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Medication Errors: The Year in Review

Glut of medication errors focuses pharmacists on event reporting

Tumultuous year ending with positive steps

Late last year, Long Branch, NJ-based Monmouth Medical Center was hit with a $12 million lawsuit and fines from the New Jersey state board after a medication error killed a 10-month-old infant. The child, who was being treated for liver cancer, died after receiving 204 mg of a chemotherapy agency instead of the correct dose of 20.4.

An investigation found that the prescribing physician left out the decimal point, and nurses administered the dose without question. So far, the hospital has responded to the charges against it by firing one employee. That's just one of many recent examples of serious medication errors that have prompted national regulatory agencies like the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to take a hard look at adverse event reporting systems and a host of other related issues.

This year alone, high-profile recalls of drugs like fenfluramine, Posicor, and Duract put drug makers in the hot seat. Physicians felt the heat, too, when the U.S. Food and Drug Administration in July found itself defending a decision not to pull the diabetic drug Rezulin off the market. Citing the unique benefits Rezulin provides Type II diabetics, the agency claimed that reports of liver failures associated with the drug had more to do with the failure of physicians to properly monitor patients and heed label warnings than the drug's potential for adverse effects.

Meanwhile, the April approval of Viagra led to record numbers of prescriptions and then questions about the drug's safety, fueling the fire over fast-track approval mandates included in the FDA overhaul bill earlier signed into law. Along the way, the Institute for Healthcare Improvement in Boston hosted a high-profile conference on reducing adverse drug events, and the Center for Health Policy Research at George Washington University Medical Center in Washington, DC, released a study stating that an estimated 1.5 million Americans require hospitalization each year — and 100,000 die — due to "injuries linked with prescription drugs."

The study noted that 51% of approved drugs "have serious adverse effects which are not detected prior to approval." It also pointed out the growing trend of post-market surveillance as the real clinical testing ground, which in turn helped prompt the FDA to increase the resources of its Division of Pharmacovigilance and Epidemiology, charged with compiling adverse reaction reports on recently approved drugs.

The study coincided with editorials in the May 20th *Journal of the American Medical Association* calling for the need for a national drug safety czar.

Across the board, officials involved with medication error and adverse event reporting systems agree that tangible benefits are emerging from all the bad news. In particular, more health care officials are talking about solutions, and more people are reporting problems.

From the FDA's MedWatch program, to programs overseen by the Institute for Safe Medication Practices (ISMP) in Warminster, PA, to JCAHO's sentinel events reporting system, the numbers for 1998 are up. At JCAHO, self-reporting of sentinel events has increased dramatically as the agency continues to revamp certain tenets of the policy. **(See a detailed update, p. 206.)**

Voluntary self-reporting by accredited institutions increased by 60% as the year came to an end, with 89% of the total sentinel events before the agency being self-reported. The figures are encouraging when it's considered that institutions potentially have more to lose by reporting to an accreditation body than to an informational service only. At the same time, the penalties for trying to hide an event that an accrediting body may discover by other means are much harsher.

Overall, of 171 sentinel events reported to JCAHO in 1997, 36 had to do with medication errors. Through July 1998, 257 events were reported, and 47 concerned medication error.

"We are also getting better root cause analyses due to a heightened awareness of the policy and the educational programs we've been doing," says **Darryl Rich**, associate director of JCAHO's Division of Accreditation and Operation. He adds that when root cause analysis forms are submitted to the Joint Commission, "the No. 1 root cause [of a problem] we're seeing is a lack of orientation and training, with No. 2 being communication issues, and those are things that can be improved on."

Also in 1998, JCAHO began publishing a sentinel events newsletter. "The first we did in February was on potassium chloride dangers, and, as a result, we've seen a substantial decrease in the number of sentinel events due to potassium chloride," he says.

The Joint Commission also is pursuing state and federal legislation to decrease the threats of public disclosure on the sentinel event documents sent to its offices. It also has begun to standardize sentinel event policies on medication use for the different types of systems — home care, MCO, or hospital — it accredits. "We're trying to build concepts of sentinel events management into the standards," says Rich, alluding to the systemwide approach to decreasing medication errors that is gaining greater acceptance.

". . . while the message of systems approaches is out there, it's not out there enough. You still get the reaction of, 'Well, I fired the director of pharmacy and solved my problem.'"

But there's much more work to do. "We're definitely in a situation where the confidentiality issue is still a problem, and also on the downside, while the message of systems approaches is out there, it's not out there enough. You still get the reaction of, 'Well, I fired the director of pharmacy and solved my problem.'"

The National Coordinating Council for Medication Error Reporting and Prevention in Rockville, MD, had its most productive year in 1998 by issuing a host of recommendations echoing advances

COMING IN FUTURE MONTHS

- A day in the life of a clinical pharmacist
- Should FDA fast-track be derailed?
- Pharmacy and the Human Genome Project
- National automation white paper
- Collaborative practice update

sought by a lot of different voices. In March, the council issued a series of recommendations urging a systemwide approach to medication errors, internal review protocols, advocated bar code scanning, improved physician prescribing technology, anonymous reporting availability, and a blameless environment.

