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Special Report: Planning for Disasters

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[Editor's note: In this issue of Drug Formulary Review, we have the first part of a series on how pharmacists can plan for disasters of any type. There are stories on making disaster planning a priority, planning for a natural disaster, making your personal disaster plan, and handling a crisis caused by a violent act at a pharmacy. In the January, 2009, issue of DFR, there will be additional articles about planning for a biochemical or pandemic disaster.]

Disaster planning should be priority for hospital pharmacists, experts say

Disasters should be defined broadly

The past decade has featured devastating hurricanes, floods, fires, and terrorist acts that have captured headlines often for weeks at a time.

What the nation's heightened awareness of disasters has shown is that every hospital, whether or not it's on the coastline, should have a disaster plan that includes the pharmacy department.

Hospital pharmacists also need to expand their personal definition of disaster to include events that could occur anywhere at any time, such as a pandemic flu outbreak, an anthrax terrorism attack, or even a highway jacking of spent plutonium.

Summary points

- Pharmacists should be ready for any type of disaster, including pandemics, bioterrorism.
- Pharmacists could help patients prepare for natural disasters.
- Know your hospital's entire emergency preparedness plans.

"Tennessee has a disposal site for used plutonium, and I-40 is a huge corridor for taking spent plutonium to Nevada for burial, a final disposal," says **Sharon S. Cohen, RN, MSN, CEN, CCRN**, an emergency preparedness clinical nurse specialist/instructor

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trainer of Broward Health in Ft. Lauderdale, FL.

The bad guys could highjack one of those trucks, leading to a potential accident and disaster that would require focused and rapid medical mobilization, Cohen says.

While this is a remote possibility, the point is that all of those hospitals along the I-40 corridor have a potential disaster risk that they might not even be aware of.

This is why every hospital and hospital pharmacist should consider writing disaster plans that will work whether a disaster is weather-related, caused by terrorism, the result of a major viral outbreak, or caused by an unanticipated event, Cohen and other disaster planning experts say. **(See story on preparing for a weather-related disaster, p. 99.)**

"You need to look at all disasters that can have a health impact," says **Erin Mullen**, RPh, PhD, an assistant vice president for Rx Response of Washington, DC. Rx Response (www.rxresponse.org) is a private sector partnership of

pharmaceutical organizations that helps provide support during severe public health emergencies.

Rx Response provides a list for pharmacists of web sites and organizations that have additional information about disaster preparedness. **(See list of disaster planning sites, p. 100.)**

"The number one thing that keeps me up at night is worrying about being prepared for pandemic influenza," Mullen says. "Pharmacists need to be aware and up-to-date on pandemic influenza."

Some hospitals are beginning to incorporate pandemic flu preparedness in their disaster plans, partly because infectious disease experts say these are cyclical and a big flu outbreak is due.

"There's a sense of history and a sense of urgency," says **Carsten Evans**, PhD, FASHP, an assistant dean in continuing professional education at Nova Southeastern University, College of Pharmacy, in Fort Lauderdale, FL.

"In 1918, there were more U.S. soldiers killed from flu than from World War I," Evans says. "It was remarkable how they piled up bodies in Washington and New York."

As the soldiers returned by boat from Europe, there were cargo ships full of the bodies of those who died from the pandemic, Evans adds.

Last year there were 50,000 deaths in the United States from the seasonal flu, Mullen says.

"We average 36,000 deaths a year from flu," she adds. "Last year was a bad year because the vaccine wasn't a good match."

But the point is that flu pandemic would have widespread public health and societal impact.

"Look at a pandemic and worst-case scenario, and you could imagine absenteeism as high as 40% in the hospital," Mullen says. "Employees would have to stay home because family members were sick and schools were closed."

For this reason, Mullen recommends that hospital pharmacists develop their own personal disaster plans before fine-tuning their professional disaster plans. **(See story on preparing a personal disaster plan, p. 101.)**

"Pharmacists need to make their own personal preparedness plans for their families, themselves, and their pets," Mullen says. "Then they need to educate themselves on what risks there are in their community, so once they're prepared for a disaster they can help their patients become prepared."

Mullen sees pharmacists playing the role of advocate for the overall health of patients, and this includes disaster preparedness.

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Editorial Questions

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"Even making sure someone is prepared for a power outage for three days is a significant part of a person's overall health," Mullen says. "It fits right in like refilling prescriptions on time and knowing your medications and conditions."

Pharmacists should talk with their patients about disaster preparedness and encourage them to fill their prescriptions in 90-day supplies, instead of 30-day supplies during hurricane season, if they live in coastal areas, she says.

