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Utilization, Criteria and Outcomes

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Hospital pharmacies find budgeting a challenging process this year

Lower bed counts, state budget cuts have impact

Hospitals from coast to coast are finding it more challenging to handle budgeting this year because of a variety of economic pressures.

On paper, hospitals in the past couple of years have seen the lowest predicted increase in drug expenditures in a decade or longer.[1]

Normally, this would make the budgeting process a little easier. But in reality, hospitals are dealing with budget cuts due to decreased hospital utilization, state budget cuts, and other economic pressures and byproducts of the national recession.

"Fewer and fewer patients are coming into the hospital, and our volumes are down," says **Lee C. Vermeulen**, BSPharm, MSPharm, FCCP, director of the Center for Drug Policy at the University of Wisconsin Hospital and Clinics in Madison, WI.

"Hospital pharmacies will definitely see their costs going down," Vermeulen says. "There is higher generic utilization overall due to more generics than before, but a lot of it is a straight-up change in patients' awareness and interest in generics."

Summary points

- Hospital pharmacies are finding 2009 to be a challenging year for budgets.
- Drug and hospital bed utilization are down, and state cuts are having impact.
- Annual report predicts lowest overall drug expenditure increase in decade.

It's one thing for patients to have someone else paying the bill and saying they won't consider a generic drug. But when patients have insurance that charges them $20 to $30 extra per month for a name brand drug, they'll choose a generic brand, he notes.

Also, increasing numbers of patients have no insurance, which means they will buy generic drugs if they can even afford those.

"The problem is that as patients lose their jobs they are losing their

insurance," says **Nadrine Balady-Bouziane**, PharmD, director of pharmacy services at High Desert Health System in Los Angeles, CA.

When patients lose their insurance they delay doctor visits, which means delayed diagnoses, Vermeulen says.

"The long-term significance is that lower costs will translate into higher costs as patients let things go," he explains. "Patients say, 'I've got this symptom, but I won't see a doctor because it will cost me a lot to manage this thing,' so they wait, and then it gets much harder and more expensive to treat."

For many hospitals in the short term this trend means unfilled hospital beds and reduced revenues. For High Desert Health System the trend means an increase in patients since the hospital is funded through the Los Angeles County Department of Health Services and serves many poor and uninsured or underinsured patients.

It also means that a health system that has faced budgeting restrictions since it was initiated in 2003 now is experiencing its most difficult year yet.

"We're reducing the money we spend on drugs, and they're monitoring even pens and pencils that we have to order," Balady-Bouziane says. "So we mandate generics now except for thyroid medication."

The hospital's tight formulary means that physicians and pharmacists have to use generic substitutes or go through an exhausting process to justify the use of a more expensive option.

For example, there is a protocol and list of drugs physicians have to try before they can document that their patient failed on these and needs Lipitor®, Balady-Bouziane says.

"We can make exceptions just maybe after a myocardial infarction," she adds. "They may put the patient on a high dose of Lipitor for 12 weeks after a heart attack, but then they have to go back to generic drugs."

So the hospital's revised formulary will allow physicians to prescribe outside the protocol for a few months, but then they have to revert back even if research studies do not substantiate the switch, she adds.

As difficult as this sounds, the alternative is worse, Balady-Bouziane says.

"The alternative to that is closing clinics so patients don't have any access to care, and this is because the real estate and property taxes and our revenue in the county have been reduced, and our patient population is growing," she explains.

"We sent physicians and pharmacies e-mails to let them know of the change," Balady-Bouziane says.

But obtaining buy-in wasn't necessary: "In our case they almost don't have any choice because we don't have to worry about losing patients," she says. "We tell them that's the way it is and if you want to prescribe something else for your patient then your patient has the choice to go outside at cost, but if they get it from us it's free."

At Oregon Health & Sciences University Hospital and Clinics in Portland, OR, the budgeting pressures are present, but not tied to state funding cuts since the institution is not state-owned and operated, says **Gae M. Ryan**, PharmD, director of pharmacy services.

"We've had a difficult year like everybody else," Ryan says. "Our inpatient volumes have declined although the outpatient volumes have increased."

So the pharmacy is doing the same work in a

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different arena, Ryan says. "We have had layoffs twice this year." **(See story about how hospitals are handling budget issues, p. 76.)**

It will be a difficult year to make a pharmacy budget, notes **Janice Dunsavage**, RPh, MAS, director of pharmacy at Pinnacle Health System in Harrisburg, PA.