In July, the council adopted and published recommendations for labeling, packaging, and storage improvements aimed across the board from drug manufacturers to all types of health care institutions. And in September, the council unanimously voted to include the Institute for Safe Medication Practices as a full voting member of the body.

"Certainly in the last two years, the industry has made remarkable progress dealing with errors from the systems perspective and away from the responsibility of the individual. It's done this by looking away from blaming the nurse or the pharmacist and instead asking, 'Why don't we have a system trapping the errors and preventing the errors?'" says **Diane Cousins**, RPh, secretary of the council.

Council pushes for national standards

Also this year, the council has continued to develop standard definitions and categories for medication errors it hopes can be used nationally, and it is recruiting hospitals into its anonymous reporting system.

"What we knew we needed to do was get everyone thinking along the same lines, from the prescribing phase to dispensing, administering, monitoring, and use. A lot of places didn't think a prescribing error was a medication error, they just thought it was the dispensing phase only, so we've brought the physician into the mix, and our definitions also bring the patient into the loop in terms of noncompliance," Cousins says.

But being a nongovernmental, nonregulatory organization, it's within the council's membership that the potential for turning rhetoric into reality lies. "It's the powers of the people, I guess," says Cousins. "The regulating agencies of the [health care] institutions and the manufacturers, the Joint Commission . . . when that kind of group can agree, and they actually come to consensus on the issues, it should be powerful in and of itself, and that level of involvement makes

ISMP issues two special medication error alerts

Lipid-based drugs and albumin targeted

Based on patient deaths and injuries reported nationwide, the Institute for Safe Medication Practices (ISMP) in Warminster, PA, has issued "special alerts" concerning the use of lipid-based drugs and their conventional counterparts, as well as on ongoing albumin dilution errors.

ISMP notes that confusion between the use of three specific lipid-based drugs and their similar, nonlipisomal conventional counterparts has become particularly dangerous because the needed dosages of the two types "differ greatly."

Specifically, problems have been reported concerning pairings of lipid-based forms of amphotericin B (Abelcet, Amphotec, and Ambisome) and conventional amphotericin B for injection (Fungizone, and available generically); the pegylated liposomal form of doxorubicin (Doxil) and counterpart doxorubicin hydrochloride (Adriamycin, Rubex); and between a liposomal form of daunorubicin (DuanoXome, daunorubicin citrate liposomas) and conventional daunorubicin hydrochloride (Cerubidine).

To help overcome the confusion, ISMP recommends that the products not be stored together; that storage should be discouraged in patient care areas and in automated units; that preparation, labeling, and dispensing should come from the pharmacy only; and that brand name usage only be introduced along with in-house educational and warning efforts.

When pharmacies are directed to prepare albumin 5% from available 25% concentrations, too often the dilution has been done with sterile water rather than 0.9% sodium chloride or 5% dextrose, leading to reports of fatal hemolysis or renal failure in patients during large-volume infusions, according medication error reporting.

Because of this, ISMP stresses the development of written guidelines for dilution and the posting of cautions near albumin storage, as well as direct communication with staff members charged with the preparation and administration of albumin solutions.

For more information, contact ISMP at 300 W. Street Road, Warminster, PA 18974. Telephone: (215) 956-9181. ■

National Council Membership

The complete membership of the National Coordinating Council for Medication Error Reporting and Prevention comprises:

- ❑ American Association of Retired Persons
- ❑ American Health Care Association
- ❑ American Hospital Association
- ❑ American Medical Association
- ❑ American Nurses Association
- ❑ American Pharmaceutical Association
- ❑ American Society of Consultant Pharmacists
- ❑ American Society of Health-System Pharmacists
- ❑ American Society for Healthcare Risk Management
- ❑ Generic Pharmaceutical Industry Association
- ❑ Institute for Safe Medication Practices
- ❑ Joint Commission on the Accreditation of Healthcare Organizations
- ❑ National Association of Boards of Pharmacy
- ❑ National Coordinating Council for Medication Error Reporting and Prevention
- ❑ National Council of State Boards of Nursing Inc.
- ❑ Pharmaceutical Research and Manufacturers of America and U.S. Pharmacopeia
- ❑ U.S. Food and Drug Administration

for readily and easily embraceable issues in health care," she says.

The council is represented by a pair of trade organizations for drug makers, along with government, accrediting, pharmacy, and other healthcare advocates.

Looking ahead to 1999, Cousins says the focus has to remain on the workplace environment and even broader types of health care. "One of the clear obstacles is still liability and a willingness to share information despite the fear of litigation," says Cousins.

