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Pharmaceutical Care Across the Continuum

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OTC is big savings for pharmacies, but consumer knowledge is lacking

Pharmacists concerned about self-medicating, lack of consumer education

The potential switch from prescription to over-the-counter (OTC) status of several popular drugs may be a boon for hospital pharmacy budgets, but it also brings its share of concerns.

"The big concern is that when anything goes over the counter, people can buy it anywhere, at a gas station or at a retail outlet, with no pharmacist around. You can see the real danger that we have," says **Nicholas Popovich**, PhD, professor of pharmacy administration at the University of Illinois-Chicago College of Pharmacy.

Consumers are also not as careful about taking OTC medications as they are about prescription drugs, he says. Consumers, having heard about adverse drug reactions and deaths from inappropriately prescribed prescription medications, sometimes even take less of the medication than prescribed. Surveys, however, have shown that consumers are more casual about the risks of OTC drugs. **(For more information on one survey, see p. 83.)**

Several OTC possibilities

Several blockbuster drugs are currently working toward OTC status, including:

• **Loratadine (Claritin).** Schering-Plough filed a supplemental new drug application with the Food and Drug Administration (FDA) to switch all of loratadine's formulations to OTC status. The company expects the agency to act on its application this month. In April, an FDA advisory committee found that loratadine's data were sufficient to support a prescription to OTC switch for chronic idiopathic urticaria, but not for general urticaria.

Schering-Plough didn't have many options. Blue Cross of California petitioned for three second-generation antihistamines (loratadine, fexofenadine [Allegra] and cetirizine [Zyrtec]) to be moved from prescription to OTC status. Then Johnson & Johnson and Wyeth told the FDA that as soon as loratadine's patent expires in December, they want to sell OTC versions of the drug. Schering-Plough isn't having much success

fighting the introduction of a generic loratadine. In August, a U.S. District Court Judge found that certain claims of a patent protecting against generic versions and expiring in 2004 were not valid. Schering-Plough said it would appeal.

• **Omeprazole (Prilosec).** Procter & Gamble (P&G) received FDA approval and expects to begin commercial non-prescription sales of the proton pump inhibitor in the first half of next year. Before the drug can be approved in OTC form, however, the FDA said P&G must conduct a study showing that consumers understand the drug's labeling, according to a company spokesman. P&G says Prilosec will be sold OTC in 14-dose packages.

• **Lovastatin (Mevacor).** In 2000, an FDA advisory committee recommended against switching the cholesterol-lowering drugs lovastatin and pravastatin (Pravachol) to OTC status, because of concerns that consumers would not understand the labels. The companies won't stop trying, though. Representatives from Johnson & Johnson and Merck say recent talks with the FDA about the possibility of switching lovastatin to OTC status have been "positive."

Reimbursement will change significantly

Once prescription drugs go to OTC status, few insurance plans will pay for them. So the switch to OTC for drugs commonly prescribed and stocked in hospitals will have a major impact on the pharmacy budget. The cost of the OTC version is usually a fraction of the prescription price. For example, a month's supply for loratadine currently costs about $100. A month's supply of the OTC version, on the other hand, might cost one-tenth of that, according to some financial analysts.

Community pharmacists, however, may find they are spending the same amount to stock the drug on the shelves as they did to keep it behind the counter.

"What you lose on the Rx side, you usually pick up on the OTC side," says **Stephen J. Clement**, RPh, chairman of the board of the Illinois Pharmacists Association in Springfield and owner of the Copper Bend Pharmacy in Belleville.

Anticipating that the end of its loratadine patent is inevitable, Schering-Plough encourages health care providers to switch to its second-generation, non-sedating antihistamine, desloratadine (Clarinex). Many, however, don't see much difference between the two. In fact, executives of several insurers have told *The Wall Street Journal* that they may not reimburse patients seeking desloratadine prescriptions once loratadine goes OTC.

WellPoint Health Networks in Thousand Oaks, CA, has already implemented new guidelines for prescriptions of cetirizine, fexofenadine, and desloratadine to encourage patients to use OTC loratadine once it's available. WellPoint has placed the prescription drugs in the highest co-pay tier and will require special physician approval to obtain them. Health insurers Humana, Sierra Health Networks, and UnitedHealth Group say they will follow WellPoint's lead, according to Reuters Business.

The cost benefits don't detract from worries about consumers medicating themselves.

"I see a problem when patients self-diagnose and try an OTC that may not be correct for them,"

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Editorial Questions

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Clement says. "If it doesn't work, then they try something else that may or may not work, ultimately prolonging their proper treatment and subsequent healing."

Popovich is worried that people may treat themselves for heartburn with OTC omeprazole when they should be diagnosed by a doctor. "You don't want anything more serious happening and have them treating themselves for the wrong reason."

Advertisements promoting the drugs contribute to the problem, Popovich adds. "People help themselves because the advertisement gives them the impression that they can take care of it themselves. They can, but they have to do it intelligently."

When consumers go to the pharmacy, therefore, they need to read the label carefully and ask questions. "They may be taking other drugs that might conflict with it and cause a drug interaction," he adds.

By checking with a pharmacist about medication usage, consumers might find out, for example, that a first-generation drug might work better — and be more cost-effective — than loratadine. "We are hoping that pharmacists will use their professional expertise to help people find a less costly alternative," Popovich says.

Overall, he says, pharmacists should try to help consumers make the right choices about OTC drugs and help them decide whether they really need the medications or whether they should see their doctor first.

"It's an opportunity for pharmacists to play a bigger role and interact more with their patients and their doctors," Clement says. ■

Survey shows concerns about use of OTC drugs

Consumers often mix or take too much

Many pharmacists are concerned about the way consumers medicate themselves with over-the-counter (OTC) drugs, and a recent survey backs them up.

Of the more than 1,000 American adults surveyed for "Attitudes and Beliefs About Over-the-Counter Medicines: A Dose of Reality," one-third say they take more than the recommended dose of a non-prescription medicine, believing that will increase its effectiveness. A third also say they are likely to combine nonprescription medicines when they have multiple symptoms, such as a headache and a sore throat.

The issues regarding self-medication with OTC drugs are getting renewed attention with the possibility that blockbusters such as loratadine (Claritin) and omeprazole (Prilosec) will soon join the OTC ranks. **(For more information on drugs going OTC, see cover story.)** The National Council on Patient Information and Education in Bethesda, MD, wondered about the extent to which the facts contained on an OTC drug's label are now being incorporated into the American public's decisions about self-care. It commissioned a comprehensive survey to track the opinions influencing self-medicating behaviors.

Conducted by Harris Interactive, the survey consisted of two complementary polls: one of 1,011 adult Americans ages 18 and over, conducted in October and November 2001, and the other involving 451 pharmacists, nurses, and general practice physicians surveyed in November and December 2001. (One hundred fifty-one respondents were pharmacists.) By comparing attitudes and beliefs of the general public with health practitioners, the survey identified areas where education about OTC use is most needed.

Here is a summary:

1. The majority of Americans take non-prescription medicines routinely for a variety of common ailments.

• Three in five Americans (59%) report having taken at least one OTC drug product in the past six months. Slightly more Americans have taken an OTC medicine during the last six months (54%) than a prescription drug.

• Americans take OTC medicines for a wide variety of ailments, most commonly for pain (78%); cough, cold, flu, or sore throat (52%); allergy or sinus problems (45%); heartburn, indigestion, and other stomach problems (37%); constipation, diarrhea, and gas (21%); minor infections (12%); and skin problems (10%).

2. Despite widespread use of non-prescription medicines, many consumers need more information about when and how to take these products.

• Health professionals are concerned about a lack of understanding about active ingredients in OTC medicines, especially because different OTC products may contain the same active ingredient. Of the 79% of physicians, nurses, and pharmacists in the poll who say the potential for inappropriate

use of OTC remedies is a concern, seven in 10 (69%) cite not understanding active ingredients as the biggest problem.

• This is confirmed by the consumer poll, which found that only 34% of the public could identify the active ingredient in their brand of pain reliever.

• In addition, only 11% correctly say that non-prescription medicines formulated for babies are usually more concentrated than formulations for older children.

