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Feds may put regulatory 'teeth' into national antibiotic resistance plan

ICPs could play key roles in sweeping plan to stem tide of drug resistance

In a move that could empower infection control programs and expand ICP responsibilities, a host of federal agencies is developing a public health action plan that may make combating antibiotic resistance a national priority backed up by regulatory mandates, *Hospital Infection Control* has learned.

The sweeping scope of the effort — with no fewer than 10 agencies involved, and discussions including everything from curtailing antibiotic use in agriculture to preserving vancomycin efficacy against nosocomial infections — underscores the mounting concern about an expanding array of drug-resistant pathogens. ICPs, who have been on the front lines of ongoing efforts to track and prevent drug-resistant infections, are well-positioned to play important roles in any resulting federal action plan, says **Fran Slater**, RN, MBA, CIC, CPHQ, manager of infection prevention and control at Methodist Hospital in Houston, and one of 70 expert consultants invited to a recent meeting with federal public health officials in Atlanta to discuss the project.

"If there is an organized process mandated by the federal government in some fashion, then it will certainly be up to the infection control professional to make sure that process flows smoothly," she tells *HIC*. "I look forward to the development of federal mandates regarding this, and not only impacting health care facilities, but also the [agricultural] sources. The time has come to do something more aggressive."

Indeed, while the emergence of glycopeptide (vancomycin) intermediate-resistant *Staphylococcus aureus* (GISA) has been the most ominous development, antibiotic resistance is developing across a broad range of bug-drug combinations.[1-3] **(See related story, p. 117.)** Canadian investigators recently reported increasing fluoroquinolone resistance in *Streptococcus pneumoniae*, a pathogen that already has established penicillin-resistant strains and is currently the most common cause of community-acquired pneumonia in the United States.[4]

"[GISA] was one of the more alarming events that has occurred in

recent years, but there has really been a pattern of virtually all important human pathogens becoming resistant to the drugs of choice to treat them," says **David Bell**, MD, a co-chair of the federal task force developing the plan and one of the principals in efforts to combat antibiotic resistance at the Centers for Disease Control and Prevention's center for infectious diseases.

Effort goes beyond warnings, guidelines

While a wide variety of federal agencies are involved in the effort — from the Department of Defense to the Health Care Financing Administration (HCFA) — the recently formed antibiotic resistance task force is spearheaded by three key agencies: the CDC, the National Institutes of Health, and the Food and Drug Administration. Public health officials are quick to point out that the effort is at a very preliminary stage, but it was clear from an ambitious array of "action options" put on the table for discussion at a July 19-21, 1999, meeting with federal officials and expert consultants in Atlanta that the effort will go well beyond the repeated warnings and guidelines that have been issued in recent years. **(See options, p. 115.)**

"The whole underlying concept here is that now it is time for an action plan," Bell says. "There have been a lot of blue ribbon commissions who have done excellent work: the Institute of Medicine, the ASM [American Society for Microbiology]. They've analyzed the problem, recommended directions forward, and now the question is, what are the federal agencies actually going to do? That is what we are trying to come up with now."

At the meeting, public health officials and invited consultants broke into work groups to brainstorm about options for action in four key areas of antibiotic resistance: surveillance, research, product development, and prevention and control. The work groups developed lists of options — without attempting to achieve consensus or establish priorities — and then the whole group ranked the importance of the options on evaluation forms that were given to task force members at the end of the meeting. The task force will use the evaluations to assist in the development of a blueprint for the activities of federal agencies to combat antimicrobial resistance.

"This is a multifaceted problem that needs to be confronted on several fronts," Bell tells *HIC*. "Right now we are sorting through the ideas. Down the road, there will probably be some effort to prioritize and assign tentative time frames to get some of the things done. We need to develop a draft of a plan and then we get additional public comments back. That will happen in coming months."

While the research group considered such issues as the need for affordable diagnostic tests that could rapidly discern between bacterial and viral infection, the surveillance group pondered whether a national surveillance system for antimicrobial resistance should be a uniform data collection system or a group of coordinated components. The majority of possible actions, however, fell under the prevention and control work group, which was co-chaired by **Julie Gerberding**, MD, MPH, director of the CDC hospital infections program. The work group listed several options in the area of health communications that address "the concept of really making antimicrobial resistance a national health priority, and using social marketing and other public health campaign approaches to promote judicious antimicrobial use," Gerberding said at the meeting. That effort could include the Surgeon General issuing a high-profile national report to underscore to the public the problem of antibiotic resistance.