"We've seen lower utilization; we've seen admissions decrease from time to time, but are not experiencing that right now," Dunsavage says. "We've seen drug shortages, which is our biggest problem."

Hospital pharmacies will be asked to tighten their budgets more than they have in the past, and they'll need to look for additional ways to impact the cost without compromising patient care, she adds.

So how should hospital pharmacists plan their budgets during these difficult times?

Pharmacy budgeting experts recommend that hospital pharmacists identify the trends that have the most impact on their hospital and proceed cautiously from that data point.

"What we recommend is that hospital pharmacies understand the data and their medication use patterns," says **James M. Hoffman**, PharmD, MS, BCPS, a medication outcomes and safety officer in the pharmaceutical department of St. Jude Children's Research Hospital in Memphis, TN.

"The challenge we always have is people often look at just the number and not the whole process," Hoffman says. "So we've done more this year of analyzing our drug expenditure trend and promoting the right drugs being used for our patients."

One of the regular budgetary pressures involves dealing with bundled products in order to get the best prices.

"We have four drugs by four different drug manufacturers, and one says, 'I want 60% of the market share before you get a good price,'" says **C.S. Ted Tse**, PharmD, MBA, clinical pharmacy coordinator at Advocate Trinity Hospital in Chicago, IL.

"That puts pressure on us to lean on one or two drug classes of medications before we can get a good price," Tse says.

It's also a continual challenge to manage the marketing pressures to use the more expensive new drugs, he notes.

"This era is a patient-driven market," Tse says. "Patients see the drug on TV at lunch time and tell the physician they want it, and the physician has no idea how much it costs."

So it's up to hospital pharmacists to learn as much as possible about new drugs and distinguish between those that are useful and those that are not, Tse adds.

Fortunately, there will be surprisingly few new inpatient drugs marketed this year, Vermeulen says.

Another budgeting issue is how the recession has caused people to postpone or cancel profitable elective surgeries, Hoffman and Vermeulen say.

In general, hospitals are seeing very clear decreases in utilization in predictable areas, such as medications like Botox® used in cosmetic surgeries, Vermeulen says.

"We're also seeing a decrease in hypertensives and in some other areas," he adds.

"We're seeing this manifest in two ways: through copayments and out-of-pocket," he says. "Beneficiaries are going to have to pay out-of-pocket more than they have before because employers are saying, 'I can't afford this, and you'll have to pay half the drug cost or a higher copayment.'"

"The downstream effect for the hospital pharmacist is trying to manage drug expenditures when these elective surgeries, which are very profitable and a good margin for the hospital, go away," Hoffman says. "If these go away then there's even more drug cost pressure on the hospital, and that's the end result of the world we live in right now."

Vermeulen and Hoffman, who are among the authors of the annual future drug expenditures report, have predicted a very low rate of growth in drug prices overall.[1]

"We're looking at price contraction," Vermeulen says. "We're hearing from GPOs (group purchasing organizations) serving hospitals that they're seeing some growth in prices."

But this could reflect the GPOs' desire to manage expectations more than the reality, he adds.

"The national data do not support this," Vermeulen says. "My experience is telling me that price growth is not the big factor that some GPOs think it is, and this is the lowest overall growth rate we've projected ever since we've been doing this."

The drug expenditure study points out two different trends in drug costs, Hoffman says.

"There's the trend of the traditional small molecules coming off patent," he says.

This pushes prices down. But then another trend holds prices high: "There's still growth in

expenditures for clinic medications, new medications, biologicals, and specialty drugs," he explains.

"We wrote a lot about specialty medications in this paper, and that's still going to be a growth area, even with the recession," Hoffman says. "It's going to be a challenge for hospitals to provide continuity of care when patients who are on expensive medications are admitted to the hospital."

St. Jude Children's Research Hospital has addressed drug budgeting and costs at grand rounds as a way to educate clinical staff on national drug expenditures.

"A lot of what we discussed was how to promote rationale drug use for our patients," Hoffman says. "Medications are a big part of St. Jude's operating budget, and it's always a target for cost management."

There is one potential issue on the horizon that could impact future drug costs, he notes.

"What's really fascinating is biosimilars, the biologics, and specialty drugs," Hoffman says. "There are a number of barriers to an abbreviated pathway for copies to come on the market, so right now there are three bills in Congress to produce the law that will do that."

This long-term trend is one hospital pharmacists should watch because there currently are no generic versions of biologics, he adds.

