modifier with a generic equivalent having a different modifier.

“They aren’t synched, as it were,” Lesar said of the modifiers. He also said health care providers may not know the differences between extended-release, sustained-release, and coated formulations of a particular product.

Lesar said FDA could help practitioners distinguish among different product formulations by attaching specific definitions to modifiers and requiring manufacturers to use those modifiers consistently.

Holquist noted that manufacturers have asked FDA to approve the use of new modifiers to convey that a new formulation within an existing product line can be taken with or without food.

“From our perspective, the modifiers don’t convey anything” in such cases, Holquist said.

She said FDA also has to contend with manufacturers’ desire to refresh their brands.

“Companies don’t want to have the same modifier for years and years. They want to come up with something new and catchy,” she said. If FDA allows such changes, she said, the agency must ensure that clinicians and consumers understand what the new branding conveys.

Labeling and packaging. Kellie Taylor, associate director of FDA’s DMEPA, said many deadly medication errors have been attributed to problems with the products’ packaging and labeling that lead to the administration of an incorrect product or dosage.

The Institute of Medicine in 2006 recommended that FDA work with a variety of stakeholders to develop, by the end of 2007, safety-related standards for drug packaging and labeling.

Taylor said common error sources include inadequate differentiation of products or product strengths; confusing, missing, or excessive information on the packaging and labeling; and the use of small type.

Several panelists also noted that graphic elements like company logos can consume space that would otherwise be available for conveying information that is essential to product users.

“I do understand how important it is for a pharmaceutical company to have their trademark for sales purposes, but that is the last thing on the mind of the user,” Feroli said. “What I want to do is first identify the vial, and what’s in there, [and] how much do I have to pull out of that to match the doctor’s order. That’s all I want to know. Those are the main elements that a user needs to know not to make an error.”

Bona Benjamin, director of medication-use quality improvement for ASHP, told the panelists that many of ASHP’s past recommendations for improving labeling practices, particularly for i.v. medications, remain applicable today. These include using bar-code verification to identify medications and making better use of human factors engineering—including the standardization of dosage and intended-use expressions on labels.

Benjamin also urged FDA to forbid the use of the same brand name for products with different active ingredients—a practice FDA refers to as umbrella branding. Benjamin gave as an example Novartis Corporation’s Maalox Total Relief, which contains bismuth subsalicylate, in contrast to traditional Maalox antacid products, which contain aluminum hydroxide, magnesium hydroxide, and simethicone.

FDA in February warned that it had received reports of serious adverse events in patients who meant to use an antacid formulation of Maalox but instead purchased the salicylate-containing product.

“I don’t understand why this is acceptable. I just don’t,” Benjamin said of umbrella branding.

—Kate Traynor
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Leapfrog Group wants hospitals to monitor, not just implement, CPOE systems

To achieve “true meaningful use” of a computerized prescriber-order-entry (CPOE) system, according to the organization known as the Leapfrog Group, a hospital must routinely test and monitor that system after implementation.

The call for hospitals to do more than “plug and play” their CPOE system comes from an organization that has been pushing for the adoption of this technology for 10 years.

Evaluation tool. In a report released on June 30, Leapfrog announced that hospitals’ CPOE systems did not produce an appropriate warning for one third of the potentially fatal medication orders entered during a simulation.

The CPOE systems also failed to produce an appropriate warning for half of the orders that would be expected to result in a serious adverse event.

But nearly half of the hospitals that adjusted their CPOE system and related protocols on the basis of the 2008 test results performed better in 2009.

To use the simulation tool, a hospital had to complete Leapfrog’s annual survey, which includes indicating whether the facility has a CPOE system functioning in at least one inpatient unit. About 323 of the 1244 hospitals that completed the survey in 2009 had such a system.

Leapfrog said 214 hospitals used the tool to evaluate their CPOE system from June 2008 to January 2010. Each hospital received a scenario of 10 patients and 50 or 51 medication orders.