Assessing potential impact on ICPs

Though it remains to be seen what measures will actually be proposed in the draft plan, the options under discussion at the meeting included several that could impact ICPs. Those include upgrading and expanding surveillance programs for resistant organisms; monitoring use of vancomycin and other important drugs; and strengthening requirements for infection control programs and training in health care settings.

Concerning the latter, one option listed calls for the task force to "mandate" that all health care facilities and systems that receive federal funds "maintain infection surveillance, prevention and control programs consistent with standards / requirements" outlined by federal agencies, the Joint Commission on Accreditation of Healthcare Organizations, and the professional infection control associations. Such requirements could certainly bolster the perceived importance of infection control programs, but they beg the question of whether ICPs can expect any additional resources to comply with any new program responsibilities.

"Certainly, if you are going to have an effective surveillance program in place for these particular

(Continued on page 116)

Task force weighs options for national antibiotic plan

[Editor's note: The following possible options for federal action to combat antibiotic resistance were among those compiled by a work group on prevention and control at a recent meeting of public health officials and expert consultants in Atlanta. A task force of federal agencies will determine which of the options will be included in an action plan, which is expected to be published in draft form and submitted for public comment in the coming months. Although the process did not formally establish priorities among the options, the word "NOW" — used below in connection with vancomycin use — is reprinted here in upper-case letters, as it appeared in the materials distributed at the meeting.]

Health communications: Appropriate/allocate resources to implement a comprehensive social marketing/education strategy targeting consumers, patients, educators, industry, policy makers, etc. to promote judicious antimicrobial use and reduce antimicrobial resistance as a national health priority. Options include:

• Prepare and disseminate a Surgeon General's report on antimicrobial resistance and judicious antimicrobial use.

• Conduct a public health campaign to promote hand hygiene as a critical public health intervention for preventing antimicrobial resistance.

• Initiate school-based programs for children that promote behaviors to prevent infections/antimicrobial resistance.

• Create a clearinghouse of information materials (printed documents, CD-ROM presentations, Internet-based information, etc.) that target prevention of antimicrobial resistance and judicious antimicrobial use and disseminate to target populations.

Transmission issues: Evaluate the efficacy, effectiveness, and cost-effectiveness of infection control strategies in health care facilities and systems.

• Evaluate strategies to improve adherence to infection control practices that work.

• Identify patient/population characteristics, facility characteristics, and other factors that promote transmission of antimicrobial-resistant pathogens in health care and community settings.

Guidelines: Fund collaborations with professional societies and other stakeholders to promote development, implementation, monitoring, and evaluation of evidence-based clinical guidelines addressing:

• Judicious antimicrobial use for infection in humans and non-humans.

• Appropriate use of diagnostic cultures and susceptibility testing.

• Self-care/symptomatic treatment for common viral infections.

• Appropriate use of and access to diagnostic tests for infectious diseases across the entire spectrum of health care delivery sites.

• Performance and interpretation of antimicrobial susceptibility tests relevant to age-specific human infections and age/species-specific animal infections.

• Appropriate in-office tests for infections/antimicrobial resistance for humans/animals.

• Infection control surveillance and prevention guidelines to encompass a) the entire spectrum of health care delivery sites including long-term care and home care; b) community-based sites including daycare.

• Guidelines for surgical prophylaxis in high-risk patients/populations.

• Fluoroquinolone use in children.

Regulatory/policy actions: Review new and existing federal regulations relevant to antimicrobial resistance to ensure consistency across agencies. Mandate that all health care facilities and systems that receive federal funds:

• maintain infection surveillance, prevention, and control programs consistent with standards/requirements articulated by federal agencies, JCAHO/NCQA, and relevant professional societies (APIC/SHEA) and monitor impact on infection incidence, antimicrobial use, and resistance prevalence.

• vaccinate eligible patients with *S. pneumoniae* and influenza vaccine.

• require and document completion of annual infection control training that emphasizes strategies to control antimicrobial-resistant pathogens for all licensed health care personnel.

• consistent with existing HCFA QIP mechanisms, monitor diagnosis-specific antimicrobial use in defined populations using an appropriate stratified sampling frame and standard report format; provide feedback and comparison to locally relevant benchmarks.

• monitor vancomycin use NOW.

In addition, encourage accrediting agencies to include standards that promote judicious antimicrobial use and infection prevention and control. Provide states with incentives to require and document completion of annual infection control training that emphasizes strategies to control antimicrobial-resistant pathogens for all licensed health care personnel.

HCFA should provide adequate reimbursement to ensure appropriate use of:

• diagnostic clinical microbiology laboratory tests.