Reference

1. Hoffman JM, Shah ND, Vermeulen LC, et al. Projecting future drug expenditures — 2009. *Am J Health-Syst Pharm* 2009;66:237-257. ■

Hospital budget cuts can result in changes

IT efficiencies can help

Not every hospital pharmacy has experienced budget cuts this year, but with the prolonged economic downturn this is a possibility for everyone.

The pharmacy at Oregon Health & Sciences University Hospital and Clinics in Portland, OR, took a 3.5-4% across-the-board budget cut — all in labor costs, says **Gae M. Ryan**, PharmD, director of pharmacy services.

"The reason OHSU needed to lay off staff is because the hospital and clinics are part of a larger campus, and its educational mission partly relies heavily on investment income," Ryan says. "And as you might expect, that didn't do too well this year."

Summary points

- Technology has helped Oregon hospital keep pharmacists despite labor cuts.
- California county-funded hospital faces severe budget cuts.
- Some pharmacies might help bottom line by starting new revenue-producing, outpatient pharmacist services.

So last fall there was an immediate deficit, and the hospital system's budgetary pressures also emerged, Ryan adds.

"Volume is down everywhere, and there are so many things impacting people's reactions to things now," she says.

The High Desert Health System, which is funded through the Los Angeles County Department of Health Services, has dealt with major budget cuts, says **Nadrine Balady-Bouziane**, PharmD, director of pharmacy services.

"We will expect a $4.5-$5 million budget, and they want to cut $500,000 to $1 million," she says. "And we have an increase in patients."

The hospital has had to change its formulary to accept generic drugs for just about every treatment, and the pharmacy has cut outpatient pharmacy hours from seven days a week to being closed on Sundays and holidays, Balady-Bouziane says.

"The outpatient pharmacy was open to 9 p.m., and now it's closed at 7 p.m.," she adds. "And we try not to use any new drugs unless we can't do without them."

For hospital pharmacies that have not taken the time to fully examine their budgets to look for cost-cutting measures, now would be a good time to do so.

However, for OHSU's hospital, the work to create a more efficient process had already taken place, Ryan says.

The hospital has been finding cost savings through technology for the past 5-10 years, she says.

"We've had ongoing projects in drug utilization for years, looking at automatic substitutions of intravenous (IV) to oral (PO) medication conversions, consolidating our utilization in thera-

peutic class so we can take advantage of market share savings," she explains. "So we didn't get significant pressure to cut drugs."

The pharmacy used the annual projected drugs expenditures report and its supplier's forecast to project a 1% inflation rate on drug costs, Ryan adds.

Fortunately, the pharmacy department was able to reduce its labor costs without laying off staff.

"In the past six months the institution has implemented computer physician order (CPOE) entry, and that's dramatically impacted workflow," Ryan says. "What it boils down to is we didn't need to cut any pharmacists, but we've decreased technician hours."

Before the new CPOE, technicians would enter data, and now the same information is entered by physicians, she adds.

"So we took cuts in those kinds of positions, and it was a stroke of luck, serendipitus timing," Ryan says.

Another way the pharmacy department will respond to the current economic downturn is through expanding business lines on the outpatient side where there are more patients, she says.

"We offer specialty pharmacy services which we didn't do before, and it will bring in more revenue," Ryan explains. "Instead of cutting costs, we'll bring in more revenue."

One new business line will focus on the hospital's transplant business, she adds.

"We'll bring in more than enough revenue for it to pay for itself," Ryan says.

Sometimes there is little a hospital pharmacy can do to improve its budget without impacting patient care.

For example, the High Desert Health System pharmacy purchased generic digoxin as part of cost-savings measures, Balady-Bouziane says.

Then the pharmaceutical company making the product issued a recall because the pills were delivering different drug dosages, she explains.

"This is a critical issue with drugs that have a narrow therapeutic index," she says. "We had to call 40 patients or so and had them come back to check their drug levels."

Then the hospital switched to giving patients a brand name version of the drug.

It ended up costing more than it would have if the hospital had used the brand name drug in the first place, Balady-Bouziane says. ■

Special Report: Preparing for Pandemic

H1N1 flu is slowing down, gives room to front-line

So far, so good — but what's next?

[Editor's note: Drug Formulary Review *presents a look at how pharmacy disaster planning experts have handled the recent novel H1N1 influenza A crisis in a two-part series. In this issue, hospital pharmacy experts discuss ways to educate and prepare the public during a pandemic. Also, there's a sample H1N1 public health report and guidelines from the federal government on providing prophylaxis antiviral treatment. In the June 2009 issue, there are articles about the importance of communication during disaster preparation, and one hospital pharmacist outlines what she and her staff learned from an infectious disease disaster drill early in 2009.]*

Just as quickly as the world media touted the novel H1N1 Influenza A as the next 1918 pandemic, the media turned on itself to say it was all much ado about nothing.

