According to a report released by The Joint Commission, 446 sentinel events occurred during the first half of 2013. The report, released by the accreditation agency in October, provides a glimpse at some of the leading issues plaguing hospitals and some insight into what is causing these errors. Because healthcare facilities report to The Joint Commission’s sentinel event database voluntarily, it’s difficult to get an accurate representation of how often such events truly occur. According to The Joint Commission, since 2004, roughly two-thirds of the reports it’s received were voluntarily submitted by healthcare organizations; the remainder came from complaints or media coverage. Further, the accrediting agency estimates that less than 2% of all sentinel events are actually reported.

Regardless, the data published by The Joint Commission highlights some of the patient safety issues that can seriously impact patient care. The top 10 sentinel events from January 1 to June 30, 2013, are as follows:

- Wrong patient, wrong site, or wrong procedure (60)
- Unintended retention of a foreign object (56)
- Delay in treatment (56)
- Fall (48)
- 446
- 2%
- 314

During the first half of 2013, 446 sentinel events were reported to The Joint Commission. Less than 2% of all sentinel events are reported. The most frequently identified root cause for sentinel events in the first half of 2013 was human factors such as fatigue or distraction, which contributed to 314 events.

SOURCE: The Joint Commission.
**QUICK HITS**

**ONLINE**

**CMS penalizes nearly 1,500 hospitals for quality scores**

CMS is paying 1,451 hospitals less for each Medicare patient they treat for the year that began October 1, 2013, based on 24 quality measurements, including surveys of patient satisfaction and death rates. Meanwhile, the agency is raising payment rates to 1,231 hospitals for having exemplary quality scores. Under the Hospital Value-Based Purchasing program, CMS cut payment rates to all hospitals by 1.25%, setting that money aside in a $1.1 billion pot for incentives.

www.npr.org

**Hospitals in Texas, Calif. win Baldrige Awards**

Baylor Regional Medical Center at Plano (Texas) and Sutter Davis (Calif.) Hospital were among the three winners of the 2013 Malcolm Baldrige National Quality Award, the nation’s highest Presidential honor for performance excellence through innovation, improvement, and visionary leadership.

www.nist.gov/baldrige/

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**FROM THE FIELD**

“...because they aren’t taking that timeout seriously. They believe that this can’t happen to them. They think they have already done adequate preparation for this patient, this procedure, or this site during their movement of the patient, and they just flat-out aren’t doing it well.”

Patricia Pejakovich, RN, BSN, MPA, CPHQ, CSHA

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**REFERENCES**

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  - CMS is paying 1,451 hospitals less for each Medicare patient they treat for the year that began October 1, 2013.
- **Baldrige Awards**
  - Baylor Regional Medical Center at Plano (Texas) and Sutter Davis (Calif.) Hospital were among the three winners of the 2013 Malcolm Baldrige National Quality Award.
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Other unanticipated event (40)
Operative/postoperative complication (37)
Suicide (35)
Criminal event (assault/rape/homicide) (26)
Medication error (20)
Perinatal death/injury (15)

Additionally, The Joint Commission lists the most frequently identified root causes for sentinel events during this time period:
• Human factor (fatigue/distraction) (314)
• Communication (292)
• Leadership (276)
• Assessment (246)
• Information management (101)
• Physical environment (70)
• Care planning (49)
• Continuum of care (48)
• Medication use (48)
• Operative care (45)

Patient Safety Monitor Journal caught up with Patricia Pejakovich, RN, BSN, MPA, CPHQ, CSHA, a senior consultant with The Greeley Company in Danvers, Mass., to get her thoughts on the top 10 most common sentinel events and some things hospitals can do to focus on these issues.

Better timeouts needed to improve care
It’s not particularly surprising that the sentinel event list is topped by issues like wrong patient, site, or procedure, as well as the unintended retention of a foreign object, according to Pejakovich. These events can be directly linked to improper timeout procedures. During hospital visits, she routinely sees surgical teams failing to perform a proper timeout before the surgical procedure begins.

“The main reason that we are continuing to see this is because they aren’t taking that timeout seriously,” she says. “They believe that this can’t happen to them. They think they have already done adequate preparation for this patient, this procedure, or this site during their movement of the patient, and they just flat-out aren’t doing it well.”

