Inside the Joint Commission

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Record drug shortages leave health care organizations with few good treatment options

With record numbers of drug shortages, health care organizations are running out of places to turn when they run low on medications.

Close to 200 medications have been in short supply during the last few years. At least 20 of those have been oncology specific drugs used in chemotherapy to treat various forms of cancer. Specifically, there have been shortages in medications such as taxol, leucovorin, cytarabine and daunorubicin, which is used to treat leukemia.

"This is unfortunately a nationwide issue," says Jeffrey Cronk, a medical oncologist and hematologist with Epic Care in

*(see **shortages**, pg. 4)*

5 essential tips to prevent medical equipment-related sentinel events

Medical equipment-related sentinel events are occurring at a much higher rate nationwide with 14 already reported from January to June in 2011, compared to a total of 25 in all of 2010, according to the Joint Commission's data summary report on sentinel events released in August. Your hospital's best defense for curbing these sentinel events is through diligent staff training and measuring the effectiveness of event policies, experts say.

Here are five tips that will help your hospital prevent equipment-related sentinel events:

1. **Evaluate what caused or could cause the event**. Regardless of the type of sentinel event, you must exhaust all possibilities that could lead to an event, says Jennifer Cowel, vice president for Patton Healthcare Consulting in Glendale, Ariz.

Example: Failing medical equipment alarms is one of the biggest contributing factors to an increase in equipment-related sentinel events, she says. Sometimes the equipment alarm itself

*(see **sentinel events**, pg. 6)*

Set clear standards for contractors; make sure they follow through

Unique standards hospitals work with every day become especially challenging when contractors are hired. When your hospital can't do something itself – whether that's constructing an add-on or installing a phone system – you hire a contractor. But it's especially important to make the right choice.

Contractors are not always up-to-date on standards or aware of the requirements they need to follow in order to complete their task to hospital-specific code. It's important to choose your contractors carefully and set specific, detailed expectations for each project. Any time the walls of your hospital are being entered, it is important to have specific goals and processes in place that you can evaluate before the walls are closed again.

Choosing the contractor may be the most difficult part, suggests Glenn Krasker, president of Krasker Healthcare Consulting. Krasker suggests the following when choosing your contractor:

- Seek references from other hospitals.
- Inspect the contractor's work in person before hiring the company. Go on site to other hospitals that have used the same contractor, and see the quality of the work firsthand.

After choosing a contractor, your hospital needs a way to evaluate the contractor's work.

"Each contract should have performance expectations, and someone at the hospital should be evaluating the contractor's performance," says Kurt Patton, president of Patton Healthcare Consulting in Glendale, Ariz.

Krasker agrees. Have an agreement that sets clear expectations for work you want contractors to do, Krasker says. Include a provision stating that the work must be inspected and found up to code before payment will be delivered, or the contractor must go back and correct any problems at no additional fee *(see related story, pg. 3)*.

Have someone spot check the work in progress and approve each site before the openings are closed, Krasker suggests. If the hospital doesn't have personnel to inspect the construction area or place the contractor is working, have inspectors from the city or state with expertise come view and approve the site to ensure it meets requirements. Have these inspectors identify any problems before the area is closed up, so there are no surprise problems later on.

Example: If the contractor is working on an electrical issue in your hospital, call the state and have a fire marshal "check it out beforehand and give you their read on it," Krasker says.

But if you don't go to a city or state official, your hospital must have the internal capabilities to inspect the updates or go to another consultant "who has the insight to check the work before it's signed off on," Krasker says.

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"Performance problems should be dealt with, just like they would be with staff," Patton adds. "And if correction does not take place, a new contractor should be sought."

Krasker agrees that hiring another contractor may be necessary. But if the contractor did not fulfill the contract, you will likely have to seek legal remedies, Krasker says. And the hospital needs to take a lesson in how to deal with contractors from the experience.

Additional requirements for clinical contracts are described in **LD.04.03.09** (care, treatment, and services provided through contractual agreement are provided safely and effectively). — *Rachael DeNale (rdenale@decisionhealth.com)*

6 ways to maintain compliance with the life safety code

Glenn Krasker, of Krasker Healthcare Consulting in Wilmington, Del. talked about ways a hospital could maintain compliance with the life safety codes in place, especially when doing maintenance on the building.

1. Conduct a safety assessment. "It starts with a very rigorous life safety assessment of your building," Krasker said. Do this assessment internally, or if you feel you hospital doesn't have the expertise to do the assessment, take the job to an outside contractor. Many hospitals are going to outside contractors because they feel the contractors are more objective when doing the assessment, Krasker said.