But hospital pharmacists and emergency planners know better: What the first run of this novel flu outbreak has shown is that Mexico's health care system and governmental crackdown on stopping the flu's spread was successful. And it has demonstrated that U.S. hospitals are well-prepared to handle both seasonal flu epidemics, as well as outbreaks of novel influenza virus.

The Mexican government's response was swift and sacrificed its own economy as restaurants, schools, and other non-essential businesses and events were shut down to prevent the flu's spread. Travel to Mexico also plummeted. The Drug Information Association (DIA), for example, postponed its 2nd Latin American Regulatory Conference, which was scheduled for May 13-15, 2009, in Mexico City, Mexico.

Summary points

- U.S. hospitals are ready for flu season.
- Hospital pharmacists need to educate public.
- Extreme pharmaceutical measures can be taken if necessary.

True, no single U.S. hospital's infrastructure was taxed by an influx of flu

cases, but most appeared to be ready. Also, pharmacist emergency planners say this dry run will make it even more likely that hospitals will be ready for the fall and winter flu season, even if H1N1 makes a more deadly and virulent comeback.

"My suspicion is there will be a second wave of this flu variant," says **Deborah J. Larison**, PharmD, BCPS, clinical pharmacy specialist in emergency medicine at Sarasota Memorial Hospital in Sarasota, FL.

"With the 1918 influenza outbreak, the first wave was slightly less serious and was easily transmissible, but the second wave of that pandemic had more severe consequences than the first wave," Larison explains. "So there's always the possibility that a second wave could be worse."

During the first wave of the H1N1 outbreak, Sarasota County and the Florida Department of Health produced H1N1 flu situation reports with status information and guidelines for health care providers and the public. **(See sample situation report, p. 80.)**

In many ways, the way hospitals typically prepare for seasonal flu is how they should prepare for the H1N1 flu, says **Carsten Evans**, PhD, FASHP, assistant dean in continuing professional education in the College of Pharmacy at Nova Southeastern University in Fort Lauderdale, FL.

"In a normal flu season we lose 32,000 people," Evans says. "I think the same things we normally do we should be doing all along."

What made H1N1 different is the public attention and potential for panic surrounding the outbreak.

Although the novel influenza virus proved no more deadly than the typical seasonal flu, there was a great deal more attention paid to each death and hospitalization associated with it.

And if it resurges this fall in a more virulent form, then there's reason to suspect the public will be both alarmed and attentive.

So in some ways what hospital pharmacists need to do is educate and prepare in the event of public panic. Here are some suggestions:

• **Educate about infectious disease safety measures:** For instance, hospital pharmacists can emphasize social distancing among staff and patients, encouraging people to give a little extra space between themselves and others during flu season, Evans suggests.

They can provide information about the proper use of personal protective equipment, including painter's masks or surgical masks, he notes.

"There are certain things we want pharmacists to preach about," Evans adds. "And when panic strikes they can do this."

Hospitals could put up signs about good hand hygiene and how to wear masks safely, says **Sharon S. Cohen**, RN, MSN, CEN, CCRN, an emergency preparedness clinical nurse specialist/instructor trainer with the department of emergency preparedness at Broward Health in Fort Lauderdale, FL. **(See Broward County's tips, p. 80.)**

"If people are very sick with respiratory illness, we try to create a respiratory section that's away from the emergency department population that doesn't have influenza," Cohen adds. "We teach mask, hand-washing, and cough etiquette, and we have masks that nurses can give to patients."

"If someone presents with a fever and other signs and symptoms characteristic of the flu, we offer them a mask," says **Richard G. Thomas**, PharmD, DABAT, emergency management coordinator in the emergency department and rapid treatment unit pharmacist at Primary Children's Medical Center in Salt Lake City, UT.

"We'll isolate them only if we have cause to do so, and then we'll take appropriate respiratory protection," Thomas says.

• **Assist with comorbidities:** Pharmacists assist with preventing drug-drug interactions in cases of patients who have a chronic disease and present with influenza symptoms, Cohen says.

"We have a large HIV population, and we look at the whole pharmaceutical perspective of the patient," she explains. "They're on such complicated protease inhibitor-type of regimens that we want to make sure we're managing their HIV and treating whatever illness it is they present with."