Pejakovich likens this to getting on a plane where the pilot hasn’t gone through the aircraft’s safety checklist.

The aviation industry has often been cited as the gold standard of the timeout or preflight process, and it’s been said that if surgical teams placed the same kind of emphasis on timeouts before beginning a procedure, many sentinel events could be eliminated.

But hospital leaders and their lack of oversight in this area are just as much to blame. One of the major problems surrounding timeout procedures is that hospital leaders don’t take the time to actually observe the process, instead relying on documentation to ensure that it has been completed. Simultaneously, surgical teams often have to contend with pressure from the hospital administration to do more surgeries in less time, which creates an “assembly line” mentality.

“If you really want to know if the facility is doing timeouts, you need to stand and observe, and I think facilities that do that will be surprised with what they see,” Pejakovich says.

In addition to having hospital leadership take a top-down approach in emphasizing the importance of timeout procedures, Pejakovich notes that successful timeouts are more likely to occur when a surgeon takes ownership of the process. One surgeon that Pejakovich spoke with recently said that during surgical briefings and timeouts, staff have found issues such as blood that wasn’t ordered and incorrect antibiotics that could have led to complications during the procedure.

“It’s definitely effective when done correctly,” she says. “I think when they go back and evaluate the wrong-site surgeries and wrong-person surgeries, they can find where it’s either been booked wrong or marked wrong, and they can really see that if they had taken the processes seriously, they would have caught it.”

Improving the surgical count process
The unintended retention of a foreign object, and the rate at which such an event occurs, is almost exclusively tied to the effectiveness of another safety procedure: the surgical count process. Because there are often multiple surgeons, surgical techs, and other clinical staff involved in a procedure, it’s important to have an established system for tracking surgical equipment, Pejakovich says.

Organizations such as the Association for periOperative Registered Nurses (AORN) and the Association for Surgical Technologists have developed policies
on how to perform these counts, but Pejakovich says ensuring the entire surgical team gets involved in the process is more important than the actual steps taken during that process. (See the sidebar on p. 5 for The Joint Commission’s most recent announcement regarding this issue.)

“AORN has tried different methods like using a whiteboard to record the pre-count and then after the surgery making sure the post-count matches the pre-count,” Pejakovich says. “There are lots of different techniques, but the bottom line is that it comes back again to scrutiny. Everyone has to participate in that so that no one slips in an extra gauze without calling it out.”

The difficulty with managing patient falls
Managing patient falls has been a consistently difficult area for healthcare facilities. CMS has very strict definitions and requirements regarding the use of restraints, and many falls result from patients who are disoriented and get out of bed against the explicit advice of the caregiver.

Furthermore, the use of bed alarms is quickly becoming a top safety concern. A Sentinel Event Alert released by The Joint Commission in April 2013 highlighted concerns regarding patient alarms, particularly involving alarm fatigue, in which caregivers become desensitized to the constant beeping of various alarms. In June, The Joint Commission approved a new National Patient Safety Goal (NPSG) for 2014 on clinical alarm safety in which hospitals will be required to establish alarms as an organizational priority and identify important alarm management issues.

With few options available to prevent falls, Pejakovich says she has seen more facilities turn to family members for assistance. In other instances, hospitals have increased their hourly rounding to ensure that a clinician is present if a patient needs to use the bathroom or needs something to drink.

“It’s a tough one to win, and the older the population gets and the sicker the population is in the hospital, it’s very tough to be able to get your arms around that and to prevent falls, no matter how much you ask or call or how many times you’re in the room,” she says. “Many times they are confused, and when they are confused they continue to get out of bed, and that’s where we need to intervene with bed alarms and people sitting with them.”

Suicide precautions
Although it’s only seventh on the list, suicide remains a hot-button issue in the hospital environment, says Pejakovich, particularly in the ED and on medical-surgical units. This dates as far back as 1998, when The Joint Commission released a Sentinel Event Alert on preventing inpatient suicides, and has continued through 2010, when the agency released a subsequent alert as a follow-up report, focusing specifically on medical-surgical units and the ED.