Also, pharmacists could advise patients to write down their emergency contacts both in and out of their area, Mullen suggests.

"These are people who would check in on them in case something happens," she adds.

At the same time, pharmacists should know their pharmacy's or hospital's plans for restoring power in the event of a disaster, and they should make certain the pharmacy is a priority for restoration, Mullen says.

"The pharmacy is the most accessible point for health care," she notes. ■

Special Report: Planning for Disasters

Those who've been there offer advice on preparing for natural disasters

Long outages can be frustrating

Pharmacists residing in Florida, Louisiana, and Texas are well aware of the disaster drill.

After all they've had first-hand experience in coping with disasters about every couple of years in recent memory.

So *Drug Formulary Review* asked a couple of pharmacists who've survived hurricanes to talk about how they and their areas prepare for natural disasters.

St. Luke's Episcopal Hospital in Houston, TX, had to put its disaster plans into action this past September when hurricane Ike hit.

"With hurricane Ike they had landfall predictions, and you watch that and as they zeroed in on our location, most hospitals had increased their emergency preparedness stance," says **Craig**

P. Frost, RPh, MBA, pharmacy manager at St. Luke's Episcopal Hospital.

Electricity at Frost's own home still was out a week and a half after the hurricane hit, but he says the hospital never lost commercial power because of the emergency planning hospital officials did after tropical storm Allison devastated Southeast Texas in June, 2001, Frost notes.

"All of the hospitals flooded in Texas, and the event caused major flooding problems," he says. "This spurred an incredible awareness of emergency preparedness, so we did very well during Ike."

The most memorable time **Erin Mullen**, RPh, PhD, assistant vice president for Rx Response in Washington, DC, personally experienced a natural disaster when she was living in Miami during category 5 hurricane Andrew's attack in August, 1992.

Mullen was a new pharmacist who had not yet received her license and didn't have a job, so she evacuated inland to her sister's house as Andrew drew closer.

"We lost our house's roof, and there was significant flooding and damage," Mullen recalls. "So we ended up selling the property at a loss."

Mullen learned a great deal from that experience, including the tip that pharmacists should protect both their personal and professional items with Ziplock bags, she says.

"Any documents, photographs, prescription copies should be put in Ziplock bags," she says. "I implemented that strategy for all hurricanes that came through Orlando in 2004 while I lived there."

"We didn't have significant damage in the pharmacy where I worked in 2004, but we had a lot of wind that went the wrong way down the vent, so everything in the store was filthy and covered from the rain that went through," she recalls.

"But we didn't have to worry about those hard copy prescriptions because those were in Ziplock bags," Mullen adds. "The computer system wasn't safe, but they had backed up its data as part of the normal disaster preparation and recovery."

When Ike struck Texas, hospitals and pharmacy staff were well prepared in a variety of ways, and the hurricane's impact struck them more because of its impact around the hospitals than inside the hospitals, Frost notes.

"We had some wind damage in the hospital, but it was more about how the community was

impacted than how we were," he says.

For instance, hospital pharmacists had learned from hurricanes Katrina and Rita that Houston's traffic would be difficult to navigate after a disaster. So they were prepared by having additional medication inventory on hand and planning ways for vendors to reach them with supplies, Frost explains.

"We were ready with people and supplies, who were prepared to act on anything that would come up," Frost says. "You have to have a good preparation plan by looking at utilization patterns and planning for a 4-5 day supply of medications, assuming you won't be resupplied in that period of time."

The medications that need to be stocked for a disaster include tetanus vaccines to treat people injured with cuts and scrapes during the clean-up period after a disaster, he notes.

"We also have plenty of emergency room type of drugs for people with allergic reactions, breathing problems," Frost adds.

It's common procedure for hospitals to assign employees in one of two disaster teams: a ride-out team and a preparation and recovery team, he says.

"That helps us maintain our staffing levels throughout the emergency, and that's pretty common for the hospitals," Frost says. "If you're in the ride-out team you are here during the storm."

Ride-out teams are called to work right before a hurricane, and the team goes into extended shifts by spending the night at the hospital with half working and half resting, he says.

"We hunker down for the storm, discharging as many patients as we can," Frost says.

The remaining patients are moved away from windows.

"Once the event passes enough to where people can get to and from the hospital, then the recovery team comes in, and the ride-out team is relieved," Frost adds.

Frost, who served on the ride-out team during hurricane Ike, says his role was to maintain operations, interface with the command center, give status reports on operations and supplies, and to make sure there were enough employees to perform tasks.

