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Perspectives on health care legal issues

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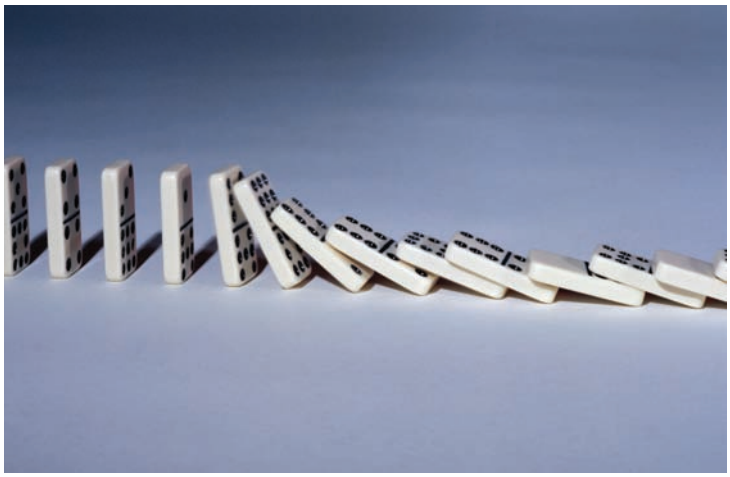
Disaster preparedness requires HEICS

Disaster planning has long been a component of hospital training and emergency preparedness activities, in part because hospitals are virtually guaranteed to feel some impact from any major emergency.



Effective disaster response, however, requires coordination of activities among all the agencies that respond to an emergency. To that end, federal, state, local and tribal governments, as well as private-sector entities with emergency response roles, must comply with the National Incident Management System (NIMS) by Sept. 30, 2006, to remain eligible for federal emergency preparedness funding.

Hospitals may comply with this directive by implementing the Hospital Emergency Incident Command System (HEICS). The HEICS is the currently recognized standard for hospital disaster management. It is designed to permit smooth incident command interface with responders such as fire service, emergency medical services and law enforcement.

History is revealing

The importance of unified command structure and communications was recognized in disaster response evaluations dating back to the 1970s, when scrutiny of the response to catastrophic fires in California revealed that inadequate response management accounted for more of the losses suffered than any other cause. As a result, the Incident Command System (ICS) was developed. The ICS is a standardized system for effective management of emergency situations, whether for large- or small-scale events. The ICS was first adopted by the fire service, and then by EMS and law enforcement.

In 1987, the first iteration of the ICS designed specifically for hospitals was developed by the Hospital Council of Northern California and further refined through the efforts of the California Emergency Medical Services Authority. Over the years, the HEICS has been revised (it is now in its third version) and has become recognized as the standard for the industry both nationally and internationally.

Work is now under way on the fourth version of the HEICS, which will be renamed the Hospital Incident Command System (HICS). The HICS will integrate modern emergency management principles and ensure consistency with the NIMS, but it remains based on the principles established by the ICS and HEICS.

Those principles revolve around a unified command structure for incidents that require multiagency responses. One overall incident commander is responsible for the total response, based on the primary attributes of the emergency. This permits establishment of one set of objectives and a collective approach to response, while maintaining reasonable scope of control.

Predictable processes

The ICS provides a predictable chain of command, common nomenclature and standardized job

descriptions in a flexible organizational structure. The incident commander defines the mission of the response and assumes overall responsibility for accomplishment of that mission. He or she typically has three "special duty" direct reports: the safety and security officer, the public information officer, and the liaison officer (who coordinates with other response agencies).

In addition, the chief of each of four major areas of responsibility reports to the incident commander:

1. The *logistics chief* establishes and maintains an environment, including necessary materials, which permits accomplishment of the mission.
2. The *planning chief* collects and analyzes data to permit short- and long-term planning and continuity of operations.
3. The *financial chief* tracks costs, identifies possible sources of reimbursement for the disaster response, and establishes and maintains the documentation necessary to request any reimbursement.
4. The *operations chief* carries out the medical objectives of the mission.

The HEICS, and the new HICS, are built along the same lines. They are intended to provide a standardized command and control structure that integrates well with other community-based ICS structures.

Because the HEICS is a responsibility-based, rather than position-based, management system, it is flexible and scalable. It is a functional framework for command and control of small, localized emergencies as well as major, multi-dimensional and large-scale emergencies.

The immediate, intermediate and long-term responsibilities of each role identified in the HEICS are set forth in job action sheets that prioritize activities. They are intended to be used during the emergency as reference points that may be adapted as appropriate to meet the needs of the organization and the population being served.

Changing command

Not all job functions will be activated in every situation, and the person who assumes a given role may be changed according to the needs of the emergency. For example, in an internal disaster the incident commander may be the hospital's chief executive officer, while in a major external disaster someone with specialized emergency management training may take the lead.

Plan surge facilities for emergency overflow

In certain emergencies, hospitals may need to expand their resources to meet increased demands. Thus, disaster preparedness planning should include identification of surge facilities such as school gymnasiums or hotels that can be used to house patients.

