out a compelling indication. For patients with hypertension and a compelling indication, one or more of the following drug types should be used: ACE inhibitor, angiotensin-receptor blocker, β-blocker, calcium-channel blocker, and diuretic.

The term “prehypertension” is used to describe the condition between normal blood pressure and hypertension. Drug treatment of patients with prehypertension is not recommended unless they have a compelling indication. The maximum values for normal blood pressure are a systolic pressure of 119 mm Hg and a diastolic pressure of 79 mm Hg.

The more comprehensive version of JNC 7 will be published separately this year.


—CAT

Compounding sterile preparations raises informed-consent issues

Patients should be informed about the risks involved in using formulations that are compounded using non-sterile ingredients, which are at high risk for contamination with infectious microorganisms, said Robert E. Rapp, professor of pharmacy and surgery at the University of Kentucky at Lexington.

When a sterile product manufactured by a drug company is unavailable and a prescriber is requesting that a hospital’s pharmacy compound a sterile preparation from nonsterile ingredients or obtain a compounded sterile preparation from an outside pharmacy, a patient should be apprised that the formulation is not approved by FDA “and therefore the risk is greater” to the patient, said Rapp, who is chair of his university’s human investigations committee.

In addition to counseling a patient about the medication, he said, a health system’s pharmacy should give the patient an informed-consent form that outlines the risks and benefits of using the particular compounded sterile preparation.

A pharmacist must strictly follow guidelines issued by the United States Pharmacopeia when compounding sterile preparations, Rapp said, and ensure that the appropriate ingredients are used and that the formulation is the proper concentration, correctly labeled, and free from contaminants.

“There have been so many instances where pharmacists have [compounded sterile preparations] and then had [the formulations] recalled. If we can’t do it right, we shouldn’t be doing it,” he said.

Carmen A. Catizone, executive director for the National Association of Boards of Pharmacy, said that all state boards of pharmacy have regulations requiring pharmacists to notify prescribers when a commercial drug product is unavailable and a compounded sterile preparation must therefore be substituted.

But few states have regulations requiring pharmacists to inform a patient when a compounded sterile formulation is being substituted for a manufactured product, he said.

Catizone advised that “anytime the prescription is modified or changed and is different than a patient believes, contacting both the prescriber and the patient is good, sound advice.”

The Alaska Board of Pharmacy requires “both the patient and the prescribing practitioner [to] authorize the use of a compounded” preparation when it is being substituted for a manufactured product.

Missouri Board of Pharmacy Executive Director Kevin Kinkade said that his state has “left it up to the professional decision process about what information goes to the patient.”
The certificate of origin used by one pharmacy O’Day had considered stated that the country of origin of its bovine tissue was the United States, but the certificate also stated that the animals obtained were from U.S. or foreign government facilities, he said.

The compounding pharmacy also did not screen every batch of raw material for viral contamination, O’Day added, in conflict with the ASHP guidelines.

He and his hospital ultimately decided not to obtain hyaluronidase from a compounding pharmacy after an FDA agent strongly recommended against using a compounder to supply the formulation.

O’Day had also consulted with surgeons who advised him that alternative surgical techniques existed that did not require the use of hyaluronidase.

O’Day said he is concerned about the increasing number of drug products that are unavailable from manufacturers and the lack of control and oversight of compounding pharmacies.

When a manufactured product is unavailable and a prescriber wants to use a compounded sterile preparation from an outside pharmacy, health-system pharmacists must assume the additional role of scrutinizing the outsourced pharmacy, he added.

“Compounding is not my expertise,” he said. “Requiring pharmacists to fulfill the role as FDA-inspector of products is inappropriate and can lead to patient harm.”

—Donna Young

But, he advised, when a product manufactured by a drug company is unavailable, “to avoid confusion, a pharmacist should explain to the patient that a compounded preparation has been substituted.”

Gay Dodson, executive director of the Texas State Board of Pharmacy, said her state adopted a regulation last year requiring pharmacies that outsource prescription dispensing, including compounded formulations, to notify patients regardless if a substitution is made. The provision, however, applies only to outpatient and community pharmacy settings, not to patients in hospitals or nursing homes.

Pharmacist and attorney Jesse C. Vivian, a professor of pharmacy practice for Wayne State University College of Pharmacy in Detroit, Michigan, said that, from an ethical standpoint, he would inform a patient when a compounded sterile formulation has been prescribed.

But, he added, patient consent forms should be considered on a case-by-case basis.

Pharmacy, Vivian noted, has ranked high among trusted professions. Compounding is a historical function of the profession and, with the increasing number of drug shortages, pharmacists are more frequently compounding preparations.

But, he added, pharmacy schools and technician training programs do not provide practitioners with adequate compounding skills.

Jane J. McCaffrey, risk manager for Oconee Memorial Hospital in Seneca, South Carolina, and president of the American Society for Healthcare Risk Management, said that when a high-risk procedure is involved, including the use of a compounded sterile preparation, most organizations make their own determinations about what information to provide to patients.

But, she counseled, when the use of a compounded sterile formulation is inherently risky, a patient should be involved in making decisions about his or her care.

Health systems should weigh the risks of using compounded preparations, McCaffrey said.

If a risk is significant or unknown, or the use of the compounded formulation is considered experimental with no supporting literature about patient outcomes, McCaffrey would advise against using the preparation.

If a health system does not require patients sign a consent form before receipt of a high-risk compounded sterile preparation, she said, and something goes wrong, the organization should be prepared to prove that it adequately explained the risks to patients.

A pharmacist should verify that a patient has been informed by the prescriber about the use of a compounded sterile preparation before dispensing the formulation, McCaffrey said.

While pharmacists have the best knowledge base about drugs and should counsel patients about their medications, she said, prescribers should be responsible for discussing a patient’s care, including explaining medications, directly with a patient and should not defer that responsibility to a pharmacist.

—Donna Young

First drug-eluting coronary stent approved

The sirolimus-eluting coronary stent (Cypher, Cordis), approved in April by FDA, is the first device that, once inserted into a coronary artery during angioplasty with a balloon-tipped catheter, releases a drug to decrease the likelihood of vessel closure in the months afterward.

Sirolimus, according to the stent manufacturer, is known to inhibit the activation of T lymphocytes and proliferation of smooth-muscle and endothelial cells in response to certain signals, although the mechanism by which the drug prevented restenosis in clinical studies has not been elucidated.

The oral formulation of the drug (Rapamune, Wyeth) is indicated to prevent organ rejection in patients who have received a renal transplant.

Restenosis develops in about 15–30% of the 800,000 patients who undergo an—Donna Young

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