3. At the same time, consumers tend to overlook important label information when selecting and using OTC products.

• Although the vast majority of Americans (95%) read some portion of the OTC drug label, the survey finds that many do so selectively when buying or using a non-prescription medicine. When asked what information they look for when buying an OTC drug for the first time, two in five (41%) cite usage information (such as directions for use and information on dosage level and symptoms), one in three (34%) mention the active ingredient, and one in five (21%) say warnings information.

• Similarly, half (51%) of those surveyed say they seek out usage information when they plan to take an OTC product for the first time. However, only 20% look for the active ingredient.

4. Because some Americans have an incomplete knowledge about OTC medicines, they may take too much of a single product or mix OTC drugs inappropriately.

• According to the consumer poll, a third of Americans say they take more than the recommended dose of a non-prescription medicine, believing that it will increase the effectiveness of the product. Of these consumers, two-thirds (69%) say they take more than the recommended amount at a single time; three-fifths (63%) say they take the next dose sooner than directed; and two-fifths (44%) say they take more than the recommended number of doses in a day.

• At the same time, one-third of Americans (36%) say they are likely to combine non-prescription medicines when they have multiple symptoms, like a headache and a sore throat. This practice can increase the risk that consumers take more than one OTC product at a time that contains the same active ingredient.

• Among the 79% of physicians, nurses, and pharmacists who said they were concerned about the problem of taking non-prescription medicines incorrectly, practitioners cited these factors: combining OTC and prescription medicines (51%); the chronic use of an OTC medicine (44%); using an OTC drug for a prescription indication (32%); and taking more than one OTC product at a time that has the same active ingredient (27%).

5. Besides new and easy-to-read label information, the involvement of health practitioners will increase the public's ability to understand the risks and benefits of OTC remedies.

• When discussing the use of non-prescription medicines, the survey finds that the majority of practitioners (65%) spend more than a minute offering specific counseling. Most of this time is spent on: how to take a product (62%); what OTC drug to use (56%); how well the product works (54%); drug interactions (50%); taking more than one OTC drug at a time (49%); cautions prior to or following surgery (43%); and taking more than the recommended dose of an OTC medicine (42%). ■

New JCAHO process designed for focus

Surveys to focus more on actual care delivery

The Joint Commission on Accreditation of Healthcare Organizations says its health care accreditation process for 2004 will sharpen the national focus on care systems that are critical to the safety and quality of patient care.

The improved process is called "Shared Visions — New Pathways." "Shared Visions" refers to the common vision of health care organizations, purchasers of care, health care consumers, and the Joint Commission and how the accreditation process can sharpen that focus, says the Joint Commission. "New Pathways" references a new set of approaches or "pathways" to the accreditation process that will support fulfillment of the shared visions.

"'Shared Visions — New Pathways' shifts the focus from survey preparation to focusing on operations and internal systems that directly impact the quality and safety of care," says **Dennis S. O'Leary**, MD, Joint Commission president.

"The net effect of these changes is to substantially increase the relevancy of the accreditation process to health care organizations and to direct even greater attention to improving patient safety

and health care quality," he told reporters in a teleconference.

According to the Joint Commission, the new pathways include:

• A required mid-cycle self-assessment during which the health care organization will evaluate its own compliance with the applicable standards and develop a plan of correction for identified areas of non-compliance. Validation of corrections and other randomly selected self-assessment findings will occur during the on-site survey at the end of the triennial period.

Because the self-assessment process will occur at the approximate midpoint of the accreditation cycle, O'Leary told reporters, it should make the accreditation process itself more continuous, reduce the ramp-up efforts many organizations undertake before their next surveys, and promote continuous organization compliance with the standards.

• Pre-survey review of organization-specific information, such as ORYX core measure data, sentinel event information, and MedPar data, through an automated process to identify critical processes relevant to patient safety and health care quality for evaluation during the on-site survey.

For example, if an organization's data indicate that it serves a large geriatric population with a high volume of medical admissions, it would most likely have a high number of prescribed and dispensed medications. Therefore, medication use issues would be critical for that organization.

• Substantial consolidation of the standards to reduce the paperwork and documentation burden of the survey process and increase its focus on patient safety and health care quality.

• On-site evaluation of standards compliance in relation to the care experience of actual patients.

• Revision of individual organization performance reports to provide performance information not portrayed in the current reports.

• Active engagement of physicians in the new accreditation process.

Russell Massaro, MD, executive vice president of the Joint Commission's accreditation operations, told reporters that organizations are going to find that the new accreditation process focuses more on the actual delivery of clinical care and that the Joint Commission is going to provide a more continuous picture of an organization's performance, particularly through the periodic gathering and monitoring of ORYX data.

An administrator of a hospital that pilot-tested the new process agreed.

"It gave the surveyors an actual, more realistic assessment of our day-to-day hospital operations," said **Charles Young**, administrator of Shriners Hospital in Spokane, WA, at the teleconference. The new procedures simplified the accreditation process, he said, and were a "natural outgrowth" of the organization's own self-assessment efforts.

For more information about the new accreditation process, see the 16-page edition of *Perspectives*, the Joint Commission's official newsletter, at the Joint Commission Resources web site: www.jcrinc.com/perspectives. ■

Studies find new drug dosages often too high

The initially recommended dosage of prescription drugs is often twice that needed for safe and effective use in clinical practice, according to two new studies by researchers in the United States and the Netherlands. An Oct. 2 article in the *Journal of the American Medical Association* looked at these studies, which were recently published in the on-line version of the journal *Pharmacoepidemiology and Drug Safety*.

In the U.S. study, researchers studied label changes for 354 "new molecular entities" that received FDA approval between 1980 and 1999. The researchers discovered that the initially recommended dosage for 21% of the drugs was later changed, and that the overwhelming proportion of such changes (70%) were dosage decreases made for safety reasons. In addition, new drugs approved in the late 1990s (1995-99) were more than three times likelier to require a dosage change than drugs approved in the early 1980s (1980-84).

These findings "may represent a systematic flaw in premarketing dosage evaluation," according to the researchers. They note that the drug

industry commonly launches Phase III trials testing the experimental drug at or near the maximum tolerated doses established in Phase I and II studies, often before dose or concentration studies from Phase II trials have been fully analyzed.

The Dutch researchers examined data compiled during the period 1982-2000 by the World Health Organization, which monitors changes in the daily defined dose (DDD). The researchers found 115 instances of changes in the DDD, of which 45 (39.1%) were increases and 70 (60.9%) were decreases. Drug classes that most frequently had dosage changes were antibiotics (mostly increases) and cardiovascular drugs (mostly decreases, especially for angiotensin-converting enzyme inhibitors and antithrombotic agents).

One implication of the findings of both studies is that more research on the process of drug dose selection is needed to help ensure that patients get the optimal dose, says *JAMA* writer **Joan Stephenson**, PhD. A better understanding of the interplay between genetic variation and patient response to drugs may also lead to drug doses tailored to a patient's genetic makeup. ▼

Pharmacists say drug companies overcharge

Pharmacists are dissatisfied with what drug companies charge for their products, claims a survey published in the Sept. 16 issue of *Drug Topics* magazine.

Almost nine out of 10 pharmacists surveyed said they felt that pharmaceutical companies put too high a price on their new product launches, while 84% said single-source drugs, not yet available as generics, cost too much. In addition, 72% of community pharmacists surveyed said differential pricing still exists, and 15% said it has even increased.

The survey, which was mailed as a questionnaire to 700 retail and hospital pharmacists across the nation, obtained a 34% response rate. Other findings in the survey reveal that nearly nine out of 10 pharmacists don't believe manufacturers are doing enough to prevent drug shortages, and almost half of respondents say the prescription cards established by many drug companies for seniors offer only negligible savings. Nearly three-quarters of pharmacists said there is too much direct advertising of drugs to consumers. ▼

FDA consolidating its new drug review duties

The Food and Drug Administration (FDA) announced in September that its Center for Drug Evaluation and Research (CDER) would have sole responsibility for reviewing new pharmaceutical products. This work is currently performed in part by FDA's Center for Biologics Evaluation and Research (CBER) and in part by CDER.

The consolidation will allow CBER to concentrate its scientific expertise and effort in the areas of vaccines and blood safety, explains **Lester M. Crawford**, DVM, PhD, FDA deputy commissioner. "Moreover, CBER will be able to concentrate its expertise on such cutting-edge biologic scientific areas as gene therapy and tissue transplantation."

