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Patient Safety Organizations: Protecting peer review materials and improving patient safety?

by Robert A. Bitterman, MD, JD, FACEP, Contributing Editor

Imagine a black box. Into the box you could put all hospital ED related peer-review data, quality assurance materials, incident or occurrence reports, and medical error reviews.

Out of the box would flow expert evaluations and feedback on the issues presented by each case, and recommendations on methods, policies, and procedures to improve patient safety and the quality of care provided in your ED. As a bonus, the box would also compare your "errors" with those of other EDs across the country and provide you with information on practical solutions others have already successfully implemented to redress the issues.

Moreover, the box also would function as an iron-clad "lock box;" plaintiffs' attorneys would never be able to access or use any of the material in the box or the analysis that comes out of the box. State medical boards, state or federal health departments, and any other governmental or private agencies also couldn't get the data for disciplinary, administrative, or civil proceedings. The data in the box would not be subject to state or federal Freedom of Information Acts.

Creation of such a black box, labeled a "Patient Safety Organization" (PSO) was the intent of Congress and President Bush in enacting the Patient Safety and Quality Improvement Act in 2005.[1]

What is the Patient Safety and Quality Improvement Act (PSQIA)?

The PSQIA was born from the 1999 Institute of Medicine (IOM) report "To Err is Human," which basically stressed that improving patient safety required a learning atmosphere rather than a punitive one.[2] Congress realized that physicians and hospitals would never voluntarily report errors to a quality improvement program out of fear that the information could be used against them in a lawsuit or disciplinary proceeding. A number of states responded to the IOM report, long before the U.S. Congress, by passing voluntary medical error reporting laws with varying degrees of legal protection for providers[3] (though a few states, such as Minnesota,[4] passed *mandatory* medical error reporting laws). Most state schemes were similar to the limited voluntary reporting system The Joint Commission instituted in 1996.[5] However, as discussed in recent *ED*

Legal Letter articles, state peer-review protections or error reporting statutes often don't hold up in the crucible of litigation,[6,7] so legal counsel for providers were loathe to recommend that providers participate in the state "voluntary" error reporting schemes.[8]

The PSQIA is essentially Congress' attempt to create a legally protected environment in which healthcare providers would be willing to report errors to organizations (PSOs) that would analyze the data and provide recommendations to improve patient care. The PSQIA also provides confidentiality of the patient safety materials as well as the privileges from litigation, and imposes penalties for breach of confidentiality or privilege.[1,9]

How does the PSQIA work?

The law directs the Department of Health and Human Services (HHS) to certify Patient Safety Organizations (PSOs).[10] The PSOs will contract with providers in a HIPAA-like "business associate" relationship with the typical confidentiality agreement.[11] The providers will create "patient safety evaluation systems" (PSES) to collect the medical error/patient safety data and implement a process to report the data to the PSO.[12] The PSO, in turn, would analyze these materials, termed "patient safety work product" (PSWP) by the PSQIA, and provide direct feedback and recommendations to the contracted providers.[13] The PSOs also would provide patient safety education, recommendations, and policies and procedures to the general public in a sanitized fashion (no patient or individual provider identification) based on its findings and learning from its interactions with its contracted providers.[14] Furthermore, the PSOs would submit its data and recommendations, also in non-identifiable format, to national databases established by HHS to disseminate the information throughout the country and for use in research to improve patient safety.[15]

What are the criteria to establish a PSO?

Any organization, public or private, can become a PSO. The organization must submit an application to HHS demonstrating that it has policies and procedures in place to perform the requisite "patient safety activities" and that it satisfies certain criteria established by the PSQIA.[16] The primary criteria include the following:[17]

- The stated mission and primary activity of the PSO must be to improve patient safety and the quality of healthcare.
- The PSO must utilize appropriately qualified staff, including licensed or certified medical professionals.
- It must contract with more than one provider for the purpose of receiving and reviewing patient safety work product.
- To the extent reasonable, it must collect patient safety work product in a standardized manner that permits valid comparisons of similar cases among similar providers.
- The PSO must use the data collected to provide direct feedback and assistance to providers to effectively minimize patient risk.
- The PSO discloses any financial, reporting, or contractual relationships with providers.
- The entity is not a health insurance issuer or component of one.

All PSOs must initially and periodically thereafter certify compliance with these criteria to the government.[18]

In essence, a PSO serves two functions: first, as repository for patient safety work product materials and second, as an engine that actively analyzes the submitted work product and recommends improvements in patient care to the contracted providers and the health care community at large.

What are the benefits of a PSO?