• **Screen for prophylaxis treatment:** The U. S. Department of Health and Human Services has extensive guidelines on antiviral drug use during an influenza pandemic, and these include details about providing both pre- and post-exposure prophylaxis. **(See excerpt from HHS guidance, p. 79.)**

"The guidelines are relatively broad both for prophylaxis and treating patients who are hospitalized," Thomas says.

"So if you have a child who presented in the emergency department, treat that child with a full-course antiviral," Thomas suggests. "Treat family contacts with prophylaxis, as well."

With an adult who has the same symptoms in the emergency department, anti-flu prophylaxis is not necessarily recommended, he adds.

• **Maintain adequate supply of drugs necessary during pandemic:** "Look at your hospital's drug supply and try to forecast what you'll

need," suggests **Erin Mullen**, RPh, PhD, assistant vice president for Rx Response, a Washington, DC-based coalition that includes PhRMA.

Since the H1N1 novel influenza outbreak occurred at the end of the normal flu season, hospitals typically would have a decreased amount of antivirals on hand, Mullen notes.

"There were some limited shortages, but not because the product is not available, but because it takes a couple of days for the supply system to fill itself up when there's increased demand," Mullen explains. "So when you're looking ahead to what's going on, you should make sure there's additional stock on hand for what you'll need to respond."

For instance, hospital pharmacists should look at both what they need for handling an influenza pandemic, including antivirals like oseltamivir (Tamiflu®), as well as treatments needed for secondary infections, such as antibiotics needed for treating pneumonia, Mullen says.

"Also, hospitals will need other respiratory support medicines, IV fluid, etc., and they should make sure those stocks are adequate," she adds.

The Joint Commission on Accreditation of Healthcare Organizations recommends a 96-hour supply in stock, Mullen notes.

• **Lead efforts to extend reach of available flu drug supply:** If there proves to be a true pandemic with more people heading to the emergency room and hospital than usual and more people requesting oseltamivir and other antivirals, exhausting available supplies, then there are additional ways hospital pharmacists can help, Evans says.

For example, hospital pharmacists can come up with strategies for extending oseltamivir doses.

"If you have symptoms of flu you are supposed to take one Tamiflu tablet twice a day," Evans says. "That should help you get through the symptoms."

People who want to take the drug as a prophylaxis should take it once a day for 10 days, he adds.

But in a pandemic situation it might be necessary to cut down on these doses so more people can be protected and helped.

"So you can take certain drugs and extend the life of these products," Evans says.

For instance, the drug probiticide can help slow down the metabolism of oseltamivir, meaning that taking the flu drug with probiticide every third day could mean that fewer doses of oseltamivir would still have a desirable prophylactic impact, Evans explains.

This is an emergency situation possibility, however.

"Pharmacists would have to figure this out based on four research papers," he adds. "Pharmacists understand what probiticide's capabilities are, but they haven't been taught about using it with Tamiflu." ■

Antiviral influenza drug guidance

Here's what HHS recommends

The U. S. Department of Health and Human Services has extensive guidelines on how health care providers and public health agencies should handle an influenza pandemic.

These guidelines, called Guidance on Antiviral Drug Use during an Influenza Pandemic, include advice on handling post-exposure prophylaxis (PEP), with antiviral drugs like oseltamivir (Tamiflu®). Here are some of the suggestions.

Antiviral drugs from public sector stockpiles:

• Treatment, PEP, and targeted prophylaxis should be provided upon an initial pandemic outbreak overseas and in the United States. This is for the purpose of containing the initial outbreak of a novel influenza virus strain and preventing or slowing down a pandemic, giving health authorities time for preparedness.

• PEP should be provided to exposed travelers entering the United States early in a pandemic. This contributes to a risk-based policy to reduce the entry of infected persons and delay U.S. outbreaks.

• Treatment should be given to persons with pandemic influenza illness to reduce influenza complications, hospitalization, and death. Treatment also will reduce duration of illness and transmission of infection.

• PEP should be provided for outbreak control in nursing homes, prisons, and other closed settings. This reduces the high risk of illness and death when outbreaks occur in such settings and is consistent with accepted public health practice.

