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CDC, we have a problem: Superbug VRSA finally makes its dreaded debut

Gene transfer makes staph vancomycin-resistant

In a sci-fi scenario researchers have long feared, vancomycin-resistant genetic material from a co-infecting enterococci strain apparently has transferred to *Staphylococcus aureus* within a patient, creating the first clinical strain of a much-anticipated superbug: vancomycin-resistant *S. aureus* (VRSA).

Infection control just got a lot more important.

"There are major implications," says **Denise Cardo**, MD, chief of the prevention and evaluation branch at the Centers for Disease Control and Prevention's (CDC) division of healthcare quality promotion. "It highlights the importance of prevention of transmission of multidrug-resistant microorganisms in health care settings. Antibiotic resistance in health care settings is a very important problem."

The case occurred in June 2002, when VRSA was isolated from a swab obtained from a catheter exit site of a 40-year-old Michigan resident with diabetes, peripheral vascular disease, and chronic renal failure.[1] The patient — who is recovering after successful treatment of the VRSA infection — had been intermittently co-infected with both vancomycin-resistant enterococci (VRE) and methicillin-resistant *S. aureus* (MRSA). **(See patient profile, p. 92.)**

"If you were to predict what patient population would get vancomycin-resistant *Staph aureus*, this is exactly the one," says **Gary Noskin**, MD, hospital

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COMING IN FUTURE ISSUES

VRSA strategies: How to avoid it; how to spot it

Mad science? The dangers and benefits of engineering bugs in the lab in an upcoming issue of *Bioterrorism Watch*

Smallpox, big confusion: Will everybody who is going to be vaccinated take one step forward?

Prevention pays: ICPs share the tips that saved dollars and lives in the 2002 Infection Control Innovation Awards

And employers pay: How much and to whom is the subject of our annual salary report

epidemiologist and medical director of infection control at Northwestern University Hospital in Chicago. "[Dialysis patients] are frequently at risk for staph and MRSA. They have both colonization and infection with this organism, and they are frequently exposed to vancomycin. One of the dilemmas that face clinicians taking care of dialysis patients is that vancomycin is very convenient to administer. You only need to give it once a week."

From VISA to full-blown VRSA

Indeed, most of the cases of vancomycin-intermediate *S. aureus* (VISA), which began occurring in the mid-1990s, have been in dialysis patients.

As of June 2002, eight patients with clinical infections caused by VISA, which is partially resistant to vancomycin, have been confirmed in the United States. The mechanism of resistance in the VISA strains was the development of thickened cell walls after repeated exposure to vancomycin.

In contrast, all indications are that the Michigan case involved a genetic transfer from VRE to MRSA. The vancomycin-resistance determinant *vanA,* typically found in VRE but never in a clinical staph strain, was found in the VRSA isolate. Researchers in England proved such a genetic transfer could occur a decade ago in controversial laboratory studies that produced a fully resistant strain in vitro.[2]

"Initially, it was speculation," Cardo says. "Now we see that it is possible. We need to prevent the spread of these organisms in health care settings. Because if they can transfer genetic materials, it means we really need to be serious about this."

While vancomycin resistance is defined as an isolate having a minimum inhibitory concentration (MIC) of at least 32 μg/mL, the infecting strain from Michigan had a MIC of 128.

"That was very high, and we thought initially since the culture was mixed with VRE that this was probably because of the VRE," Cardo says. "We haven't seen something like that with *Staph aureus*."

In addition to the *vanA* vancomycin resistance gene from enterococci, the isolate contained the oxacillin-resistance gene *mecA.* Essentially, it was an MRSA strain that developed vancomycin resistance, but the result was not an untreatable pathogen. The isolate was susceptible to the relatively new drugs linezolid and quinupristin/

dalfopristin, as well as tetracycline, and trimethoprim/sulfamethoxazole. The patient was successfully treated with trimethoprim/sulfamethoxazole. Though the organism is still susceptible to several drugs, the appearance of complete resistance to vancomycin in a staph strain has long been one of the dreaded milestones toward a "post-antibiotic era."

"It is clearly a significant event; you have the first *staph aureus* that is vancomycin-resistant," Noskin says. "But it is a little bit different now then when we first started talking about this five or 10 years ago, mainly because we do have antibiotics that have activity against this organism. While it is a serious concern, this is not the multidrug-resistant organism that is resistant to every known antibiotic that I think many of us feared."