The main problems surrounding inpatient suicide risks stem from a confluence of outside issues. As more state-funded mental health facilities close around the country, there has been an influx of mental health patients coming to the hospital, especially the ED, for treatment. In many cases, hospitals aren’t prepared to handle this kind of patient population and may need to hold the patient for 24–48 hours while looking for an open bed in a psychiatric facility.

To combat these issues, Pejakovich says clinicians need more training on how to recognize and handle a potentially suicidal patient.

“I think outside of the psychiatric healthcare providers and the behavioral healthcare providers, I don’t believe clinicians really know what the signs and symptoms are and how to keep people safe,” she says. “And many of our emergency departments just aren’t set up to actually have a safe room for mental health patients.”

Joint Commission standards address these requirements explicitly. Under NPSG.15.01.01, hospitals are required to do the following:

- Perform a risk assessment that identifies specific patient characteristics or environmental factors that may increase the risk of suicide
- Address the most appropriate setting for treatment
- Provide suicide prevention information to the family if a patient is deemed a suicide risk and leaves the hospital

However, a suicide risk assessment can be difficult for physicians to perform, especially because suicide risk manifests in many different ways. Physicians may
be hesitant to label someone suicidal, especially when his or her symptoms aren’t particularly clear.

“It’s a tough call for a medical professional or a physician,” Pejakovich says. “It’s not anything that is black and white. They really need good interviewing skills and the better they know the patient, the better they are making decisions about them, but it’s still a tough call to determine suicidal risks.”

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The Joint Commission’s Sentinel Event Alert on foreign objects

On October 17, just two weeks after The Joint Commission published its report on sentinel event statistics in the first half of 2013, the agency released a Sentinel Event Alert that focused on preventing unintended retained foreign objects (the second-most frequently reported sentinel event in 2013).

According to the alert, The Joint Commission has received 772 voluntary reports of unintended retention of foreign objects (URFO) or retained surgical items (RSI) between 2005 and 2012. Of these cases, 16 resulted in death and 95% resulted in additional care or an extended hospital stay. Often those cases are accompanied by hundreds of thousands of dollars in medical liability payments.

“Leaving a foreign object behind after surgery is a well-known problem, but one that can be prevented,” Ana Pujols McKee, MD, executive vice president and chief medical officer at The Joint Commission, said in a press release. “It’s critical to establish and comply with policies and procedures to make sure all surgical items are identified and accounted for, as well to ensure that there is open communication by all members of the surgical team about any concerns.”

In the alert, The Joint Commission recommends the following actions:

- Creating a highly reliable and standardized counting system to prevent URFOs, which should be performed audibly and visibly by two persons engaged in the process
- Developing and implementing evidence-based, organizationwide policies and procedures for the prevention of URFOs through a collaborative process promoting consistency in practice to achieve zero defects
- Development of specific recommendations for counting procedures, wound opening and closing procedures, and intraoperative radiographs
- Research into the potential of using assistive technologies to supplement manual counting procedures and medical wound exploration
- Effective communication as a standard part of the surgical procedure, including team briefings and debriefings, to allow the opportunity for any team member to express concerns they have regarding the safety of the patient, including the potential for an URFO
- Appropriate documentation, which should include the results of counts of surgical items, instruments, or items intentionally left inside a patient (e.g., needle or device fragments deemed safer to remain than remove), and actions taken if count discrepancies occur

Some of the most common objects left behind during surgical procedures include:

- Soft goods, such as sponges and towels
- Small miscellaneous items, including unretrieved device components or fragments (e.g., broken parts of instruments), stapler components, parts of laparoscopic trocars, guide wires, catheters, and pieces of drains
- Needles and other sharps
- Instruments, most commonly malleable retractors

Ultimately, prevention of URFOs and RSIs comes down to developing a reliable tracking system that everyone is involved with, says Patricia Pejakovich, RN, BSN, MPA, CPHQ, CSHA, a senior consultant with The Greeley Company in Danvers, Mass.

