CMS Rules for Hospital-Acquired Conditions Pose Challenges and Opportunities

In October 2008, the Centers for Medicare and Medicaid Services (CMS) implemented new rules affecting inpatient prospective payment systems for hospital-acquired conditions (HACs) that result in additional treatment and lengthened stays. The new rules cite 10 conditions (up from the original eight) that, if they are not deemed to be present on admission (POA), are no longer covered or are covered at a reduced rate. (See “List of HACs.”) Additionally, Medicare has indicated that starting in 2013, there are plans to stop paying for “excessive readmissions,” which in 2004 accounted for $17.4 billion of the $102.6 billion Medicare paid to hospitals that year.

The change has already had a dramatic impact on patient care and hospital budgets, and discussions are underway about adding even more conditions to the list. Some experts also predict that commercial payers will soon follow suit.

The scope of the issue was highlighted in a study from HealthGrades, a Colorado-based health care ratings organization, which documented more than 900,000 patient safety incidents between 2006 and 2008. More troubling still, the study showed that 99,000 mortalities associated with patient-related safety events occurred during the same period. The data also revealed that lengthened hospital stays due to HACs and other nosocomial treatment-related expenses amounted to about $8.9 billion. And while preventive measures have been taken in many hospitals, a survey of 1,256 hospitals by the Leapfrog Group found that 87 percent of hospitals do not take all recommended steps to prevent hospital-acquired infections.

Pre-existing Concern
Heightened concern regarding hospital-acquired conditions stems from the 1999 Institutes of Medicine report, “To Err is Human,” says Dr. Gary Kalkut, chief medical officer at Montefiore Medical Center in New York. “Reporting HACs and tying them to payments promotes better care in the hospital,” says Dr. Kalkut. “It puts a premium on documentation of pre-existing conditions and efforts to improve care during the hospital stay.”

Dollars and Sense
Institutions have found that reducing, and whenever possible, eliminating HACs requires broad-based use of resources, re-examination of protocols, and retraining staff. Medication errors, for example, can be reduced by adopting computerized physician order entry (CPOE) systems, but that alone won’t solve the problem.

While sloppy handwriting, misinterpretation of abbreviations, and improper dosing might be expected to disappear with the purchase of a

continued on page 2
computerized system, a survey of 62 hospitals with CPOEs showed a reduction in potentially fatal medication orders in just 53 percent of the cases. Overall, the reduction of error ranged from 10 percent to 82 percent.5

There is also a question about whether hospitals, after purchasing a CPOE, can afford the upgrades often required to customize a system for their use. As Dr. Rohit Bhalla, chief quality officer at Montefiore explains: “We’ve had success after modifying the system, so it not only...orders what the doctor prescribes, it can tell the doctor what they might want to prescribe.”

Other measures hospitals should be taking to reduce HACs include emphasizing the need for hand sanitizing compliance, which is free. Yet, according to the Leapfrog Group, only 35.6 percent of surveyed hospitals followed proper hand washing practice.4 Beyond making hand-sanitizing foams or liquids available in hallways and throughout hospitals, institutions can reduce infection rates by training nurses and other staff to monitor hand cleanliness.

“A key to driving up compliance is the empowerment of personnel,” says Sheila Namm, Esq., RN, MA, vice president of professional affairs at Maimonides Medical Center in Brooklyn, who oversees performance improvement, risk management and infection control. “Ideally the organizational culture supports, even expects, any staff member to speak up and remind others to wash their hands. Staff must feel safe in speaking up, despite where they see themselves in the hospital hierarchy. Studies have shown that most staff are uncomfortable reminding physicians to wash their hands.”

**Never Events**

In an ideal world “never events” should, indeed, never happen. Unfortunately, mistakes are made and breakdowns in the system do occur. A national review of hospitals by The Joint Commission found that 908 wrong-site...
an unfortunate but inevitable consequence of providing care to an aging population.

Changing Habits in a Changing World

While everyone agrees that the rate of HACs must be reduced at a reasonable cost, some point to physician habit as a major obstacle to implementing evidence-based guidelines to improve protocols. “Most surgeons will go through their entire careers without performing a wrong site surgery,” says Namm. “But surgeons may be set in their ways after a long, possibly exemplary career, so it isn’t surprising that they may have a hard time adapting to a new system that intends to prevent this type of event in the first place.”

As to developing protocols that will help hospitals prevent these events, Dr. Bhalla says it is vital for organizations to share what they’re doing and to learn from each other. “Not everyone’s suggestions are going to succeed,” Dr. Bhalla says. “But it is just as important to

continued on page 4

2007

June: CMS proposed to deny Medicare payment for costly and sometimes deadly preventable HACs, effective October 2008. CMS listed eight conditions that it judged to be “reasonably preventable” during a Medicare beneficiary’s hospital stay and that would be subject to nonpayment if any of them constituted sole major complicating conditions (MCCs) or complicating conditions (CCs).

The first set of conditions identified by CMS as subject to the nonpayment provision were:
- Stage III, IV pressure ulcers
- Fall or trauma resulting in serious injury
- Vascular catheter-associated infection
- Catheter-associated urinary tract infection
- Foreign object retained after surgery
- Certain surgical site infections
- Air embolism
- Blood incompatibility

In addition, CMS added 42 new quality measures for which hospitals will have to report data in order to receive the full annual payment update for their services.

October: CMS began collecting POA information on all inpatient Medicare claims. Hospitals were required to submit information regarding whether a list of specific diagnoses were POA or acquired during hospitalization. The POA indicator was necessary to identify which conditions were HACs for payment purposes. This information was also potentially valuable for broader public health uses of Medicare data.

2008

CMS expanded the list of HACs to 10 conditions considered reasonably preventable through proper care, and for which Medicare will no longer pay at a higher rate if the patient acquires them during a hospital stay.