Crawford has established a working group to develop by January an implementation action plan and time line for the consolidation. The action plan will address issues related to the product and process logistics of the consolidation. Current FDA policy on generic biologics will not be affected by this decision. ▼

Protein C: Study finds its value for sepsis

Recombinant human activated protein C is relatively cost-effective for treating severe sepsis patients with an Acute Physiology and Chronic Health Evaluation (APACHE II) score of 25 or more, according to a study published in the Sept. 26 issue of the *New England Journal of Medicine*. The economic implications of widespread use of the drug are important, given the high cost of activated protein C ($6,800 per therapeutic course) and the high incidence of severe sepsis.

The Food and Drug Administration (FDA) had conducted a post hoc reanalysis of data from the Recombinant Human Activated Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) study. Researchers, who estimated the cost-effectiveness of activated protein C as compared with conventional care for patients with severe sepsis, used data on the effectiveness of activated protein

C from the PROWESS study and analyses by the FDA. The researchers performed an economic analysis involving all patients, as well as analyses of subgroups defined according to age and severity of illness.

Results showed that the cost per life-year gained by treating all patients with activated protein C was $27,936. It was more cost-effective to treat patients with an APACHE II score of 25 or more ($24,484 per life-year gained) than those with a lower APACHE II score ($35,632 per life-year gained). For patients with an APACHE II score of 25 or more, the cost per life-year gained increased with age ($16,309 for patients less than 40 years of age; $28,100 for those 80 years of age or older). The researchers say further research is needed to determine the cost-effectiveness of activated protein C for patients with sepsis and less severe illness. ▼

For more information, see www.fda.gov/medwatch/SAFETY/2002/safety02.htm#premar.

In other labeling changes, AstraZeneca has announced that the FDA has approved the inclusion in labeling of data from a clinical trial program showing that AstraZeneca's angiotensin II receptor blocker candesartan cilexetil (Atacand) was superior to Merck's angiotensin II receptor blocker losartan potassium (Cozaar) in lowering both systolic and diastolic blood pressure when administered at the maximum recommended once-daily doses. The approval follows the unanimous recommendation of the FDA Cardiovascular and Renal Drugs Advisory Committee, which concluded that candesartan cilexetil demonstrated greater antihypertensive efficacy in reducing systolic blood pressure by about 3 mm Hg and diastolic blood pressure by about 2 mm Hg compared to losartan potassium in the CLAIM clinical trial program. ■

Labels change for HRT and candesartan cilexetil

New safety information has been added to the labels of conjugated estrogens/medroxyprogesterone acetate tablets (Prempro/Premphase) and conjugated estrogens tablets, USP (Premarin). The labeling changes reflect new risk data, primarily from the Women's Health Initiative.

Because of the potential increased risks of cardiovascular events, breast cancer, and venous thromboembolic events, use of the drug therapies should be limited to the shortest duration consistent with treatment goals and risks for the individual woman, and should be periodically re-evaluated. When used solely for the prevention of postmenopausal osteoporosis, alternative treatments should be carefully considered. Note that conjugated estrogens/medroxyprogesterone acetate tablets and conjugated estrogens tablets, USP are not indicated for prevention of coronary heart disease and should not be used for that purpose.

New FDA Approvals

The following drugs have received final approval from the Food and Drug Administration (FDA):

• *Valacyclovir HCl (VALTREX) caplets by GlaxoSmithKline*. The FDA has approved a supplemental new drug application for valacyclovir HCl (VALTREX) caplets for the treatment of **cold sores** in healthy adults, making Valacyclovir HCl the first one-day, oral antiviral medication proven to shorten the duration of a cold sore outbreak.

• *New indication for irbesartan (Avapro) by Bristol-Myers Squibb Co. and Sanofi-Synthelabo.* The FDA has approved irbesartan (Avapro) for use in slowing the progression of **kidney disease**. Irbesartan is also indicated for the treatment of hypertension.

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- Multitasking and pharmacists' personalities
- Efforts to combat antibiotic resistance
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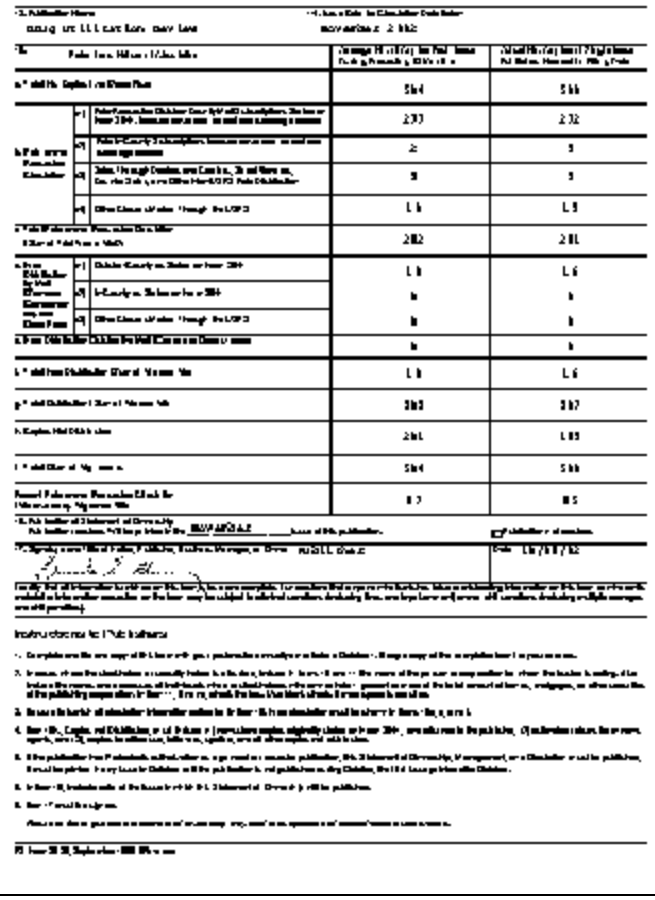

• *New formulation: Amoxicillin/clavulanate (Augmentin XR) Extended Release Tablets by GlaxoSmithKline.* The FDA has approved amoxicillin/clavulanate (Augmentin XR) Extended Release Tablets for the treatment of adults with **acute bacterial sinusitis (ABS)** or **community-acquired pneumonia (CAP)**. Specifically, amoxicillin/clavulanate Extended Release Tablets are indicated for the treatment of patients with ABS or CAP confirmed or suspected to be caused by b-lactamase-producing bacteria such as *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae* with reduced susceptibility to penicillin.

Amoxicillin/clavulanate Extended Release Tablets employ bi-layer tablets that provide a release of amoxicillin and 62.5 mg of clavulanate potassium and an extended release of amoxicillin for a total of 1000 mg of amoxicillin. GlaxoSmithKline stresses that amoxicillin/clavulanate Extended Release Tablets cannot be used to provide the same dosages as the original formulation (250 mg or 500 mg). ■

DRUG CRITERIA & OUTCOMES™

Formulary evaluation: Olmesartan medoxomil (Benicar)

By **Kevin Lewis**, PharmD candidate
Harrison School of Pharmacy
Auburn (AL) University

Background

The management of hypertension remains a primary focus of health care. Hypertension is a cardiovascular risk factor that is directly associated with other disease states, including congestive heart failure (CHF), myocardial infarction, cerebrovascular accidents, and peripheral arterial insufficiency. Heart disease and stroke are two major causes of death and are correlated with more than $259 billion in costs. There is great concern regarding hypertension because it usually progresses undetectably, with no distinguishing signs or symptoms of the condition. The only accurate diagnosis of hypertension is an elevated blood pressure.

Numerous classes of anti-hypertensive agents are used to reduce blood pressure, each with a different mechanism of action. A variety of combinations are commonly implemented to produce an added therapeutic benefit. The angiotensin II receptor antagonists (AIIRBs) are a relatively new class of anti-hypertensive agents that have recently emerged and established a role in the therapy of hypertension. The drugs in this class include the following: irbesartan (Avapro), losartan (Cozaar), telmisartan (Micardis), valsartan (Diovan), candesartan cilexetil (Atacand), eprosartan (Teveten), and olmesartan medoxomil (Benicar). Olmesartan is the most recent AIIRB approved by the U.S. Food and Drug Administration (FDA) for the treatment of hypertension, and the information below is an evaluation to determine whether olmesartan should be added to the hospital formulary.