"We have back-up generators, so if we lose power we have an emergency power supply, and the refrigerators are plugged into emergency outlets," Frost says. "We have regular inspections to make certain critical equipment is plugged into emergency outlets." ■

Here is list of information about pharmacists as first responders

Rx Response [www.rxresponse.org] of Washington, DC, has compiled a list of sources of information about disaster preparedness, and this is a sample pulled from that list:

- **American Society of Health System Pharmacists:** The web site has a link for an emergency preparedness checklist at www.ashp.org/s_ashp/cat1c.asp?CID=505&DID=547
- **Centers for Disease Control and Prevention:** www.bt.cdc.gov
- **Citizens Emergency Response Team (CERT):** The CERT program provides emergency preparedness training. Its web site is www.floridadisaster.org/citizencorps/
- **Color Coding Kids:** This source provides color-coded emergency treatment guidelines for pediatrics at www.colorcodingkids.com
- **Hazard and Vulnerability Analysis Tool (Kaiser Permanente):** This sample tool helps assess relative threats for a health care facility. More information is available at www.gnyha.org/22/file.aspx
- **Homeland Security Field Guide:** This waterproof guide is for terrorist and incident response planning. For more information, go to www.informedguides.com/?action=ViewProduct&ProductID=12
- **National Disaster Medical System (NDMS):** Here is information about NDMS teams: www.ndms.hhs.gov
- **NSU - Center for Bioterrorism and All-Hazards Preparedness:** www.nova.edu/allhazards
- **Pandemic Influenza:** For information on pandemic flu viruses, see www.pandemicflu.gov
- **US Army Medical Research Institute of Infectious Diseases (USAMRIID):** For information on the USAMRIID's Medical Management of Biological Casualties Handbook, check out the web site at www.usamriid.army.mil

Personal disaster plans first and professional plans next

Think of Maslow's hierarchy of needs

One of the key strategies for preparing for a disaster or crisis is to encourage pharmacists and other health care professionals to take care of their own families and homes and themselves first, and then they can prepare for the public's needs.

"When you think about emergency prepared-

Summary points

- Make a list of important contacts and share with friends, family.
- Use voicemail to keep callers up-to-date.
- Protect belongings and have disaster kit handy.

ness, think about Maslow's hierarchy of needs, and worry about taking care of yourself, your family, and then your community," says **Erin Mullen**, RPh, PhD, assistant vice president for Rx Response in Washington, DC.

American psychologist Abraham Maslow

discussed how humans have a pyramid of needs that begins with the most basic needs for survival and extend to the highest level of needs, which include creativity, morality, spontaneity, problem-solving, acceptance of facts, and lack of prejudice. He discussed this hierarchy of needs in his 1943 paper, "A Theory of Human Motivation."

"So if you plan ahead and make sure you and your family are safe, then you can move to the next step," Mullen explains.

This means that hospital pharmacists should have their personal disaster plans ready to be put into action when a crisis or disaster occurs. Here are some suggestions for this list:

- **List your important contacts:** Collect names of people who need to be contacted when a disaster occurs in your area, and give this list to someone who lives outside of your region, Mullen suggests.

"We learned from hurricane Andrew that so many people are trying to make phone calls that it's difficult to make calls in the area," she explains.

So when a disaster strikes, pharmacists should call their family or friend with the list, let them know that all is well, and have them call everyone else on the list, Mullen says.

- **Use voicemail instead of an answering machine:** The difference is that answering machines will only work if there is electricity, and in flood or wind-damage areas, they could be damaged and destroyed. Voicemail is recorded off-site by the telephone carrier or another entity, so it's less likely to be disrupted because of a disaster.

"This makes a lot of sense because if you have voicemail then people can still call you and leave a message, and you can change your message on the voicemail to let people know that you're fine or the house is gone," Mullen says. "You could even leave a message on your voicemail of who your friends could contact if they need to reach you."

- **Discuss your disaster plan with friends and family:** Someone outside of your immediate household should know what you will do in the event of an emergency.

For instance, if a pharmacist is scheduled to be working at the hospital during the duration of an emergency and he or she cannot be reached during this time, then it will prevent panic if family and friends know that this will happen.

- **Protect your personal belongings:** If you anticipate hurricane winds or flooding, protect the personal items that are most important to you through the use of Ziplock plastic bags, moving electronics away from windows and on to higher levels, etc., Mullen says.