The additional two conditions are:
- Certain manifestations of poor blood sugar control
- Certain deep vein thromboses or pulmonary embolisms


CMS Rules for Hospital-Acquired Conditions Pose Challenges and Opportunities

continued from page 3

learn from what doesn’t work as it is to learn what does. We must have the courage to come together in a collaborative effort to address health and safety concerns and to put novel interventions in place.”

Will Rule Changes Improve Care?

While CMS has increased awareness of HACs, there is concern that the newer regulations will eliminate reimbursement for conditions that are unavoidable despite a first-rate standard of care. Pressure ulcers are an example of how quickly a condition can go from obscurity to front and center on the radar of hospitals nationwide.

“Pressure ulcers had largely been a silent issue,” says Dr. Vincent Marchello, vice president of medical affairs at Brooklyn’s Metropolitan Jewish Health System. “Until recently, medical students weren’t even taught about pressure ulcers. Now, hospitals perform thorough physical and informational risk assessments as a preventive measure. That’s an obvious patient benefit, particularly in an aging population where the condition is both prevalent and serious.”

However, “one can argue that by penalizing the facilities that are not doing well in reducing rates of HACs, we are hurting those who have the fewest resources and the highest rate of at-risk patients,” says Dr. Bhalla. “It may be the case that those facilities are doing what they can, but don’t have the resources to increase efforts where they are needed.”

In the end, Namm says, the CMS regulations are a magic bullet that will improve care, drive down costs and leave every stakeholder satisfied. “As much as we try to eliminate risk on a macro level by designing error-free systems and redundancies, the quality of care ultimately depends on the staff and the clinicians who deliver that care.”

While some hospital resources will go to pay for non-billable HACs—even where the condition was not preventable—the heightened attention to HACs and a host of new protocols developed to address and prevent them will undoubtedly benefit patients. And where rates of HACs are reduced, hospitals can conserve resources and time and focus on other areas to improve quality of care.

Documentation and Treatment of Pressure Ulcers

A positive result of the CMS rule changes regarding HACs is the increased attention now being paid to pressure ulcers in patients admitted for other conditions. Pressure ulcers are common, recent studies indicate, affecting as many as 2.5 million patients in acute care facilities nationwide. Despite the impact of these conditions, many physicians have not been taught to manage and prevent them.

However, the CMS rule changes leave some questions regarding pressure ulcers unanswered. For example, the CMS and Centers for Disease Control and Prevention (CDC) have yet to identify clinical criteria for unavoidable pressure ulcers. Hence, hospital clinicians must thoroughly assess patients at risk of developing pressure ulcers during a hospitalization and implement aggressive preventive treatments, as well as thoroughly document wounds that are present on admission (POA).

To assist in the process, experts recommend the following strategies for preventing, treating, and documenting pressure ulcers:

Perform a thorough skin assessment on admission
Present on admission is defined as present at the time the order for inpatient admission occurs. Any condition, including a pressure ulcer, developed during a previous hospital stay, at home, or in a long-term care facility, for example, is considered present on admission.

Assess risk factors
Those at the highest risk for pressure ulcers include bedridden patients and those with nutritional deficiencies, dementia, or cognitive deficits, and bowel or bladder incontinence. A doctor or wound care nurse should frequently assess a high-risk patient’s skin condition. Typically, patients presenting with cardiac or respiratory issues may be elderly and at high risk for developing ulcers during their hospital stay, although younger patients can be at risk as well.

Document appropriately if ulcers are POA
Determining if pressure ulcers are POA should be based on the provider’s best clinical judgment in staging skin conditions according to evidence-based guidelines developed by the National Pressure Ulcer Advisory Panel (NPUAP). Reimbursement will be based on provider documentation. Nursing records and wound flow sheets, including notes by the Wound, Ostomy and Continence (WOC) nurse, can be used by coders for information on the stage of the pressure ulcer.

Diagnose and document other skin conditions
Unstageable and unspecified skin conditions beyond pressure ulcers now qualify as preexisting conditions and should be noted in POA documentation.

Suggestions for prevention and treatment
Prevention is critical and requires working closely with the nursing and wound care teams at your hospital to maintain skin integrity. Both the prevention and treatment of pressure ulcers include the following concepts:
• Relieving pressure quickly
• Frequent turning of the patient
• Ensuring adequate patient nutrition
• Treating any infections associated with wounds
• Ensuring skin is dry
• Treating underlying comorbidities that could contribute to skin integrity problems

For more information and updates, visit: http://www.cms.hhs.gov/transmittals/downloads/R1610CP.pdf.

RESOURCES:
Protocols for Preventing Retained Surgical Items

Although rare, instances of retained foreign body after surgery significantly increased in emergency situations, with unplanned changes in procedure and with higher body-mass index patients. The Gawande et al study also found that the risk of retention of a foreign body after surgery is generally indefensible.

The American College of Surgeons suggests the following guidelines to minimize the risk of a retained foreign object in the perioperative setting: the consistent application of a standardized counting process, performance of a methodical wound exploration before closure of the surgical site, use of x-ray detectable items in the surgical wound, maintenance of an OR environment optimal for focused performance, clear communication, careful documentation and the use of x-ray or other electronic devices as needed.

Although rare, instances of retained foreign objects can still occur. One of the most troubling situations for any surgical team is logging a correct final count and then at a later date finding that an object has been left inside the patient. Generally, this is not because a baseline count was incorrect, according to Lola Chlupsa and Pamela Davis, nurses at Beth Israel Medical Center in New York. However, it is more likely the result of the placement of additional instruments or pads on the surgical field—items that were inadvertently not recorded.

The accuracy of the counting process can be impacted by: (1) the complexity of the surgery, (2) whether the surgery was an emergency, and (3) factors related to the surgical team’s fatigue and workload (e.g., duration and late day procedures). In addition, discrepancies can occur when multiple nursing relief teams are involved in a surgical procedure.

Accurate counting methods can be one of the best measures to prevent retained foreign objects. To assist in the process, the Association of Perioperative Registered Nurses (AORN) has developed guidelines for counting procedures to reduce the likelihood of retained objects.