For more information, contact:

Diane Cousins, *RPh, Secretary, National Coordinating Council for Medication Error Reporting and Prevention, 12601 Twinbrook Pkwy., Rockville, MD 20852. Telephone: (301) 881-0666.*

Darryl Rich, *Associate Director, Division of Accreditation and Operations, Joint Commission for the Accreditation of Healthcare Organizations in Oakbrook Terrace, IL. Telephone: (630) 916-5600.* ■

Automated systems cut medication error risk

Study focuses on cabinet system access

With the push for a systemwide approach to decreasing medication errors, the role of automated distribution cabinets increasingly is being tested. A recent observational study undertaken at a 700-bed tertiary care referral hospital in the Midwest focused solely on the access phase of drug distribution — the actual removal of drugs from the cabinet, The researchers found 13 errors out of 188 transactions for an error rate of 6.9%.

Clinical pharmacists overseeing the study established "incorrect drug, incorrect dose, incorrect dosage form, incorrect frequency, incorrect patient, and access without an active physician's order" as the error categories, as well as error comparison categories based on drawer types and errors occurring in general vs. intensive care units.

Analyzing a Pyxis Medstation offering both single-access (one medication, multiple doses) and multiple-access (different drugs, multiple doses) drawers, researchers found no basic difference in access error rates. Likewise, they found no significant differences between the use of cabinets in the general or intensive care units. In both settings, the hospital's cabinets were used for controlled substances, basic floor stock, intravenous solutions, and sets.

To ensure the resulting data were sound, staff checked cabinet inventories for proper stocking and restocking prior to each hospital shift. They followed up with inventories every two to four hours to guard against crossover discrepancies in cases where, for example, inventory counts may be accurate even though two patients received drugs meant for each other. Study data included patient names, ID, and room numbers; transaction dates and times; the ordered and removed drug; and whether access was from single or multiple drawers or done within general or intensive care units.

The 13 errors found included nine cases (69.2%) based on access without an active physician's order, two cases (15.4%) of incorrect frequencies, one incorrect dose (7.7%), and one incorrect dosage form (7.7%). No errors involved accessing drugs for the wrong patient or at the wrong dose.

After reviewing the results, the study's authors found that drug access without a doctor's order, by far the largest breakdown in the cabinet system, was largely based on the removal of a controlled substance beyond the automatic stop-order date.

As a solution to this type of problem, the authors note that "upgraded software that creates a link to the hospital pharmacy computer system is available for use with many automated storage and distribution cabinets. This link ensures access to a medication for a particular patient only if a physician's order for the medication is processed by the pharmacy and entered into the system. Our results suggest that this kind of linkage software may be an important component of an automated storage and distribution system and could have a substantial impact on access discrepancies."

The authors argue that besides software, everything from the physical layout of a cabinet system, the use of a mousepad, touchscreen, or keyboard, and the use of single- or multiple-access drawers can make a difference.

Most important, however, is how an institution handles what the authors call formulary convention: whether medications are listed by brand or generic names, whether cross-referencing is used, how drug names are put into the system and then accessed, and whether similar drugs are stored in different drawers. Researchers praised hospital officials for separating drugs with similar-sounding names and those that simply look alike.

For more details or a reprint of the study, contact: David Mott, PhD, Assistant Professor of Social and Administrative Pharmacy, University of Wisconsin School of Pharmacy, 425 N. Charter St., Madison WI 53706. Telephone: (608) 262-1416. ■

State boards address errors

While national organizations are setting the priorities and tone of medication error oversight, state pharmacy boards and associations are at work at the community pharmacy level. Initiatives in North Carolina, Tennessee, and California are focusing on the relationship between workload and medication errors, includng newly adopted regulations and others being considered.

In North Carolina, a regulation has been adopted to hold employers equally liable in medication error cases at times when a pharmacist's daily prescription workload exceeds 150. The state board also is weighing a proposal to prohibit pharmacists from working more than 12 continuous hours in one day and to require 15- and 30-minute breaks every six hours. North Carolina officials also are looking at regulations to hold pharmacist-managers responsible for "all documents, labels, vials, supplies, substances, and internal investigative reports relating to the event" that would be turned over to the state board during an investigation.

In Tennessee, a regulation adopted this year designates a pharmacist-in-charge who must report to the state board "any situation in which a medical or prescription order has caused serious personal injury or death."

The California Pharmacists Association is conducting a tracking and reporting study aimed at compiling adverse reaction data while trying to determine whether the effects of pharmacist workloads and the use of technicians play a definitive role in medication errors.

For more on state initiatives, contact the National Association of Boards of Pharmacy at (847) 698-6227. ■

HCFA writes SCRIPT for elderly medication use

HCFA medication initiative a 2-year effort

Begun late this year and still in its earliest stages, a two-year project aimed at developing national measures to improve medication use standards and decrease errors has been funded and launched by the Baltimore-based Health Care Financing Administration (HCFA).

The Study of Clinically Relevant Indicators for Pharmacologic Therapy (SCRIPT), will focus on medication use for ambulatory patients over 65. It will be conducted by a multidisciplinary steering committee chaired by the Joint Commission on Accreditation of Healthcare Organizations under a HCFA contract. Members include the American Pharmaceutical Association, American Medical Association, Agency for Health Care Policy and Research, American Association of Health Plans, American Health Quality Association, National Committee for Quality Assurance, and individuals

from the Harvard School of Medicine and University of Iowa.