Mechanism of action

Olmesartan is an angiotensin II receptor blocker that is selective for the AT_1 subtype. The AT_1 receptor is primarily found in vascular smooth muscle and is directly associated with cardiovascular homeostasis. By blocking this receptor, the pressor effects of angiotensin II (e.g., vasoconstriction, stimulation of the synthesis and release of aldosterone, cardiac stimulation, renal reabsorption of sodium, and stimulation of the sympathetic system) will be prevented. This produces a pharmacological effect of lowering blood pressure. The mechanism of action of olmesartan is basically the same for all AIIRBs.

Indication

Olmesartan currently has an indication similar to that for the other agents of this class, which is the treatment of hypertension. Olmesartan can be used as monotherapy or in combination with other anti-hypertensive agents. Unlike olmesartan, other agents of this class have been studied for therapeutic indications such as CHF. Long-term data for the treatment of CHF is still pending, but several AIIRBs have shown beneficial effects. For example, valsartan has recently received Food and Drug Administration (FDA) approval for therapy for CHF.

Dosing

Olmesartan is available in dosages of 5 mg, 20 mg, and 40 mg. The full prescribing information does not specify when the 5 mg dosage should be used. According to the manufacturer, the choice of a lower dose is at the discretion of the health care provider in treating patients who are volume-depleted or who have significant renal and/or hepatic impairment. These are precautionary measures, and the 5 mg dose allows the practitioner to decrease the dose as deemed necessary. The initial dose of monotherapy with olmesartan is 20 mg once daily in those individuals who are not volume-depleted. It is recommended to increase the

dose to 40 mg once daily after two weeks of therapy if an additional lowering in blood pressure is necessary. No greater therapeutic benefit was demonstrated with doses over 40 mg daily, and there is also no advantage to taking the equivalent daily dose twice daily compared to once daily. Dose adjustment based on gender or age is not required because of similar clinical responses. There is no dose adjustment necessary in hepatic dysfunction, but caution in hepatobiliary disease is advised because olmesartan is significantly metabolized by the biliary system. Dose adjustment for renal dysfunction has not been adequately addressed in clinical trials.

Pharmacokinetics

The table below illustrates the differences and similarities of the various pharmacokinetic parameters. As the table illustrates, olmesartan is similar to other drugs in its class in terms of maximal onset, protein binding, and dosing frequency. Olmesartan is formulated as a prodrug similar to candesartan and losartan. It is not metabolized by the CYP-450 enzyme system, so potential drug interactions are less likely compared to losartan and irbesartan, which are metabolized by this system. Food does not affect the absorption of olmesartan, irbesartan, and candesartan, but it does decrease the absorption of other AIIRBs, with valsartan being the most affected.

Irbesartan represents the most bioavailable agent, and telmisartan displays the longest half-life. There are no specific recommendations for AIIRB dosage adjustment in renal dysfunction, but caution should be taken in dosing valsartan in severe dysfunction. When dosing losartan, valsartan, and telmisartan, severe hepatic dysfunction should be considered, as dose adjustment is necessary. Overall, olmesartan does not exhibit any important, unique pharmacokinetic features compared to the other drugs in its class.

Contraindications

No significant contraindications exist except for those who are allergic to any of the components within the drug product.

Variable	**Olmesartan**	**Irbesartan**	**Candesartan**	**Valsartan**	**Telmisartan**	**Eprosartan**	**Losartan**
Prodrug	Yes	No	Yes	No	No	No	Yes — active metabolite
Cmax	1-2 hrs	1.5-2 hrs	3-4 hrs	2-4 hrs	0.5-1 hr	1-2 hrs	1 hr parent molecule; 3-4 hrs active metabolite
Bioavailability	26%	60-80%	15%	25%	42-58%	13%	33%
Maximal onset	2 weeks	2 weeks	2-4 weeks	2 weeks	3 weeks	3 weeks	2-3 weeks
Metabolism	Biliary/renal excretion	Liver — 2C9	Biliary/renal excretion	Biliary/renal excretion	Liver-glucuronide	Biliary/renal excretion	Liver — 2C9, 3A4
Food effect	No effect	No effect	No effect	↓ 40%	↓ 6-20%	↓ <25%	↓ 10%
Half-life	13 hrs	12-20 hrs	9 hrs	6 hrs	24 hrs	5-9 hrs	2 hrs
Protein binding	99%	90%	>99%	>95%	>99.5%	98%	99%
Fecal elimination	50-65%	80%	67%	83%	98%	90%	60%
Urinary elimination	35-50%	20%	33%	13%	<1%	7%	35%
Dosages available	5, 20, 40 mg	75, 150, 300 mg	4, 8, 16, 32 mg	80, 160 mg	20, 40, 80 mg	400, 600 mg	25, 50, 100 mg
Dosing frequency	QD	QD	QD/BID	QD	QD	QD/BID	QD/BID
Dose adjustment for hepatic dysfunction	None specific, but caution in hepatobiliary disease	No	No	Use caution with 80 mg QD	Caution (may need to consider other agents)	No	Yes ↓ dose 2 mg bid
Dose adjustment for renal dysfunction	Not addressed in clinical studies	No	No	Caution in severe dysfunction	No	No	No

Warnings and precautions

As with the other AIIRBs, olmesartan should not be administered during the second or third trimester in pregnant women. There have been reports that agents that act directly on the renin-angiotensin system can lead to injury or death to the fetus. It is recommended to discontinue olmesartan therapy as soon as pregnancy is detected, even though fetal adverse effects have not been correlated with the first trimester. The AIIRBs are classified as pregnancy category C in the first trimester and D for the second and third trimesters. There are also precautionary measures to be taken in those individuals who are volume-depleted and/or salt-depleted based upon symptomatic hypotension incidence. Also, those individuals who rely on the renin-angiotensin system for renal function need to be carefully monitored upon initiation of olmesartan or any of the AIIRBs.

Adverse reactions

Along with the other AIIRBs, olmesartan is generally a well-tolerated drug, with temporary side effects that are not associated with the dose. Placebo-controlled studies revealed the following adverse events in greater than 1% of patients (note: incidence was about equal to or greater than incidence for those receiving placebo): headache, hematuria, hyperglycemia, back pain, bronchitis, increase in creatine phosphokinase, flu-like symptoms, inflicted injury, hypertriglyceridemia, pharyngitis, rhinitis, sinusitis, and upper respiratory tract infection. Another adverse event that occurred was dizziness. Unlike the other effects listed above, there was a higher incidence of dizziness in the treatment group compared to the placebo group; this was a similar effect with the other AIIRBs. Overall, these adverse reactions are similar for the entire class.

Drug interactions

Because olmesartan is not metabolized by the CYP-450 system, there are no significant drug interactions involving this system. This is also true for candesartan, valsartan, and eprosartan. Those that are metabolized by the CYP-450 system may have altered pharmacokinetics, but in general these interactions are not considered to be clinically significant. The bioavailability of olmesartan is not significantly affected when taken with antacids. There have been no notable drug interactions with warfarin or digoxin reported.

Product	Hospital cost per tablet
Olmesartan	
5 mg	$1.05
20 mg	$1.05
40 mg	$1.05
Telmisartan	
40 mg	$1.06
80 mg	$1.06
Eprosartan	
400 mg	$0.74
600 mg	$0.98
Candesartan	
8 mg	$1.02
16 mg	$1.02
32 mg	$1.38
Irbesartan	
75 mg	$0.97
150 mg	$1.03
300 mg	$1.23
Losartan	
25 mg	$0.93
50 mg	$0.93
100 mg	$1.39
Valsartan	
80 mg	$0.99
160 mg	$1.04

Cost

As illustrated by the above cost/comparison table, all AIIRBs are similar in price. Currently, all strengths of olmesartan are the same price.