“If we have lots of hands involved in that surgical procedure—from the scrub tech handing items, to the surgeon, to the assistant surgeon and the circulating nurse—it’s about the methodology of trying to keep track of what is going on,” Pejakovich says. “Are we capturing everything that is going in and recognizing everything that is going out?”

To download the full Sentinel Event Alert, visit The Joint Commission website at www.jointcommission.org/sea_issue_51.
Pennsylvania Patient Safety Authority identifies EHR errors related to default values

Patient Safety Organization shows improper default values can cause serious errors

Electronic health records (EHR) were created with the intention of improving healthcare quality and making it easier to care for any and all patients. However, the transition toward this ultimate goal has already seen its fair share of bumps in the road.

A recent advisory released by the Pennsylvania Patient Safety Advisory (PPSA) in September 2013 focuses on one aspect of EHRs that has been particularly challenging in terms of improving patient safety. Default values in EHR systems—prepopulated figures used for dosing protocols, coordinating times for therapy delivery, or lab draws—can actually do more harm than good if hospitals don’t take the time to develop facility-specific guidelines based on clinical best practices. In the advisory, analysts identified 324 events related to EHR software defaults: 200 related to wrong-time errors, 71 related to wrong-dose errors, and 28 involved the use of an automated-stopping function. These reports also indicated a source for the erroneous data, and overwhelmingly those sources included failure to change default values, user-entered values being overwritten by the system, and failure to completely enter information, causing the system to insert information into blank parameters.

“Default values are often used to add standardization and efficiency to hospital information systems,” said Erin Sparnon, MEng, patient safety analyst for the PPSA and lead author of the advisory, in a press release. “For example, a healthy patient using a pain medication after surgery would receive a certain medication, dose, and delivery of the medication already preset by the healthcare facility within the EHR system for that type of surgery.”

Sparnon noted that 97% of the 324 reports were classified as “event, no harm”; however, the reports did indicate that hospitals need to consider how users enter information and how default values are determined.

This isn’t the first time that the PPSA has analyzed the effectiveness of EHRs on patient safety. In a preliminary report in December 2012, analysts evaluated more than 3,000 reports and found the majority of them involved errors in human data entry, while a few reflected technical failures on the part of the system itself. The September report has taken a deeper dive into those technical failures and discovered that in many cases, default values are the main culprit.

“The problem related to default values was one of the categories that jumped out at us back then, and ever since that initial report we’ve sort of been drilling down to the next level of detail and hitting the high-level categories,” says Bill Marella, MBA, program director at the PPSA. “So it was a very intentional subject for us to pick. That being said, it’s a little ironic insofar as default values are a way to standardize care which is safer. If they aren’t implemented properly or not implemented with forethought, they can cause problems rather than solve them.”

Other organizations have also warned about possible patient safety issues related to EHRs. In June 2013, authors of an article in the Annals of Emergency Medicine wrote that EHR errors can have unintended consequences on patient safety, particularly in EDs, where rapid turnover and transitions in care make EHRs especially prone to error.

A few weeks later, in July, the U.S. Department of Health and Human Services (HHS) released its finalized Health Information Technology Patient Safety Action and Surveillance Plan, which was created in response to a 2011 Institute of Medicine report. In the finalized plan, HHS proposed three specific actions:

• Learn about EHR effectiveness through the quantity and quality of data about health IT safety
• Use this data to target resources and improve IT safety and patient safety
• Work with the private sector to promote a culture of safety related to health IT

“When implemented and used properly, health IT is an important tool in finding and avoiding...
medical errors and protecting patients,” said Farzad Mostashari, MD, the national coordinator for health IT, in a press release. “This plan will help us make sure that these new technologies are used to make healthcare safer.”

For hospitals, this focus on errors involving default values indicates that more work needs to be done to improve the effectiveness of EHRs and create a customized and accurate system.

“Standardization is one of the basic tools for improving safety in any industry,” Marella says. “It’s not that we’re against default values, but rather that when they are implemented without some planning and oversight, they can cause problems.”

**Reviewing default values**

The default values that come with EHR software are intended to standardize patient care, but hospitals should be using a multidisciplinary team approach to ensure that they are meeting the clinical standards of care that are appropriate for their patient population.