2. Develop timeframes. Develop life safety plans with timeframes of completion.

3. Estimate costs. Estimate the cost of repairs and the assessments your hospital will conduct. Be sure to stay within the allotted budget, or appropriate funds as necessary to maintain the necessary life safety standards. Include an estimate of the dollar amounts for each repair.

4. Stick to the schedule. Be sure to stick to the timeframe when scheduling assessments, maintenance, or anything else. Make sure all testing and repairs are done according to the schedule you laid out when developing your plan.

5. Assess and reassess. Make sure to continually assess the life safety of the building. Assign staff to do life safety assessments on a scheduled basis to help prevent the deficiencies in the first place.

6. Repair working damages. When you hire outside contractors, make sure that whenever they finish their work, if they did anything to create additional life safety issues, they repair these issues before leaving the site.

Clinical contractor elements of performance

LD.04.03.09 (Care, treatment, and services provided through contractual agreement are provided safely and effectively.)

- EP 1. Clinical leaders and medical staff have an opportunity to provide advice about the sources of clinical series to be provided through contractual agreement.
- EP 2. The hospital describes, in writing, the nature and scope of services provided through contractual agreements.
- EP 3. Designated leaders approve contractual agreements.
- EP 4. Leaders monitor contracted services by establishing expectations for the performance of the contracted services.
- EP 5. Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted series.
- EP 6. Leaders monitor contracted services by evaluating these services in relation ot the hospital's expectations.
- EP 7. Leaders take steps to improve contracted services that do not meet expectations.
- EP 8. When contractual agreements are renegotiated or terminated, the hospital maintains the continuity of patient care.
- EP 9. For hospitals that do not use Joint Commission accreditation for deemed status purposes: When using the services of licensed independent practitioners from a Joint Commission-accredited ambulatory care organization through a telemedical link for interpretive services, the hospital accepts the credentialing and privileging decisions of a Joint Commission-accredited ambulatory provider only after confirming that those decisions are made using the process described in Standards **MS.06.01.03** through **MS.06.01.07**, excluding **MS.06.01.03**, EP 2.
- EP 10. Reference and contract laboratory services meet the federal regulations for clinical laboratories and maintain evidence of the same.

This can happen any time cables are being repaired or any work is being done within the actual walls of a building. Any time contractors go through the walls of the building, make sure they seal up the penetrations before they leave. Some examples of work that could result in additional deficiencies are pulling cable, installing computer systems, installing or repairing information systems equipment or working on telephone cables.

Krasker suggested to tie the payment for the job into fixing the issues they created. If the contractor has not repaired the life safety code deficiency they created, and have not shown that it is completed and repaired, hold the payment up in accounts payable until the deficiency is repaired according to standards. — *Rachael DeNale (rdenale@decisionhealth.com)*

shortages

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San Francisco. And it's not only a problem with oncology drugs. This is a problem that's been hitting health care providers all over the country.

Some of the drugs with common shortages are also used in pre-transplant surgeries and during transplants, says Cronk, whose facility has noticed the shortage especially during the last year.

The shortages haven't all happened at once. They've been staggered, but there have been overlaps in the shortages.

Cronk's facility has specifically noticed shortages of taxol in the last four months and leucovorin in the last seven months.

Prepare for a shortage before it happens

Network. Before a shortage takes place, network with other health care systems, suggests Cronk, who is also the vice president of the Association of Northern California Oncology. Get in touch with distributors and with other health care facilities that may have additional resources. That gives you an 'in' to getting the medications your facility needs. "Try to make those contacts as early as possible," Cronk says.

Inform the FDA. Inform the FDA of any shortages or potential shortages that may occur, says Valerie Jensen, associate director for the Drug Shortage Program within the FDA's Center for Drug Evaluation and Research.

The Drug Shortage Program, instituted in 1999, examines potential and actual drug shortages in order to facilitate prevention and help shortages come to a resolution, provides drug shortage information to the public, and reaches out to health care professionals, the public and other stakeholders with information on shortages.

The FDA has the capacity to facilitate the prevention of drug shortages through regulatory discretion, expedited review of new manufacturing sites and suppliers and encouraging firms to increase production. In some rare cases, the FDA can issue temporary importation of medications from unapproved sources, for medically necessary drugs until a better solution is available, Jensen says.

Inform your network. As a member of a larger association or network, Cronk's organization tries to inform other members of shortages as they find out they're happening by sending out information in the association's newsletters or by calling the individual practices and hospitals.