Evidence of efficacy and safety based on clinical trials

Several abstracts are available to demonstrate the efficacy of olmesartan. All of the study designs included a randomized, double-blind, intent-to-treat, placebo-controlled clinical trial. All of the abstracts evaluated had a sample size of at least 325 patients. Multiple studies concluded that olmesartan is a proven anti-hypertensive agent based on ambulatory blood pressure assessment after six or eight weeks of therapy compared to placebo. The safety profile of the drug was also demonstrated in these studies.

General conclusions were that most side effects occurred at about the same incidence rate in both the treatment group and the placebo group. In one study, after 12 weeks of therapy with 10 mg

of olmesartan or 50 mg of atenolol, it was shown that there was no significant difference between the two in lowering diastolic blood pressure. However, there was a statistically significant difference in favor of olmesartan therapy in reduction of systolic blood pressure. The trial's overall reliability is hard to determine because only the abstract of the trial is currently available, and systolic blood pressure was not a primary endpoint outcome measure in the conclusion section of the study. In addition, there were not any statistical analysis tests described within the abstract. The efficacy of the other AIIRBs has proven to be equivalent in reducing blood pressure compared to other antihypertensive drug classes (i.e., ACE inhibitors, calcium channel blockers, beta-blockers, and hydrochlorthiazide).

Another study evaluated olmesartan QD regimen of 5 mg, 20 mg, or 80 mg compared to a BID regimen of 2.5 mg, 10 mg, or 40 mg and illustrated that there was no significant advantage with the twice-daily regimen because olmesartan maintained its peak effect 24 hours after administration. Diastolic blood pressure was reduced by 8-11 mm Hg, and systolic pressure was reduced by 10-17 mm Hg. Olmesartan was also compared to amlodipine, a calcium channel blocker, and both lowered blood pressure with similar results, showing no statistically significant difference. Olmesartan lowered systolic pressure by an average of 13 mm Hg while amlodipine reduced it by 12.9 mm Hg.

A similar comparative study was conducted with olmesartan and felodipine. Once again, there was no statistically significant difference regarding reduction of blood pressure. It was stated in the abstract that 5.9% of patients experienced adverse drug reactions (ADRs) with olmesartan, while those in the felodipine group had a 12.4% incidence of ADRs. This can be misleading, because the abstract also noted that the distribution of ADRs between the two groups was approximately equal. There were no further comments on ADR issues; therefore, one should question the reliability of the ADR incidence statement until further details are available.

One clinical trial compared olmesartan 20 mg daily to three other AIIRBs, including losartan 50 mg, valsartan 80 mg, and irbesartan 150 mg daily; these doses are considered to be approximately equivalent. The clinical trial consisted of a randomized, double-blind, parallel group, starting dose study including 588 patients diagnosed with hypertension. Ambulatory blood pressure measurements were taken every 24 hours for an eight-week period. The results portrayed a statistically significant reduction in diastolic and systolic blood pressure in the olmesartan group compared to the other three groups. Olmesartan produced an average decrease in diastolic pressure of 11.5 mm Hg, losartan 8.2 mm Hg, valsartan 7.9 mm Hg, and irbesartan 9.9 mm Hg. The average systolic pressure reductions were as follows: olmesartan 13 mm Hg, losartan 8.9 mm Hg, valsartan 9.2 mm Hg, and irbesartan 10.8 mm Hg. All differences were seen within the first two weeks of therapy. However, at the end of four weeks, the changes in systolic pressure were not statistically different among the four drugs but remained statistically different in regards to diastolic pressure. Olmesartan also proved to produce significantly more lowering of the average 24-hour diastolic and systolic blood pressure (8.5/12.5 mm Hg) vs. losartan (6.2/9.0 mm Hg) and valsartan (5.6/8.1 mm Hg). However, there was no significant difference between olmesartan and irbesartan (7.4/11.3 mm Hg). The limitations of this study included a small sample size, exclusion of the total number of individuals assigned to each treatment group, and all results being based on a mean reduction of blood pressure. In addition, the study was terminated after an eight-week period. There are no long-term data available to validate these conclusions.

All of the studies listed above are limited by various factors. For example, the number of patients included in the studies was too small to make reliable conclusions in relationship to the general population. Also, another factor seen in all of the studies is the absence of long-term data. There is not enough information currently to make a definite conclusion on relative efficacy of olmesartan compared to the other AIIRBs. More studies need to be conducted to validate the preliminary data given in these early studies.

Conclusions and recommendations

Based on the above information pertaining to olmesartan, there are no distinguishing differences between it and the other AIIRBs. They are all indicated for the treatment of hypertension, all have basically the same mechanism of action, and all are generally well-tolerated in terms of adverse events. Olmesartan is also limited relative to the others regarding indications. For example, several other AIIRBs have broader indications, some that are not FDA-approved but that

have demonstrated efficacy (such as CHF). The FDA has recently approved valsartan for the treatment of CHF.

Olmesartan is effective for hypertension, but there is not enough reliable information to demonstrate important advantages compared to the other AIIRBs. With this in mind, the cost of the product needs to be addressed. As noted above, there are other AIIRBs that are less expensive, but this cost difference is most likely minor. Although it is true that olmesartan has shown statistically significant differences among some of the AIIRBs with blood pressure reduction, more studies need to be done to establish any clinically significant differences in the treatment of hypertension. Studies are not strong enough to conclude that olmesartan has a distinct advantage over the other agents for treatment of hypertension. There is no substantial reason to add olmesartan to the hospital formulary at this time. Olmesartan orders should be converted to the formulary drug irbesartan in approximate equivalent dosage regimens (i.e., olmesartan 20 mg converted to irbesartan 150 mg or proportionately) unless "no substitution" is written with the drug order.

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Can chromium be used for diabetes?

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In today's world of nutraceuticals and self-care, we as practitioners must keep up with the latest information on the uses of nutritional supplements to help our patients make decisions about their use. Diabetes is the seventh-leading cause of death in the United States, with 16 million people in this country affected by the disease. Because of the wide variety of complications that can be life-changing, it is important to keep tight control on glucose levels.

Chromium is currently being touted as a supplement for diabetic patients to increase control of their blood glucose levels. When searching the Internet for chromium's use in diabetes, 52,000 citations were found, and 27 articles were found on Medline. Due to this vast array of information about chromium available to patients, we as practitioners must be aware of the clinical effects of this dietary supplement.

Chromium was thought to be essential in body processes prior to 1977 when a landmark case confirmed this importance. A woman on total parenteral nutrition (TPN) developed severe diabetic symptoms that could not be controlled with insulin. Upon further evaluation, physicians noted a deficiency in chromium, which is normally supplied in foods such as organ meats, mushrooms, wheat germ, broccoli, and processed meat products. After adding only a small amount of chromium (<50mcg) to the TPN, the symptoms

subsided, and the patient's blood glucose level returned to normal. The U.S. Food and Drug Administration (FDA) and the Food and Nutrition Board of the National Research Council then designated chromium as an essential nutritional trace element. This case led researchers to begin investigating the role of chromium in insulin-resistant type II diabetes mellitus (DM).

Chromium is an element found in the body; it is believed to work with insulin to transport glucose into cells. The mechanism by which this is thought to take place involves chromium increasing insulin binding to cells, increasing the number of insulin receptors, and activating insulin receptor kinase, leading to increased insulin sensitivity. Due to this mechanism, chromium would not be useful in insulin-dependent diabetes. Insulin resistance seems to be the focal point of the research. Additionally, chromium has been investigated in steroid-induced diabetes and gestational diabetes as well as other disease states such as obesity and hyperlipidemia.

Many studies have investigated the use of chromium in insulin-resistant diabetes mellitus. The results are varied but point in a favorable direction for the benefit of chromium; however, most of the trials involve small sample sizes, and only a few are well-controlled clinical trials. Dosage and salt forms also contribute to the variations in the results. The chromium picolinate and chloride salt forms have been most widely studied, with the picolinate form showing the most efficacy due to increased absorption. The most common dosages studied include 200 mcg, 600 mcg, and 1000 mcg daily.