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Results-based recommendations. Based on the results from 2009, said David Knowlton, chairman of Leapfrog’s board of directors, the organization recommends that

- The federal government insert into its definition of “meaningful use” of health information technology a requirement for hospitals to test and monitor all of their adopted technologies,
- Stakeholders share information about the best practices for hospitals’ adoption of health information technology, and
- Those hospitals without a CPOE system adopt one.

“As medicine grows more complex, it will not be adequate to rely on the individual memories of each and every clinician to assure a plethora of medication errors are avoided,” Knowlton said during a June 30 briefing for reporters. “We’ll need to rely on advancing technology to support clinicians, and we’ll need to improve on the performance of that technology over time.”

Earlier in June, the ASHP House of Delegates approved a professional policy concerning the definition of meaningful use of health information technology. That policy calls for the Society to advocate to policymakers for the definition to address continuous improvement, among other things.

On July 13, the Department of Health and Human Services released its initial definition of “meaningful use.”

The definition is actually the set of initial criteria that hospitals must meet to qualify for an incentive payment for adopting and successfully demonstrating meaningful use of certified electronic health record technology.

Those initial criteria do not include a requirement for hospitals to test and monitor all adopted technologies.

The initial criterion on CPOE at hospitals states that this technology be the method used by licensed health care professionals to order at least one medication for more than 30% of the inpatients receiving pharmacologic therapy.

Two years ago, Leapfrog used the results from its first-ever CPOE test to issue a caution on the importance of hospitals ensuring proper implementation of CPOE systems to prevent serious medication errors.

Hospitals using the same CPOE product to process the same orders achieved different scores, the developers of the tool reported in the April 2010 issue of Health Affairs. Some 13 hospitals using the same vendor’s product, for example, achieved scores ranging from roughly 10% to about 74% out of a possible 100%.

Preference for alerts. Northwestern Memorial Hospital, in Chicago, was declared a top urban hospital by Leapfrog in 2008 and 2009.

The organization has not announced the top hospitals for 2010.

Anne M. Bobb, Northwestern’s clinical informatics pharmacist, said she helped set up the hospital’s CPOE system for the 2010 test and sat with the physician as he entered the orders.

“I support the idea of testing your CPOE system to identify medication orders that can lead to patient harm,” Bobb said. “I think it’s a great idea.”

Part of CPOE system maintenance, she said, is the continual addition of clinical decision support, coupled with confirmatory tests, to avoid errors.

But Leapfrog’s tool tests CPOE systems only for decision support in the form of alerts, she said.

Decision support in the form of standard order sets—for example, when a prescriber enters an order for gentamicin therapy the system prompts the prescriber to order a gentamicin serum-level measurement as well—is not evaluated by the tool, Bobb said.

And, unfortunately, she said, the tool has not changed with time.

“There are drugs on there that have been removed from the market in the United States,” she said.

For that situation and others in which the tool’s medication order cannot be entered exactly as specified, Bobb said a hospital reports the drug as not being on the formulary.

The downside, she said, is that the tool does not provide replacements for orders of nonformulary drugs. Thus the hospital has fewer testable orders.

In the 2010 test, Northwestern received three different orders in the medication-checking category “Contraindicated Route of Administration,” but the testing physician could not enter any of them, Bobb said.

Northwestern’s CPOE system, she said, does not permit prescribers to order certain medications for administration by obviously unsafe routes. For example, the system does not accept orders to administer enoxaparin sodium by i.m. injection.

“We’ve engineered that [safety problem] out of the system, which arguably is safer than just giving an alert about it,” Bobb said. “And we got no credit for meeting that category because all those test questions were thrown out, so it actually hurt us to design a safer system.”

One of the criteria for being a top hospital in an urban setting in 2009 was fully meeting the standards for implementing a CPOE system and passing Leapfrog’s test.

To pass the test, a hospital’s CPOE system had to catch at least 50% of the potential problem orders in 6 or more of 11 medication-checking categories, 2 of which had to be allergies and drug-drug interactions. The system also had to have a score of at least 25% on the checks for false positives.

Leapfrog typically announces the top hospitals each year in September–December.

—Cheryl A. Thompson

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