An aggressive search for transmission

Nevertheless, the CDC was extremely aggressive about obtaining "hundreds" of cultures from any possible contacts, including dialysis workers, hospital staff, family members, and even a nail parlor the patient visited. All known results thus far are negative. The CDC is well aware what can happen if a drug-resistant strain starts getting transmitted around until it finds a niche and establishes a reservoir. VRE, for example, started in a few East Coast hospitals and then rapidly expanded nationwide.

"I think we have learned," Cardo says. "That's the reason we are being very radical in terms of testing more people than we would have in the past. We are trying to contain any potential transmission. People [wonder] why are we testing patients [who] are hospitalized now since they did not have any contact with the index patient? Because we want to detect any potential transmission and stop it right now. We are being aggressive."

Infection control practices in the dialysis center included standard precautions consistent with CDC guidelines. After the identification of VRSA, dialysis center staff went to special precautions that included gloves, gowns, and masks for all contacts with the patient. They also performed dialysis on the patient using a dedicated machine during the last shift of the day in an area separate from other patients.

A dialysis technician was dedicated to provide care only for the patient, using dedicated, noncritical patient-care items. Assessment of infection control practices in other health care settings in which the patient was treated is ongoing.

The CDC was already in the process of revising its patient isolation guidelines, but Cardo could not say whether special measures would be added, for example, for dialysis patients co-infected with VRE and MRSA. There is no obvious indication in the clinical course of the patient that would suggest a similar genetic transfer could not occur again under similar circumstances.

"I don't know that this patient's clinical course was significantly different from others with complicated diabetes and chronic ulcerations," says **Matthew Boulton**, MD, MPH, state epidemiologist at the Michigan Department of Community Health in Lansing.

"It's not at all uncommon to have seen multiple courses of vancomycin used in individuals like this," Boulton says. "I don't think that the clinical history and the pattern of antibiotic use were particularly unique. The question now is: Are we going to see this arise elsewhere through gene transfer, now that we have seen this first one?"

Anomaly or harbinger?

Is the long-awaited arrival of VRSA some kind of an anomaly or a harbinger of widespread emergence? "Perhaps neither of those," says **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Hospital in Nashville.

"Once the vancomycin intermediate strains appeared, everyone anticipated that at some point, a totally resistant *Staph aureus* would occur. I would not anticipate a rash of new observations, but from time to time, I think we will see other institutions reporting such organisms. Unless great attention is given to containment, we may see gradual spread," he says.

MRSA has been endemically entrenched for decades in some hospitals and is increasingly found in the community. Could a similar path be carved out by VRSA?

"It is an important question that is hard to answer," Noskin says. "Vancomycin has been out since 1958, so it had been out for 40-plus years before we saw this. Why is it that it took so long for staphylococci to become resistant to vancomycin? For other classes of antibiotics resistance can develop within months and years. It is impossible to predict. [But] there is clearly well-documented person-to-person transmission of

Chronic foot ulcers set stage for VRSA

Vancomycin, other drugs given for a year

The Centers for Disease Control and Prevention (CDC) provided the following clinical profile of the first reported case of vancomycin-resistant *Staphylococcus aureus*.

- **In June 2002**, VRSA was isolated from a swab obtained from a catheter exit site from a Michigan resident age 40 with diabetes, peripheral vascular disease, and chronic renal failure. The patient received dialysis at an outpatient facility. Since April 2001, the patient had been treated for chronic foot ulcerations with multiple courses of antimicrobial therapy, some of which included vancomycin.
- **In April 2002**, the patient underwent amputation of a gangrenous toe and subsequently developed methicillin-resistant *S. aureus* bacteremia caused by an infected arteriovenous hemodialysis graft. The infection was treated with vancomycin, rifampin, and removal of the infected graft.
- **In June 2002**, the patient developed a suspected catheter exit-site infection, and the temporary dialysis catheter was removed; cultures of the exit site and catheter tip subsequently grew *S. aureus* resistant to oxacillin (MIC >16 μg/mL) and vancomycin (MIC >128 μg/mL). A week after catheter removal, the exit site appeared healed; however, the patient's chronic foot ulcer appeared infected. VRSA, vancomycin-resistant *Enterococcus faecalis* (VRE), and *Klebsiella oxytoca* also were recovered from a culture of the ulcer. Swab cultures of the patient's healed catheter exit site and anterior nares did not grow VRSA.
- **As of this report**, the patient is clinically stable, and the infection is responding to outpatient treatment consisting of aggressive wound care and systemic antimicrobial therapy with trimethoprim/sulfamethoxazole. The VRSA isolate recovered from the catheter exit site was identified initially at a local hospital laboratory using commercial MIC testing and was confirmed by the Michigan Department of Community Health in Lansing and the CDC.