One of the strongest trials, by Anderson et al[1], was conducted in Beijing, China, with a total of 180 diabetic patients. The patients were 35-65 years of age, free of other disease, and had a fasting blood glucose concentration of 7.2-15.5 mmol/l (130-279mg/dL) with an HbA1c ranging from 8.0-12.0%. Patients were randomized into three groups, each with 60 individuals, with groups receiving chromium picolinate — either 200 mcg/d in two doses or 1000 mcg/d in two doses — or placebo. All of the groups were similar in many ways. After four months of treatment, the two active groups demonstrated a significant decrease in fasting glucose, two-hour glucose challenge tests, fasting insulin, two-hour insulin, and HbA1c measurements. The 1,000 mcg/d dose demonstrated the most clinically significant decreases in glucose levels. This trial supports the use of 1,000 mcg/d of chromium picolinate and reported no side effects. Weaknesses of this trial include all subjects being Chinese and glucose levels not being reported. Because the Chinese population has a lower incidence of obesity and diabetes, it is difficult to extrapolate these data to other populations.

Many of the other trials have assessed the use of chromium in diabetes. Bahadori et al[2] investigated chromium picolinate's effects on insulin levels and glucose control in obese patients with type II DM. Sixteen patients with a mean age of 56 years of age and body mass index of 32 kg/m^2 were stabilized on sulfonylurea and metformin before receiving 500 mcg BID of chromium picolinate for four months. This trial, as well as many others, only reported outcomes as decreases in insulin levels, which the authors concluded might not support the use of this supplement. There were no changes in body weight, HbA1c, or steady-state glucose levels from baseline. This study also has a small sample size and was not placebo-controlled, blinded, or randomized.

In general, due to weak study design and large variability in results, the data from individual trials is not strong enough to recommend the use of chromium to better control hyperglycemia. However, when all of the results are combined, they suggest chromium may be efficacious. Studies using stronger study design are needed. None of the studies to date reported any serious side effects; those that were reported were minor and generally limited to effects that could be explained by other causes, such as hypoglycemia or rash that could be due to excipients in the particular brand of chromium. The literature suggests discontinuing use of the supplement if effects do not subside with continued use or changing brands.

Also, chromium supplements are rather inexpensive, ranging from $5-$15 per month. Of the two forms, picolinate appears to be the most efficacious, and 1,000 mcg/d provided the most benefit in clinical trials. Due to its proposed mechanism of action, some experts believe that chromium should show more of a benefit; with stronger studies, these benefits may be demonstrated. Long-term use has not been sufficiently studied. However, Cheng et al[3] performed a follow-up survey of the trial in China discussed above and found no side effects at one year. Presently, for patients who are insulin-resistant, refractory to other hypoglycemic medications, and maintaining a healthy diet and regular exercise program, chromium picolinate may provide

added glucose control. Patients' questions about chromium's use in diabetes give practitioners an opportunity for diabetic education and monitoring, as well as for informing the patient about the correct dose, possible side effects, and the benefits of chromium for better control of glucose levels.

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• Adolor Corp. has announced completion of enrollment in the first Phase III clinical trial (OBD 304) for use of its product candidate, alvimopan, in managing **opioid-induced bowel dysfunction**.

• AnorMED has initiated a new Phase I clinical trial in cancer patients to determine the safety and potential of AMD-3100 as a new agent for **stem cell transplantation**. AMD-3100 blocks a specific cellular receptor, triggering the movement of stem cells out of the bone marrow and into circulating blood.

• ID Biomedical has completed enrollment for its ongoing Phase II clinical trial of FluINsure, the company's intranasally delivered trivalent **influenza vaccine**.

• Inhibitex has started a Phase I clinical trial of its lead product, Veronate, for the prevention of **staph infections** in premature infants. Veronate is an antibody-based product that belongs to a class of drugs referred to as immune globulins.

• SuperGen has announced that decitabine has received orphan-drug designation from the FDA for the treatment of **sickle cell anemia**. SuperGen is developing decitabine for MDS, sickle cell anemia, and refractory chronic myelogenous leukemia as well as exploring its use in solid tumors.

• Apovia AG and its wholly owned subsidiary Apovia have announced the initiation of its first human Phase I clinical trials for its candidate **malaria vaccine**, MalariVax.

• Keryx Biopharmaceuticals has announced that it has filed a protocol for its Phase III trial to advance sulodexide (KRX-10), a novel treatment for **diabetic nephropathy**.

• Genmab A/S has announced that the FDA had approved its Investigational New Drug filing for HuMax-CD4 for **psoriasis** and the initiation of a Phase IIb study. This will be the fifth study carried out by Genmab with HuMax-CD4 for psoriasis or **rheumatoid arthritis** indications.

• Biomira and Merck KGaA have announced that investigators have enrolled the first patient in a Phase II trial of Theratope vaccine in women with **metastatic breast cancer** who are being treated with aromatase inhibitors or fulvestrant (Faslodex), an estrogen-receptor antagonist. Theratope vaccine contains a synthetic antigen.

• Esperion Therapeutics has initiated a second Phase I clinical study of its RLT Peptide product candidate ETC-642 in patients with **existing vascular disease**.

• GenVec has completed patient accrual in the Phase I study of its lead oncology product candidate, TNFerade, in patients with **soft tissue sarcoma** of the extremities.

• Sucampo Pharmaceuticals has begun a Phase II clinical trial with its proprietary compound RU-8811, a functional fatty acid, for the treatment of patients with **non-alcoholic steatohepatitis disease**.

• Angiotech Pharmaceuticals has initiated a Phase II clinical study for the use of micellar paclitaxel for Injection (Paxceed) in the treatment of patients with **rheumatoid arthritis**.

• Marshall Edwards has announced that its lead anti-cancer compound phenoxodiol is entering a Phase II human clinical trial in patients with **leukemia**.

• Antisoma plc has reached the target for patient recruitment in its Phase III study of pemtumomab

for **ovarian cancer**.

• Antex Biologics has announced that two Phase II trials are scheduled to begin next quarter for its Helivax vaccine against *Helicobacter pylori*, a bacterial pathogen responsible for **peptic ulcers and stomach cancers**.

Pharmacia announces recall of its contraceptive

Pharmacia Corp.has announced that it is initiating a voluntary recall of medroxyprogesterone acetate and estradiol cypionate injectable suspension (Lunelle Monthly Contraceptive Injection) in prefilled syringes due to a lack of assurance of full potency and possible risk of contraceptive failure. As a precaution, Pharmacia is voluntarily recalling all the prefilled syringe lots currently on the market. Medroxyprogesterone acetate and estradiol cypionate injectable suspension packaged in vials is not affected by this recall, nor is any other Pharmacia contraceptive product.

Medroxyprogesterone acetate and estradiol cypionate injectable suspension is a combined hormonal contraceptive that is administered to women by a health care professional as a monthly injection. A sub-potent dose of medroxyprogesterone acetate and estradiol cypionate injectable suspension may not be effective in preventing pregnancy. Women who have been using medroxyprogesterone acetate and estradiol cypionate injectable suspension as their contraceptive are advised to seek the advice of their health care professional regarding alternative methods of birth control and to use an additional barrier method of birth control (such as male or female condoms, diaphragm, or spermicide) until beginning a new form of hormonal contraception.

For further information, health care professionals may call the Pharmacia medical information service on (800) 323-4204.

The following drugs have received final approval from the Food and Drug Administration (FDA):

• *Adefovir dipivoxil (Hepsera) by Gilead Sciences.* The FDA has approved antiviral adefovir dipivoxil (Hepsera) for the treatment of **chronic hepatitis B virus** (HBV) in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Adefovir dipivoxil, administered as an oral 10 mg tablet, is the first nucleotide analogue to receive FDA approval for the treatment of chronic hepatitis B. Adefovir dipivoxil slows the progression of chronic hepatitis B by interfering with viral replication and causing DNA chain termination after its incorporation into viral DNA. Adefovir dipivoxil has also been shown to be effective in treating patients with clinical evidence of HBV that is resistant to lamivudine.

The major adverse events associated with the use of adefovir dipivoxil include severe, acute exacerbation of hepatitis B after discontinuation of the drug, and kidney toxicity. This adverse event occurred in up to 25% of clinical trial participants. Therefore, the labeling for adefovir dipivoxil states that patients who discontinue the drug therapy should be monitored at repeated intervals over a period of time for hepatic function.

Gilead says the wholesaler acquisition cost for adefovir dipivoxil in the United States will be $440 for a bottle of 30 tablets, or one month of therapy. The company also has established a U.S. Patient Assistance Program for people who do not have insurance or cannot afford to pay for treatment. For more information, call (800) GILEAD-5 or (650) 574-3000.