Another practice gaining widespread use in the prevention of retained foreign objects is the use of radio frequency technology and bar codes to count and/or detect soft goods such as lap pads, sponges and towels. Currently there is a bar code system that can count these items, a passive radio frequency system that can detect these items, and a radio frequency identification system that can both count and detect.

There are many things to consider when selecting an electronic system to assist in the prevention of retained surgical items. At Maimonides Medical Center in Brooklyn, for example, the OR nurses chose a radio frequency system that employs a wand for detection instead of a system with a wand and item identification tags. This decision was made because nurses were concerned that reliance on technology would make them complacent and possibly contribute to a false sense of security. Their goal was to leave in place the wand saves time when there is a missing item because the entire room, including the garbage, can be scanned rather than sorted through by hand. The wand is also routinely used to scan patients at the end of the procedure to detect a sponge, lap pad or towel that may have been inadvertently left in a patient, despite a correct count.

Strengthen communication among the surgical team

Among the practices believed to help reduce the occurrence of a retained foreign object is good communication among members of the surgical team. Team members need to understand the importance of the count and cooperate during the process. A preprocedure briefing by the surgeon should occur during the “time out” before the start of a case. Briefings should note whether there is any possibility of an unexpected event or portions of the surgery are particularly critical, as well as any high risk situations.

Handoffs

When personnel changes occur during a procedure, there should be a consistent, structured mechanism for the complete and accurate transmission of relevant information about the surgical field and its contents. Use of a formal checklist might be helpful.

Documentation is Key

Documentation of the surgical count in the patient’s medical record should include:

- results of surgical item counts and notification of the surgeon
- instruments or items intentionally left as packing
- actions taken if count discrepancies occur and the outcome
- rationale if counts are not performed or completed according to hospital policy

If a retained foreign object is discovered, accurate documentation of the event is required. Documentation of a count discrepancy should include all measures taken to recover the missing item and the outcome. Staff should follow hospital policy regarding the completion of an Occurrence Report.

RESOURCES:

2. Ibid.
DVTs and PEs

Despite the best-made and well-executed plans to prevent hospital-acquired conditions (HACs), some patients may fall victim to HACs for no other reason than their own biology. Research shows that this can be the case with deep vein thrombosis (DVT) and pulmonary embolisms (PE).

“The incidence of HACs can be cut sharply with implementation of evidence-based treatment guidelines,” says Gary Kalkut, MD, chief medical officer at Montefiore Medical Center in New York. “Although we have made substantial progress, continued focus on preventing hospital-acquired conditions is an essential element of performance improvement today.”

“Even if you administer patients the appropriate DVT prophylaxis, you can still incur at least a 5 percent (venous thromboembolism) VTE rate in high-risk hospitalized patients,” adds Latha Sivaprasad, MD, hospital medical director for quality management and patient safety at Beth Israel Medical Center, also in New York. Another challenge in preventing clots is doing so without creating dangerous bleeds, although this is more of an issue with higher treatment doses needed for diagnosed DVT or PEs as opposed to prophylaxis or prevention doses which are lower. Balancing the two carries risk under any circumstances.

Medication errors represent another problem area in the prevention of DVTs and PEs. Research estimates have found that more than one million serious medication errors occur each year in U.S. hospitals, with about 7,000 deaths annually due to adverse drug events. Errors are more serious with some classes of drugs than with others; anti-coagulation drugs are among the most risky.

“In order to prevent DVTs and PEs, you need to monitor the relevant drugs to make sure they are used appropriately and in the right setting with accurate dosing to minimize harm from this potentially unsafe drug class,” Dr. Sivaprasad says. Because of the inherent variability in a patient’s drug response to warfarin, coumadin, and enoxaparin, a designated professional needs to closely monitor indications for treatment and prophylaxis, accurate dosing, and drug interactions with a constant eye on the risk-benefit ratio. This can be a real challenge.”

Beth Israel has customized its Computerized Physician Order Entry (CPOE) system to address this problem, compiling evidence-based information required to choose and prescribe drugs properly. The hospital has also created dosing protocols and decision support tools to help promote evidence-based care delivery by medical providers. These tools are also available on the intranet to enhance access, Dr. Sivaprasad points out.

To address the potential for “point-and-click” errors, the system requires that physicians use a different portal for each of the three anti-coagulation drugs in use at Beth Israel: warfarin, heparin and enoxaparin. This streamlines the ordering process and decreases variability. Results have included reductions in medication errors, certain adverse drug reactions, and rates of inappropriate dosing, Dr. Sivaprasad says.

“It was an interdisciplinary effort—an intense collaboration between pharmacy, nursing, physicians, laboratory, IT,” explains Dr. Sivaprasad. “Together we asked, ‘What are the goals of an anti-coagulation therapy safety program?’ DVT and PE prophylaxis is a piece of this, but we also need to broaden our program to encompass all the major medical conditions which warrant anticoagulation use for appropriate therapy and treatment, address medication interactions, and have protocols for patients who suffer a bleeding complication.”

While the electronic component is key to reducing human error and dispensing with handwriting issues, it’s still essential to analyze practice patterns and hold people accountable for breakdowns in safe medication delivery. “If an inappropriate dose of enoxaparin is administered to a patient, that is because someone ordered it, someone verified it, and someone delivered it. You have to have champions in every discipline to implement a program like this. The challenge is to maintain a consistent approach to daily monitoring of the drugs and the several levels of impact they are having on patients.”

Gainsharing

Gainsharing, a program based on a pay-for-performance model, has been extremely effective in improving hospital efficiency and medical quality at Beth Israel Medical Center in New York. The program, which won approval from the CMS Office of the Inspector General in 2008, rewards doctors (with periodic monetary bonuses) based on factors such as decreases in length of stay, readmission rates, and increased hand hygiene compliance, and penalizes them for increases in rates of hospital-acquired infections (HAI) and the number of unnecessary blood tests and x-rays performed, as well as overuse of medications and blood products.