It is important to remember that a surge facility may be required to replace, rather than supplement, a fixed facility. Therefore, an effective surge capacity plan must include facilities that will remain operable if the primary facility is damaged.

Ambulatory surgery centers and veterinary hospitals often make excellent surge facilities. They are typically well maintained and have the added advantage of being piped for medical gases. There also has been increasing interest in developing purpose-built surge facilities, such as the prototype ER One, an all-risks, modular and rapid-deployable emergency facility under development by Washington Hospital Center in Washington, D.C.

Regardless of where a surge facility is located, it's important to have plans for equipping and staffing it. Consider the Strategic National Stockpile (SNS), the federal repository of drugs and medical/surgical equipment for use in emergencies, as well as surge agreements with equipment and supply vendors.

Coordinate with other community organizations, both to ensure that multiple hospitals are not counting on the same individuals to staff the facility, and to facilitate sharing of equipment and supplies.

Hospitals must implement an ICS, and the individuals who are primarily responsible for emergency response activities must receive at least minimal training in the NIMS and ICS. Pending finalization of the HICS, which is expected this year, hospitals that implement the HEICS meet the requirement for continued federal emergency preparedness funding.

Don't lose focus

Although adoption of the HICS appears imminent, hospitals are advised to continue implementation, training and drilling of the HEICS to ensure preparedness for the next disaster. The question is not whether that disaster will occur, but when and where. <

When is innovative care really research?

It is a relatively well-accepted fact that physicians are permitted to prescribe medications or use medical devices for purposes other than those indicated on the label. The Food and Drug Administration (FDA) regulates the manufacture and marketing of drugs and devices, not the practice of medicine. In fact, off-label use can eventually become the standard of care.

It is important to remember, however, that what you view as innovative care may be research in disguise. When it is, it must be carried out properly if you are to avoid potentially onerous penalties.

Following the rules

The mere fact that something is research doesn't condemn it — it simply means that it should be conducted under the oversight of an institutional review board (IRB) and comply with the ethical constructs expressed in the Belmont Report. The Belmont Report, issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, is the basis for ethical research requirements today in the United States.

Research that isn't properly conducted and overseen can put you at significant risk of liability, as well as generate extensive adverse publicity. If you seek third-party payment for research interventions, it may also result in allegations of billing fraud. To avoid such difficulties,

encourage physicians to seek early IRB review of proposed novel interventions.

Definitions of research

Current federal regulations define research (which may also be referred to as a clinical investigation, clinical trial or some similar term) as "any experiment that involves a test article and one or more human subjects ..." for which approval to market may be sought from the FDA, or, for research which receives federal funding, as "a systematic investigation ... designed to contribute to generalizable knowledge ... ."

Therefore, if the results of the innovative use of a drug or device are intended to support an FDA application to market the drug or device, it is

research and must be conducted in accordance with the applicable FDA regulations. If the activity is federally funded and the intent is to develop generalizable knowledge, it must comply with the 1991 federal regulation known as the "Common Rule." This regulation provides the basic procedures and principles that are to be followed in conducting human-subject research sponsored by federal agencies.

In either case, the research must be conducted under the oversight of an IRB, pursuant to a protocol, using scientifically valid means, and using only subjects who have given informed consent before participation.

No easy answers

There are times, however, when distinguishing between innovative care and research is difficult. Consider the following scenario: Dr. Smith, an oncologist, has a pediatric patient with seizures. Dr. Smith believes that Compound T, which is approved for use in adults with Parkinson's disease but has not been approved for use with epilepsy or in children, may be beneficial. If Dr. Smith gives Compound T to his pediatric patient, is it innovative care, or research?

The size of the sample is not dispositive. It is possible (though unlikely) to conduct a research study with a patient population of one. The mere fact that Dr. Smith hopes the medication will be therapeutically effective for his patient is also insufficient. Clearly, the goal of many clinical trials is to demonstrate clinical efficacy and safety of the drug in a given situation.

Similarly, the fact that the drug is approved for use in adults with a different type of neurological disease does not resolve the question; use in a pediatric patient with a different disease is, at minimum, off-label use.

The question may come down to the physician's intent. If the reason Dr. Smith is using the medication is strictly that he believes it is the best possible intervention to treat his patient's condition, it is likely to be innovative care. If he also intends to publish the results of this intervention or hopes to develop evidence that it is safe and efficacious, however, it becomes research.

Indicators of research

Although not dispositive, here are some indications that a novel intervention is research, rather than innovative care:

- Patients are assigned to receive the novel intervention vs. another intervention on a basis other than their clinical presentation, such as random assignment.
- The condition being treated is significantly different from that for which the use is approved — for example, the use of Neurontin®, an antiepilepsy drug, to treat diabetic nerve pain.
- The patient population receiving the intervention is significantly different from the patient population described in the approved drug literature.
- The novel intervention uses a device or chemical compound not approved for any therapeutic or diagnostic use in the United States.
- The physician maintains special records documenting the response to the novel intervention.