• *Eplerenone tablets (Inspra) by Pharmacia.* The FDA has granted marketing approval for eplerenone tablets (Inspra), the first agent designed to selectively block aldosterone, for the treatment of **high blood pressure**. Clinical trials in approximately 3,000 patients demonstrated that eplerenone tablets are effective in lowering high blood pressure, both alone and in combination with other antihypertensive therapies, and are generally well-tolerated.

AMERICAN HEALTH CONSULTANTS

2002 SALARY SURVEY RESULTS

Pharmacist shortage continues to boost wages

Wage hikes outpace increases in cost of living

Despite a continued shortage of pharmacists, many say their salaries are not competitive with industry wages.

Drug Utilization Review recently tabulated the results of its 2002 salary survey to assess the financial and workplace demographics of its readership. Of the respondents, 54% report earning less than $90,000 annually. In addition, more than half work more than 46 hours a week. More than 70% also report they are directors of pharmacy.

Pharmacists would have to earn more than $90,000 annually to be competitive with industry wages, says **Carsten Evans**, MS, PhD, assistant dean for professional affairs at Nova Southeastern University in Fort Lauderdale, FL.

Pharmacists provide proactive care

"Both the knowledge and skills of the clinical pharmacists — coupled with the proactive styles of getting directly involved with patient care — are the real dollar value of pharmacy salaries as measured by the health care [business] leaders," Evans says. "Those pharmacists who can contribute this positive cash flow impact should be paid $95,000 to $100,000 to keep pace with the [industry] competitor."

Pharmacist shortages continue to be reported from sources such as a staffing survey conducted earlier this year by the American Society of Health-System Pharmacists in Bethesda, MD. The survey showed that vacancy rates were slightly less in 2002 (6.9%) than in 2000 (8.9%). The annual pharmacist turnover rate was reported at 8.5%, less than the typical industry benchmark of 12%.

Perceptions were that the experienced front-line pharmacists continue to be the most difficult to find (93%), similar to 2000 results (94%).

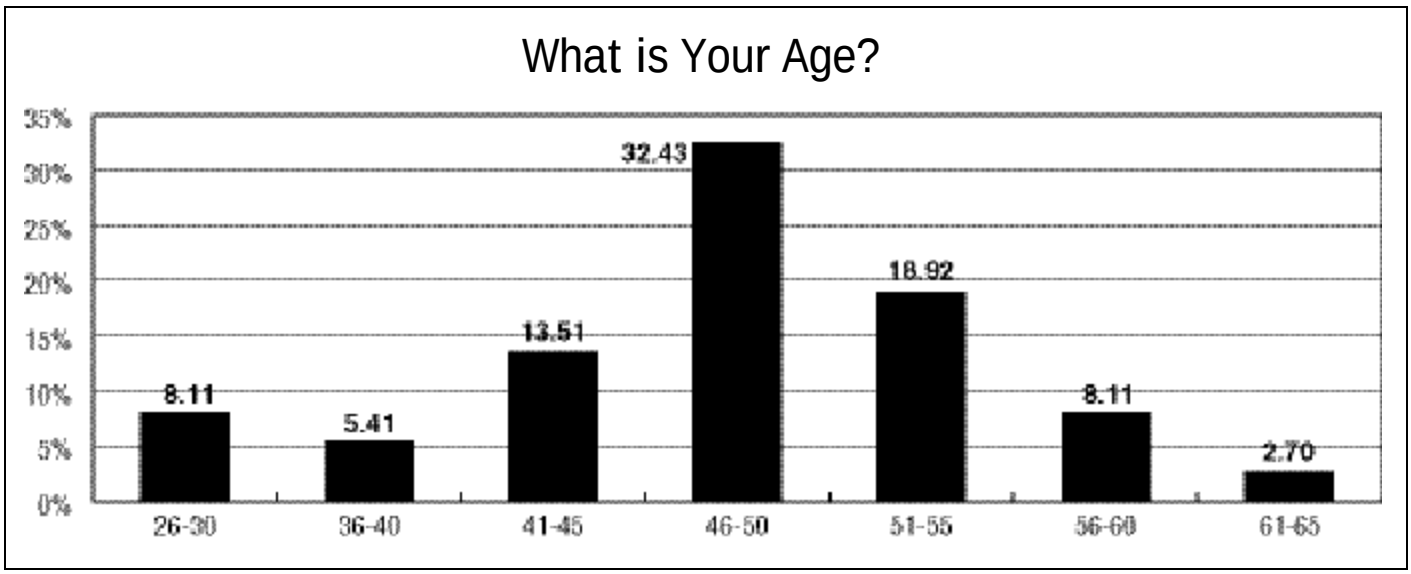
Perceptions also indicated that manager positions were more difficult to fill than in 2000 (74% perceive a severe shortage, compared to 67% in 2000).

Compared to the 2000 *DUR* salary survey, the average salary for pharmacists seems to be following the latest automatic cost-of-living adjustments (COLAs), as reported by the Social Security Administration (SSA). This year, the SSA calculated the COLA to be 2.6%. COLAs prevent inflation from eroding Social Security and Supplemental Security Income benefits. (To learn how COLAs are calculated, go to www.ssa.gov/OACT/COLA/COLA.sum.html.)

Plurality of respondents earn $80k-$90k

In the 2000 survey, the majority of the respondents reported earning a salary of $75,000 to $85,000. In 2002, more respondents (30%) report a salary in the $80,000 to $89,999 range than in any other salary range.

In comparison, median household income (the point at which half of households have higher income, and half have lower) fell 2.2% in inflation-adjusted terms in 2001, the first significant income



decline since the last recession in 1990-91, according to the Economic Policy Institute in Washington, DC. The $934 annual loss sent household income down to about its 1998 level, reversing some of the gains made in the latter 1990s, when the robust economy was generating persistent income growth for most families.

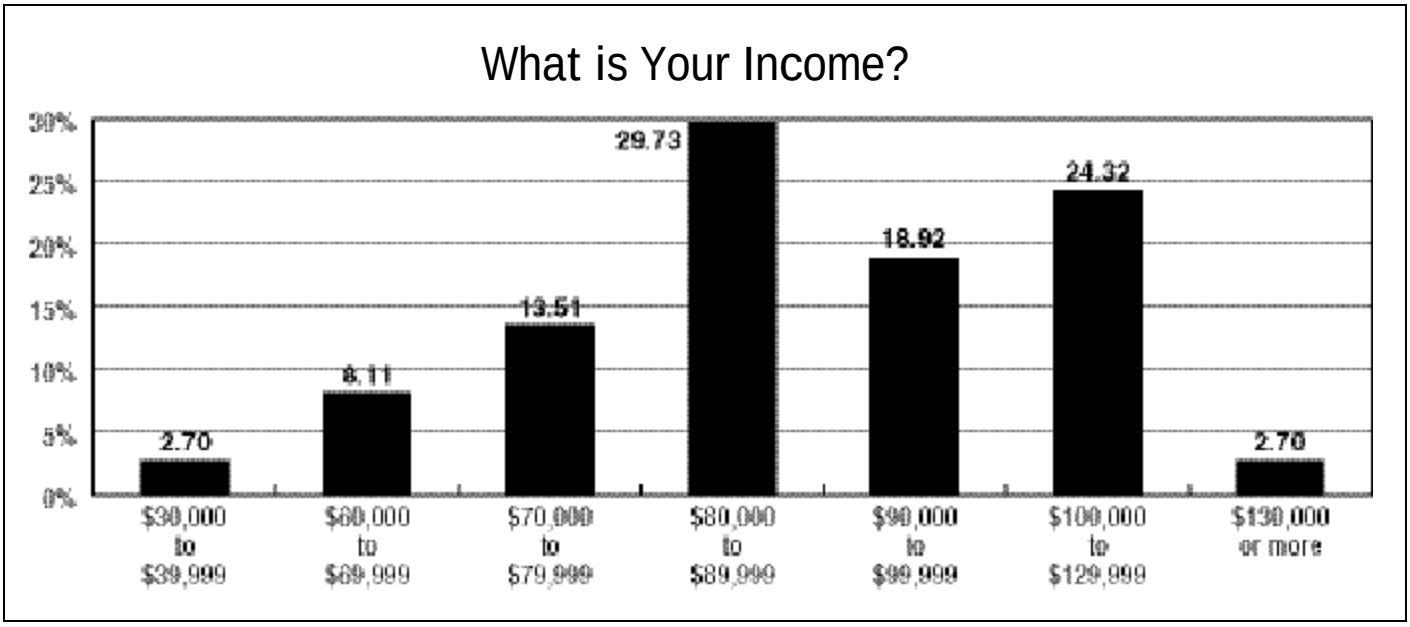
In the 2002 survey, about 30% of respondents say their salary increased in the range of the latest COLA, from 1% to 3%. Thirty-five percent, however, had an increase in the 4% to 6% range, 11% in the 7% to 10% range, and 8% in the 11% to 15% range. (Three percent reported no change in salary at all.)