Antiviral drugs primarily from private sector stockpiles:

• Pre-exposure prophylaxis should be provided to health care and emergency service workers who are at high risk for exposure. Post-exposure prophylaxis should be provided to health care workers who are not at high risk for exposure. This strategy reduces infection and absenteeism in a critical workforce and protects those at highest

Influenza pandemic tips for public

The Broward County Health Department in Florida quickly issued public health recommendations when the novel H1N1 influenza virus outbreak first reached the United States. The county had no cases at that time, but issued these recommendations on how to prevent transmitting or becoming infected with the flu:

- People with respiratory illness should stay home from work or school to avoid spreading infections, including influenza, to others in the community.
- Avoid close contact with people who are coughing or otherwise appear ill.
- Avoid touching your eyes, nose, and mouth.
- Wash hands frequently to lessen the spread of respiratory illness.
- People experiencing cough, fever, and fatigue, possibly along with diarrhea and vomiting, should contact their physician/health care provider.
- Cough or sneeze into a tissue or into your upper sleeve, not your hands and put your used tissue in the waste basket.
- If you think you have influenza, please call your health care provider and discuss whether you need to be seen.

The county also advised the public that swine influenza viruses are not transmitted by food, and the infections spread from person to person.

occupational risk. It also reduces the chance of transmitting infection to high-risk patients with illnesses other than influenza.

- PEP should be provided to persons who are severely immunocompromised because of the high risk for severe complications and mortality from pandemic influenza, if infected, and because antiviral drugs are the only option for disease prevention. ■

Here's a sample H1N1 flu situation report

Sarasota County keeps everyone in loop

During the early weeks of the H1N1 flu outbreak, the Florida Department of Health and Sarasota County kept health care providers and others apprised of the potential epidemic through situation reports. Here's a sample of a May 4, 2009, report:

Sarasota County Health and Human Services (SCHHS) Situation Report

Today (Monday — May 4, 2009)

- As of 11:00 EST CDC has confirmed 286 cases in the United States and one death.
- There are five confirmed cases in the State of Florida: Lee County (2); Broward County (1); Orange County (1); and Pinellas County (1).

Sarasota County does NOT have any probable or confirmed cases at this time.

- World Health Organization (WHO) has reported as of 18:00 GMT on May 4, 2009, 21 countries have officially reported 1085 cases of influenza A (H1N1) infection.
- SCHHS participated in daily conference call with State DOH and EM at 1330.

As a reminder there is no Government Executive Order at this time. We are currently operating under the Department of Health's Public Health Emergency, which gives Florida Surgeon General the authority for the next 60 days to allow transfer of antiviral medications, e.g., Tamiflu® and Relenza®, to other providers to utilize in the event of spot shortages.

Agencies and departments working the H1N1 (swine flu) event are encouraged to keep track of costs in the event an executive order is issued.

The Strategic National Stockpile has been pushed out to local health departments in Florida.

CDC will begin reporting probable cases, as well as confirmed cases, on a national level.

Florida DOH guidance for local health department pharmacies and hospitals is expected Tuesday, May 5.

- The State continues in the community mitigation mode. SCHHS will continue to follow the CDC's community mitigation guidance. This includes recommendation of self-isolation of cases as well as taking measures to reduce transmission of the disease. SCHHS is strongly urging people who are ill to stay at home and refer to the general safety information listed below.
- The Florida Flu Information Line number is 1-800-342-3557. This is manned by staff from 0800 to 2000 and recorded message for the remaining 24 hours a day/7 days per week.
- SCHHS met with local School Board Officials. The SCHD, School Board, and PSAG will follow

CDC guidelines for potential school closures and make decisions based on the severity of the case as well as the number of confirmed cases. ■

Stocking emergency medications: Research first

Find the treatments most needed for area

Stocking antidotes and other rarely-used emergency medications is almost an afterthought at many hospitals.

"A lot of these are drugs that are used to treat relatively uncommon conditions," says **Nancy S. Jordan**, PharmD, BCPS, pharmacy clinical coordinator at Albuquerque, NM-based Presbyterian Healthcare Services and Espanola Hospital's department of pharmacy in Espanola, NM.

"It takes a certain effort for hospitals to wrap their hands around this issue," Jordan adds.

Leaders at Presbyterian Healthcare Services, which is a multihospital system that includes both large and small hospitals, decided to improve procedures for stocking antidotes and other emergency medications, she says.

"There are a lot of emergency conditions where patients need medications to treat them, and the typical ones are antidotes," Jordan explains. "We looked at the patients coming into the emergency room with poisoning and wanted to see if the pharmacy had the drugs we needed in the right quantities."

The first step was to update the antidote list. Jordan first researched the topic of antidotes and emergency medications, and then she compared what she found in the literature with what the hospital system already stocked for emergencies.

"We looked at our antidote list and decided there are additional medications we should have that weren't on the list," Jordan says.

For instance, it's rare for a hospital to see a case of cyanide poisoning, yet hospitals still need to stock a recommended antidote to this potential emergency because a case of cyanide poisoning is fatal if not treated quickly, she explains.