“The impact of gainsharing has been dramatic at our hospital,” said Dr. Michael Leitman, director of the surgical residency program at Beth Israel and associate professor of clinical surgery at the Albert Einstein College of Medicine. “Initially we tracked procedures such as colon operations, where surgical site infection rates are high,” Dr. Leitman said. “The benchmark in New York State is 4.4 percent and at one point at our facility in Brooklyn we went down to zero, which is remarkable. Now we’re tracking all HAI and we’ve had consistent decreases across the board.”

According to Dr. Leitman, the success of gainsharing is due, in part, to the competitive nature of physicians. “The program allows physicians to compare one another’s performance, such as measuring their reduction of surgical site infections. Doctors tend to be high achievers during medical school training and throughout their careers. When they see that their rates of readmission or adverse outcomes are inferior to those of their peers, it’s a powerful motivator.” The program at Beth Israel has been so successful, Dr. Leitman said, that under the new federal health care reform bill, it has been extended to 2012.
An estimated 2.6 percent of nearly 30 million operations are complicated by surgical site infections (SSIs) each year, according to results from the CDC’s National Nosocomial Infections Surveillance (NNIS) system, which monitors reported trends in nosocomial infections in 2,646 participating acute care hospitals in the United States. Studies show that these perioperative infections are a major cause of patient injury, increased length of stay, mortality, and increased national healthcare costs, estimated at almost $845 million per year.

Here are some suggested guidelines for preventing or reducing the rate of SSIs:

Skin Antisepsis
Proper skin antisepsis is one of the simplest and least expensive ways to reduce SSI risk. Clinicians need to take skin preparation seriously, but old habits die hard. “Surgeons are creatures of habit,” says Dr. Michael Leitman, chief of general surgery and director of the surgical residency program at Beth Israel, “and many are very attached to their technique, which makes them more resistant to change. That said, physicians respond well to data and are willing to change if they feel it is in the best interest of the patient.”

Rigorous adherence to the principles of asepsis by all scrubbed personnel, including staff in close proximity to the sterile surgical field, such as anesthesiologists and nurse anesthetists, is the foundation of SSI prevention. To ensure good skin antisepsis, the team must have meticulous technique as well as the appropriate antimicrobials and scrub supplies.

Hand/Forearm Washing
The consequences of poor surgical scrubbing can be fatal, but thorough scrubbing can also disrupt skin health. A doctor who scrubs four or more times a day, five days a week, can get raw, irritated skin. Hence, it is important for hospitals to provide solutions that are both efficient and easy on the hands.

Studies suggest that scrubbing for at least two minutes is as effective as the traditional 10-minute scrub in reducing hand bacterial colony counts, but the optimal duration of scrubbing is not known. The first scrub of the day should include a thorough cleaning underneath fingernails (usually with a brush).

Shaving vs. Clipping
Preoperative shaving versus clipping was a much debated issue, but it is now believed that clipping is better because it produces less skin trauma. Research shows that shaving puts patients at a higher risk of infection by drastically increasing the amount of organisms growing on the skin. The adoption of the SCIP (Surgical Care Improvement Project) measure by CMS has led many hospitals to discard shavers.

Antibiotic Cycling
While the shaving-versus-clipping debate may be settled, the literature on antibiotic cycling remains inconclusive. Some proponents favor antibiotic cycling, the rotating of a specific antibiotic or a class of antibiotics using one or more substitutes in a repeated rotation or cycle. Cycling is performed in ICUs to prevent hospital-acquired methicillin-resistant staphylococcus aureus (MRSA); others believe that cycling decreases the development of antibiotic-resistant strains of gram-negative organisms. However, antibiotic cycling has not yet become the standard of care. The benefits of cycling appear to reduce the “monotonous exposure” to one agent over time and reduce the selection pressures for any single agent. The potential risk, however, is that by exposing bacteria in an ICU to a series of antibiotics, doctors may actually increase the likelihood that resistance will develop to a multitude of agents. Hospitals should decide where they stand on this issue and set protocols.

Avoid Prolonging Antibiotic Prophylaxis
New evidence suggests that antibiotic prophylaxis, or antimicrobial prophylaxis (AMP), is often unnecessarily prolonged after surgical procedures. One recent University of Milan study that evaluated the risk of surgical site infection associated with the prolongation of AMP after clean and clean-contaminated surgery, found that AMP longer than 24 hours raised the risk for intra-hospital and post-hospital discharge SSIs. Additionally, this observational study showed that AMP prolongation for 24 hours in patients with at least one risk factor did not reduce the risk for intra-hospital SSI, but it increased the risk in patients without risk factors. The conclusion was that postoperative AMP prolongation should be avoided.

Patient Warming
There is evidence of a direct correlation between hypothermia and SSIs. While health care
professionals generally agree that hypothermia is a factor in SSI occurrence, they do not agree on a solution. What has been established, however, is that unplanned hypothermia (even mild hypothermia) has been attributed to postoperative patient complications such as shivering, wound infections, and cardiovascular problems. Such complications can contribute to prolonged postoperative recovery, so maintaining the patient’s temperature during the intraoperative period can help to prevent hypothermia.

Despite the lack of consensus, research suggests that the consequences of hypothermia can cause adverse myocardial events, coagulopathy, reduced drug metabolism, thermal discomfort for the patient, and increased risk of surgical site infection. Most experts agree that active warming in the operating room will decrease the number of patients who develop SSIs and that more studies are needed so that protocols for patient warming can be developed. Most agree that patient warming should become commonplace for all surgical procedures, starting in the preoperative setting.

Improving Practices

Health care providers are also faced with the challenge of trying to integrate new evidence-based infection prevention strategies into their practice. Adherence to measures from the Surgical Care Improvement Project (SCIP) and the Association of Perioperative Registered Nurses (AORN) can significantly reduce the risk of surgical site infections. With this support, hospital teams will be empowered to make any necessary changes to their surgical units and to incorporate additional safety considerations into their everyday practices.