Another coalition also will be tapped for input. That group includes the American College of Clinical Pharmacy, Association of Managed Care Pharmacists, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and Pharmaceutical Care Management Association. This group will provide methods for developing medication use indicators and quality criteria, a compendium of existing evidence-based measures of medication use and error reduction, and core performance measures.

From there, the science of indicator selection and initial screening of indicators will begin, followed by data collection, beta testing, and outside comment. The steering committee hopes to have published materials on the program early in 2000.

For more on SCRIPT, contact HCFA at (202) 690-6726 or JCAHO at (630) 916-5600. ■

JCAHO sentinel events policy revamped again

For the third time this year, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in Oakbrook Terrace, IL, has changed its sentinel events policy. Adopted in September, the latest change extends from 30 to 45 days the time allowed an institution to submit a root cause analysis after a sentinel event occurs. The Joint Commission defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."

In July, JCAHO began offering on-site review of written root cause analyses, and it has instituted provisions for "direct assessment of root cause analysis information without explicit review of the underlying document." Those changes respond to concerns about the possibility of outside liability based on root cause documents being submitted to the Joint Commission, as well as Accreditation Watch provisions that could allow parts of the documents to be made public.

Those changes follow more comprehensive ones that took effect in April. The earlier provisions made sentinel event reporting voluntary but added harsher penalties if an event occurs and is not reported. If an event is not reported and the Joint Commission learns of it elsewhere, the institution could face immediate Accreditation Watch status and potential public disclosure. But if self-reporting occurs within five days of an event, the institution is given 45 days to construct a root cause analysis and seek on-site review. Refusal to permit review of a response to a reported sentinel event can also result in Accreditation Watch status.

For more on the policy, contact JCAHO at (630) 916-5600. Also, see Drug Utilization Review, *March 1998, for a policy overview and a pullout worksheet used by JCAHO as a sentinel events response document.* ■

Tracking resistance to *Steptococcus pneumoniae*

The following statement was given by Clyde Thornsberry, PhD, professor in the department of pathology at Vanderbilt University School of Medicine in Nashville and principal investigator of "Tracking Resistance in the U.S. Today." He spoke at the 38th Interscience Conference on Antimicrobial Agents and Chemotherapy on Sept. 25, 1998, in San Diego.

Pneumococcal resistance to several antimicrobial agents can develop rapidly. Therefore, the ability to monitor the activity of newly released agents is important. Since the release of levofloxacin (LEVO) in January 1997, we have systematically tracked pneumococcal susceptibility to levofloxacin and seven other antimicrobials against common respiratory pathogens.

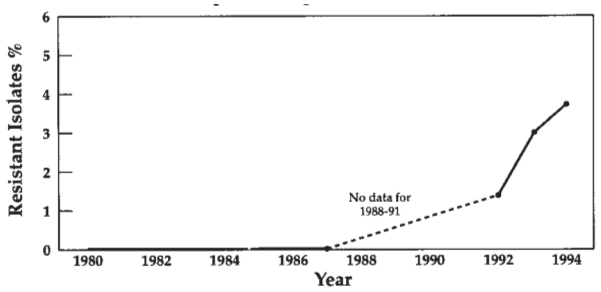
In 1997-1998, penicillin (PEN) nonsusceptibility (MIC > 0.125 ug / ml) in 3,340 strains of *Streptococcus pneumoniae* (SP) was 36% [22% intermediate (I), 14% resistant (R)] compared to 34% nonsusceptible (20% I, 14% R) in 1996-1997. **(See charts, p. 215.)**

Clarithromycin resistance increased from 18% to 23% in SP. In 1997-98 blood isolates, 29% of SP was not susceptible to PEN (19% I, 10% R) compared with 39.8% (24% I, 15.5% R) in respiratory isolates.

For PEN-resistant SP (MIC > 2 ug / ml), nonsusceptibility (I+R) for other antimicrobials was 93% for amoxicillin-clavulantate (AC), 80% for ceftriaxone (CTX), 98% for cefuroxime (CUX), 71% for

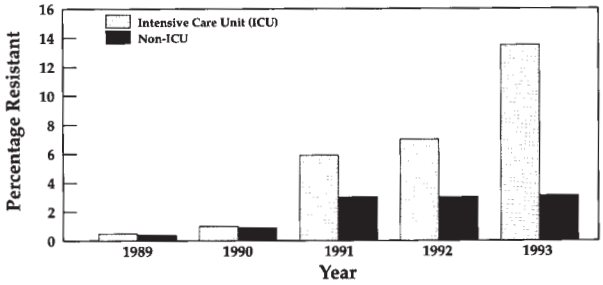
(Continued on page 215)

Rate of High-Level Penicillin Resistance among 6,721 Invasive Isolates of *Streptococcus pneumoniae*, U.S., 1980-1994



Data from this CDC surveillance system were not reported from 1988-1991. (From Butler JC, Hofmann J, Cetron MS, et al. The continued emergence of drug-resistant *Streptococcus pneumoniae* in the United States: an update from the CDC Sentinel Surveillance System. *J Infect Dis* 1996; 174:986-993.) *Source of both charts:* Ortho-McNeil Pharmaceutical, Raritan, NJ.