- **Create a disaster kit:** A basic emergency supply kit should include three gallons of water per person; a three-day supply of food; a battery-powered radio; flashlights and extra batteries; a first aid kit, whistle, moist towelettes, garbage bags, and dust mask; a wrench and pliers to turn off utilities; local maps, pet food, and water for pets; prescription medications, glasses, local maps, and can opener, etc. Pharmacists could find additional details and suggestions at the federal government's disaster preparedness web site: www.ready.gov. ■

Pharmacy manager's murder was disaster

Friend & colleague was tragically killed at work

Pharmacists and staff at Florida hospitals are well prepared for the disasters wrought by

100-mile-per-hour winds, rain, and hurricanes. But pharmacists and hospital staff at Shands Jacksonville Medical Center in Jacksonville, FL, could never have prepared themselves emotionally for the tragedy of the on-site murder of a friend and co-worker.

Sharron McCants, age 37 and pregnant with her third child, was shot and killed by Brenda Coney in November, 2006, according to newspaper accounts of Coney's first-degree murder trial. Coney was convicted in September, 2008.¹

Coney had been a client of the hospital's stand-alone, ambulatory pharmacy, located near the hospital's emergency room. Trial testimony portrayed the killer as a paranoid schizophrenic who had not been taking her medication.¹

But the "why" details were the very least of the hospital management's concerns on the morning pharmacy manager McCants died.

The murder was an incredibly traumatic event for McCants' many friends and co-workers in the pharmacy, and crisis counseling support was needed. Also, the pharmacy was closed, and a plan had to be developed about when and how to re-open it. New safety measures needed to be taken, as well.

Shands Jacksonville handled the crisis in such a competent and heroic way that the American Society of Health-System Pharmacists (ASHP) presented the staff with the Executive Vice President's Award for Courageous Service in July, 2008.

"We are a level 1 trauma center hospital, and we deal with disasters on a regular basis at the hospital," says **Thanh Hogan**, PharmD, director of pharmacy at Shands Jacksonville.

"We go through regular training for disasters, and after 9/11, we were a primary hospital for first responders," Hogan says. "When this occurred, the hospital leadership immediately responded and responded in a way that I don't know of any other hos-

Summary points

- Shands Jacksonville received ASHP's Executive Vice President's Award for Courageous Service in July, 2008, for its handling of a crisis at the hospital's ambulatory pharmacy.
- Pharmacy team decided to open doors next day, despite the tragedy's emotional toll.
- Hospital's leadership supported pharmacy with meals, extra staff, and triage process.

pital that could pull things together so quickly."

Within minutes of the shooting, Hogan was at the site, along with other administrators. Within an hour, hospital support staff, including a chaplain, were there, as well, Hogan says.

"We had security blocking everything off and securing the scene," she adds. "We had the facilities crew roping things off."

The hospital's preparation and practice dealing with natural disasters had helped when this tragedy occurred, Hogan notes.

"We've learned to deal with crises, although this was one that no one had ever expected," she says.

The entire hospital pulled together to help the pharmacy staff deal with the emotional and physical aftermath of the tragedy.

"I just remember all of us coming together right after the event occurred," says **Karen Malcolm**, PharmD, manager of the ambulatory pharmacy.

"When the shooting occurred, it occurred in the morning, so the pharmacy was closed for the day," Malcolm says. "We went to a common meeting place in a big auditorium, and we received updates from the leadership."

Each employee in the pharmacy, including Malcolm, was contacted by a counselor.

"We had counselors holding people's hands, letting them cry on their shoulders, squeezing their hands, and talking with them," Hogan says.

In another room, employees gathered as a group to talk about what happened, with a counselor present, she says.

In yet a third room, Hogan and a vice president discussed the pharmacy operations and what would need to be done that day and in the immediate future. **(Here's how the hospital handled the tragedy's aftermath, p. 103.)**

The pharmacy serves underprivileged patients, filling on average 1,500-1,800 prescriptions in an eight-hour day, Hogan notes.

"We fill more prescriptions there than your average 24-hour pharmacy in any one given day," Hogan says. "We have inside the pharmacy 6-8 pharmacists."

While many businesses suffering such a tragic loss might close for the rest of the week, this action could have a severe impact on the pharmacy's many clients, who depended on it for medication to treat chronic diseases.

Malcolm and other pharmacy staff met shortly after the tragedy to discuss what the pharmacy's operations would look like. They

asked and tried to answer these questions:

- What kind of security will we need to help us?
- How many patients could we serve?
- Who would show up the next day?
- Will you be here tomorrow or not?

“We needed to tell the leadership what realistically we could pull off and let Thanh know from the perspective of all pharmacists what additional resources we would need from the department of pharmacy,” Malcolm says.

The pharmacy team decided they would return to work the next day because their clients needed them, she says.