Reference

1. Centers for Disease Control and Prevention. *Staphylococcus aureus* resistant to vancomycin, United States, 2002. *MMWR* 2002; 51:565-567. ■

Staph aureus and MRSA, so you would think that just because this organism had acquired resistance determinants it shouldn't prevent it from person-to-person transmission."

After the initial success of penicillin in treating *S. aureus* infection, penicillin-resistant *S. aureus* became a major threat in hospitals and nurseries in the 1950s, requiring the use of methicillin and related drugs for treatment of *S. aureus* infections.

In the 1980s, methicillin-resistant *S. aureus* emerged and became endemic in many hospitals, leading to increasing use of vancomycin. Now we have the next chapter.

"Anybody with any kind of contact with hospital infection control is acutely aware of the inexorable and undeterable march of these resistant organisms," Boulton says. "They seem to have the capacity to develop resistance to just about everything that we develop. That's very disconcerting."

Though it remains susceptible to other drugs, the fact that the VRSA strain is impervious to both vancomycin and methicillin-class drugs limits its treatment options. "It is potentially treatable; that would be fair to say," Noskin says. "It is very complex for the clinicians out there because, on the one hand, on a national level, 40% to 50% of staph are MRSA, which means your initial therapy for the most part has been vancomycin. So when you understand the epidemiology of S*taph aureus* and the need to use vancomycin, then you can see it is a vicious cycle to select out for these resistant strains."

Prevention of transmission remains a critical issue should subsequent cases arise, Boulton emphasizes. "We have gone to an extraordinary extent to make sure there is not transmission from this [patient] to others," he says. "That, of course, is very resource- and personnel-intensive. Is that practical in the hospital setting? Now that we actually have VRSA, it is really changing the complexion of the discussion about this."

Much in the way the anthrax attacks transformed the bioterrorism discussions from theory to reality, the arrival of VRSA may galvanize the longstanding struggle for judicious antibiotic use and stringent infection control.

"The approach is the same that we have been preaching for a long time," Cardo says. "The difference is now this shows that we really need to be serious. Health care settings should have this as one of their first priorities."

(*Editor's note: Will the first case of VRSA lead to full emergence and endemic spread like we have seen with VRE and MRSA? Answer our poll question on this important subject on your subscriber web site at* www.HIConline.com.*)*

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Can linezolid take some pressure off vancomycin?

New drug as effective in MRSA study

In encouraging findings in the ongoing battle to stem antibiotic resistance, linezolid proved to be an effective alternative for vancomycin for certain types of methicillin-resistant *Staphylococcus aureus* (MRSA) infections, researchers report.

"It's certainly an alternative for treating MRSA infections," explains lead researcher **Dennis L. Stevens**, PhD, MD, professor at the University of Washington School of Medicine in Seattle.

However, certain severe infections, including endocarditis and decubitus ulcers associated with diabetes, were excluded from the comparative study.

"I would say that in two situations, there would be a question, and that would be endocarditis and osteomyelitis," he says. "We need to do the clinical trials. I would be hesitant to treat MRSA endocarditis [with linezolid] at this point in time. There is the old 'saw' that you need bactericidal antibiotics to treat endocarditis. Linezolid is probably somewhere between static and cidal in terms of *Staph aureus*."

The randomized, open-label trial evaluated patients with presumed MRSA infections at 104 sites in North America, Europe, Latin America, and Asia from July 1998 to July 1999.[1]

Hospitalized patients were randomized to receive either linezolid (600 mg IV twice daily) or vancomycin (1 g IV twice daily) for at least seven days. When they had shown clinical improvement, linezolid-treated patients could have their treatment changed to oral linezolid (600 mg twice daily) at the discretion of the investigator.

Skin and soft-tissue infection was the most common diagnosis, followed by pneumonia and urinary tract infection.

At the test-of-cure visit (15-21 days after the end of therapy) among evaluable patients with MRSA, there was no statistical difference between the two treatment groups with respect to clinical cure rates (73.2% of patients in the linezolid group and 73.1% in the vancomycin group). Both regimens were well-tolerated, with similar rates of adverse events.

MRSA threat growing

A common cause of nosocomial pneumonia and bloodstream infections, MRSA has increased from 2% in 1974 to as high as 64% in surveys of the MRSA proportion of nosocomial staph infections.[2-4]

Until recently, there were few therapeutic options for the treatment of MRSA infections. Intravenous vancomycin remains the standard therapy, but linezolid and quinupristin-dalfopristin have been developed in recent years. An advantage of linezolid is that the patient can be switched to oral medication, Stevens says.