The Importance of Documentation

Centers for Medicare and Medicaid Services’ (CMS) regulations require more vigilance when documenting patient conditions, as well as knowledge of the appropriate present-on-admission (POA) coding system. According to CMS, the attention given to the patient’s condition upon admission will improve the quality of patient care because conditions can be diagnosed and treated at an earlier stage. The following are some documentation guidelines for physicians:

Coding

Hospital billing professionals will designate whether a condition is present on admission based on physicians’ documentation. The hospital will be reimbursed if a condition was present as a primary or secondary diagnosis when the patient was admitted to the facility. If the documentation is unclear or inconsistent, coders may need to ask doctors for clarification.

Take a thorough patient history

Doctors must perform a comprehensive patient history. The CMS history components include documentation of the history of present illness (HPI), review of systems (ROS), and past medical, family, and social history (PMF SH). These elements can be documented separately or made in one statement.

CMS does allow for situations where the physician is unable to obtain a history from the patient or another source. If the patient is unable to give a history, practitioners must describe the patient’s condition or the circumstances that prevented them from obtaining a history. A foreign language barrier does not qualify. Common examples include altered mental status, dementia, and urgency of condition. It is also advisable to make attempts to gather the history from other sources and document as much as possible. CMS also allows the ROS and past history to be recorded by ancillary staff or the patient, as long as doctors document that they reviewed, supplemented, or confirmed the information.

Patient falls resulting in fractures, dislocations, intracranial injuries, and other trauma are among the hospital-acquired conditions the Centers for Medicare and Medicaid Services (CMS) treats as “never events.” Yet, according to a June 2009 article in the New England Journal of Medicine, “some 3 to 20% of inpatients fall at least once during their hospital stay; these falls result in injuries, increased lengths of stay, malpractice lawsuits, and more than $4,000 in excess charges per hospitalization.”

Although the high cost and volume of hospital falls is a significant patient safety and public health issue, many experts believe falls are not the result of negligence and can occur, particularly among elderly patients, even when hospitals provide the best possible care. An additional risk factor is mental-status change or dementia. Research also shows that younger patients are not immune to hospital falls.

A study at Barnes-Jewish Hospital in St. Louis, MO, that evaluated 200 consecutive patient falls during 2002 found that falls occurred within all populations and most involved unassisted and elimination-related activities. The study also revealed that 30 percent of these falls caused injury, with 4 percent to 6 percent resulting in serious trauma such as fractures, subdural hematomas, excessive bleeding, and even death.  

While falls are difficult to prevent in any hospital, clinicians and hospital administrators can take steps to dramatically reduce the risk of falls:

- **MAINTAIN PATIENT MOBILITY**
  Safe mobility among all ages and populations can be enhanced by avoiding the use of physical restraints and removing immobilizing devices such as Foley catheters, intravenous lines, and cardiac monitors as soon as possible. Research has shown that physical restraints can increase the rate of complications, including delirium, agitation, pressure ulcers, asphyxiation, and death. An effective alternative may be one-on-one observation. However, one-on-one observation is expensive and does not guarantee that patients will not fall and injure themselves.

- **REGULARLY ASSESS MENTAL STATUS**
  Hospitals should make daily risk assessments on all patients, considering age, dementia, and other mental conditions. Many Alzheimer’s patients do poorly in unfamiliar surroundings, for example, which can increase their anxiety and confusion during hospital stays. If a patient is transferred to the hospital from a nursing home, the home can be contacted and information about risk factors can be obtained and documented. This may improve accurate and effective assessment of patient risk factors.

- **LIMIT PSYCHOACTIVE MEDICATIONS**
  Doctors should limit use of standing prescriptions for sleep, anxiety and agitation where possible because those medications can cause sedation, dizziness and confusion. Even blood-pressure medications can cause sudden dizziness. Hospital procedures should also include a regular review of all medications and a reduction of those that may be necessary in an acute setting but are not appropriate for long-term use for the elderly.

- **IMPLEMENT A BATHROOM SCHEDULE**
  Clinicians should be aware of the patient’s bowel and bladder issues, especially those of patients with dementia, and provide easy access to the toilet. In some cases, commodes should be placed near the beds and bathroom trips should be scheduled every two hours.

- **PREVENT DELIRIUM**
  Hospitals can prevent delirium by providing orientation and therapeutic activities, making adaptations for the vision- and hearing-impaired, and maintaining proper hydration and nutrition.

- **FALL-PROOF THE HOSPITAL ROOM**
  Hospital rooms should be evaluated from a safety perspective. Provide sufficient lighting and ensure the room is clutter-free for nighttime visits to the bathroom. Consider placing beds at the lowest height allowable to reduce the risk of falls and fall-related injuries. Patients can also be given socks with treads to prevent slipping.

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Vascular Catheter-Associated Infections

Infections contracted in U.S. hospitals resulted in 48,000 patient deaths in 2006 and added an extra $8.1 billion in health care costs, according to a study by Resources for the Future (RFF), a Washington, D.C.-based research firm.\(^1\)

One significant avenue for hospital-acquired infections is the central venous catheter (CVC). Guidelines exist for inserting and managing CVCs with minimal risk to the patient and the institution, but how frequently and how well are they followed? A 2008 survey of 1,282 acute care hospitals by the Leapfrog Group revealed that 65 percent of the institutions did not take all recommended steps to prevent hospital-acquired infections. CVC-related bloodstream infections are among the most common, according to the survey. Additionally, Leapfrog found that only 50.5 percent of institutions met the criteria for recommended hand hygiene protocol for preventing aspiration and ventilator-associated pneumonia and central venous catheter-related bloodstream infections.\(^2\)

Following are highlights from “Strategies to prevent central line–associated bloodstream infections in acute care hospitals,” developed by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America.\(^3\)