Obvious benefits of utilizing a PSO include:

1. Centralized quality improvement (CQI) systems.

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Instead of a myriad of independent provider based quality programs such as quality assurance, CQI incident reports, and root-cause analyses, everything could be under one roof — the provider's "patient safety evaluation systems" (PSES), which would collate all the data and interact with the PSO.

2. Real patient safety improvement process. Freed from the fear of discovery for use in litigation or administrative proceedings, providers could candidly share near-misses, personal or personnel errors, system errors, or any other information they viewed as valuable to improving patient safety or the health care delivery system as a whole. The PSQIA could promote a more promising culture of safety across all health care settings, and be as Dennis O'Leary, President of The Joint Commission said, "a breakthrough in the blame and punishment culture that has literally held a death grip on health care."[19]

3. Data sharing. The PSQIA's creation of a network of PSOs and HHS computer databases may provide meaningful opportunities for providers to report and share data on the true quality of healthcare. It may allow research into the deeper and perhaps systematic reasons about why medical errors occur and/or reoccur in predictable patterns.

4. Federal peer-review privilege. The key component of the PSQIA is its federal peer-review protections. First, it solves the uneven and often suspect protection of peer-review materials provided by the various states.[7]

Second, the law preempts the federal rules of evidence,[20] which do not recognize state peer review protections in cases based on federal law. For emergency medicine this particularly means EMTALA claims. For example, in the case of *Smith v. Botsford General Hospital* the federal court allowed a very damaging EMS incident report into evidence against the hospital on an EMTALA claim for failure to stabilize the patient prior to transfer. It held that state peer-review protections are not applicable under the federal rules of evidence. [21] One of the reasons the plaintiffs in *Smith* filed their claim under EMTALA in federal court was specifically to seek discovery and admissibility of the EMS peer-review materials, which would certainly have been deemed privileged under Michigan law in an ordinary state malpractice claim.[6]

The material protected, called "patient safety work product" (PSWP), is intentionally broadly defined to ensure "that providers will feel safe and secure in participating in a patient safety system."[22] The act defines PSWP as:

> Any information in written or oral form (data, reports, analysis such as root cause analysis or failure mode analysis, etc.) that may result in improved patient safety, health care quality, or health care outcomes and is either 1) collected by a provider to be reported to a PSO *and* is actually reported, or 2) developed by a PSO for patient safety activities.[23]
>
> PSWP does *not* include original source materials such as individual patient medical records, billing and discharge information, other original patient or provider records (even if reported to a PSO), or any information that is collected or maintained separately from a patient safety evaluation process (even if reported to a PSO).[24]

Essentially this definition means that all quality improvement materials and analysis can be protected under the PSQIA, but with two very important caveats:

1. To be PSWP protected under the PSQIA, the quality improvement materials must be included in the patient safety evaluation system (PSES) and must not be maintained in any fashion outside the PSES. Providers will need to be absolutely certain that all patient safety materials are handled only within their PSES, because if any copies of the data are kept separate from that system those copies are not considered PSWP and lose their protection. PSWP simply does not include data that is collected, developed, or maintained separately from the PSES.[24] Furthermore, the definition of PSWP excludes data held outside the PSES, even if it is reported to a PSO.[24] This means that a hospital and its ED physicians would need to work together closely to ensure that all quality measures are centralized solely within a single system.
2. The PSWP must actually be reported to the PSO. Collating or developing data for the purpose of reducing medical errors or improving quality is not in and of itself sufficient to qualify for the statutory privilege under the PSQIA; the information must actually be *reported* to the PSO for the privilege to attach.[25]

The PSQIA creates a strong incentive for providers to voluntarily report patient safety information to a PSO. With rare exceptions, PSWP cannot be subpoenaed or discovered for use in civil, criminal, or administrative proceedings, and may not be introduced as evidence in any civil, criminal, or administrative proceeding or in any "professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law."[26] The confidentiality of PSWP also remains in situations outside of legal proceedings.[27]

If stronger state confidentiality or privilege protections exist, they are not preempted by the PSQIA. The provisions of the PSQIA do not replace or preempt any state mandatory reporting requirements regarding serious health care errors.[28]

What are the risks related to a PSO?

The main risk related to establishing a PSO is lack of experience with the law. HHS has yet to issue the implementing regulations to guide providers on how to

structure the PSO and how to format or utilize the patient safety work product, particularly in electronic fashion. No court opinions upholding the federal peer-review protections exist yet, which may be necessary to reassure providers that this federal attempt to create unbreakable peer review protection will fare better than the patchy history of peer-review in state courts. Few providers are willing to be first into the frying pan as the test case for legal interpretation of the PSQIA.