“It was so monumental what the staff did, and Karen was right in the middle of it, and so humble about it,” Hogan recalls.

“In the midst of all the tears and fears from what happened, the employees were so dedicated to the patients that they kept asking what they needed to do to take care of all the other patients, those who truly needed their services.”

Fighting through their tears, they came up with a plan for how to open the pharmacy doors the next day, she adds.

The biggest lesson the hospital leadership learned from this experience was that it was a team effort to get the work done, Hogan says.

“The team was grieving together while working together,” Hogan says. “Every staff member committed to walking through the door and doing what they had to do, and they did it — but they needed support from each other.”

Reference

1. Coney guilty of killing pharmacy manager. News4 Jax.com. Sept. 18, 2008. Available at: www.news4jax.com. ■

Special Report: Planning for Disasters

How the Florida hospital handled aftermath of tragic shooting in pharmacy

Entire hospital pulled together to help

Hospital staff deal with other people’s tragedies every day, but when something horrific hap-

pens in the hospital, it pushes the site into disaster mode.

This is what happened two years ago when a hospital pharmacy manager at Shands Jacksonville in Jacksonville, FL, was shot and killed while at work. The killer was a pharmacy client.

Pharmacists who had worked with the victim for years and were her friends suddenly found themselves in the bewildering role of grieving victims, who still had hundreds of clients to consider, even as they were overwhelmed by their own feelings.

Here’s how the hospital leadership and the pharmacy staff handled the crisis:

• Provide leadership from the start.

As soon as a crisis, tragedy, or disaster happens, hospital leaders need to have a prompt response. This lesson was driven home to administrators at Shands Jacksonville when one of their employees was murdered at the hospital pharmacy.

“We learn from every disaster response, and whether it’s a mock disaster or real disaster, we have found as an organization that we learn from each one,” says **Thanh Hogan**, PharmD, director of pharmacy at Shands Jacksonville.

Hospital administrators immediately met with staff at the pharmacy and had the hospital’s employee assistance program (EAP) make it to the site to provide support. A hospital chaplain and certified grief counselors also met with employees within an hour of the shooting, Hogan says.

“Immediately, the employees were sequestered together and were in a group together, and the ones who needed independent support were one on one with the counselors,” she adds.

• Find out what the staff need to continue their work.

The hospital might have considered shutting the pharmacy for a week, but the pharmacy team said, “No,” Hogan says.

“We couldn’t get to the point of thinking about it because the team was so compassionate about what they needed to do, and they were so committed to their patient care mission that they came to me first, saying they needed to have the pharmacy open tomorrow,” Hogan explains.

Hospital administrators briefly considered switching the pharmacy staff, to allow the traumatized pharmacists to work in a different area for a while, but the pharmacists also rejected that idea, Hogan notes.

“We thought about it, but before we could think any further, the team said, ‘We need to be open for our patients,’” Hogan says. “They felt strongly that

they needed to take care of these patients, some of whom they had treated for years.”

One pharmacist even said, “Mrs. X is coming tomorrow to get her insulin, and we have to be here to give her the insulin,” she recalls.

So hospital leaders tried to find out how they could help.

“We asked the pharmacy team what it would take for them to walk through the doors tomorrow to do what they needed to do to get prescriptions to patients,” Hogan says.

“They said, ‘We could walk through the door if we had someone out front who would triage for us the patients who truly needed to come in and the patients who could wait a day or two,’” Hogan adds. “There was no way they could handle 1,500 patients the next day.”

So the hospital leadership stepped up and had nurses, case managers, and even the vice president of nursing at the pharmacy on the day after the tragedy, Hogan says.

“They were doing triage in shifts with the rest of us,” she adds. “It was an all-out organization-wide effort.”

Also, there was hospital security at the front door, and the facilities crew put in an extra telephone to improve the pharmacy’s communication, Hogan says.

“We had the information technologies (IT) staff put up a portable computer so we could look up things in the make-shift triage area,” Hogan adds.

Many of the hospital’s inpatient pharmacists and pharmacy technicians would finish their shifts and then walk over to the ambulatory pharmacy to help out, Hogan notes.

“Some pharmacy employees have different days off during the week, so they’d come in and work in the ambulatory pharmacy at that time,” she adds. “They worked in all areas of the outpatient pharmacy, wherever they were needed.”

The inpatient pharmacy staff helped fill prescriptions and checked for drug interactions, as well as for duplications and overdoses, Hogan says.

“We couldn’t work at 100% capacity the next day, but we were all there, and we were all together,” Hogan adds.