"You can put them on an oral pill and send them home," he says. "Whereas, with vancomycin what we have had to do in the past is either keep the patient in the hospital longer or send them home with home IV care. That is more costly. The oral option gives you another avenue to maybe not have to use intravenous device in the first place, not have to use home IV, and not have to use intravenous preparations. If you don't have an IV catheter, that is reducing some [infection] risk."

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FDA says it's needlestuck without more sharps data

Critics say petition response 'paltry'

Claiming it needs device-specific data to take action on needle safety issues, the Food and Drug Administration (FDA) is requesting information as a possible prelude to regulatory action.

"In the absence of such information about specific devices, the FDA was unable to conclude that any particular device presented . . . an unreasonable and substantial risk of illness or injury," the FDA stated in its request for more data.[1] The deadline to submit data and comments is Sept. 19, 2002. **(See editor's note at the end of this article.)**

The FDA action comes in response to a petition filed jointly last year by Public Citizen's Health Research Group, a consumer advocacy group; and the Service Employees International Union (SEIU), a major health care union. They asked the FDA to withdraw conventional needle devices from the market place. In making the case for a recall, the petition cited the continuing spread of bloodborne infections such as HIV and hepatitis C virus to health care workers via hundreds of thousands of needlesticks annually. The petition listed 55 documented and 136 possible cases of occupationally acquired HIV among health care workers in the United States.

Public Citizen and the SEIU specifically asked the FDA to ban high-risk needle devices such as IV catheters and phlebotomy equipment for which there is currently available FDA-cleared technology to minimize exposure. In addition, the organizations sought the replacement of IV tubing with needleless designs and a recall of glass capillary tubes in favor of plastic products that won't shatter in the hand. The petition also asked for a warning label on conventional syringes. The FDA did not grant any of the requests, but agreed to pursue further data if specific hazardous devices can be identified. **(See FDA responses, p. 95.)**

"Our position is there is enough accumulated knowledge over the last 20 years of the HIV epidemic . . . to take action and not issue an extremely general request for information," says **Peter Lurie**, MD, deputy director of the health research group at Public Citizen. "It's not clear to me why any device manufacturer would respond to this. I would think they would leave well enough alone from their point of view. I think that very little will come of this. As much as anything, [FDA] is wishing to demonstrate that [it is] responding to us in some way. The response is paltry."

Data cited in the petition include a study where the number of catheter stylet injuries was reduced 84% by switching to a safety design. The injury rate was 7.5 per 100,000 devices for conventional catheters, but fell to 1.2 per 100,000 devices for safety catheters, a reduction of 84%.[2] Similarly, blood-drawing devices that incorporate a protective mechanism in their design have been shown to be effective in reducing needlesticks. In one study, statistically significant reductions of 66% and 76% were demonstrated for two blood-collection devices.[3]

"In our petition, we steered away from discussions of particular devices," Lurie says. "We cited two major data-collection efforts, so I don't see what [else] is going to come out of the woodwork on this. It is likely to not be as expansive as what we cited, otherwise it would have already been published."

However, the data that could meet the FDA criteria are in the process of being collected by the Occupational Safety and Health Administration (OSHA), says **Katherine West**, BSN, MSEd, CIC, infection control consultant with Infection Control/Emerging Concepts in Manassas, VA.

"According to what [FDA is] held to by law, they have to have additional information and it has to be device-specific," she says. "The data are already being collected under the new OSHA 300 log and the safety sharps injury log, because you have to list the specific device and the brand.

In its response to the petition, the FDA says it has been working together with OSHA to reduce the risk of sharps injuries to health care workers and others. FDA regulates medical devices, including those containing sharps, under the Federal Food, Drug, and Cosmetic Act. OSHA has authority to regulate workplace controls for the protection of workers. That authority was extended, including the two record-keeping changes, with revisions of OSHA's bloodborne pathogen standard mandated by the 2000 Needlestick Safety and Prevention Act.

"The mechanism is in place to collect this information," West says. "[It] probably won't happen as quickly as these petitioning groups would like. I think it's needed. Hospitals want to contain costs. They are looking at this as being costly, instead of looking at the fact that if you reduce exposures, you don't have the cost of post-exposure follow-up. They're looking at it short term, not long term, and some have been slow to respond."