A relatively undiscussed risk in the legal literature is whether health care providers will actually be willing to voluntarily report medical errors, even with the promise of stronger federal confidentiality and peer-review protections. Decades of largely justified disgust, fear, and distrust of the legal system will be difficult to overcome. Despite the incentives discussed above, nothing in the PSQIA requires reporting or participation by any provider.[1]

Summary

The PSQIA was enacted to encourage physicians, hospitals, and other health care providers to voluntarily participate in medical error reporting systems designed to improve patient safety and the quality of medical care. It establishes broad confidentiality and privilege protections of information pertaining to medical errors and other quality information that is developed within a "patient safety evaluation system" and reported to a "patient safety organization." However, to date, both hospitals and physicians have been very reticent to establish PSOs because the government has not yet written regulations implementing the law. Only time will tell if providers voluntarily participate in patient safety oriented reporting systems and whether the statutory protections are rock-solid. ■

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Beware of inconsistent care when treating VIPs

Patients are "only as famous as you allow them to be"

by Stacey Kusterbeck, Contributing Editor

You might assume that when ED nurses and physicians care for VIPs —whether this means a family friend, another physician, the hospital

CEO, or a sports celebrity — that care would be stellar.

Experts say the opposite may actually be true. ED staff may omit unsavory parts of the history or examinations, order unnecessary tests, or just practice a little differently. Any of these actions could result in an adverse outcome and potential malpractice suit.

"The natural tendency is for VIP patients to be over treated or undertreated, depending in part on how much staff may fear them, and in part how on much we assume they know," says **Louise Andrew,** MD, JD, a consultant specializing in emergency medicine and liability issues and former emergency medicine faculty at the Baltimore-based Johns Hopkins University School of Medicine.

For physicians not accustomed to treating other physicians, there may be an unspoken fear that their patient may know more than they do." Therefore, one may try to outperform them in a sense," says Andrew. "And if they are a VIP who is noticeable to the outside world, there is an underlying fear that if they don't do well, it may reflect poorly on you or your institution in the public eye."

Nurses and physicians tend to be overly cautious when treating these typically vocal patients, says **Carolyn Capoccia Smith**, RN, JD, an attorney with Houston, TX-based McGlinchey Stafford. "The VIP's tendency to demand more tests and the threat of possible media exposure tends to make the health care worker more nervous, thus performing more, or fewer, tests than necessary."

This could result in a malpractice lawsuit if a bad outcome occurs, Smith warns. "If an ED physician is too embarrassed to perform a rectal exam on a demanding VIP patient, that patient could go home and die of a gastrointestinal bleed which could have been detected on exam," she says.

Many VIP patients tend to arrive with the expectation that they won't have to wait for services and that their needs preclude those of the other patients present. "They may demand that they be coded as a more severe emergency than they actually are, to avoid having to wait," says Smith.

There also may be subtle (or not so subtle) intimidation by the VIP or their entourage. Such patients may expect to receive some interventions that are not normally accessible to your standard patients. "So that can make things even more difficult," says Andrew.

The VIP might demand immediate treatment when their condition is not as severe or serious as others already waiting, expect a private room in a location which is usually reserved for specific types of cases, request special security, or want to be discharged or hospitalized for a condition which ordinarily is handled differently.

Andrew recalls the case of a department chair who reportedly refused to have a lumbar puncture done and ended up having meningitis with a delayed diagnosis. "As lawyers love to point out, physicians and medical families can and do sue other physicians," she says. "In this case, I think the 'chagrin' factor prevented it, plus perhaps his position at the institution. The key problem is that physicians 'know too much,' expect the best, and as we know, all too often seem to get the complications."

Another significant problem is that colleagues ask to be seen or advised as "curbstone consults" rather than as formal patients. It is illegal in most states to treat any patient without doing an exam and keeping medical records, and this type of informal care is invariably fragmented and suboptimal, says Andrew. "Then when a complication occurs, not only was there incomplete care, but no record with which to defend it," she says. "This is an incredibly unsafe practice."

Follow protocols closely

To reduce risks, pay strict attention to your ED's protocols for dealing with various conditions and illnesses. For example, all ED patients must be registered to receive care, including staff and physicians. "Do not waver from that protocol even if there is strong pressure to do so," says Andrew. "Emphasize paying attention to normal protocols and giving the same degree — not a greater degree or a lesser degree — of rigor to your treatment and analysis."

If your ED cares for VIPs frequently, consider educating staff in advance so that problems can be avoided. The protocol should simply state that all patients are treated in a medically appropriate manner despite any special needs that may dictate a departure from normal triage, placement, and discharge, advises Andrew.

"The VIP patient is only as famous as you allow him to be," says Smith. "Remind staff to continue to provide care to the other patients in the department as they would any other day."