“A lot of hospitals are using order sets to standardize care, which is a good thing, but I think what some hospitals do is take the defaults that come with the system, and those aren’t being reviewed by a clinical panel who could look at it and say ‘the defaults that you’re using are not appropriate,’ ‘this isn’t how we practice,’ or ‘this isn’t the most up-to-date way to provide these guidelines,’ ” Marella says.

This variance between default and appropriate values can be particularly pronounced with opioid management. Marella says the PPSA has been collaborating with some hospitals regarding this issue, and some patients were getting excess doses of narcotics simply because the default values were not appropriate for the patient.

“One hospital found that their default dose of hydromorphone was 1 milligram per ml, and that’s too high a dose for someone who might not have had opioids before and may not have developed a tolerance of them,” he says. “All they did is change the default value to .25 and they found they had a significant drop in patients that had overdoses to hydromorphone.”

**The six-month test**

The hospitals that have had the most success in reevaluating their default values have been those that implement a six-month testing period to ensure the changes they have made to any default values are appropriate for patient care.

“I don’t think that’s necessarily the norm,” Marella says. “There are lots of things that should be done at an organizational level to monitor and ensure the safety of the EHR prospectively rather than in a reactionary mode.”

How those changes are made should be a shared responsibility between the software vendor and the clinical team. Although the vendor is providing the service, the hospital will ultimately decide how much involvement it will have in customizing the system. Larger hospitals may have the ability to make changes on their own if they have a large informatics department, whereas smaller hospitals may be more inclined to rely on the vendor for support in making those customizations.

“But even in that case, the order sets that are developed should be reviewed by a multidisciplinary committee and reviewed before they are accepted,” Marella says. “The benefits of the EHR are only going to come about when it’s finely tuned with the way clinicians want to and should be practicing.”

**EHR growing pains**

Marella notes that many of the issues discovered by the PPSA are likely just growing pains as more hospitals are rushing to implement EHR technology. Although there are clearly many benefits to making the switch to electronic records, failing to step back, recognize potential issues with the software, and take the time to customize it to the needs of clinicians can impede those benefits.

“I think it’s a given that ultimately this technology will enable us to improve care in 100 different ways, and there are many examples that this is already happening,” Marella says. “But again, in the rush to take advantage of the financial incentives that the government has made available to hospitals and physician practices to implement EHR, people are rushing to do that and not putting an important premium on safety and thinking prospectively about how they are going to monitor the safety of this implementation and, indeed, even plan for safety as they are implementing the EHR.”
FDA releases final rule on unique device identifiers

Rule emphasizes improving quality of information for adverse event reporting

They say that good things come to those who wait, and professionals in just about every sector of healthcare have been patiently waiting—nearly six years, in fact—for the FDA’s final ruling on unique device identifiers (UDI) for medical devices, with the expectation that the new system will provide needed changes regarding medical device safety.

An advance announcement of the rule was made on September 20, 2013, at the UDI Conference in Baltimore, and the rule was officially published in the Federal Register on September 24. The rule is effective December 23, 2013, although portions of the rule already went into effect beginning October 24.

The rule requires most medical devices to include a UDI code, which will improve the quality of information pertaining to medical devices, particularly when it comes to adverse event reporting, recalls, and improving patient safety. Ultimately, the rule aims to improve patient safety by ensuring that medical devices are easier to identify both by the general public and medical professionals.

“UDI represents a landmark step in improving patient safety, modernizing our postmarket surveillance

Understanding the UDI rule

According to guidance published by the FDA, a unique device identifier (UDI) is a “unique numeric or alphanumeric code that consists of two parts”:

- A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device
- A production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - The lot or batch number within which a device was manufactured
  - The serial number of a specific device
  - The expiration date of a specific device
  - The date a specific device was manufactured
  - The distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device

The FDA is also creating a Global Unique Device Identification Database that will allow the public, as well as medical professionals, to easily search and access information about a specific medical device.