Resistance to the Antibiotic Vancomycin in Enterococcal Infections* in U.S. Hospitals



*Enterococcal infections affect the intestines and can be life-threatening, primarily for the very old and sick.

(Continued from page 206)

azithromycin (AZ) and clarithromycin (CLAR), and 93% for trimethoprim-sulfamethoxazole (SXT); all SP were susceptible to vancomycin (VAN) and LEVO. For AC, CUX, VAN, and LEVO, these rates among PEN-resistant isolates were comparable to those in 1996-1997, and there was an increase in CLAR resistance (10%) and CTX resistance (7%). AZ and SXT were not tested in 1996-1997.

Resistance in the other respiratory organisms, *Heomophilus influenzae* (HI) and *Moraxella catarrhalis* (MC) has remained relatively constant between the 1996-1997 and 1997-98 studies. Both organisms are 100% susceptible to LEVO, CTX, and CUX, and the percentage of organisms producing beta-lactamase is comparable to the 1996-1997 study (33.2% vs. 33.4% for HI and 91% vs. 93% for MC). While pneumococcal resistance to many antimicrobials continues to increase, LEVO and VAN have maintained a high activity level. ■

Antibiotics Update

Resistance tracking upward in latest study

1998 tracking figures highlight conference

Resistance of *Streptococcus pneumoniae* has either increased or held steady against a host of commonly prescribed antibiotics, according to an in vitro resistance tracking study presented at the 38th Interscience Conference on Antimicrobial Agents and Chemotherapy held in late September in San Diego.

The national tracking study compared 1996-1997 data to 1997-1998 data at 161 U.S. hospitals involved 6,625 total samples, including more than 4,000 samples of *S. pneumoniae.*

The study monitored the resistance of *S. pneumoniae, Haemophilus influenzae,* and *Moraxella catarrhalis* against penicillin, amoxicillin-clavulanic acid, ceftriaxone, vancomycin, cefuroxime, clarithromycin, and levofloxacin. Of the drugs studied, levofloxacin and vancomycin fared well, while *S. pneumoniae* resistance to macrolides increased the most, and resistance to penicillin remained constant.

But remaining constant was not seen as good news. "These data not only highlight our continuing dilemma with resistance to penicillin, but they raise concerns about trends we are now beginning to see with other classes of widely used drugs," says **Clyde Thornberry**, PhD, a professor in the department of pathology at Vanderbilt University in Nashville, TN. Thornberry was the lead investigator in the study, which was partly funded by Ortho-McNeil. **(See his overview statement to the conference, p. 206.)**

Thornberry's comments, and the conference, end a particularly anxious year over issues of antibiotic resistance and drug development, heightened this summer by deadly cases of vancomycin-resistant *Staphylococcus aureus.* Agencies such as the Centers for Disease Control and Prevention in Atlanta quickly responded with usage guidelines, while hospitals raced to evaluate their formulary protocols. Newly approved antibiotics such as Synercid and Trovan helped assuage some of the resistance fears, but an even more deadly outbreak of a virulent Group A streptococcus killed two

In-vitro Activity of Linezolid against Vancomycin-Resistant Enterococci, Methicillin-Resistant *Staphylococcus Aureus*, and Penicillin-Resistant Pneumococci

		Linezolid				Vancomycin	
Organisms	No.	MIC_{90}	MIC Range	MIC_{90}	MIC Range	MIC_{90}	MIC Range
*van*A VRE	11	2	1-4	>8	>8	>128	>128
*van*B VRE	11	4	0.5-4	>8	>8	>128	64->128
*van*C1 VRE	7	2	2-4	>8	>8	8	8-16
*van*C2/3 VRE	8	4	2-4	>8	>8	8	4-8
MRSA	26	8	2-8	>8	4 - >8	2.0	0.5-2
PRSp	21	1	≤0.125-2	>128	≤0.125-128	0.5	0.25-0.5

MIC_{90} or MBC_{90} are the values of 90% of the isolates tested.

Source: Pharmacia & Upjohn, Kalamazoo, MI.

dozen people in Texas, keeping the issue on the front pages of health care and commercial publications. **(*Drug Utilization Review* was no exception; see related cover story packages in the May and July 1998 issues.)**

The conference also included discussions concerning the fears of cross-resistance, especially with regard to vancomycin. For example, concerns are increasing that genes conferring vancomycin resistance, found in vancomycin-resistant enterococci, may be transferable to methicillin-resistant *S. aureus,* creating a more virulent and untreatable bacteria.