• home health care for antimicrobial infusions other than vancomycin NOW.

organisms, you need to have the resources to support it," Slater tells *HIC*. "We spoke to the fact that this needed to be in place at all levels of the health care system, not only in acute care, but long-term care, home care, and all sectors. The other thing that we talked about was tying it to accreditation, to licensing, to the NCQA [National Council of Quality Assurance] as far as managed care contracts and so forth. That's the only way you would be able to put some teeth into it. Otherwise, it would just be 'paper' compliance."

Infection control can't do it alone

For example, Joint Commission accreditation interpretation language could emphasize the importance of providing adequate resources for antibiotic resistance efforts, Slater says. Still, while ICPs may play vital roles in any national effort, the solutions to such a multifaceted problem lie beyond the bailiwick of infection control programs, reminds **Patti Grant**, RN, MS, CIC, director of infection control at RHD Memorial Medical Center and Trinity Medical Center, both in Dallas.

"Antimicrobial resistance is a thread that runs through everything we do," says Grant, who reviewed some of the federal options under discussion for *HIC*. "But this has to be 'institution-owned.' ICPs [alone] cannot control the transmission or the mutation of multiple-resistant organisms. We are a very important player, but we are not the end." While conceding the problem certainly warrants national action and a coordinated effort by public health officials, Grant was leery of attempts to regulate the use of antibiotics in medicine.

"I'm not saying [regulation] shouldn't be done, but it will be very hard to implement," she says. "What you are dealing with here are patient care treatment practices by individual physicians. Imagine passing a federal law that is written into a HCFA rule that says you can only give vancomycin for [certain situations]. We have to be cautious not to cross that line. But we have to get really close to that line if we are going to effect change and stop these mutations [of resistant organisms]. This is definitely needed on a national level. But how invasive do we want this to be? I think education is the key vs. regulation."

An important avenue for addressing the problem in the hospital setting may be pharmacy and therapeutics committees, which typically have the most physician representation and access to drug utilization data, she notes. "As far as monitoring vancomycin use, that would be overwhelming to me as an ICP to try and incorporate that into my infection control program," Grant says. "What would be better for infection control, which would still involve a lot of empowerment, would be to make sure that we are on the quality management and 'P and T' committees as active, consulting members."

Regardless, there was no attempt at this stage of the process to clarify which federal agencies would enforce any mandates, though the FDA and HCFA appeared to be the most likely candidates to give the plan regulatory teeth and/or monetary incentives to comply. Moreover, the task force could develop an action plan outlining a coordinated federal response without recommending regulatory enforcement, Bell says.

"You can have plenty of actions that facilitate or encourage voluntary measures," he says. "There may be some items that involve regulatory actions and there may be some that involve other ways to improve [antibiotic] use that are not regulatory."

New regulations or not?

Beyond that, there remains some question of whether the effort could be enforced with current regulations or whether new rules would have to be approved. For example, **Sandy Kweder**, MD, acting deputy director of the FDA office of drug evaluation and research, said some of the matters discussed at the meeting would require new regulation for FDA enforcement.

"FDA could develop a regulation that actually required pharmaceutical firms to provide periodic updates on product use and distribution, as well as resistance surveillance data," she told meeting attendees. "These are not current requirements. But we could, with appropriate encouragement, bolster our regulations to do that. It would require a regulation." However, Bell says the FDA "may be able to take a number of measures just within their existing authority."

Likewise, another consultant at the meeting expressed the hope that actions could be taken without passing new regulations. "I think there is probably a lot that can be done with existing authority," says **Patricia Lieberman**, PhD, staff scientist at the Center for Science in the Public Interest (CSPI) in Washington, DC. "We're not suggesting a whole new structure to deal with this."

CDC steps up SEARCH for resistant staph isolates

Alarmed by emerging vancomycin resistance in strains of *Staphylococcus aureus*, the Centers for Disease Control and Prevention is upgrading surveillance for the pathogen and urging clinicians to submit isolates for confirmation.

Since the first strains of glycopeptide (vancomycin) intermediate-resistant *S. aureus* (GISA) were reported in Japan and the United States, concerns have increased that full-blown resistance to the last-line drug could arise in staph strains. **(See *Hospital Infection Control,* October 1997, pp. 145-152.) Julie Gerberding**, MD, MPH, director of the CDC hospital infections program, recently reiterated those concerns in Baltimore at the annual meeting of the Association for Professionals in Infection Control and Epidemiology.

Hoping the pipeline will catch up

"We all need to be on the alert for S*taph aureus* with reduced susceptibility to vancomycin and jump on these organisms as quickly as we can," she said. "If we don't, we will see the full emergence of vancomycin-resistant *Staph aureus* sooner rather than later. Our goal is not realistically to prevent this from occurring, but to delay it for as long as we possibly can and hope against hope that the pipeline in the pharmaceutical industry will catch up to our urgent clinical needs."