It is important to avoid the impression that all the ED's resources are being used on a VIP patient at the expense of the other patients present, says Smith. "Do not alter your interview and assessment techniques, despite the fact that there may be some embarrassing questions you will have to ask in order to get the proper medical history from the patient," she says.

At George Washington University Hospital, ED staff have cared for a significant number of VIPs. Most notably, ED staff treated President Reagan after he was shot in 1981. "We do see a fair number of patients of various status, be they movie stars, politicians, or foreign dignitaries," says **Anthony MacIntyre,** MD, an ED physician at the hospital and associate professor

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SPECIAL REPORT

VP shunt malfunction in the emergency department

*By **Stephanie Rifkinson-Mann, MD, JD,** Neurosurgical Consultant, Mount Kisco, NY; Attorney, New York City.*

Symptoms of shunt malfunction often can be misconstrued as representing less dangerous medical conditions. Risk of a mistake in diagnosing a shunt malfunction is great, since the opportunity to prevent major morbidity and/or death is significant with early diagnosis of the problem and timely surgical correction. Hence, liability in such instances should be of concern to the ED physician.

Physician-patient relationship

A physician's indirect contact with a patient may not preclude the determination that a physician-patient relationship existed.[1]

Ashley Irvin was born with hydrocephalus and required a shunt in infancy to relieve her increased intracranial pressure. At the age of 12, Irvin developed symptoms of possible shunt malfunction, including flu-like symptoms, seizures, and neck and back pain. She was transferred from a hospital in Ulysses, Kansas, to a medical center in Kansas City on an emergent basis. She underwent shunt x-rays, which were reported to show no disruption or foreshortening of the shunt tubing, and a neurosurgical consult, at which time no evidence of a shunt malfunction was found. Since tests in Kansas City apparently revealed no other abnormalities, Irvin was discharged home.

The following month, Irvin again developed the same symptoms. She was admitted to Wesley Medical Center, where x-rays suggested that the shunt was in need of repair due to apparent foreshortening of the distal tubing, which had slipped out of the peritoneum and was embedded within the abdominal wall. The treating physician, Dr. Smith, telephoned Dr. Gilmartin for a neurological consultation. The two doctors discussed the case, and Dr. Gilmartin agreed to see Irvin the following morning. Prior to her being seen by Dr. Gilmartin, Irvin's condition deteriorated to the point that she required resuscitation and intubation. A shuntogram, the injection of a radioactive isotope into the shunt to evaluate blockage in the system, indicated a shunt obstruction, which was the cause of Irvin's injuries. Surgery was performed to correct the shunt malfunction, but Irvin suffered permanent and severe brain damage prior to undergoing the shuntogram procedure.

The trial court granted summary judgment in favor of Dr. Gilmartin, the neurologist, ruling that a physician-patient relationship had not been established in his case. On appeal, the Kansas Supreme Court affirmed. The Court initially observed that the question of whether a physician-patient relationship exists is a question of fact and noted that:

> [t]he existence of the duty of care is dependent on the existence of a physician-patient relationship. ... Generally, a ... relationship is created only where the physician personally examines the patient ... A physician's indirect contact with a patient, however, does not preclude the finding of a physician-patient relationship ... Indeed, an implied physician-patient relationship may be found where the physician gives advice ... through another health care professional. A physician who gives an "informal opinion" at the request of a treating physician, does not owe a duty to the patient because no physician-patient relationship is created. A physician who assumes the role of treating the patient, however, can be liable for medical malpractice.[2]

The Kansas court in Irvin noted that a physician's indirect contact with a patient does not preclude the finding of a physician-patient relationship.[3] The Irvin court stated that Kansas law requires that the doctor must take some affirmative action with regard to treatment of a patient in order for the physician-patient relationship to be established.[4]After a review of cases around the country, the Kansas court held that the mere act of Dr. Gilmartin agreeing to see the patient at a later time did not establish the physician-patient relationship, reasoning that the case basically boiled down to public policy concerns. The court noted that the type of telephone conversation that took place frequently occurs in the medical profession and is vital to the treatment of patients. It refused to extend liability to doctors who act solely as an informal consultant, even where their participation in the case is extensive, since discouraging such conversations is not in the patients' or the public's best interests.

Courts have used great caution when responding to requests that they recognize legal duties within this medically important but legally ambiguous world of the curbside consultation, noting that the extension of the physician-patient relationship to include this type of informal consultation would be contrary to public policy, noting that "[i]t would have a chilling effect upon practice of medicine. It would stifle commu-

nication, education and professional association all to the detriment of the patient. The like effect ... would be that such informal conferences would no longer occur."[5]

For the ED physician, this means that while a physician may not be held liable for medical decisions based on consultations with specialists via this rationale, this type of analysis may be state specific and different court decisions may yield different results.