The next step was to update the antidote list's quantities.

"We translated the recommended quantities into something more user-friendly," Jordan says.

For example, the literature suggests quantities in grams, but not all of the necessary drugs are packaged in gram quantities or they might be packaged in liquid form, Jordan says.

The idea was to provide a guide that would quickly show clinicians how many vials they would need of a particular medication.

"We worked as a system to get some cohesion and agreement so we would all carry the same quantities and products," Jordan says.

The hospital's antidote list has more than 20 items.

"A typical example of an antidote medication on the list and which we're stocking is oral acetylcysteine, a medication used to treat Tylenol® overdoses," Jordan says. "Another one we've added and classified as an emergency medication is IV dantrolene, which is used to treat malignant hypothermia."

Malignant hypothermia is a dangerous condition precipitated by use of neuromuscular blockers, she explains.

"Anti-venom for treating snake bites is also on our emergency list," Jordan says. "We had a lot of discussion within our organization as to whether we should change the nationally recommended quantities and stock more of this, and we decided to stock more."

This is something every pharmacy director should consider: Which types of poisonings are more common in your region, Jordan suggests.

"What do you need to stock and how much is practical for you?" she says.

Stocking these drugs can be costly, she notes.

"When we constructed the original list it looked like it would cost around $40,000, not inconsequential, especially for a small facility," Jordan says. "Some of the big ticket items are now available generically, so the price may have come down."

But the reality is that some of the drugs are expensive and hospitals would need to keep a large quantity of them for conditions they hope to never see, she adds.

Summary points

- In updating a hospital's emergency medicine list, include both emergency treatments and antidotes.
- Decide which medications to stock and in what quantities.
- Figure out the logistics of where to stock emergency medications.

Also, hospital pharmacy directors could check with other local hospitals to see how easy it would be to borrow a certain medication if the hospital were to run out of one.

"Do we need XYZ amount of something, or can we stock enough to get the patient started and then borrow from a colleague down the street?" Jordan says. "We decided not to count on borrowing anything because with some medications there's not enough time to borrow."

Reach a consensus on what and how much to stock, she adds.

"We agreed on stocking quantities and prepared charts that directors of pharmacies took to their pharmacy and therapeutic committees for approval," Jordan says. "The pharmacists said, 'Here's our recommendations as to what products to have in stock to adequately treat emergencies that come through our door.'"

The next issue was deciding where to stock the products.

"The main hospital in Albuquerque has 24/7 pharmacy services," Jordan says. "So where do you stock something that isn't so critical in an organization like that?"

The smaller facilities have pharmacists on call at night, so where would they keep cyanide antidote kits, for example, which need to be available quickly if needed but might not be best suited for automatic dispensing cabinets, Jordan adds.

"You can have all the right products in stock, but if they're locked up then that's not very helpful," she says.

"The other thing we tried to do with a standardized list is to encourage facilities to come up with a designation on a chart as to where the products were physically located," Jordan says. "This way the nursing supervisor at night could quickly look at the list and see where the cyanide kits were."

Once a hospital pharmacy has established an emergency medication list and made changes to which medications and quantities would be kept in stock, it's important to monitor these changes on a regular basis.

For example, someone will need to check these uncommonly used medications periodically to see if they've expired and need to be replaced, Jordan suggests.

"Often in smaller facilities, it's easy to lose track of these sorts of things," she adds. ■

Drug News

FDA issues alert, revisions for prescribing ceftriaxone

The FDA has revised information about ceftriaxone (Rocephin®) regarding its interaction with calcium-containing products.

Here are the FDA's recommendations:

• Concomitant use of ceftriaxone and intravenous calcium-containing products is contraindicated in neonates of 28 days of age or younger. Ceftriaxone should not be used in these neonates if they are receiving or are expected to receive calcium-containing intravenous products.

• In patients older than 28 days of age, ceftriaxone and calcium-containing products may be administered sequentially, provided the infusion lines are thoroughly flushed between infusions with a compatible fluid.

• Ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions via a Y-site in any age group.

• The FDA now recommends that ceftriaxone and calcium-containing products may be used concomitantly in patients older than 28 days, using the precautionary steps above because the risk of precipitation is low in this population. The FDA had previously recommended, but no longer recommends, that in all age groups ceftriaxone and calcium-containing products should not be administered within 48 hours of one another.