To that end, the CDC has created SEARCH (Surveillance for Emerging Antimicrobial Resistance Connected to Health care). SEARCH is a network of voluntary participants (i.e., hospitals, private industries, professional organizations, and state health departments) joined together to report the isolation of *S. aureus* with reduced susceptibility to vancomycin. All U.S. health care organizations or practitioners are encouraged to report such isolates to the program, and after notifying their state health departments, to send the isolates to CDC for confirmatory testing. The program is using the following definitions and reporting protocol:

Definitions: *S. aureus* with reduced susceptibility to vancomycin: Isolates having a minimum inhibitory concentration (MIC) to vancomycin of greater than or equal to 4 µg / ml. This definition includes isolates determined to be glycopeptide (vancomycin) intermediate-resistant *S. aureus* (GISA / VISA; MIC= 8-16 µg / ml). Glycopeptide (vancomycin) -resistant *S. aureus* (GRSA / VRSA): Isolates of *S. aureus* that have a vancomycin MIC greater than or equal to 32 µg / ml.

Reporting isolates: Notify your state health department before reporting or sending an isolate to CDC for confirmatory testing. Test the isolate on two separate occasions using acceptable quantitative methods to detect a vancomycin MIC of greater than or equal to 4 µg / ml after 24 hours of incubation. Acceptable methods include broth microdilution (e.g., MicroScan Conventional, Vitek, Sensititre, Pasco), Etest, and agar dilution. Disk diffusion is not an acceptable method. When these criteria are met, send an e-mail to SEARCH@cdc.gov with your name, title, phone number, and fax number. You will receive an information sheet that must be included with the isolate sent in for confirmatory testing. ■

The consumer advocate group has come out strongly in favor of government action to preserve the efficacy of antibiotics. "The CSPI definitely feels that it is time for the government, either through the health care it funds or at its own hospitals, to institute the best practices in infection control, vaccinations, and prudent use of antibiotics," Lieberman tells *HIC*. "The system that we have thus far with practice guidelines mostly isn't working. In order to protect the antibiotics and make sure they continue to work, it may be time for regulations and more strict control of how antibiotics are used."

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CDC lauds model VRE plan in Siouxland Health District

Identifying bug rather than assigning blame

In an effort that is being lauded as a model collaboration across the health care continuum, ICPs and colleagues in a tri-state Midwest region called the Siouxland Health District have brought emerging vancomycin-resistant enterococci (VRE) to a grinding halt.

In all, 32 acute-care and long-term care facilities are collaborating with each other and public health officials in a region that includes sections of South Dakota, Nebraska, and Iowa. In addition to sharing information about VRE cases, the program includes selective screening of patients, isolation measures, and a checklist for VRE roommate decisions. **(See boxes, pp. 119, 120.)**

"When facilities get together, communicate, and really look at how they are going to isolate the bug rather than fix the blame, it really impacts what you are doing," **Dee Pedersen**, RN, CIC, infection control coordinator at St. Luke's Medical Center in Sioux City, IA, tells *Hospital Infection Control*. "Because we could have easily become divided here."

Indeed, interfacility transfers of VRE patients without adequate communication can result in frayed relationships between long-term care facilities and hospitals, making it difficult for either setting to move patients back and forth across the health care continuum. The Centers for Disease Control and Prevention is collaborating on the ongoing project, and has been particularly encouraged by the findings.

"I think the attitude that has occurred in this region as a result of this project has been unbelievable," **William Jarvis**, MD, chief of the investigations and prevention branch in the CDC hospital infections program, tells *HIC*. "The long-term care facilities have no problem having their patients go to the acute-care facilities. The acute-care facilities have no barrier getting their patients into long-term care. Many of the barriers that everybody is facing in moving these patients back and forth do not exist in this community."

Jarvis described the program at the annual conference of the Association for Professionals in Infection Control and Epidemiology, held recently in Baltimore. In contrast to Siouxland's successful program, VRE continues to increase in CDC sentinel hospitals in the National Nosocomial Infections Surveillance (NNIS) system, he warned.

"We are seeing a continued increase in VRE in both acute ICU and non-ICU settings, and we now [find] that over 20% of the isolates reported from infections in our NNIS participants are due to vancomycin-resistant strains," Jarvis said at APIC. "Colonization is a major risk for infection [and] control of VRE can be difficult due to interfacility transmission. There has not been a comprehensive, community-of-health-care-facilities approach to control of VRE."