According to the FDA’s guidance document, once the rule is fully implemented, the UDI system will provide the following benefits:

- Allow more accurate reporting, reviewing, and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reduce medical errors by enabling healthcare professionals and others to more rapidly and precisely identify a device and obtain important information concerning its characteristics.
- Enhance analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources, and registries. A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Provide a standardized identifier that will allow manufacturers, distributors, and healthcare facilities to more effectively manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Lead to the development of a medical device identification system that is recognized around the world.
system for medical devices, and facilitating medical device innovation," said Jeffrey Shuren, MD, JD, director of the FDA’s Center for Devices and Radiological Health, in a press release.

Although manufacturers will shoulder most of the burden of meeting the final requirements, hospitals and clinicians should at least familiarize themselves with the requirements and understand how the system will impact their day-to-day operations.

Reactions to the rule
The FDA fielded an overwhelming amount of input regarding the proposed rule, noting that it received 270 comments totaling 1,700 pages from various healthcare groups, including doctors, hospitals, and manufacturers.

The fact that the UDI rule is finalized will likely come as a relief to many in the medical field, but the details of the rule are still drawing criticism from some. In July 2013, just two months before the final rule was issued, the Advancing Patient Safety Coalition—led by Premier, Inc., and made up of 18 healthcare organizations including the AMA, the Federation for American Hospitals, and the Association for Professionals in Infection Control and Epidemiology—submitted a letter to the Office of Management and Budget (OMB) urging the OMB to shorten the seven-year implementation timeline in the proposed rule; however, that timeframe remained in the final rule.

“Unfortunately, the rule proposes an excessively lengthy implementation timeline,” Premier said in a statement following the announcement of the final rule. “Since we have already been waiting six years for UDI, it’s unfortunate that patients will have to wait until 2020 to have a fully functional device-tracking system, particularly since such systems are so pervasive in the retail setting. It is our goal to work with our member hospitals to implement the provisions of this rule as quickly as possible to ensure that...

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The following is a list of key compliance dates under the unique device identifier (UDI) final rule, according to the FDA:

- **September 2014**
  - Dates on the labels for Class III medical devices must be formatted as required under § 801.18 and data must be submitted to the Global Unique Device Identification Database (GUDID)
  - A one-year extension for this compliance date must be submitted by June 23, 2014
  - Class III standalone software must provide a UDI
- **September 24, 2015**
  - Labels and packages for devices identified as implantable, life-supporting, and life-sustaining must have a UDI and must be formatted according to § 801.18
  - Standalone software that is life-supporting or life-sustaining must also provide a UDI
  - If a life-supporting or life-sustaining device is intended to be used more than once and reprocessed before each use, that device must have a permanent UDI marking, and that data must be submitted to the GUDID
- **September 24, 2016**
  - All Class III devices that are intended for multiple uses must be labeled with a permanent UDI
  - Labels and packages of Class II medical devices, as well as Class II standalone software, must have a UDI and the dates must be formatted according to § 801.18
  - Class II UDI information must be submitted to the GUDID
- **September 24, 2018**
  - Class II devices that are intended to be used more than once and reprocessed before each use must have a permanent UDI marking
  - Labels and packages of Class I medical devices and devices that have not been classified into Class I, II, or III must have a UDI and the UDI information must be submitted to the GUDID
  - Dates and labels of all devices, including those excepted from UDI labeling requirements, must be formatted according to § 801.18
- **September 24, 2020**
  - Class I devices, and those that have not been classified into Class I, II, or III, that are intended for more than one use, must have a permanent UDI marking on the device itself
patients will have confidence that the devices implanted in their bodies are safe and effective.”

Phil Lamory, senior consultant with Clarkston Consultants, headquartered in Durham, N.C., was at the UDI Conference when the announcement was made. He expects the rule will have significant impacts on patient safety and the ease with which people can access specific information about medical devices. Manufacturers have mixed feelings about the rule—many CEOs look at it as another compliance hurdle—but Lamory says the rule can be of value to manufacturers if implemented correctly. Fielding complaints about medical devices can be very burdensome, but UDI codes will help manufacturers streamline their process and control their inventory.

“When they get complaints about a device, they might spend weeks and months just trying to track down information on the device and figure out what it is and make sure they have the right information,” he says. “If they have a bad product, they generally do want to address it right away, especially if they think it’s going to cost more money if they don’t. So when we speak with manufacturers, we try and point out the good points. If you are

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Staff Trainer

Test staff knowledge on provision of care requirements with the following questions. Answers can be found on p. 12.