- Health care personnel involved in the insertion, care, and maintenance of central venous catheters should be educated on catheter use, appropriate insertion and maintenance, the risk of central line–associated bloodstream infection (CLABSI), and general infection prevention strategies.
- Personnel’s knowledge of, and adherence to, preventive measures should be assessed periodically.
- At the time of insertion, a catheter checklist should be used to ensure and document compliance with aseptic technique.
- CVC insertion should be observed by a nurse, physician, or other health care professional who has received appropriate education to ensure that aseptic technique is maintained. These health care personnel should be empowered to stop the procedure if breaches in aseptic technique are observed.
- Perform hand hygiene before catheter insertion or manipulation. Note that use of gloves does not obviate hand hygiene.
- Avoid using the femoral vein for central venous access in adult patients, as the groin site is associated with greater risk of infection.
- A catheter cart or kit that contains all necessary components for aseptic catheter insertion should be available and easily accessible in all units where CVCs are inserted.
- A mask, cap, sterile gown and sterile gloves are to be worn by all health care personnel involved in the catheter insertion procedure. The patient should be covered with a large sterile drape during catheter insertion.
- Before catheter insertion, apply an alcoholic chlorhexidine solution containing a concentration of chlorhexidine gluconate greater than 0.5 percent to the insertion site. The antiseptic solution must be allowed to dry before making the skin puncture.
- After insertion, disinfect catheter hubs, needleless connectors, and injection ports before accessing the catheter. Before accessing catheter hubs or injection ports, clean them with an alcoholic chlorhexidine preparation or 70 percent alcohol to reduce contamination.
- Assess the need for continued intravascular access on a daily basis. Remove catheters not required for patient care.
- For nontunneled CVCs in adults and adolescents, change transparent dressings and perform site care with a chlorhexidine-based antiseptic every five to seven days or more frequently if the dressing is soiled, loose, or damp; change gauze dressings every two days or more frequently if the dressing is soiled, loose, or damp.
- Perform surveillance for CLABSI.

If the prevention strategies above are unsuccessful, the recommendations below should help prevent CLABSI in areas of the hospital and among patients that have unacceptably high CLABSI rates:

- Bathe ICU patients older than two months of age with a chlorhexidine preparation on a daily basis.
- Consider the use of catheters impregnated with antiseptics (e.g., chlorhexidine-silver sulfadiazine) or antimicrobials (e.g., minocycline-rifampin).
- Use chlorhexidine-containing sponge dressings for CVCs in patients older than two months of age.
- Use antimicrobial locks for CVCs.\(^\square\)

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1 Michael R. Eber, BSE; Ramanan Laxminarayan, PhD, MPH; Eli N. Perencevich, MD, MS; Anup Malani, PhD, JD, “Clinical and Economic Outcomes Attributable to Health Care–Associated Sepsis and Pneumonia,” Arch Intern Med. 2010; 170 (4): 347-353.
Case Details
A 46-year-old male was admitted for a restorative proctocolectomy with J-pouch for ulcerative colitis that was non-responsive to medication. His history included steroid therapy, hypertension, and cardiac stenting. Pre-operatively, there was no documentation regarding a DVT (deep vein thrombosis) risk assessment or prophylaxis. An epidural catheter was placed for post-operative pain management. The four-hour surgery was then done under general anesthesia without complications. Afterward, the PACU nurse documented that Venodyne sequential compression boots were in place. This was the first documentation about DVT prophylactic measures. No anticoagulants were ordered.

On post-op day one, the patient complained of left-leg weakness (left-leg DVT found on autopsy). The complaint was attributed to the dose of epidural infusion; the dose was decreased, but the complaint persisted until post-op day five. During this time, the patient was followed by physicians from surgery, anesthesiology (pain service), cardiology and gastroenterology. None documented an examination of the left leg. Nursing repeatedly documented the complaint of left-leg weakness, but did not describe the leg. On post-op days one and two, documentation indicated Venodyne boots in place, but the record was otherwise silent regarding their use. Compliance with nursing practice guidelines, which recommend q eight-hour boot removal and limb assessment, was not documented. The patient was slow to ambulate; on post-op day two, he was out of bed for only one hour. The anesthesiology attending documented the plan to discontinue the epidural on post-op day three; but this was not done until post-op day five, and there was no documented rationale for continuation. That day, the patient experienced profuse sweating and abdominal pain. The cardiologist's evaluation included EKG and cardiac enzymes (which were normal), but no assessment of the extremities was documented. X-ray revealed an ileus, which was treated conservatively, and the new symptoms resolved. From post-op days six through 11, the record was silent regarding any leg complaints, and no leg assessment was documented. On post-op day 11, there was an order to discontinue the Venodyne boots, and the patient went home.

The next day, he died suddenly. Autopsy by the medical examiner revealed bilateral pulmonary embolisms (PE) and DVT of the left lower extremity. The exact location of the DVT was not included in the autopsy report. The documented cause of death was, “Pulmonary embolism, bilateral. Due to: deep venous thrombosis of lower extremities. Due to: Hospitalization for resection of bowel.”

Allegations
Wrongful death due to insufficient DVT prophylaxis pre-operatively, intra-operatively, and post-operatively was alleged.

Investigation and Case Development
The main issue in this case is whether the DVT prophylaxis with sequential compression boots met the standard of care in 2004. The expert opinions were mixed. The surgery expert believed it did; the cardiology expert believed anticoagulation, in addition to the boots, was required. Nonetheless, the surgery expert could not defend the case because of the glaring holes in documentation. The boots should have been applied pre-op, continued intra-op, and been used continuously post-op. The involved surgeon reported his patients always had boots applied for surgery. Unfortunately, the record is silent about the actual time of this patient’s boot application, and what was documented suggests a delay initiating the DVT prophylaxis. As for the post-op period, the standard may have been met, but it was impossible to substantiate. The use of the boots was only documented on post-op days one and two, and did not indicate if the use was continual or intermittent. At the same time, the patient was mostly in bed, which increased the risk for DVT.

Standards of care change over time and may vary among specialties. Careful, thorough documentation remains a constant maxim even when the standards of care shift.
The plaintiff alleged treatment with heparin was indicated. Although the experts were mixed regarding the use of anticoagulants, they all agreed heparin was contraindicated because of the increased risk of bleeding associated with the epidural. However, the experts agreed that a plan of care addressing the risk factors for DVT and risk of anticoagulation should have been formulated. The involved surgeon and anesthesiologist reported this was part of their usual practice. But again, there was no documentation to verify this was done.