Specialist consultation

Physician's appropriate consultation with specialists may not preclude findings of negligence in all cases.[6]

The plaintiff in this case, Darwin Green, was born with hydrocephalus and received a shunt in early infancy to drain excess cerebrospinal fluid in his ventricles and alleviate increased intracranial pressure. His shunt was revised twice by the time he was age 4. Darwin, while having limited intellectual capacity, was able to attend school, taking special education classes, and to join his family on vacation, etc.

At age 11, Darwin developed a headache for which he took Tylenol to no avail. He began to vomit and by the next day, he had developed drowsiness. He was taken to the ED at North Arundel Hospital, where Dr. Fields, the physician on duty, examined him and ordered several laboratory tests, including an emergency CT scan. Dr. Axelbaum, the radiologist at the hospital, reported several abnormalities, including multiple shunt tubes, a subdural hygroma causing mass effect on the left hemisphere, a large right-sided porencephalic cyst, and an apparent acqueductal stenosis. The radiologist concluded that these findings reflected "old changes." Dr. Fields, the ED physician, then consulted a neurologist, Dr. Mody, who cleared Darwin for discharge once the headache was relieved. Darwin was given Vicodin and then discharged, after the ED physician called Dr. Lee, Darwin's primary care physician. Following discharge, Darwin's pain recurred. His father gave him another Vicodin that evening. The next morning, still in pain, Darwin was evaluated by Dr. Lee, who noted that not only was he complaining of headache, but that he also was drowsy and staggering. Dr. Lee consulted Darwin's neurosurgeon and arranged for Darwin to go to the University of Maryland Hospital in Baltimore. Upon Darwin's arrival in the ED at the University of Maryland, his shunt was tapped and another CT scan was performed, at which time Darwin was diagnosed with a shunt malfunction and increased intracranial pressure. He was admitted to the Neurosurgery service that night although no surgery was performed, and the following morning, he suffered a cardiac arrest, which left him essentially in a chronic vegetative state, unable to communicate and completely dependent upon others for all of his care.

A claim was filed on behalf of Darwin with the Health Claims Arbitration Office in Maryland against Dr. Fields, the ED physician, and North Arundel Hospital (where the applicable standard of care allegedly was breached by failing to diagnose the shunt malfunction and that a proper diagnosis would have prevented the child's subsequent devastating injuries); the University of Maryland; and eleven physicians at the University of Maryland, alleging that he was injured by negligent care he received in the ED at North Arundel Hospital and while a patient at the University of Maryland. While the case was pending before the Health Claims Arbitration Office, the plaintiff settled with the University of Maryland defendants for $1,489,000. The remaining parties waived arbitration and a suit was filed in the Circuit Court for Baltimore City against North Arundel Hospital and Dr. Fields, the two defendants in Anne Arundel County. The case was transferred to the Circuit Court for Arundel County for proper venue. Two weeks before the start of the trial, the plaintiff asked for a postponement, adding two additional defendants, Dr. Mody, the neurologist, and Dr. Axelbaum, the radiologist at North Arundel Hospital. Both defendants filed answers to the amended complaint. At the conclusion of the plaintiff's case, the judge granted North Arundel Hospital's and Dr. Mody's motions for judgment and the jury returned verdicts in favor of Drs. Fields and Axelbaum.

In this particular lawsuit, while no liability was found on the part of the ED or Dr. Fields, the ED physician, the case demonstrates several areas in which potential liability might have arisen. The ED physician depended upon an abnormal radiological report, which was transmitted without comparison to a prior study, to assume that no shunt malfunction was occurring and transmitted this information to the neurologist, who cleared the child for discharge. While the ED physician appropriately called a neurological specialist and was not held liable for his actions, this is a situation in which symptoms of shunt malfunction need to be recognized in the ED to prevent potentially catastrophic neurological consequences. It is incumbent upon the ED physician to recognize signs and symptoms of subarachnoid hemorrhage to prevent significant morbidity or mortality associated with cerebral aneurysmal rupture.[7]

Conclusion

Although ED physicians are often involved in complex and complicated emergency situations and most

medical malpractice cases settle out of court, findings of liability for medical negligence in the ED depend largely upon the state in which the action is brought. For the ED physician, this means that while the appropriate standard of care may have been met and clear documentation of the physician's decision-making exists, the credibility of witnesses, the qualifications of the experts involved, the experience of the defense attorney and his or her understanding of the medical issues at hand, the court's jury instructions, and other factors may all play a role in the ultimate outcome of the ED physician's defense. ■

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with the department of emergency medicine.

"We strive to treat them as we would any other patient and try not to order extra things or skip things because of who they are," MacIntyre says. "The whole goal is to provide the same medical care you would to any other patient."