Thornberry's tracking study did find that *S. pneumoniae* strains with strong penicillin resistance also were resistant to other penicillins, cephalosporins, and macrolides, but no associated resistance was found to vancomycin or levofloxacin.

The tracking study also found:

❑ *S. pneumoniae* resistance, after doubling in recent years, remained constant at 14% in 1997-1998 compared to the previous year.

❑ The largest jump found was *S. pneumoniae* resistance to the macrolide clarythromycin, which increased from 18% in 1996-1997 to 22% in 1997-1998.

❑ *S. pneumoniae* resistance to the fluoroquinalone levofloxacin did not increase. The drug also was active against all isolates of *Haemophilus influenzae* and *Moraxella catarrhalis.*

❑ *H. influenzae* and *M. catarrhalis* strains, though, did produce the enzyme B-lactamase, which could make penicillins ineffective. Specifically 33% of *H. influenzae* strains and 92% of *M. catarrhalis* strains produced B-lactamase.

Oxazolidine, a new class of antibiotic aimed at inhibiting protein synthesis of gram-positive bacteria earlier than other antimicrobials, debuted at the Interscience Conference on Antimicrobial Agents and Chemotherapy. Linezolid, from Pharmacia & Upjohn in Bridgewater, NJ, is the first drug in this class to be tested in Phase III clinical trials.

Researchers hope that oxazolidine-class drugs will preventing bacterial reproduction at an earlier phase, thereby avoiding cross-resistance between the drug and other antibiotics.

Pharmacia & Upjohn has oral and IV formulations in development, aimed at treating gram-positive infections and vancomycin-resistant enterococci (VRE), methicillin-resistant *S. aureus* (MRSA), and penicillin-resistant *Streptococcus pneumoniae* (PRSP). In a preclinical study by the company and the Mayo Clinic in Rochester, MN, susceptibility tests were done of resistant bacterial isolates to Linezolid and vancomycin. The testing was possible because of gene amplification techniques developed at the clinic, which allow researchers to sensitively detect vancomycin-resistance-associated genes, then identify isolates of VRE and group them by genetic differences.

Clinicians established minimum inhibitory concentrations (MIC) and minimum bacterial concentrations (MBC) of linezolid and vancomycin as a collection of resistant bacterial isolates, with the MIC being the lowest concentration of antimicrobial agent that inhibits the growth of an organism, while the MBC is the lowest concentration that kills the bacteria. An

MIC value of four µg/ml or less of vancomycin was interpreted as sensitive or susceptible. A similar value for linezolid has not been determined. **(See chart, p. 216, for the breakdown of the susceptibility of resistant bacterial isolates to linezolid and vancomycin.)**

Also at the conference, early efforts to develop a vaccine and antibody process against vancomycin-resistant strains of *S. aureus* were presented by the biopharmaceutical firm Nabi in Boca Raton, FL.

In a paper titled, "In Vivo & In Vitro Evaluation of Previously Isolated Vancomycin Intermediate Strains of *Staphylococcus aureus,*" researchers explained how, through in vitro assays, antibodies killed *S. aureus* strains showing a reduced sensitivity to vancomycin and offer protection to animals carrying resistant bacteria. The company's experimental vaccine, StaphVAX, is in Phase III trials for hemodialysis patients, while its preventive antibody, Altastaph, is in Phase I/II trials for low birth weight babies.

The rush to attack vancomycin-intermediate resistant *S. aureus* (VISA) was heightened this summer when a hemodialysis outpatient died after developing the resistant strain. That followed two other U.S. cases this year. In all the cases, the patients were either on hemodialysis or peritoneal dialysis or were experiencing some form of renal failure. **(For details, see *DUR*, July 1998, p. 109.)** Vancomycin became the drug of choice against *S. aureus* after infectious strains became resistant to methicillin.

The American College of Gastroenterology (ACG) in Arlington, VA, is recommending the use of oral metronidazole over that of vancomycin for the common treatment of Clostridium difficle-associated disease (CDAD) to help reduce the risk of vancomycin resistance. That position has been endorsed by the American Society of Health-System Pharmacists in a therapeutic position paper aided by the Centers for Disease Control and Prevention and the Society of Infectious Disease Pharmacists. The organizations say vancomycin should be considered only for life-threatening cases or in cases where patients have failed to respond to metronidazole, as both drugs are equally effective in treating the majority of CDAD cases. According to the ACG, many cases of mild CDAD can be treated by simply taking the patient off a given antibiotic that may have sparked the condition, followed by fluid and electrolyte treatment.

Largely a hospital- or nursing home-born condition, CDAD is a gastrointestinal bacterial infection resulting from bacteria pooling in the colon, creating toxins that lead to mild to serious diarrhea. ■

For more information, contact:

- **Pharmacia & Upjohn**, 95 Corporate Dr., Bridgewater, NJ 08807. Telephone: (908) 306-4400.
- **Nabi Inc.**, Baco Raton, FL. Telephone: (561) 989-5815.
- **The American Society of Health-System Pharmacists**, 7272 Wisconsin Ave., Bethesda, MD 20814. Telephone: (301) 657-3000, ext. 1203.