Incoming cases spark effort

In efforts primarily based out of Sioux City, IA, a VRE task force of public health officials and clinicians was formed when cases began appearing in the Midwest region in late 1996. The CDC was invited in and performed the first of two prevalence surveys in August of 1997. After interventions had been adopted, the CDC repeated the prevalence survey 14 months later in October of 1998. The surveys involved perianal swabbing of some 2,200 patients / residents at four acute-care facilities and 28 long-term care facilities.

Overall, the prevalence of VRE decreased from 2.1% in 1997 to 1.5% in 1998, Jarvis reported. In acute care facilities, VRE prevalence decreased from 6.6 % to 5.4% of patients cultured. In long-term care, prevalence dropped from 1.7% to 1.1%. Moreover, while three of the four acute care facilities had at least one VRE patient in both surveys, the number of long-term care sites with at least one VRE case fell from 12 to eight.

"In other words, we were able to eradicate VRE from a number of these facilities," Jarvis told APIC attendees. While the declines would not be considered dramatic for some pathogens, VRE typically has been so successful after establishing an initial foothold that holding the line — let alone actual reduction — is viewed as a victory.

"This serves as model for how hospital personnel, state health departments, regional departments, and federal agencies can work together," Jarvis said at APIC. "I would challenge you show me a community of health care facilities where VRE has been introduced [and]

Infection control methods used to stall VRE spread

Clearly indicate status of patient on transfer

The following infection control measures were recommended to control the transmission of vancomycin-resistant enterococci in acute care facilities as part of a program implemented by a VRE task force in the Siouxland Health District. The recommendations for VRE-positive patients are summarized as follows:

Room assignment: Private room, when possible. Cohort with other VRE-positive patients if private room not available. May share a room with a VRE-negative roommate if appropriate criteria are met. **[See box, p. 120.]**

Barrier precautions: Place isolation supply cart outside of patient's room whenever possible. Use clean, nonsterile gloves for direct patient care and contact with frequently touched surfaces. Use clean, nonsterile, impervious gown if substantial contact with patient or environment is anticipated, or if patient is incontinent or has diarrhea or uncontained drainage of body fluids.

Hand washing: Hand washing is crucial. Employees should wash hands with antimicrobial soap or waterless antiseptic gel for at least 15 seconds (30 seconds preferred), even after glove removal. Instruct patients to wash hands with antimicrobial soap after using the toilet, before eating, and before leaving the room. Verify patient's ability to wash hands. If hand washing is inadequate, patient should use waterless antiseptic gel after washing hands. Visitors should be encouraged to wash their hands with an antimicrobial soap upon leaving the room.

Care of equipment: Non-disposable: Dedicate non-critical items (i.e., stethoscope, blood pressure cuff, thermometer) whenever possible. All items must be disinfected if reused for other patients. Disposable items soiled with body fluids (dressings, diapers, used gloves) should be tied in a plastic bag before being placed in the trash per institution protocol. Environmental surfaces should be clean and disinfected.

Transfer outside facility: The known VRE status of patient will be indicated verbally and written on transfer sheet. Facilities should establish a system for highlighting the records of infected or colonized patients in order to promptly identify and initiate precautions.

Screening: VRE screening on admission is recommended for patients transferred from acute care facilities outside the community. VRE screening on discharge is not recommended for patients dismissed to long-term care facilities who have been in acute care less than 72 hours and have not received antibiotic therapy. Patients screened before discharge and whose results are not final could be transferred to long-term care prior to final results.

Termination of precautions/isolation: Optimal requirements for termination are unknown. Patient should have VRE-negative results on at least three consecutive occasions (greater than one week apart). Cultures from multiple body sites suggested as criteria for removing patients from precautions include stool or rectal swabs, perineal area, axilla, umbilical, wound, foley catheter, and/or colostomy sites. Change in health status, administration of antibiotics, or signs and symptoms of infection may warrant re-establishing precautions. ■

it remained static or decreased. I don't know of another one. I think it is a testimony to the interventions at these institutions."

Concerning the interventions, the majority of the VRE patient screening is done in the acute care facilities when clinicians are preparing to discharge patients to long-term care, or when they are receiving patients from long-term care or hospitals outside their region, Jarvis reports. However, the long-term care sites may culture some patients that come from other areas of the country or other hospitals outside the region, he noted. No successful decolonization protocol for VRE has been established, so screening is primarily done to trigger isolation measures or roommate placements in colonized patients.

Checklist to assess VRE roommate issues

Series of questions triggers decision

The following checklist was used to reduce transmission of vancomycin-resistant enterococci (VRE) in roommates at long-term care facilities and hospitals participating in the VRE task force program in the Siouxland Health District in the Sioux City, IA, area.

Roommate checklist for VRE-Positive Patient/Resident: If the answer is "Yes" to any of the following, placement with a VRE-negative roommate is not advised.