Inform your associates at your hospital. Follow Joint Commission standard **MM.02.01.01** (the hospital selects and procures medications) EPs 10 and 11.

Let your peers know what drugs you think are in short supply and what pathways you think will be useful for getting the drugs before they run out. The risk is that facilities will hoard medications in short supply, but greater awareness and networking facilitates sharing the products instead of hoarding them, Cronk says.

What you can do if there is a shortage

Determine the root cause of the shortage. Investigate what is going on with the drug, its production and its distribution. If it's preventable, your hospital may not even be affected. For instance, if your hospital learns that a drug will no longer be supplied by a particular manufacturer, you may have the ability to find another manufacturer before the shortage hits you.

Contact the manufacturer. Jensen encourages health care facilities to get in touch with the manufacturer and/or the distributor of the drugs to determine

what the issues are. If there is something that can be easily fixed, something as simple as talking to the firm could help mitigate a shortage in your area.

Encourage other firms to increase production. If a drug is in low supply due to lack of production from one company, talk to other companies, Jensen says. Encourage the remaining manufacturers to increase their production or to start producing that drug if your original source has stopped producing it.

How to treat patients during a shortage

Hospitals have options for treating patients during a drug shortage, though each has negative aspects.

Substitute the drug. If you are treating a patient who needs a drug that's in short supply, you may need to substitute the drug with another that is more readily available. But remember:

- This may mean that you must use a drug that doesn't have as good a track record. Some substitutes have more side effects and other toxicity. Determine if the patient has any negative reactions to the new drug.
- These drugs may also be more expensive. Because of the shortage, there is increased demand for the small supply of drugs, effectively raising the price of those drugs.

Take note of standard **MM.02.01.01** EPs 12 through 15. When bringing in a new medication to your facility, you must develop appropriate criteria to determine if the medication is a viable substitute, and you must have procedures in place to monitor the patient's response to the substitute medication.

Note standard **MM.06.01.01** (the hospital safely administers medications) EP 9, which says, "Before administering a new medication, the patient or family is informed about any potential clinically significant adverse drug reactions or other concerns regarding administration of a new medication."

Use an alternate method of treatment. In some cases, physicians can recommend alternate forms of treatment for patients in dire need of the medication. Sometime alternatives can work, but in many cases, the initial route is the one the doctor thinks will do best, and changing that method may have severe impacts on the patient and his or her treatment.

Prioritize the patients. When a health care facility does get the drugs it needs, it may only get a limited

Reasons for shortages of older sterile injectables

- Not enough manufacturing capacity
- Industry consolidation
  - Fewer firms are making these products, with only seven manufacturers making up a large percentage of this market.
  - Contract manufactures – firms contract out manufacturing as well as acting as contract manufacturers.
- Lack of redundancy
  - Multiple products are made on existing manufacturing lines.
- Complex manufacturing process
- Not economically attractive
  - Drugs like propofol sell for $.48 per vial (20ml).

Medication management elements of performance

MM.02.01.01 (The hospital selects and procures medications.)

- EP 10. The hospital has a process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.
- EP 11. The hospital implements its process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.
- EP 12. The hospital develops and approves written medication substitution protocols to be used in the event of a medication shortage or outage.
- EP 13. The hospital implements its approved medication substitution protocols.
- EP 14. The hospital has a process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages or outages.
- EP 15. The hospital implements its process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages and outages.

supply that doesn't actually cover the needs of all the patients. In these situations, the facility needs to prioritize the patients, Cronk says.

Questions to ask:

- Can this patient use an alternate method of treatment?
- Can this patient use a substitute medication?
- How seriously does this patient need treatment at this moment?
- Can this patient be transferred to another facility that does have the resources he or she needs?

If you determine that a patient cannot use any type of alternative treatment, cannot go to another hospital and cannot delay their treatment until a larger supply is available, this patient should be given higher priority access to the medication in shortage.

Send the patients to another treatment facility. If your facility cannot treat the patient due to lack of drugs, a negative reaction to alternate forms of medication or for any other reason, before delaying the treatment, work with the patient to find an alternate facility or hospital system that does have the necessary drugs, Cronk says. This may be an inconvenience to the patient – i.e., he or she may not be able to travel a great distance, or in the case of cancer patients, the cancer or treatment itself may cause a great toll on their health – but getting a treatment, even at the inconvenience, is a better option than delaying the treatment.

Delay treatment. As a last resort, when all other types of treatment options have been exhausted and the only way to treat a patient is with the drug in short supply, you may need to delay a patient's treatment.