Plaintiff also alleged the epidural should have been discontinued earlier. Although the experts refuted this allegation, the defense attorney did not want to put this issue before a jury. They could easily have been swayed to believe this allegation because the documented plan was to discontinue the epidural earlier than was done, and no rationale for the delay was documented.

The question of whether the left-leg weakness was due to the epidural or a developing DVT will never be answered. The experts concurred the weakness was probably due to the epidural, not the DVT, and the occurrence in the same leg was a coincidence. However, to convince a jury that two separate events occurred coincidentally in the exact same leg would have been nearly impossible because of the deficiencies in documentation. No physician or nurse documented an examination of the left leg despite the patient’s ongoing complaint, which did not resolve with epidural adjustments. The surgeon reported he routinely assessed his patients’ legs daily for DVT, but the record cannot confirm it was done for this patient. Moreover, on post-op day five when there was the sudden change in condition, a cardiovascular origin was considered, but there was no documentation of examination for DVT. The cardiologist’s customary practice would have included examination of the extremities, but again the record was silent. In contrast, the autopsy report was not silent regarding the left leg. Plaintiff’s attorney could have used this to convince a jury that a DVT was present, but missed by the physicians.

Resolution
The absence of key documentation was an insurmountable obstacle for the defense of this case, and drove the hospital to settle for $750,000.

Conclusion
Standards of care change over time and may vary among specialties. As long as a physician meets the contemporaneous standard within their scope of practice, documents assessments and plan of care relevant to the standard, a defense can be mounted if a lawsuit ensues. For this case, the complaint of left-leg weakness was likely due to the epidural and was unrelated to a DVT. However, in the absence of documentation reflecting a thorough assessment including abnormal findings as well as pertinent negatives, this minor complaint provided a focus for the plaintiff’s malpractice claim. Careful, thorough documentation remains a constant maxim even when the standards of care shift.

Risk Reduction Strategies

Treatment Protocols
Multiple specialties are often involved in a patient’s care, and standards may vary among specialties. As this case demonstrated, experts from different fields did not agree about DVT prophylaxis, a topic that has been well researched. To address these different practices, many hospitals have developed protocols for DVT prophylaxis for use across all specialties. The protocols vary from generalized guidelines to detailed treatment algorithms. Physicians should familiarize themselves with the protocols in place at their hospital. If a DVT assessment checklist is available, make use of it; if no checklist, include the risk assessment information in a progress note. When clinical circumstances warrant a divergence from the hospital protocols, document the rationale for this decision.

Addressing Changes in Condition
When a patient has an unanticipated complaint, an examination is warranted to identify the objective and subjective findings in order to synthesize the diagnosis. Abnormal findings as well as pertinent negatives are analyzed. In this case, there was no way to validate that the physicians examined the patient’s leg according to their usual custom and practice. The medical record was devoid of any leg exam findings, normal or abnormal. Documentation related to the diagnostic process should include all relevant exam findings as well as pertinent negatives.

Assessing Response to Treatment
This patient’s complaint of leg weakness was attributed to the epidural. Yet when the complaint did not resolve with dose adjustments, there was no further exploration for its origin. If a patient is not responding to an intervention, further investigation is warranted. The absence of an expected response is a trigger to look further. As with all care, the clinical rationale, evolving plan of care, and the patient’s response require ongoing medical record documentation.

Revising Treatment Plans
The plan of care may require revisions as the clinical picture evolves. In this case, the anesthesiologist’s plan was to discontinue the epidural on post-op day three. However, it was not done until post-op day five, and no rationale for the change in plan was documented. This lapse opened the door for the plaintiff’s attorney to argue that the hospital dropped the ball. Whenever there are changes in the plan of care, the clinician should document the rationale. This is important in the immediate care of the patient so the entire health care team can be on the same page. In addition, in the event of a lawsuit, a well-documented record will help support the defense; missing documentation will make it more difficult.

Communication Across Clinical Specialties
In today’s health care environment, multiple clinicians are often involved in one patient’s care. All of the care providers must be on the same page regarding a patient’s status. The progress notes are often the principal communication method among clinicians. In this case, there was no documented rationale for the change in plan to continue the epidural. Documentation of the clinical rationale for a revision fosters good communication, which in turn promotes patient safety.
Whatever one thinks about the CMS rule changes regarding hospital-acquired conditions (HACs), most agree that the directives are here to stay.

In addition to increasing the need for careful documentation by admitting physicians, the new CMS rules require all clinicians to carefully attend to preventive measures to reduce the likelihood of HACs occurring during the hospital stay. As outlined in the CMS rule, determining whether payment will be withheld for an HAC depends on whether the condition was present on admission (POA). That is determined by the assessment and evaluation of the patient upon admission. The admitting staff must carefully document any condition, such as a pressure ulcer, present when the patient came to the hospital, as well as other factors they believe could lead to a higher risk of HACs (e.g., poor nutrition status, poor skin integrity, and a higher risk of falls). The hospital, for all intents and purposes, will no longer be compensated for treatment of conditions that are not documented on admission, the assumption being that if it was not recorded, it must have occurred during the patient’s stay.

The Admitting Physician

Documentation by the admitting physician is essential in determining whether a condition is present on admission or not. To meet this responsibility, the physician must assess and document multiple risk factors, including skin conditions, risk of falls, and the need for nutritional counseling or monitoring—just a few items on a list that is likely to grow in the future. (See “List of HACs.”)

“The guidelines are designed to heighten a doctor’s awareness of risk factors,” says Dr. Martin Feuer, a New York-based internist and pulmonologist and former chief of the Department of Medicine at Beth Israel Medical Center’s Singer Division. “But when financial penalties are imposed and the criteria for patient evaluation are so wide ranging, the admitting physician can lose sight of the reason the patient came to the hospital in the first place.”