- **The small gestures matter a great deal.**

When the pharmacy’s staff decided to reopen the ambulatory pharmacy the day after their colleague was killed, the senior leadership provided them with the support they needed to make this happen.

Senior leadership saw to it that the pharmacy

staff had breakfast and lunch for a month, says **Karen Malcolm**, PharmD, manager of ambulatory pharmacy at Shands Jacksonville.

Hospital laboratory and radiology staff provided the lunch, continuing it longer than planned once they saw how important it was to the pharmacy staff’s morale, Hogan notes.

While this seems like a small detail, it made a huge difference to the pharmacists, Malcolm says.

This simple act made it possible for the pharmacy team to stay together in the pharmacy. It relieved them of the emotional burden of having to interact with the rest of the hospital staff, who — while well-meaning — would make comments or ask questions that the pharmacists weren’t ready to answer.

“We didn’t have to go out in the hall and have people say, ‘I can’t believe that happened,’” Malcolm explains.

“We were like in a cocoon almost,” Malcolm says.

The hospital’s support helped keep the pharmacy staff intact.

“We did not have any employees quit directly after this,” Hogan says. ■

New treatment for cancer patients and constipation

New class of drugs featured

A new class of drugs, called peripheral-acting mu opioid receptor antagonists, offers cancer patients and other advanced illness patients relief from some of the debilitating side effects of opioid use.¹

The first of this class to be approved is methylnaltrexone, which helps advanced illness patients who suffer from opioid-induced constipation (OIC).

Methylnaltrexone blocks the peripheral effects of opiates, especially those in the gastrointestinal tract, by selectively blocking peripheral mu opioid receptors.¹ However, because it does not cross the blood brain barrier, it does not reverse the analgesia caused by opioids.

“It decreases the peripheral side effect of opiates without impacting the pain relief,” says **Jonathan Moss**, MD, PhD, a professor and vice chair for research in the department of anesthesia and critical care at the University of Chicago in Chicago, IL.

Summary points

- New class of drug provides patients with relief from opioid-induced constipation.
- Methylnaltrexone decreases the peripheral side effect of opiates without impacting the pain relief.
- Alvimopan, an oral drug, has been proven useful in facilitating gut recovery in the perioperative period.

“It’s been an incredible benefit for these patients, who may often have to choose between opiates for relief of their cancer pain and having a bowel movement,” Moss says.

“About half will choose to forego pain relief so they can have the bowel movement.”

Methylnaltrexone, given subcutaneously, is intended for use in cancer patients and other patients with advanced illness receiving palliative care when response to conventional laxatives has not been sufficient.

“Many of these patients only move their bowels once or twice a week despite all drugs, and they get very distended,” Moss says. “It’s not really a casual problem.”

There has been a great deal of interest in the drug since it was approved by the FDA in April, 2008, as Relistor for the treatment of OIC™ in advanced illness patients receiving palliative care when response to laxative therapy has not been sufficient, he adds.

Many physicians are interested to see if its use can be extended to treat some of the other effects of opiates, Moss says.

Other peripheral side effects of opioids that have been studied experimentally include pruritis, nausea and vomiting, gastric emptying, and urinary retention, he adds.

“We tried to use the drug to distinguish between central and peripheral effects of opiates,” he says. “We have some data showing it also may have use in intensive care units in terms of facilitating feeding of patients and gastric emptying, but these are not approved, indicated uses.”

Also there are clinical trials underway to extend the drug’s use to OIC in chronic pain, but this research is not yet complete, Moss says.

Another new drug in the same new class, alvimopan, to facilitate gut function after bowel surgery, was recently approved by the FDA, Moss says.

“Alvimopan, an oral drug, has been proven useful in facilitating gut recovery in the perioperative period, but to date has not been successful

in trials for chronic pain or cancer pain,” he says. “People have tried chewing gum and a lot of things, but aside from alvimopan there are no other approved therapies to facilitate gut function after surgery.”

Unlike methylnaltrexone, alvimopan is actually contraindicated at its current dose in patients taking chronic opiates and requires enrollment in a Rise Evaluation and Mitigation Strategy (REMS) program.

How this little drug got to market

Methylnaltrexone’s journey to reach market is somewhat unusual since the first investigators working on the product had personal investments of time and interest in finding a successful treatment for cancer patients to use.

Methylnaltrexone is an old drug developed decades ago. In 1978, **Leon Goldberg**, a University of Chicago chair on the Committee on Clinical Pharmacology, was asked by a colleague with metastatic prostate cancer for help in coping with morphine-induced constipation. The man had declined morphine because of the side effect of constipation.²

Goldberg studied methylnaltrexone as a possible peripheral antagonist, but died before he could complete his investigations.²

“Dr. Goldberg was a close, personal friend of mine, and I knew him before I came here,” Moss says.