1. True or false: It is not necessary for community hospitals to have processes in place for accepting referrals if they do not want to.

2. True or false: The time frame allowed to complete an initial patient assessment can be defined by the hospital as long as it is consistent with law and regulation.

3. True or false: An RN is required to complete the nursing assessment.

4. Fill in the blank: Restraint and seclusion policies should outline the _________ in which restraint and/or seclusion is appropriate.

5. Fill in the blank: When behavioral management techniques such as restraint are used, it is important to use ____________.

6. The decision for a hospital to provide care, treatment, and/or services to a patient should be based on what?
   a. The patient’s ability to pay
   b. The hospital’s ability to provide the care the patient needs
   c. Both

7. Fill in the blank: The scope and content of ____________, ____________, and ____________ must be clearly defined and documented.

8. What are the time parameters for completing a history and physical?

9. Fill in the blank: Each patient should have a written plan of care that has ____________ and ____________.

10. Identify three things that are monitored on a continual basis while a patient is receiving anesthesia or moderate-to-deep sedation.
required by law to do something, you might as well see what value you can get out of it for your company.”

What hospitals should know

Although manufacturers will take on most of the workload in meeting the FDA’s requirements, hospitals should certainly be aware of the rule, the timeline for implementation, and how the new system operates. Clinicians—particularly doctors and surgeons—should receive some training on how to use the new Global Unique Device Identification Database (GUDID) system to look up and compare medical devices.

“They need to know what it is, how they can use it, and how they get into the FDA’s database,” Lamory says. “Say a doctor is faced with seven different syringes; he can type in the UDI number, and information on that particular device will pop up on the screen right in front of him.”

In terms of the direct impact on patient safety, Lamory says the new rule will improve the way physicians and surgeons practice simply because they will have more easily accessible information. For example, one of the fields in the GUDID database denotes whether a device is sterilized, which should help avoid confusion with a similar device that isn’t sterilized. The new system will also help ensure that surgeons have the right equipment at their fingertips during procedures.

“I know surgeons get frustrated when they are in the operating room and they are in the middle of a critical operation and they don’t have the right piece of equipment or right tool there,” he says. “This rule should help solve that. Also, if they need to complain about an instrument or tool, this will make it a lot easier for them to do that.”

PSMJ 2013 Index

**Healthcare IT**

AHRQ report: Where healthcare stands on quality measurement through health IT. Dec., p. 7.


**Healthcare worker safety**


Revisiting safe sharps to ensure protection for all. March, p. 1.

Supporting staff after adverse events. Feb., p. 1.

**Infection control**

Annual CDC report finds reduction in certain HAIs. May, p. 11.

Cutting *C. diff* by 70%. Oct., p. 11.


Johns Hopkins Children’s Center cuts CLABSIs. Nov., p. 8.


UV light machine helps reduce infection rates. March, p. 6.

**Joint Commission/NPSG**


Alarm safety is focus of new proposed Joint Commission NPSG. April, p. 1.


**Medication errors**


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Stop administering contaminated medications ASAP. June, p. 5.

**Miscellaneous**

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Successfully getting input from frontline staff. May, p. 7.

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The Joint Commission’s infection control standards quiz. Sept., p. 11.
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The Joint Commission’s standards on miscellaneous topics quiz. Jan., p. 9.
The Joint Commission’s standards on miscellaneous topics quiz. Oct., p. 11.
The Joint Commission’s standards on miscellaneous topics quiz. Nov., p. 11.
The Joint Commission’s standards on miscellaneous topics quiz. Dec., p. 11.

Answer key (from p. 10)
1. False. The Joint Commission requires hospitals to have defined procedures for accepting referrals.
2. True.
3. True.
4. Specific situations.
5. The least restrictive device that will work.
6. b. The hospital’s ability to provide the care the patient needs.
7. Screening; assessment; reassessment.
8. Up to 30 days prior to the patient’s admission to the hospital or within 24 hours after admission.
9. Goals; expected time frames to meet those goals.