Also, the FDA reiterates three of its previous recommendations from September, 2007:

• Do not reconstitute or mix ceftriaxone with a calcium-containing product, such as Ringer's or Hartmann's solution or parenteral nutrition containing calcium, because particulate formation can result.

• There are no data on interactions between intravenous ceftriaxone and oral calcium-containing products or between intramuscular ceftriaxone and intravenous or oral calcium-containing products.

• Report patients who have adverse events following ceftriaxone administration to the FDA's MedWatch program.

To report any unexpected adverse or serious event associated with the use of this drug, please

contact FDA MedWatch program and complete a form on-line at www.fda.gov/medwatch/report/hcp.htm, or report by fax to 1-800-FDA-0178. ■

Company recalls 39 lots of transdermal patches

Shire Pharmaceutical Group of Philadelphia, PA, has announced a voluntary market withdrawal/recall of thirty-nine (39) lots of the ADHD patch methylphenidate transdermal (Daytrana®).

Shire is taking this action because some methylphenidate transdermal patches no longer meet their release liner removal specification, and as a result, patients and caregivers could have difficulties removing the liners.

Pharmacists who have questions about the recall should call Shire's Daytana customer service line at 1-888-202-3822. ■

FDA has updated labeling for antiepileptic drugs treating epilepsy

The FDA notified health care professionals in May that it approved updated labeling for antiepileptic drugs used to treat epilepsy, psychiatric disorders, and other conditions (e.g., migraine and neuropathic pain syndromes).

The FDA also required development of a medication guide, to be issued to patients each time the product is dispensed. Since issuing safety alerts on Dec. 16, 2008, and Jan. 31, 2008, the FDA has been working with the manufacturers of drugs in this class to better understand the suicidality risk. Eleven antiepileptic drugs were included in a pooled analysis of placebo-controlled clinical studies in which these drugs were used to treat epilepsy as well as psychiatric disorders and other conditions. The increased risk of suicidal thoughts or behavior was generally consistent among the 11 drugs, with varying mechanisms of action and across a range of indications. This observation suggests that the risk applies to all antiepileptic drugs used for any indication.

Based on the outcome of this review, FDA is requiring that all manufacturers of drugs in this class include a Warning in their labeling and develop a Medication Guide to be provided to patients prescribed these drugs to inform them of the risks of suicidal thoughts or actions.

In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug and continued through 24 weeks. The results were generally consistent among the 11 drugs. The relative risk for suicidality was higher in patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.

Health care professionals should closely monitor all patients currently taking or starting any antiepileptic drug for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

Although 11 drugs were included in the analysis, FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling changes will be applied broadly.

For more information, visit the FDA's web site at www.fda.gov. ■

FDA warns consumers to stop using Hydroxycut®

The FDA warned consumers in May 2009 to immediately stop using Hydroxycut products

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by Iovate Health Sciences, Inc. of Oakville, Ontario, Canada, because they are associated with serious liver injuries. Hydroxycut products are dietary supplements that are marketed for weight-loss, as fat burners, as energy-enhancers, as low carb diet aids, and for water loss under the Iovate and MuscleTech brand names.

In May, the FDA sent out a "Dear Healthcare Professional Colleague" letter about the recall.

The FDA has received 23 reports of serious health problems ranging from jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplants and death.

One death due to liver failure has been reported to FDA. Other health problems reported include seizures; cardiovascular disorders; and rhabdomyolysis, a type of muscle damage that can lead to other serious health problems such as kidney failure.

The injuries reported to FDA occurred in persons between 21 and 51 years of age. No other cause for liver disease was identified. In the majority of cases, no preexisting medical condition that would predispose the consumer to liver injury was identified.

In some cases, discontinuation of Hydroxycut usage resulted in recovery of liver function.

Although the liver damage appears to be relatively rare, FDA believes consumers should not be exposed to unnecessary risk.

Hydroxycut products bear the Iovate or Muscletech brand name and are multi-ingredient dietary supplements marketed for weight loss, as fat burners, energy enhancers, as low carb diet aids, and to promote water loss.

The agency has not yet determined which ingredients, dosages, or other health-related factors may be associated with risks related to Hydroxycut products. FDA continues to investigate the potential relationship between Hydroxycut dietary supplements and liver injury or other potentially serious side effects.

The FDA urges health care professionals to review their cases of hepatitis in order to determine if any may be related to the use of dietary supplements in these patients. Adverse events associated with the use of dietary supplements should be reported as soon as possible to FDA's MedWatch program by telephone (1-800-332-1088) or Internet (www.fda.gov/medwatch).

For additional information, see www.cfsan.fda.gov. ■