The ED has a protocol for VIP patients, with the stated objective to provide quality medical care and not let the person's status affect their care. "Most of what is done differently is on the administrative side, not the medical side, such as restricted access and increased security," MacIntyre says. "The patient privacy issue is probably the most problematic. You don't want everyone coming to ask for autographs." ■

Caring for government dignitaries: Report from an ED physician

Some rules broken, but never at the expense of other patients

As former chief of emergency medicine for the largest hospital and medical treatment facility operated by the U.S. military South Korea, **Sean O'Mara**, MD, JD, treated many senior level government officials and dignitaries.

"It was generally recognized within our military leadership that a bad medical outcome in one of these individuals would be critically important to avoid," he says. "We usually went out of the way to provide very good care for these people who had quite an influential position over our government hospital."

As the senior emergency physician, O'Mara typically would care for VIP patients. "While we purported to provide high quality care for everyone, I think it would be safe to say that VIPs were probably given greater scrutiny than the typical person," says O'Mara. "It would also be safe to say that no one else's care was compromised for the sake of a VIP, which would understandably also potentially be quite problematic for our hospital command." O'Mara currently practices emergency medicine on a full-time basis in Winchester, VA and works as a consultant in legal medicine and homeland security.

VIPs on an individual basis

During medical examinations and histories, O'Mara says that questions or interventions were never intentionally omitted. "Instead, I would opt to simply operate under a heightened level of sensitivity over how they might perceive certain questions or exams," he says. "I have had to perform rectal exams and other challenging exams on extremely important people and believe I have done so in a very sensitive and dignified manner."

In addition, VIPs were generally given expedited care to accommodate their unusual time requirements. However, this was done by adding additional resources

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to avoid delaying care for the patients already waiting in the ED.

"We would simply bring in an extra doctor and nurse to care for the VIP, so the on-duty physicians and nurses would not be directed from caring for other patients," says O'Mara.

On one occasion, O'Mara got a call from an official asking him to care for a "government representative" having chest pain. "I was informed that they were important, but not adequately informed of their exact seniority," he says. "When the patient arrived, I was astounded to find that they were in just about the highest level of government service one could aspire to and few ever achieve."

The patient clinically required admission to the hospital, but needed to have their medical workup and care completed earlier than the ED could with its existing resources. The patient needed to be discharged from the hospital to meet with the President and the Secretary of Defense within hours.

This would require an employee to be brought in two hours earlier. Following policy, O'Mara consulted with a senior physician about the special accommodation. "This physician directed me to not do anything special for this person, and instead offer them to stay within our schedule or simply leave," says O'Mara.

For the first time in his military career, O'Mara knowingly violated a directive from a senior officer in his chain of command. "I simply was unable to get beyond what would have been the loss to our country, had this person been allowed to leave prematurely and consequently experienced a bad medical outcome from a lack of proper treatment," he says.

This interesting case makes the point that every VIP treated in the ED must be considered on an individual basis, so long as special accommodations do not adversely impact other patients, says O'Mara.

"Ultimately as medical professionals, we need to be able to sort through the added layers of complexity which oftentimes accompanies VIPs seeking medical care," says O'Mara. ■

Source

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Do psych patients wait hours to be "medically cleared"?

Patients may escalate if interventions are delayed

Some emergency physicians argue that the most urgent needs of psychiatric patients are often pushed aside in the ED until a wide range of testing is completed for medical clearance. On the other hand, without appropriate diagnostic testing, ED physicians may miss an underlying medical condition. Either scenario can result in a lawsuit.

Missing an emergent medical problem is the greatest liability risk regarding medical clearance of psychiatric patients, says **Gregory P. Moore,** MD, JD, an attending physician in the emergency department at Sacramento, CA-based Kaiser Permanente Medical Center. "The patient will leave the ED and go to an area where there is essentially very little clinical medical care," he says.

The major liability risk for the ED physician is misdiagnosing the patient's symptoms as psychiatric and missing the patient's medical illness, says **Thomas W. Lukens,** MD, PhD, FACEP, operations director for emergency medicine at MetroHealth Medical Center in Cleveland, OH. The "psychiatric" patient may actually be suffering from delirium or dementia, not a new psychiatric complaint, says Lukens. Delirium or dementia are medical illnesses, not psychiatric, and need to be recognized and treated as such, he says.

Another mistake that raises liability risks is lack of communication if the ED physician fails to speak with the receiving agency to explain the patient's medical issues, if any, says Lukens. "The patient's symptoms are considered psychiatric and the meningitis is missed, for example," he says. "This usually arises from not doing a sufficient history and physical examination."

What should medical clearance consist of?