FDA responds on needle ban, standards, labeling

The Food and Drug Administration (FDA) cited the following response to a petition demanding the agency take action to protect health care workers from bloodborne infections due to needlesticks.[1] The response is summarized as follows:

Banning conventional needle devices: The legal standard to be applied by the FDA in deciding whether it is appropriate to ban a device is set out in section 516 of the act (21 U.S.C. 360f). In short, this section states that the FDA may ban a device if it finds that the device presents a "substantial deception or an unreasonable and substantial risk of illness or injury." The regulations implementing section 516 state that, in determining whether the risk of illness or injury is substantial, the FDA will need to consider whether the risk posed by continuing marketing of the device is important, material, or significant in relation to the benefit to the public health from continued marketing [21 CFR 895.21(a)(1)]. In its petition response, the FDA stated that it did not have sufficient information to conclude that there is a legal basis for banning the devices identified in the petition.

Although the petition addressed the number of injuries related to generic types of devices, it did not show: which specific devices were used; how many devices of that type were used during the relevant time period; and what the design characteristics of those devices were or whether the devices met any or all of the design criteria listed.

In the absence of such information about specific devices, the FDA was unable to conclude that any particular device presented a "substantial deception or an unreasonable and substantial risk of illness or injury." The agency invites interested people to submit data and information that would provide insight on the basis for banning one or more of these devices.

Performance standards: The petition requested that the FDA issue performance standards based on five design criteria previously identified by the FDA:

- A fixed safety feature provides a barrier between the hands and the needle after use.
- The safety feature allows or requires the worker's hands to remain behind the needle at all times.
- The safety feature is an integral part of the device and not an accessory.
- The safety feature is in effect before disassembly, if any, and remains in effect after disposal.
- The device should be simple and easy to use, requiring little training.

The petition listed the criteria but did not discuss how the FDA could apply these criteria to specific devices in the context of a mandatory performance standard, or how such a standard would provide reasonable assurance of the safety and effectiveness of these devices.

In its response, the FDA stated that it did not have sufficient information to develop a standard to address the risk of needlestick injury. The FDA believes that these criteria are a good starting point to develop a standard, but it needs additional information to determine how best to apply these criteria to specific devices in the context of a standard. The FDA invites interested people to submit any information or data addressing the appropriateness of developing a performance standard, based on these criteria or others. The FDA is also prepared to enter into discussions with any organization that wishes to develop a voluntary consensus standard for one or more of these devices that the FDA may adopt or recognize in some form.

Labeling: The petition requested that the FDA require that the labeling for "conventional syringes" state: "to prevent possible exposure to HIV and hepatitis, do not use for standard blood draws." The petitioners stated that current labeling for syringes does not contain adequate warning of the hazards that the device presents. In its response, the FDA stated that the information in this statement is well known to health care professionals who use these types of devices and, therefore, under 21 CFR 801.109(c), it would not ordinarily require such a statement in the labeling. The FDA invites interested people to comment on whether the proposed labeling statement or any other labeling requirement is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

Reference

1. 67 *Fed Reg* 41,890-41,892 (June 20, 2002). ■

Many of the devices mentioned in the petition, including nonsafety IV catheters, blood collection device, and glass capillary tubing, could be replaced by safety designs, adds **Cindy Fine**, RN, MSN, CIC, infection control practitioner at John Muir Medical Center in Walnut Creek, CA.

"Speaking theoretically and just asking, 'Would it be possible?' Yes, I think it would be," she says. "IV catheters might present the most problems because we have physicians using them for things such as external jugular lines. They need a longer IV catheter, and the safety catheters don't come in the long length."

Despite such exceptions, in general, there are safety designs now to replace much of the conventional sharps products, she adds.

"I don't see why you couldn't get rid of the glass capillary tubes," Fine says. "I think we could also do away with the nonsafety IV tubing without having any problems. I can't come up with any reason why we couldn't do away with the nonsafety devices for blood collection."

Of course, issues of worker training and compliance — some will hoard the old devices or fail to use the new ones correctly — have long been part of the needle safety issue. In addition, quality of protection varies among the various needle safety devices.

"Are all of these safety devices better and safer than standard devices?" Fine asks. " I don't think that is necessarily true." Rather than pursuing a FDA ban on devices, she favors adding to the existing momentum OSHA has achieved under its revised regulatory mandate.

"I think it would be more effective to increase OSHA enforcement, and educate OSHA inspectors a little more on what the standard requires and what a good safety device is," Fine says. "Get OSHA out there inspecting and helping people get the devices into their facilities. That would be a more effective way of increasing employee safety."