There's a lot of concern about this, Cronk says. Physicians will be frustrated because they have very little control over treatments and helping patients if one drug is the only treatment option and there are no suitable alternative products to use.

"We don't know when it will be fixed," Cronk says. But until then, he encourages all practices to maintain communication with each other and work together to overcome the shortages. – *Rachael DeNale (rdenale@decisionhealth.com)*

sentinel events

(continued from pg. 1)

is faulty and causes an event while other times it could be that the alarms sound off, but medical staff are desensitized to them and tune them out since they are always going off, she says.

NOTE: There are more alarms on equipment now than there were several years ago, and often times the alarms sound similar so a critical alarm isn't distinguishable from a low battery alarm, Cowel says.

TIP: Run alarm drills and time how long it takes for a nurse or other staff to respond.

TIP: Make sure all alarms are turned on at the nurse's station and on the actual unit, Cowel advises. Don't assume that you can see each patient and don't need an equipment alarm, she says.

2. Make sure staff is adequately trained on new equipment. Each hospital department should hold formal training sessions when new equipment arrives, Cowel says. It's common for staff to learn from each other about new equipment on the job when a patient is already involved. But this kind of equipment education leaves holes in training, such as handling equipment failures, and often doesn't include a thorough read of the unit's instruction manual, she says.

TIP: The best time to train staff is when the equipment is being processed through your hospital's biomedical equipment department *before* it's put on the hospital floor for patient use, Cowel says. Have the equipment vendor come in and train certain staff members delegated as training leaders for the entire staff, then set up specific times for the training leaders to teach other staff, she says.

TIP: Train staff on upgraded equipment, even if it is the same machine from the same company as the one staff currently uses, Cowel says. There could be subtle changes to the unit that could lead to a sentinel event if staff is left untrained on them, she adds.

TIP: Test your staff's competence with new equipment by administering an online quiz after the training session, having them demonstrate tasks on the unit post-training or by simply observing them use the machines on the work floor, Cowel suggests.

3. Establish equipment quality leaders in each department. While everyone should be checking equipment and keeping an eye out for failures, make it the unit manager's job to test machines to ensure they are operational (e.g., check parameters and make sure all alarms are turned on), Cowel says.

TIP: You may want to have a different department conduct equipment checks, such as putting the ICU nurse manager in charge of testing clinical alarms, she adds. Also, you could have the biomedical department in to check alarms monthly.

4. Encourage staff to report and discuss near sentinel events. It's typically not broadcast when someone discovers a defect or error with a piece of equipment, but it should be, Cowel says. You must celebrate your near misses as a way to hone in on possible causes of sentinel events and their prevention. If a nurse realizes a pump infusing intravenous medication was not working properly, he or she must tell other staff and management, she says. Staff shouldn't worry about getting blamed for the error, and the manger on duty must make a point to discuss what led to the mistake.

5. Review and update your sentinel event policies. Here are some tips to follow if you have a medical equipment-related sentinel event:

- Review your hospital's definition of a sentinel event.
- Do a root cause analysis by detailing the event, identifying and prioritizing the contributing factors that caused the event and pinpointing any "weak links" that facilitated the event such as inadequate staff training, time of day, or that the event occurred during a shift change.
- Work on a prevention plan and tweak or add to your sentinel event policies.

TIP: Monitor the effectiveness of revised policies by revisiting the procedures with staff 30 days after implementation. Also, do spot checks to make sure the policies are being followed a year later and beyond, Cowel says. — *Lauren C. Williams (lwilliams@decisionhealth.com)*

Root cause information for Joint Commission reviewed medical equipment-related events from 2004 to the second quarter of 2011

Human Factors	111	20.9%
Leadership	97	18.26%
Physical Environment	93	17.51%
Communication	91	17.14%
Assessment	82	15.44%
Information Management	22	4.14%
Care Planning	19	3.60%
Operative Care	7	1.32%
Medication Use	5	0.94%
Continuum of Care	4	0.75%
Total	**531**	**100%**

Note: Many events have multiple root causes.

Use this fire drill scenario tool provided by Hawaii Health Systems Corporation.

Fire Drill Scenario: First Q 2011

Prepared by: _____

Shift _____

Scenario: At _____ am/pm Fire Panel sounds and reads:

Smoke _____ Nurse Station. What do you do?

START YOUR FIRE DRILL: Log the Time _____

Please list your comments below:

What did NOT go well?

_____

_____

_____

_____

What DID go well?

_____

_____

_____

_____

Was R.A.C.E. used in this fire drill and how?

_____

_____

_____

_____

Charge Nurse Signature

Print: _____

Sign: _____

Date: _____