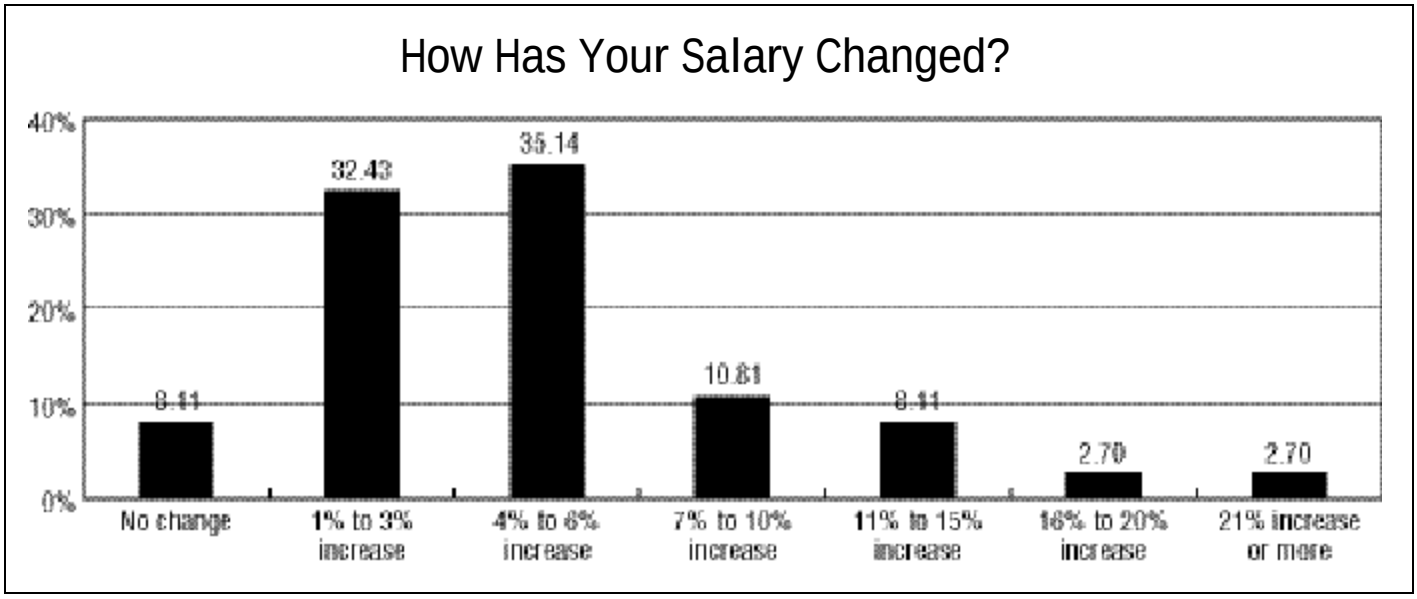
Evans is discouraged by the salary increases reported by the survey. "You don't address serious shortage needs by increasing salaries 6% a year. You lose the best pharmacists that way, such as to industry liaisons, at the $90,000 to $95,000 mark."

Using modal answers to create a composite picture of a *DUR* pharmacist, the average respondent is a man in his late 40s who has been working in a 101- to 200-bed hospital for more than 20 years. He earns $80,000 to $89,999 a year and works 46 to 50 hours a week.

Most respondents work long hours

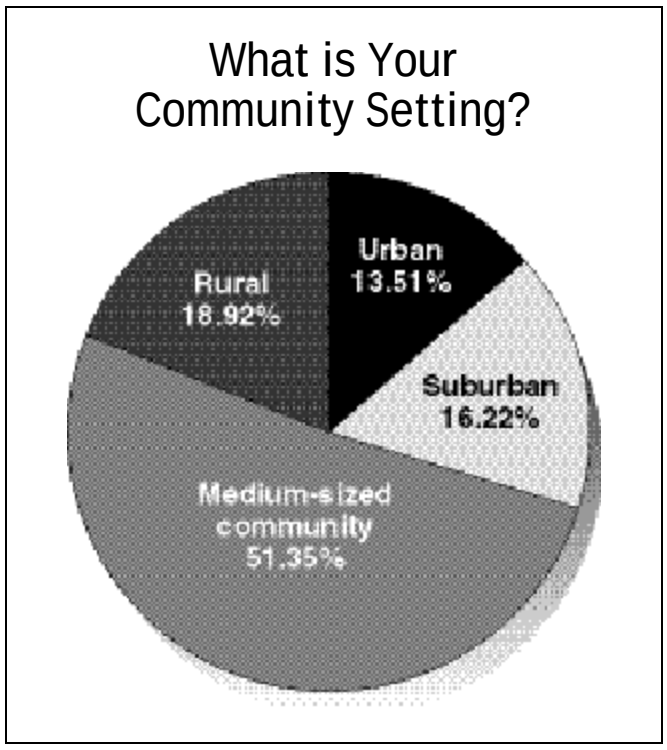
Sixty-two percent of the respondents work 46 hours or more a week. This is not unusual, says **Peggy G. Kuehl**, PharmD, FCCP, BCPS, director of education and member services for the American College of Clinical Pharmacy in Kansas City, MO. "Health professionals in general should be focused on what is best for their patients, which does not usually fit a 40-hour work week."





Most respondents also report they work in a hospital. Fifty percent work in a medium-sized community, and 62% work for a nonprofit. Respondents almost evenly represent different regions of the country.

The survey also indicates that many pharmacists are content with having a bachelor's degree, rather than pursuing a PharmD. In the 2000 survey, 27% reported having a PharmD degree. In 2002, the numbers increase slightly to 32%. This is similar to the results from a 2001 survey published by *Drug Topics* magazine. The vast majority of those respondents (89%) had a BS degree, but only 5% of those pharmacists planned to pursue a PharmD. Eighty percent rejected the idea of heading back to pharmacy school.



Evans says he wonders why many pharmacists don't want to pursue their PharmD.

"The job opportunities for PharmDs are numerous — period, no contest," he says. "The opportunities for BS pharmacists to become PharmD are numerous. If 80% of the survey stated they are content to not grow with the professions' needs, then they will probably find themselves competing with automation and technicians on the budget lines of administrators."

Evans has found that pharmacists who are content with the way things are do not tend to tabulate their financial contribution within their own health care systems.

Licensure laws protect status quo

"State licensure requirements currently protect pharmacists who are content with status quo," he says. "If somehow the laws were to change because of the never-ending shortage of pharmacists, I don't think there would be an employer in the country who would keep content pharmacists if they could use the financially beneficial alternatives described above."

Each pharmacist must decide what is important to him or her, Kuehl says. "For some, it is the familiarity of working in the same place. For others, it is availability of opportunities to develop and advance their clinical skills. Some desire a convenient work schedule or a work location that is near where they live. Still others are focused on financial aspects or benefits."

Once pharmacists make that decision, they should actively seek the position that best fits with their priorities, she continues. "They need to be ready to speak up regarding their desires, to place them in writing as part of an employment agreement, and to relentlessly pursue them. They need to be willing to change positions, move, or do whatever it takes to satisfy their work goals. Of course, these goals must be balanced by the needs of their family and their personal lives."

The time is ideal for those who are seeking opportunities to develop and advance their clinical skills, she says. "If a current employer does not facilitate their development, there are many positions open with other employers in which advanced practice opportunities and related skill development do exist." ■