A counseling training session at work

Study targets skills, confidence levels

Lee, A.J., et al. **Staff development in pharmacist-conducted patient education and counseling.** *Am J Health-Syst Pharm* 1998; 55:1792-8.

A new study conducted at the Veterans Affairs Medical Center of San Francisco has found that counseling training programs are necessary for pharmacists to gain the competence and confidence they need to effectively counsel patients.

The study complements the findings of a recent survey of pharmacists in Ohio covered in the September 1998 issue of *Drug Utilization Review* **(see p. 159 in that issue)**. In that study, surveyors found that while the vast majority of respondents want to counsel patients, most simply don't.

Specifically, 67% of the Ohio pharmacists said they counsel no patients, 21% said they counsel one to two patients per day, just 5% counseling three to four patients daily, and 2% counseled more than six per day.

Most respondents said a lack of time/workload, lack of private setting or hospital support, and even patient attitudes were the main barriers to effective counseling. But while most Ohio pharmacists did not cite the lack of a counseling

Medications Covered in Role-Playing Sessions

- ❑ **Atrial fibrillation:** digoxin, warfarin
- ❑ **Liver disease: ascites:** furosemide
- ❑ **Psoriasis:** fluocinonide ointment
- ❑ **Glaucoma, depression:** Timolol, nortriptyline
- ❑ **Coronary artery disease:** isosorbide dinitrate
- ❑ **Infection, hypercholesterolemia:** ciprofloxacin, pravastatin
- ❑ **Chronic obstructive pulmonary disease:** albuterol metered-dose inhaler with a spacer, triamcinolone metered-dose inhaler

Role-Playing Session Reference Guides

- ❑ **Sampling of medications included:** cimetidine, diltiazm, fluoxetine, glipizide, ibuprofen, metoprolol, nortriptyline, omeprazole, phenytoin, prazosin, warfarin
- ❑ **Sampling of disease states included:** angina, asthma, benign prostatic hyperplasia, CHF, gastric or duodenal ulcers, glaucoma, gout, hypertension, ostroarthritis, reflux esophagitis, types I and II diabetes

training program as a major barrier, the San Francisco study found that without such a program, the competence and confidence needed to effectively counsel patients was lacking. This was despite the assumption that "pharmacists are expected to provide individualized patient consultations in a variety of pharmacist-managed clinics, in decentralized outpatient pharmacy modules, and at the time of discharge."

The VA's pharmacy staff development committee reacted by launching a counseling training program detailed by the authors.

The program began with the formation of a planning subcommittee within pharmacy, staffed by inpatient and outpatient pharmacy supervisors, the VA's education and quality-improvement coordinator, a regional pharmacy coordinator from the University of the Pacific in Stockton, CA, an outside pharmacoeconomics specialist, and a pharmacy practice resident.

As part of the training sessions, the group established seven patient cases based on VA files for role-playing techniques. These consisted of the patient's list of problems, a simulated medication profile, and a group of prescriptions to be filled. Included in the role-playing were cases that "involved patients with communication barriers such as visual or auditory demonstrating the use of an inhaler and spacer to a hypothetical patient with asthma."

Pharmacists were required to rotate as either a patient or pharmacist, followed by counseling two real patients while being observed by a facilitator.

Another major part of the program required pharmacists to pass with a score of 90% or higher an open-book, written exam of 50 multiple choice questions concerning use indications, adverse effects, interactions, administration, precautions, storage, and compliance.

To assist pharmacists when the real counseling began, manuals were compiled as references covering 70 individual drugs commonly used at the center, along with 32 common disease states. Pharmacists carried the manuals during the training programs, along with handouts describing proper techniques for oral and nasal inhalers, spacers, and ophthalmic agents.

As the training programs were conducted, pharmacy officials established standard counseling policies on identifying what types of patients would receive mandatory counseling. Policies also dictated that documentation of counseling sessions must be put into the center's computer system.

And in another major step, the VA created the position of the discharge counseling pharmacist (DCP), who is "responsible for counseling patients who are not being monitored by one of the ward pharmacists," note the authors. The DCP position is filled by all inpatient pharmacists on a rotating basis, with the DCP available weekdays, 7:30 a.m. to 3:30 p.m. For ambulatory care, pharmacists were made available in decentralized private counseling rooms.

The authors also note that about 100 hours were needed to "plan the program, develop the cases and the examination, and reproduce the references." It took another five hours for pharmacists to complete the program (minus the time it took to complete the written exam).

Pharmacists were queried before and after the program about their experience and confidence levels concerning patient counseling. Predictably, the latter increased after completion.

For more details or reprints, contact Audrey Lee, PharmD, BCPS, Veterans Affairs Medical Center, 4150 Clement St., San Francisco, CA 94121. ■

NEWS BRIEFS

HIV gene therapy tests broadening

Cell Genesys Inc. in Foster City, CA, has begun a second Phase II trial of AIDS gene therapy aimed at a different patient population. Already studying the effects of gene therapy on patients failing antiviral drug therapy, the company is focusing its new enrollments on patients who have been treated successfully with drugs and have undetectable HIV levels in their blood.