Other researchers at the University of Chicago decided to continue the research.

“We thought the idea was a very good one and elected to try to finish his work,” Moss says. “We thought we could complete his mission of developing the drug successfully within a few years, but it took far longer.”

The investigators worked on their own, taking the drug from conception to animal studies to human studies before licensing the drug to Progenics Pharmaceuticals Inc., a biopharmaceutical company located in Tarrytown, NY, says Moss, who has continued to use the drug in clinical and cellular research.

Progenics chose to develop the drug initially in patients with the greatest need, those with advanced illness receiving palliative care.

“Palliative care physicians are very protective of their patients, and doing trials that would pass ethical review required thoughtful deliberation,” he explains. “It is very difficult to develop a new drug in the palliative care setting.”

During the past decade, as the drug was being studied, it was made available to patients on a compassionate use basis, Moss says.

"The drug eases a tremendous burden," Moss says. "Within 15-20 minutes, patients usually start to move their bowels and sometimes pass three to four pounds of stool if they have not laxated in several days."

"Methylnaltrexone helps advanced illness patients to receive adequate analgesia and maintain GI function," Moss adds.

"My personal recommendation is that patients should start out with the recommended dose," he says. "Although patients reported some discomfort with the side effects, generally related to the return of bowel function, they almost all chose to continue Relistor."

Progenics partnered in producing methylnaltrexone with Wyeth Pharmaceuticals in December 2005.

Initial trials involve IV use, but investigators found that subcutaneous administration was very effective, Moss says.

"One thing we like about subcutaneous usage is the onset is reported to be 30 minutes in 30% of patients," Moss says. "Once injected, the drug works quickly and reliably, so nurses can time when patients will need help with defecation."

Also, there is an oral methylnaltrexone product currently in development, Moss adds.

References

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Research finds higher risk of CV-related deaths among patients using ipratropium

Results were surprising to researchers

When investigators studied a cohort of Veterans Affairs (VA) patients, they found a surprising link between ipratropium use and cardiovascular-related deaths.

"We were interested in understanding the safety of respiratory medications in patients with

Summary points

- Patients using ipratropium had higher risk of cardiovascular-related deaths than other cohorts, study shows.
- Ipratropium is used very frequently in newly diagnosed COPD patients.
- Pharmacists should be aware of safety questions involving ipitropium.

chronic obstructive pulmonary disease (COPD)," says **Todd A. Lee**, PharmD, PhD, a research assistant professor at Northwestern University in Chicago, OH. Lee also is a senior investi-

gator at Hines Veteran Affairs Hospital in Hines, IL.

"There was some evidence there might be some risks for medications for asthma, especially long-acting broncodilators, and we wondered if the same risks were present in patients with COPD," Lee says. "So we evaluated safety, mortality, cardiovascular mortality, and the medications they were using."

Lee and co-investigators found that patients who used ipratropium had a higher risk of cardiovascular-related deaths and all-cause mortality when compared with patients who used short-acting bronchodilators or who didn't use respiratory medication.

There were 2,405 patients who had respiratory deaths and 3,159 patients who had cardiovascular deaths.¹

"We studied patients from 1999 through 2003, and followed them for at least one year, although most were followed for 2.5 years on average," Lee says. "This is national VA data — we were able to observe all patients in the VA between 1999 and 2003 who had a new diagnosis of COPD."

Ipratropium is used very frequently in newly diagnosed COPD patients, and at the VA it's used in almost half of this population, Lee notes.

"It's one of the first medications focused on COPD," he explains. "The others traditionally have been for treating asthma with a role in treating COPD, so there haven't been a lot of alternatives for patients with COPD."

Clinicians have found that ipratropium has helped COPD patients improve their quality of life and makes them feel better, Lee adds.

"But we may have missed some risks associated with the medication," he says.

Ipratropium also is available in a combination

medication of albuterol and ipratropium, but the study analysis showed that the risk revolved around ipratropium, Lee adds.

Lee and co-investigators often are asked how this research relates to the new drug tiotropium, which is in the same class of drugs as ipratropium.

"We weren't able to study tiotropium in our analysis, so we can't answer this question," Lee says. "But we think it's important to ask the same questions of tiotropium, which is made by the same manufacturer and is a longer-acting version of the medication.

The study also found an increased risk for respiratory death in patients who took theophylline.¹

But this association could have been due to the theophylline patients having more severe disease, Lee notes.