1. Does the patient / resident have non-intact skin, open wounds, stasis ulcers, decubiti, burns, or indwelling devices?

2. Does the patient / resident have diarrhea?

3. Does the patient / resident have long-term fecal or bladder incontinence (i.e., body wastes not fully contained in stoma, catheter bag, or incontinence diaper)?

4. Does the patient / resident have other drainage which is not contained?

5. Is the patient / resident unwilling or unable to cooperate in strategies to contain his / her body secretions?

6. Is the patient / resident cognitively impaired in ways that may promote VRE transmission?

Checklist for VRE-Negative Roommate: If the answer is "Yes" to any of the following questions, placement with VRE-positive roommate is not advised.

1. Does the roommate have non-intact skin, open wounds, stasis ulcers, decubiti, burns, or indwelling devices?

2. Does the roommate have renal failure?

3. Is the roommate significantly immunocompromised (i.e., neutropenic or on oral steroids or chemotherapy)?

4. Is the roommate on antibiotics or has the roommate been given antibiotics within the previous three months?

5. Is the roommate known to be colonized with methicillin-resistant *Staphylococcus aureus*?

6. Is the roommate unable to cooperate in the proposed infection control measures?

7. Is the roommate cognitively impaired in ways that may prohibit compliance with precautions? ■

Jarvis clarified that the acute-care facilities are primarily using CDC guidelines for isolation and prudent use of antibiotics, while the long-term care facilities use what is "manageable" based on their local situation.[1] "Some of them wanted to know about the [VRE-] positive patients and immediately place them in acute-care-facility-type isolation. Others did other things," Jarvis tells *HIC*. In addition, the CDC is studying whether a simple approach like "universal gloving" for contacts with VRE patients in long-term care might be a cost-effective alternative to more extensive isolation of residents, he says.

A 'no-fault' approach

Overall, the removal of "blame" factors and the clear charge to notify other facilities about known VRE-colonized cases is probably as big a factor as any other in the success of the program, report ICPs involved in the project. "I think it was the communication between all of the facilities — long-term care and acute," Pedersen says. "We screened long-term care facility admits and dismissals. If we saw something, we shared it with the [other] facility right away. The communication here was one of the big things."

It was Pedersen and colleague **Diane Prieksat**, RN, CIC, manager of infection control and epidemiology services at Mercy Health Center in Sioux City, who originally alerted state and local health departments to the emergence of VRE in the community and suggested a coordinated response.

"We wanted it to be a 'no-fault' type of thing," Prieksat says. "Initially, in some communities when VRE comes about, there may be a lot of speculation about who gave it to whom. So by doing this and involving the health department, we had an objective party that was working with the acute care and long-term care facilities. I think that helped make it a lot more effective."

Another factor in the program's success is encouraging prudent vancomycin use according

to CDC guidelines, Prieksat adds, noting that clinical pharmacologists monitor vancomycin use at her facility. Clinical problem areas identified for additional education efforts have included nephrology, oncology, and orthopedic surgery services. That aspect of the program has resulted in significant improvements in appropriate vancomycin usage, she says.

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'Lazarus' rising in U.S. but HIV still taking global toll

"When the history of AIDS and the global response is written, our most precious contribution may be at the time of plague we did not flee, we did not hide, we did not separate ourselves." — Jonathon Mann, MD, to whom the 1999 APIC conference was dedicated.

Ongoing advances in antiretroviral drug therapy are dramatically changing the face of the HIV epidemic, yielding a dramatic "Lazarus effect" in some patients that only a few years ago may have been part of mortality statistics. Yet while the death toll has dropped in those with access to new combination-drug therapies, much of the globe has not been invited to the HIV "cocktail" party and the pandemic is still exacting a terrible toll in non-industrialized countries, ICPs were advised recently in Baltimore at the annual conference of the Association for Professionals in Infection Control and Epidemiology.

Delivering an HIV update at APIC was **Carlos del Rio**, MD, chief of HIV inpatient services at Grady Memorial Hospital and assistant professor of infectious diseases at Emory University School of Medicine, both in Atlanta.

"As antiretroviral therapy has become more commonly used in the United States, mortality from HIV has dramatically gone down," he said. "This is one of the most dramatic events in the history of the epidemic. Any of you who has seen or taken care of AIDS patients can attest to the dramatic Lazarus effect that we have seen. Patients who are very sick — near death — are all of a sudden back to normal. [They are] working, taking their medications, and doing fine. Some hospitals have literally stopped having HIV admissions because HIV has become — for people who can take the medications — essentially an outpatient disease."