But based on science presented at the 12th World AIDS Conference **(see *Drug Utilization Review*, September 1998, p. 161)**, reservoirs of HIV-infected cells are remaining in patients with even undetectable viral loads in their blood. These patients are responding well to, and remaining stable on, drug therapy, but it's been unable to completely wipe the virus from their systems.

10 patients enrolled in test

Believing this patient population may be more likely to respond to cell gene therapy than those failing drug therapy, the company has enrolled 10 patients for gene therapy. It involves removing CD4 and CD8 T-cells from the patient, genetically modifying them to seek and destroy HIV-infected cells, expanding their numbers, and then returning them to the patient. These patients will be compared with patients being infused with unmodified cells.

From its original trials of failing patients, the company reported to the 38th Interscience Conference on Antimicrobial Agents and Chemotherapy this fall that decreasing levels of HIV were found in gastrointestinal lymphoid tissues, thought to be a primary reservoir for HIV-infected cells. Overall, a 0.5 or better log decrease in viral load was found in 10% of the study group, while CD4 counts increased in the majority of patients.

For more information, contact Cell Genesys at (650) 425-4542. ▼

Certification numbers increase, board says

This fall's round of certification testing by the Board of Pharmaceutical Specialties (BPS) in Washington, DC, attracted 675 applicants, a record number of pharmacists seeking to enhance their skills, according to the board.

The largest areas of interest were pharmacotherapy, with 323 applicants, followed by the board's newest option, oncology pharmacy, with 218. Oncology pharmacy as a certification test was added in 1996. Among the other certifications sought were 51 for psychiatric pharmacy, 44 for nuclear pharmacy, and 39 for nutrition support.

Along with new certification testing, the board reports that 192 pharmacists also applied for recertification this fall, 114 in pharmacotherapy, 64 in nuclear pharmacy, and 14 in nutrition support. All told, BPS says it has certified 2,500 pharmacists since 1978.

For additional information, contact BPS at 2215 Constitution Ave., Washington, D.C. 20037. Telephone: (202) 429-7591. ▼

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Editorial Questions

For questions or comments, call **Greg Fulton** at (404) 262-9609.

Drug makers begin to settle price-fixing suit

Four of eight pharmaceutical companies have offered to settle a class action lawsuit brought by community pharmacists in 1993 that accused drug makers of price fixing by offering managed care organizations better discounts than those offered to chain drug stores. The suit alleged the discounts were not allowing community pharmacists to compete and therefore were forcing them out of business. So far, Hoechst Marion Roussel has agreed to pay $149 million, Pharmacia & Upjohn $102.5 million, Abbot Labs $57 million, and Rhone-Poulenc Rorer $34 million as a settlement offer being negotiated among attorneys. Still to come is whether Forest Labs, Johnson & Johnson, Novartis, and Searle will join a settlement or go to court. Several wholesalers also are named as dependents in the suit, which alleges collusion between them and the drug makers. ▼

Pharmacist collaboration ImPACTs new study

The American Pharmaceutical Association (AphA) in Washington, DC, is reporting good results from Project ImPACT (Improve Persistence and Compliance with Therapy), a hyperlipidemia effort stressing collaborative practice between physicians, pharmacists, and patients.

After the first 14 months of the study, begun in 1996, APhA reports 84% medication compliance overall, while 44% of patients have maintained national cholesterol level goals. The study involves 29 participating pharmacies nationwide, divided into clinic, home care, HMO, chain, and independent settings, with each pharmacy enrolling 30 patients who have been newly diagnosed with dyslipidemia or are poorly controlled.

Ongoing pharmacist input involves testing, monitoring, and counseling patients in one on-site visit. Patients visit the pharmacist regularly for a finger stick, results analysis, and appropriate counseling. APhA notes that pharmacists can help lower lipid levels directly and decrease incidents of heart attack. It also reports that managed care organizations have begun contracting with some of the study's sites as partof its plan's benefits.

For details, contact APhA at (202) 429-7537. ▼

Pharmacists left out of HCFA reimbursement

Despite lobbying efforts from national pharmacy organizations, it's likely that pharmacists will not be included in a payment plan by the Health Care Financing Administration (HCFA) that reimburses other caregivers for training Medicare recipients to self-manage diabetes care.

HCFA began the new benefit this summer and listed physicians, nurse practitioners, physician assistants, clinical nurse specialists, nurse-midwives, clinical psychologists, and clinical social workers meeting National Diabetes Advisory Board standards as health care practitioners eligible to receive payments. Industry groups have proposed the pharmacists certified as diabetes educators or carrying 16 or more hours of continuing education in the subject should be included.

HCFA says eligibility for the program could expand to include pharmacists, but no expansion can be made until 1999 under its guidelines.

For more details, call AphA at (800) 237-2742. ■