The goal of medical clearance should be finding out if there is a medical etiology for the patient's symptoms, says Lukens. "This may take some laboratory testing, but may not. A history and physical is the minimum that should be done, however, in the ED," he says.

Often, it is assumed that the behavior of the patient is due to their underlying psychiatric illness and no further evaluation is undertaken, including a good history and examination. "This can cause problems down the road," says Lukens. "If the patient is transferred to a psych facility, there usually isn't any further medical

testing or evaluation done and the patient's medical illness can get worse."

The patient's history and physical exam should be the basis for clearance in the ED, argues Lukens. "Patients with normal vital signs and unremarkable history and exam, including normal mental status, generally don't need any further testing in the ED. This is what the literature has shown," he says. "It's also shows there is no specific battery of blood tests or X-rays that prove the patient is medically clear." Any additional testing should be directed by the patient's history and physical, says Lukens.

Medical clearance should include a thorough history, a complete set of vitals, and a good medical examination. Further testing should be guided by suspected possible diagnoses, says Moore.

Since the biggest legal risks regarding medical clearance are missing an overdose or withdrawal state, an infectious disease, or a diabetic emergency, Moore recommends performing simple diagnostic tests. "It would be very easy to get a quick blood sugar level on all patients," says Moore. "Many experts recommend an [acetaminophen] level since you can't diagnose that overdose on vitals and physical exam, and it is lethal. Patients often are not honest and may not admit or tell you they have overdosed on this easily available medication."

Moore does the following screening evaluation for patients with psychiatric complaints: An acetaminophen level, an electrocardiogram to look at QRS width, and a Chem 7 panel to evaluate blood sugar and acidosis. "I often get a urine drug screen and alcohol level, not because it helps me evaluate the patient but because it speeds up the disposition of the patient to psychiatric facilities that require these tests for admissions," he adds.

Many psychiatric facilities have been burnt in the past by receiving a "psychiatric" patient in transfer that really is medically sick and deteriorates, says Lukens. "Therefore, many facilities request a battery of blood tests before transfer to 'prove' the patient is clear, even though the evidence-based literature does not indicate this approach at all," says Lukens.

Are tests needless?

Typically, the ED physician immediately realizes that a psychiatric assessment is needed, but before that can occur, the patient is required to be "medically cleared," with a predefined assortment of ancillary tests, says **Mark Pearlmutter**, MD, chief of Caritas Emergency Medical Group in Boston.

Asking patients in a mental health crisis to wait for hours while an assortment of tests are done is "sending a terrible message," says Pearlmutter. These patients may present with anxiety and depression and after hours of waiting may become increasingly agitated or even suicidal as a result, he adds.

The term "medical clearance" itself is a misnomer, says Pearlmutter. "At face value, it seems to imply a prolonged state of stability. However, it truly represents only a snapshot in time," he says. "Despite this, given how much the term is embedded in our medical nomenclature, we are forced to work with it."

Medical clearance of psychiatric patients typically involves two components: To rule out an organic cause for a patient's presenting symptoms, and to determine whether a psychiatric emergency medical condition exists.

"Most of us have approached this with a focused history and exam," says Pearlmutter. "Many, however, still seem to automatically order blood tests and a urine toxicology screen, largely due to a receiving facility's protocols or demands, or simply to expedite throughput and placement," he says.

There is very little evidence to suggest this approach is cost effective or clinically useful, says Pearlmutter. "Nonetheless, it is a difficult paradigm to change and many simply order these tests for the above noted reasons, as well as some potential liability concerns," he says.

What is considered medically cleared to an emergency physician may be very different than what is considered medically cleared to anyone else, adds **Robert B. Takla,** MD, FACEP, medical director of emergency services at St. John Oakland Hospital in Detroit. A history and physical may be sufficient from a medical perspective, but laboratory tests may be either needed or required, he explains.

"If they are needed, that is an excellent reason to obtain them. If they are required but without clinical indication, there is a problem," says Takla. "Often we are at the mercy of an accepting facility to order tests that have no clinical indication."

A typical "psych clearance panel" includes a complete blood cell count, electrolytes, blood urea nitrogen, creatinine, glucose, urine drug screen, alcohol level, and any medication the patient may be on that a level can be obtained for, such as dilantin, depakote, or lithium. If you get all these labs, there is always a chance you may identify a problem, acknowledges Takla. "If you throw a large enough net out there, you are bound to catch something," he says. "There is always the chance of a serendipitous finding."

However, Takla says that the question is whether the net value of all the tests is more beneficial or more harmful. "I am of the opinion that it is more harmful, because you are wastefully using resources without clinical foundation and incurring additional delays to disposition, as opposed to applying your clinical judgment," he says.

Also, by doing a lot of unnecessary tests, you are delaying the definitive care the patient may really need — a psychiatric intervention.