As a result, AIDS mortality has fallen from the leading cause of death in 25-to-44-year-olds in the late 1980s and early 1990s to the fifth-leading cause currently, he noted.

The haves and have-nots

In stark contrast to the U.S. situation, the vast majority of the estimated 33 million HIV-infected people worldwide have little or no access to the new drug regimens, particularly those living in sub-Saharan Africa or the Indian subcontinent, he noted. Del Rio invoked the memory of the renowned AIDS researcher and human rights activist Jonathon Mann, MD, to whom the 1999 APIC conference was dedicated, in reminding that the epidemic has become as much a struggle for human rights as to vanquish a disease. Mann, the keynote speaker at the 1993 APIC conference, died in a plane crash in 1998.

"We think we have a large HIV problem in this country, where the CDC estimates half a million to 750,000 [people] are infected with HIV," del Rio said. "Literally, in sub-Saharan Africa it is hard to go to a village and not find a family that has one or two or more members who have either died of HIV or who are infected with HIV."

The result is that life expectancy rates in such countries have fallen dramatically, as HIV infection offsets gains over the last few decades in sanitation and immunizations for other diseases. Every day, 16,000 new HIV infections occur worldwide, most of them in developing countries, del Rio said. "To a great majority of these individuals, antiretroviral therapy — which has dramatically changed the epidemic in this country — is simply not available," he said. "It is estimated that only 5% of the people living with HIV worldwide actually have access to antiretroviral therapy."

There are ongoing efforts to try to improve the situation, for example, by administering drug

therapy to interrupt perinatal transmission and break the chain of HIV from one generation to the next, he noted. Antiretroviral therapy has proven effective in blocking perinatal transmission, and some pharmaceutical companies have offered zidovudine at discounted prices for developing countries. The challenge then becomes getting at-risk populations tested so zidovudine can be administered appropriately.

"The problem [then] is not the drug availability, but the testing," del Rio says. "How do you get cheap testing? How do you know who is infected?"

Noting that in some areas of Africa as many as 30% of the pregnant women are HIV-infected, del Rio said the situation is such that public health officials may have to weigh the feasibility of administering therapy to all pregnant women rather than try to discern the truly infected without resources for testing.

U.S. gains undercut by resistance

In addition, even amid the striking successes against HIV in the United States, del Rio reminded that the dramatic improvements seen in many patients are not being realized by all. Many are infected with resistant strains and must keep seeking new combinations of the currently available drugs in an effort to find an effective regimen. Indeed, today's complex HIV therapy must be administered by highly specialized clinicians who are treating patients on a day-to-day basis.

"We have right now 14 HIV-approved medications, so the combinations are quite numerous," he said. "In 1999, we don't have one option, we have several options [as] to what to start the patient with. The treatment decision needs to be tailored to the individual needs."

Sometimes patient readiness is key to the drug regimen, he added.

"I have patients who simply tell me [they are] not ready to take 20 pills a day for the rest of [their] life," he said. "Then you are not ready to start therapy. Because if you take it for three days and then you skip two and take it again, your virus is going to rapidly become resistant to those drugs and we are wasting our money and our energies. . . . A lot of patient education is needed before we commit ourselves to antiretroviral therapy."

In a situation similar to emerging antibiotic resistance in bacteria, the AIDS virus has shown the ability to mutate into resistant strains that foil therapy. Resistant strains began to emerge not long after zidovudine began proving effective in reducing viral replication more than a decade ago. The advent of two-drug therapies in 1994 significantly improved the situation, and another dramatic stride occurred with the triple-drug cocktails in 1997, he noted.

"We saw that viral replication was being driven down by more than two logs, and indeed, that has continued," del Rio said. "The virus does not rebound if you continue to take your medications appropriately, and this essentially has led to the changes in mortality that we have seen. If [HIV] is unable to replicate, then it won't become resistant, because the virus needs to be able to replicate in order to develop resistant mutations."

Viral latency makes adherence crucial

However, adherence to drug regimens can be surprisingly difficult, particularly because some 90% of the medications must be taken for life due to viral latency factors that allow HIV to emerge rapidly when medications stop. New drugs requiring fewer daily pills may help the situation, but side effects are another ongoing concern in maintaining compliance, he notes.

COMING IN FUTURE MONTHS

- The role of rapid HIV tests in PEP protocols
- IC implications of increasing drug resistance seen in *S. pneumoniae*
- Will FDA finally crack down on reuse of disposables?
- Seasonal update on flu shots for HCWs
- Results of our 1999 reader survey on Y2K readiness in infection control

The 1999 APIC Conference

About 40% of patients — more if education is heavily emphasized — will still be taking their drugs as part of a successful regimen two years out. But the rest of the patients typically fail antiretroviral therapy because they stop taking the medications, develop liver function abnormalities or other side effects, or the virus becomes resistant to the regimen, he said.