A New Challenge

The CMS changes are not the only mandates that dictate a standard of care. As a result, some in the medical community have expressed concern that the additional requirements may lead to confusion as clinicians and hospitals work to adhere to the mandates of several governing bodies. “The federal government has produced one list of financial disincentives based on assessment of care and the state has produced another,” says Dr. Rohit Bhalla, chief quality officer at Montefiore Medical Center. Another example of this recently became top news around the country. “If you look at whether a 45-year-old woman should have a mammogram every year, physicians and professional societies disagree about what the standard should be. This creates a real problem in trying to prioritize areas of focus for best practice.”

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New Self-Query Site on National Practitioner Data Bank

The National Practitioner Data Bank (NPDB) now provides an online “self-query” site where practitioners, providers, or suppliers can request information about themselves or their organization contained in the NPDB and the Healthcare Integrity and Protection Data Bank (HIPDB). A self-query may be performed at any time, but must be submitted through this online service.

The NPDB collects information on medical malpractice payments, Medicare and Medicaid exclusions, and adverse actions including licensure, clinical privileges and professional society membership actions. The HIPDB collects similar information, as well as health care-related criminal convictions and civil judgments and actions against facilities. The self-query process applies to both databases.

After providing the required information on the Self-Query Input screens, you must print a copy of the generated self-query, sign the formatted copy, in ink, in the presence of a notary public, and mail the notarized form to the NPDB-HIPDB. The notarized hard copy is required so the data bank can verify the identity of the person making an inquiry and can protect the privacy of those in the database. A Web site link, “Helpful Hints for Submitting a Self-Query,” accesses useful information regarding the application process.

Once a query has been submitted, a response will be sent either by mail or electronically (depending on the individual’s choice) within 7 to 10 days. The National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank self-query service is available at http://www.npdb-hipdb.hrsa.gov/welcomesq.html. For additional information, call 800.767.6732 or e-mail help@npdb-hipdb.hrsa.gov.
Sheila Namm, vice president of professional affairs at Maimonides Medical Center agrees. “It creates difficulty for clinicians in making appropriate care decisions when regulatory agencies do not agree on the standard of care.”

Another problem for medical practitioners and health facilities involves penalizing hospitals for conditions where it will be very difficult to reach a rate of zero, such as infections and falls. “Preventive measures will not eliminate an inevitable increase in the number of falls,” explains Dr. Navneet Kathuria, former vice chairman of quality at Mount Sinai School of Medicine. (See “Hospital Falls and Trauma.”) “As our population ages, more people with dementia and complex illnesses are admitted. The doctor’s responsibility to document risk does not correspond to the ability to prevent them; prevention is a multidisciplinary team effort.” Additionally, earlier this year, panelists at a National Pressure Ulcer Advisory Panel consensus conference agreed that there are clinical situations in which the development of pressure ulcers can be unavoidable.

The Big Picture
In addition to the aging population, demographics play a significant role in determining the performance of a hospital. “One could argue that a facility that does poorly under the new rules may do so due to a lack of resources within the hospital and in the surrounding community,” says Dr. Kathuria. “I don’t know if withholding funds is going to get a physician or a hospital to do better.”

As the list of CMS conditions continues to grow, physicians and institutions will face competing challenges as they deal with continuing pressure to prevent HACs, and reduce readmission rates and lengths of stay.

“In the final analysis, doctors should strive to deliver the best possible care and do our best to practice evidence-based medicine,” says Dr. Kathuria. “Even when bureaucracy leads to penalty, we must never lose sight of the primary reason we do what we do—to help people in a time of need.”
The Don Hoskins Fellowship in Quality and Patient Safety

Beth Israel Medical Center offers a one-year fellowship in the name of Dr. Donald W. Hoskins, its former chief medical officer, medical director, and senior vice president of medical affairs. The fellowship, open to physicians who have completed their clinical training, enables them to gain experience in hospital and physician management, and develop skills in quality improvement, system design, patient safety, and overall medical leadership. One of the few of its kind in the country, the program offers fellows the opportunity to work one-on-one with senior managers of the Beth Israel system, particularly the chief medical officer and medical director of quality management and patient safety. Fellows participate in the day-to-day management of the medical center, eventually leading management projects under supervision. Fellows can also supplement their hands-on experience with course work and seminars on patient safety, health care reform, and quality improvement.

“This fellowship is unique because it gives participants an opportunity to experience clinical operations in a hospital by working directly with senior management,” says Dr. David Bernard, chief medical officer at Beth Israel Medical Center, who oversees the program. “Fellows are mentored by senior staff, who, in effect, are training the next generation of physician executives.” The program began in 1995 at the University of Pennsylvania and expanded to Beth Israel in 2005. To date, it has offered 16 fellowships at both hospitals.

For more information on the fellowship and application requirements, go to www.bethisraelgme.org/.

CDC, Groups Issue Framework, Call to Eliminate HAIs

A number of public health and infectious disease groups have issued a “call to action” and a framework for achieving the elimination of healthcare-associated infections (HAIs) using evidence-based practices, alignment of financial incentives, research and data collection.

The four-part framework is detailed in a white paper, “Moving Toward Elimination of Healthcare-Associated Infections: A Call to Action,” issued by the Centers for Disease Control and Prevention, Society for Healthcare Epidemiology of America, Association for Professionals in Infection Control and Epidemiology, Infectious Diseases Society of America, Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists and Pediatric Infectious Diseases Society. The paper was also published in the journal Infection Control and Hospital Epidemiology and the American Journal of Infection Control.

“Currently, there exists a real opportunity to eliminate specific HAIs, including central line-associated bloodstream infections (CLABSI),” the authors note. “Recent local and regional initiatives have shown 60%-70% overall decreases in the rate of CLABSI in intensive care units (ICUs), with no CLABSI for many consecutive months in some ICUs.” In addition, the American Hospital Association’s Health Research & Educational Trust has received some federal funding to help hospitals implement HAI prevention strategies.

The white paper is available at www.apic.org/cdc.