"Frequently, there is a knee jerk reflex to get these labs done because facilities request it done before they accept patients," says Takla. "Because we are at the mercy of facilities, we have nonclinical people making decisions as to what tests they need to medically clear someone. In reality, it should be whatever the ED physician feels is necessary."

Takla reports that his ED is starting a new pilot study to improve care of high utilizers by having them receive care at a single ED, so physicians have more knowledge of their medical and psychiatric background. "We have a high number of repeat visits for psych, but they tend to just go to the closest ED," says Takla. "So what we are trying to do is if one of these patients needs to be hospitalized, we would like to have the pysch evaluation take place in our ED."

Long delays for non-clinical reasons also can put patients at risk. Takla gives the example of a patient with an alcohol level of 0.08 who ordinarily could be discharged home, but if they are a potential psych patient and need evaluation, the patient will not be seen until the level is zero or close to it.

"This delay is neither necessary nor safe, as it delays definitive psychiatric intervention," says Takla. "It keeps the patient in the ED too long and that is a very unsafe environment for them." This scenario poses two big risks: Elopement and restraint use, he says.

Hours spent waiting for a mildly elevated alcohol level to normalize just adds delays to the patient's final disposition, says Takla. "We have psychiatric patients remaining in the ED, oftentimes in restraints, who are just waiting to get to normal values, when in reality they should have been transported much sooner," says Takla. "Instead they are waiting in the ED to establish legal limits of sobriety rather than clinical limits of sobriety."

During this time, Takla says he sees these patients become more volatile and less cooperative. "When you make them wait in the ED for longer periods of time than necessary, it just adds to the emotional instability that exists," he says.

Guidelines can cut delays

Having clear guidelines to identify patients who do not require toxicology screens, medical testing, or imaging studies means psychiatric patients get the help they need more quickly, according to Takla.

Takla is former medical director at St. John Northeast Community Hospital, also in Detroit, where screening guidelines were implemented. He reports that due to the guidelines, turnaround times were dramatically shorter than at his current ED which has not implemented guidelines.

"We had much timelier turnaround times than we do now," says Takla. "This make things less safe for the patient and the remainder of the ED. We are having to

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CNE/CME instructions

Physicians and nurses participate in this CE/ CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. After completing the semester's activity, you must complete the evaluation form provided and return it in the reply envelope to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you. ■

CNE/CME objectives

After completing this activity, participants will be able to:

1. Identify legal issues relating to emergency medicine practice;
2. Explain how these issues affect nurses, physicians, legal counsel, management, and patients.
3. Integrate practical solutions to reduce risk into the ED practitioner's daily practices. ■

use more chemical restraints, more physical restraints, as a result."

The biggest hurdle to implementing guidelines is to get buy-in from receiving facilities and mental health clinicians, says Pearlmutter. He adds that, in general, third-party payers are in support of this since it may reduce costs.

"I think that if evidence-based guidelines are universally agreed to by all parties, one's liability risk is reduced," says Pearlmutter. "That is not to say that one's risk is totally eliminated. But one probably has more of a legal defense stating that they practiced according to published evidence-based guidelines, rather than an abstraction based upon their experience and clinical judgment," he says.

Guidelines for medical clearance do reduce risks if they are followed, says Lukens. "These guidelines have to be worked out with your psychiatric colleagues, otherwise they fail for the most part," he says. "Having the psychiatric problem evaluated and treated sooner rather than later is a very desirable outcome for the patient and guidelines help achieve this." ■

CNE/CME *Questions*

31. Which is recommended to reduce liability risks of caring for VIP patients in the ED?
    A. Do not deviate from protocols.
    B. Order additional diagnostic tests.
    C. Deviate from normal triage practices.
    D. Alter interview techniques to avoid sensitive topics.

32. Which is true regarding advising a physician colleague?
    A. No documentation is generally needed as long as the care is informal.
    B. Verbal consults with other physicians do not pose any liability risks
    C. ED physicians should avoid documenting this type of care.
    D. Avoid treating anyone without doing an examination and keeping medical records.

33. What should a "medical clearance" entail to reduce risks of psychiatric patients in the ED?
    A. Only what the receiving facility requires.
    B. Always a full panel of laboratory tests.
    C. A thorough history, a complete set of vital signs, a medical examination, and further testing as needed.
    D. Waiting for a blood alcohol level to normalize.

34. Which occurred as a result of implementing guidelines to identify psychiatric patients who do not require toxicology screens, medical testing, or imaging studies?
    A. Turnaround times increased significantly.
    B. Patients became more agitated.
    C. Use of physical restraints increased.
    D. Turnaround times decreased.

Answers: 31. A; 32. D; 33. C; 34. D