When in doubt

It can be difficult to distinguish between innovative care, which is not regulated by the FDA or other research regulations, and research. When attempting to properly characterize a given treatment program, you should consider both the intent and the decision-making process.

If the intent is to contribute to generalizable knowledge, it is research. If the intent is solely to treat a patient, it is likely to be innovative care. Similarly, if you decide which therapy to use based solely on the best interest of the patient, it is more likely to be innovative care.

When in doubt, refer to the relevant IRB or ethics committee. Either can be of invaluable assistance in determining how to properly characterize a nonstandard intervention. <

The Provider Self-Disclosure Protocol: Worth considering

It is the phone call all hospital executives dread: Your compliance officer has just told you that allegations of improper Medicare or Medicaid billing or other improprieties appear to be true. Your hospital may have violated the law. Now what?

First, consider whether the problem is simply an error such as an overpayment, or a violation of the law. If the problem is the result of a mistake, you may refund any overpayment, often without incurring any penalty. If, however, the problem appears to involve a violation of law, the Provider Self-Disclosure Protocol offered by the Office of Inspector General (OIG) of Health and Human Services should be considered.

Self-disclosure = self-protection?

Published in 1998, the Self-Disclosure Protocol allows providers to advise the OIG if they find irregularities in their activities. The intent is to both protect the government from further damage and to permit a reasonable resolution of illegal activities.

Prompt investigation and reporting of possible violations may increase the likelihood of an acceptable outcome. Before deciding it is appropriate, however, you should understand what is involved in self-disclosure.

Sharing the details

The Self-Disclosure Protocol requires you to disclose the details of the problem in writing, as well as whether you are already under government investigation, or the problem is, and why you believe the problem may involve a violation of law.

You are expected to conduct an internal investigation that:

- Identifies the possible causes of the problem,
- Describes how the practice developed,
- Details the impact on health, safety or quality of care, and
- Identifies corporate officials or employees who participated in the problem or who should have detected it, but failed to do so.

It is important to also communicate that you responded with an effective, prompt investigation and timely correction of the improper conduct. Include any disciplinary action taken against responsible individuals. Any attempt to shield personnel will be viewed as a serious failure of the compliance program.

Risks and benefits

Because of the detail and extent of information that must be disclosed and the degree of cooperation required by the OIG under the Self-Disclosure Protocol, there is some concern that participation could essentially hand the government its case. But although the OIG states that it is “not obligated to

resolve the matter in any particular manner," it has indicated that it views the fact that a provider identifies, resolves and reports a violation of law voluntarily as a good indication that the provider has an effective compliance plan.

As a result, self-disclosure makes it more likely that the OIG will either not require a burdensome and expensive corporate integrity agreement (CIA) or will impose less stringent oversight requirements and a shorter term.

Alternatively, you may enter into a certification of compliance agreement (CCA), which typically has a shorter term and imposes less stringent audit requirements than a CIA.

Don't hide

Given the complex regulatory environment surrounding health care, even the best-intentioned provider may identify failures of compliance. A thorough investigation and careful legal analysis will often be necessary to determine whether the problem is a simple error or a more serious violation of law.

If you do uncover a violation of law, your initial inclination may be to hide, but the best approach very well could be to use the Provider Self-Disclosure Protocol. Demonstrating your commitment to compliance, the effectiveness of your compliance program and your good-faith desire to work with the OIG will go a long way toward resolving any issues as fairly and painlessly as possible. <

The power of an apology

Traditionally, health care providers have responded to allegations of bad outcomes with a "deny, dispute and debate" posture, refusing to admit that a medical error might have contributed. Today, however, a slow revolution is occurring: Some providers are working to reach fair, nonadversarial resolutions to any medical errors associated with bad outcomes.

A coalition of medical malpractice stakeholders, including physicians, lawyers, hospital administrators and legislators, has created an initiative called "Sorry Works!" The initiative promotes apologies as effective risk mitigation tools, and several state legislatures have enacted or are considering legislation to prevent providers' apologies from being used against them in court.

The solution is not simply to apologize and walk away, however. A critical part of the process is careful investigation of the bad outcome and a thorough analysis of whether medical error played a role. If medical error is involved, a four-step resolution is appropriate:

1. Admit the error.
2. Explain what contributed to the error and what changes will occur to prevent the error from recurring in the future.
3. Express remorse.
4. Propose a reasonable upfront settlement.

This process requires open, honest and compassionate communication with the patient and/or family members.

An honest dedication to determining whether a medical error contributed to a bad outcome and to preventing future errors helps allay concern that a similar problem will occur again, while reasonable upfront compensation for losses diminishes the appeal of a malpractice recovery. All in all, properly implemented, sorry just might work.

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of ***Practical Health Law***. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of **www.HallRender.com**.

We understand the value of good information when making sound business decisions. ***Practical Health Law*** is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you'd like to see addressed.

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