"While you see results in pharmaceutical-sponsored trials saying 96% [success rate] at one or two years, the fact is that happens to be a study setting," del Rio said. "In real clinical practice, we are over and over seeing a success rate of about 40%."

Disease leaves no room for error

Patients on failing regimens are relegated to "salvage" therapies that become increasingly less likely to succeed as successive regimens fail. That makes it all the more important to strictly comply with the initial regimen, he said, underscoring the importance of "compliance nurses" that constantly educate HIV patients about the importance of adhering to therapy. Such efforts are critical because there may be only a scant margin for error between a successful regimen and a failing one. Many of the drugs have a short half-life, meaning a missed dose by a only a few hours can be significant because the virus may be only one mutation away from developing resistance, he said. Compliance is further complicated by such factors as the need to take some medications with food and the need to take others before eating.

"The bottom line is you need to take most of your drugs every day, all of the time," he said. "Again, I remind you, if you have ever taken any medication, it is very hard to take it every day and not to miss doses. They are very unforgiving drugs."

Though HIV — with certain caveats — has evolved from a near uniformly fatal infection to a chronic disease, considerable challenges remain despite the stunning successes.

"It is a manageable [disease], but only for those fortunate enough to acquire a wild-type virus — in other words not a resistant virus — who live where combination therapy is accessible and have no problem taking drugs every day all of the time," del Rio told APIC attendees. "We are a long way from saying that HIV is over." ■

JOURNAL REVIEWS

Weinstock DM, Rogers M, Lim S, et al. **Seroconversion rates in healthcare workers using a latex agglutination assay after varicella virus vaccination.** *Infect Control Hosp Epidemiol* 1999; 20:504-507.

Though finding a considerably lower rate of varicella vaccine-induced seroconversion at their hospital compared to that of the published literature, the authors still report that universal vaccination is "an extremely cost-effective alternative to the furloughing of exposed, seronegative health care workers." They projected hospital savings in excess of $53,000 in the first year after vaccination alone.

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The Centers for Disease Control and Prevention recommends that all health care workers should ensure that they are immune to varicella (chickenpox). The authors tried to determine the seroconversion rate after varicella immunization of health care workers and the effect of seroconversion rate on current cost-based recommendations for universal vaccination. A voluntary vaccination program for health care workers was performed at a tertiary-care cancer center in New York City. A commercial latex agglutination assay was used to test post-vaccination antibody response. Costs for vaccination and post-vaccination serological testing were compared to potential costs of post-exposure employee furloughs.

Of 263 seronegative workers, 96 (36.5%) began the vaccine program. Thirty-nine workers received only one dose of vaccine. Seven returned for follow-up antibody testing, of whom four were seropositive. Of the 57 workers who received two doses, 38 returned for follow-up serology. Thirty-one (81.6%) were positive for varicella antibodies, and seven (18.4%) remained negative.

At a cost of $80 per two-dose series of the vaccine, immunization for all 263 susceptible workers would cost $21,040, the authors calculated. Post-vaccination testing using the LA assay to confirm the presence of antibodies in vaccinated workers would cost $7,890. An 18.4% seronegative rate after vaccination implies an annual expense of $18,584 for the furlough of exposed, vaccinated workers who failed to seroconvert. Therefore, the total cost of a universal vaccination program for the first year would be $47,514.

"Universal varicella vaccination offers the health care industry an attractive alternative to the financial burden of varicella-susceptible workers," the authors conclude. "Our data indicate that, despite the lower seroconversion rates found in our study population using the LA assay, universal vaccination remained a cost-effective strategy."

With expenses totaling $47,514 for universal vaccination and projected expenses of $101,000 in furloughs without vaccination, potential savings exceed $53,000 in the first year alone. Only 36.5% of the susceptible health care workers at the institution participated in voluntary vaccination, reinforcing the potential need for mandatory, universal vaccination, the authors emphasize. Universal vaccination remains a cost-effective proposition as long as the average salary of furloughed workers is above $21,000. With an average salary of $60,000, seroconversion rates of as low as 30% still support universal vaccination, they conclude. ■

CE objectives

After reading each issue of *Hospital Infection Control*, the infection control professional will be able to do the following:

- identify the particular clinical, legal, or educational issue related to epidemiology;
- describe how the issue affects nurses, hospitals, or the health care industry in general;
- cite solutions to the problems associated with those issues, based on guidelines from the federal Centers for Disease Control and Prevention or other authorities, and/or based on independent recommendations from clinicians at individual institutions. ■