation to confirm the correct placement. A second intubation was performed and followed by two chest X-rays. The first scan showed the endotracheal tube placed in the right main stem bronchus and atelectasis of the upper lung, and the second scan showed the tube had been pulled back. Due to the severe brain anoxia, the child was airlifted to another hospital where she was evaluated and treated.

On March 1, 2016, an MRI was taken. When compared with the original MRI taken Feb. 26, it revealed the patient's traumatic brain injury caused by global hypoxic/anoxic hypoperfusion insult. The MRI also revealed the injuries to the brain had occurred separately from those resulting from the underlying injury, the playground fall.

The child's parents filed a medical malpractice lawsuit against the hospital and physicians who initially treated the child and performed the improper intubation. The plaintiffs alleged multiple bases for the purported medical malpractice, including the physicians and staff failed to properly assess the injury when the child first arrived at the ED, negligently administered paralyzing drugs to perform the CT scan, failed to use less dangerous alternatives, intubated the patient incorrectly, failed to confirm the proper placement of the endotracheal tube, and failed to monitor the patient's condition. Because of the myriad negligence, the child suffered permanent debilitating injuries. She will never live a normal life, and will never develop cognitive functions beyond the level of a two-year-old.

Approximately three years after the plaintiffs filed the lawsuit, the defendants conceded liability and stipulated their negligence caused the child's anoxic brain injury. The parties further agreed the defendants owed damages for the plaintiff's pretrial medical expenses in the amount of $500,000. The parties proceeded to trial to determine the remainder of the damages, leading to an award of $16 million.

What this means to you: This case presents a rare occasion where a defendant care provider — a federally funded hospital — acknowledges and stipulates to liability, rather than challenging liability in the first instance. It is a rare occasion, but not without a logical explanation. In this case, the patient presented indisputable evidence demonstrating the defendant hospital's staff breached the standard of care on multiple occasions during the child's brief stay at the ED. When faced with this reality, it is reasonable to acknowledge liability and focus defensive efforts elsewhere, such as on challenging the nature and extent of the patient's injuries and damages calculations.

In this case, the patient was a healthy 6-year-old girl who suffered a relatively minor injury, but the defendant care provider's negligence caused significant injury to the patient, whose developmental and cognitive skills regressed to the level of a 2-year-old. Scans performed after the second intubation revealed the staff failed to properly position the tube and had to readjust it a third time, which was confirmed by the final scan. The two brain scans clearly excluded the possibility any of the injuries the child suffered resulted from the playground fall. The patient's experts opined the injuries appearing in the later scan could only be attributed to severe brain anoxia. In light of this evidence, arguing no breach in the standard of care had occurred would have been an impossible task and would have severely undermined any other arguments raised by the defendant care provider.

The second factor that most likely led the defendant to admit liability is the extent of the child's injuries. Because of the injuries, the child must be supervised at all times, and her verbal ability is extremely limited. Because the injury extended to all areas of her brain, she suffered severe cognitive impairment and cerebral dysfunction, leading to permanent setbacks for every basic function of life, from motor skills to cognitive ability and communication, as well as visual and emotional impairments. The court noted that at the time of trial, the child was 9 years old and required diapers to manage bodily functions, exhibited physically aggressive behaviors toward herself and her caregivers, and did not understand social boundaries.

Under such circumstances, the defendant's liability was confirmed through the clear link between the child's injuries and the negligent conduct. Experts confirmed had it not been for the improper intubation and negligent administration of drugs, the child never would have suffered from anoxic brain injuries and would have continued to live and grow as a healthy child.

Respiratory therapists and emergency physicians train for endotracheal intubation. There are several safety checks that must take place to assure correct placement. Intubation of a young child can be especially challenging due to the size of the child's airway. Assuring the correct tube size is particularly important. Using a meter to detect carbon dioxide exhaled by the lungs is a device that can help assess proper placement. Visualization during the insertion of the tube is used as well. Finally, a confirming X-ray is taken to show exactly where the tube lies within the lung. It is not uncommon to have to pull back on the tube or insert it a bit further to place it properly. But taking the confirmatory X-ray is an accepted standard and commonplace. Blood gas studies can confirm the patient is receiving the appropriate amount of oxygen and ventilation is adequate. These all are standard safety measures used in EDs and intensive care units.

Another important lesson relates to damages: A child with permanent, extensive injuries that affect a variety of aspects of the child's life is likely to receive a significant award given the ensuing medical expenses. In this case, the amount awarded by the court was calculated on a life expectancy of 81 years and accounted for the nearly three years of caretaking the child's mother already performed. Even if a defendant care provider acknowledges liability, it remains critical to understand the nature and extent of the patient's injuries to consult and retain experts who could testify the patient's interpretation of the injuries is overstated. Retaining a qualified expert to consult and/or testify concerning injuries and damages also can facilitate settlement positions, which is particularly helpful if liability is not disputed. Preventing trial and reaching a mutual settlement without an adverse jury verdict can reduce costs, expenses, and negative exposure. ■

REFERENCE

Decided on July 27, 2020, in the United States District Court for the District of New Mexico, Case Number 1:17-cv-00384.