"We were worried those patients had more severe COPD and were more likely to die of respiratory disease," Lee says. "That's one of the problems with using an observational dataset."

Since the study used VA patients, its patient population lacked some diversity, too.

Most of the patients were elderly men, Lee says.

"It's important to see if these findings are consistent across different populations, especially with respect to women," Lee explains. "Less than 2% of the people in the study were women."

The VA's dataset is very good, but it will be interesting to study other datasets for to see if the findings are consistent, Lee says.

"Unfortunately we don't have a lot of good information about medication use on patients ages 65 and older outside of the VA system on a large population level, and that's where COPD primarily exists," Lee says. "The Medicare dataset will be an incredibly important dataset to address these issues when the medication use data become available."

Although the study's findings are suggestive, it's too early to draw a definitive conclusion around the safety of ipitropium, Lee notes.

"We need more evidence," he explains. "Our study begins to ask important questions about

the safety of ipitropium, and if we continue to see replication of the results in other settings, then that would allow us to draw a conclusion about taking the medication off formulary, but now it's too early to take those kinds of steps."

So the take-home message for hospital pharmacists is to be aware of the safety questions involving ipitropium, Lee says.

"There might be risks associated with the medication, and pharmacists need to help patients and providers understand that there are treatment alternatives to ipitropium," he says. "So it comes down to a risk-benefit trade-off because the drug will reduce symptoms and it may improve the quality of life."

The potential cardiovascular risks should be weighed against this, Lee adds.

Reference

1. Lee TA, Pickard AS, Au DH, et al. Risk for death associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med* 2008;149:380-390. ■

NEWS BRIEFS

Reports of deaths related to drug-device interaction

According to the "FDA Drug Safety Newsletter Volume 1, Number 4

Summer 2008," health care professionals need to be alert to a dangerous drug-device interaction of icodextrin (Extraneal®) and point-of-care glucose monitoring. The report says the following:

FDA continues to receive reports of adverse events, including fatalities, related to a drug-device interaction associated with the use of icodextrin, a

COMING IN FUTURE MONTHS

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peritoneal dialysis solution, and certain point-of-care glucose monitoring devices that do not use a glucose-specific test strip. Icodextrin is broken down into maltose in vivo. Some test strips used with portable glucose meters cannot differentiate between maltose, glucose, and other sugars as they use methods that are not glucose-specific. The test strips associated with this drug-device interaction use glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) as reagents. Examples of meters currently using these types of test strips include the Accu-Chek® (manufactured by Roche) and FreeStyle Navigator® (manufactured by Abbott) models. Health care providers and patients should refer to test strip package inserts or to consult the glucose monitoring device and test strip manufacturer(s) to confirm the glucose methodology in any system that is to be used for monitoring patients receiving icodextrin. A list of toll-free numbers for glucose monitor and test strip manufacturers is available at the Baxter Renal Clinical Help Line (1-888-RENAL-HELP).

Due to the presence of maltose in the blood of a patient receiving icodextrin therapy, the use of test strips that are not glucose-specific provides falsely elevated glucose readings. Falsely elevated blood glucose readings may lead to inappropriate insulin administration, which has caused hypoglycemia,

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coma, and death. Additionally, cases of true hypoglycemia can go untreated if masked by falsely elevated glucose readings.

As indicated in the Warning section of icodextrin's label, blood glucose measurement in patients receiving icodextrin must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose released from icodextrin. Glucose-specific methods (i.e., methods that are not affected by this interaction) include those that use glucose oxidase, glucose hexokinase, glucose dehydrogenase nicotinic adenine dinucleotide (GDH-NAD), or flavin adenine dinucleotide glucose dehydrogenase (FAD-GDH) based reagents.

This drug-device interaction was identified prior to approval of icodextrin and it is described in product labeling. Several safety measures, including patient/health care professional education, have been undertaken by the manufacturer. Because FDA continues to receive reports of this adverse event, we are highlighting this drug-device interaction in additional FDA communications to the public. For a complete discussion on this drug-device interaction, including detailed case reports, see the recent FDA communiqué in the Institute for Safe Medication Practices' publication Medication Safety Alert. ■

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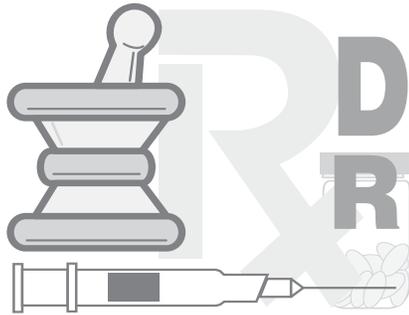
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