OSHA has stepped up enforcement of the needle safety provisions. The new provisions in the revised bloodborne pathogen standard became effective April 18, 2001, but OSHA delayed enforcement action until July 2001.

As of May 2002, the agency had issued 1,876 citations to hospitals with penalties totaling about $1.3 million. Only 369, or 20%, were generated from inspections related to a complaint. OSHA issued 142 citations for failure to use engineering and work practice controls — including safer devices. By contrast, in a 16-month period after the 1999 compliance directive on bloodborne pathogens was released, OSHA issued a total of 144 citations to hospitals related to the standard; just 18 of those involved lack of engineering controls or safer devices.

In the past year, OSHA issued 165 citations for failure to have a written exposure control plan and 170 citations for failure to update the exposure control plan annually. The agency issued another 25 citations for failing to reflect changes in technology in the exposure control plan and failure to document annual consideration and implementation of safer devices.

[Editor's note: Submit written comments or information to the Food and Drug Administration regarding Docket No. 01P-0120 by Sept. 19, 2002, to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to www.fda.gov/dockets/ecomments.

For further information, contact: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. Phone: (301) 443-8879.]

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APIC and SHEA may hold joint conferences

A key collaboration amid health care changes

Crossing professional, and to some extent, gender barriers, the primary national groups of infection control physicians and nurses are considering joining forces in a new partnership.

The Association for Professionals in Infection Control and Epidemiology (APIC), which primarily comprises nurses and other non-MD medical professionals, is exploring new opportunities for linkage with the main physician group, the Society for Healthcare Epidemiology of America (SHEA). With patient safety, bioterrorism, and the continued movement of care beyond the hospital, the collaboration could raise the profile of infection control rather than divide and dilute it.

The idea was endorsed at APIC's annual conference in Nashville, TN, by SHEA president Barry Farr, MD, epidemiologist at the University of Virginia Hospital in Charlottesville. Also in favor was **Gigi Dash**, RN, MS, CIC, president of APIC.

"We see it as a key alliance," she tells *Hospital Infection Control*. "There are strengths that APIC has, strengths that SHEA has, and there can be nothing but benefit from a marriage of those strengths."

The collaboration may lead to holding joint

educational conferences or meetings that are slated back to back at the same location.

"We are beginning to talk about doing that," Dash says. "We have a representative from SHEA on our annual conference task force; and next year, SHEA will have an APIC representative on the planning committee for the SHEA conference. We both recognize the advantage of the partnership."

Research collaborations also are a possibility, as SHEA has expressed interest in participating in APIC's Research Foundation program, she adds. ■

Reprocessing guidance, compliance dates given

FDA addresses open-but-unused devices

The Food and Drug Administration (FDA) recently answered three new "frequently asked questions" regarding its sweeping revisions of requirements for reprocessing of single-use devices. Under the new regulations, third-party and hospital reprocessors of single-use devices (SUD) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including pre-market submission requirements.

Since the initiative began Aug. 14, 2000, the FDA has received numerous questions about its requirements, including these three:

Q. *What are the regulatory requirements for opened-but-unused SUDs reprocessed by a third-party (commercial) reprocessor?*

A. The FDA's guidance document *Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals* (dated Aug. 14, 2000), defined *opened-but-unused* single-use devices as "single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not been used on a patient, that is, they have not been in contact with blood or bodily fluids." (Appendix B, p. 40.)

In section "C. Scope" of the guidance document, it states that the enforcement priorities do not apply to *opened-but-unused* SUDs.

This means that at this time, the FDA is not requiring third-party or hospital reprocessors of SUDs to submit PMAs (pre-market approval applications) or 510(k)s (pre-market notification submissions) for *open-but-unused* SUDs. However, FDA's existing policy for *opened-but-unused* SUDs that are reprocessed by third parties remains unchanged: *Opened-but-unused* SUDs reprocessed by commercial reprocessors are subject to the Quality System Regulation.

Q. *Must a reprocessor of SUDs validate its cleaning/disinfection process if the device being reprocessed is not intended to be sterile?*

A. Yes. Validation is needed because the results of the cleaning/disinfection process cannot be fully verified by subsequent inspection and testing.

Dates for Meeting PMA Submission Requirements

PMA Applications (Pre-market Approval) or 510(k) Submissions (Pre-market Notification)	Due by	Cleared or Approved by
Class III	Feb. 14, 2001	Feb. 14, 2002
Class II nonexempt	Aug. 14, 2001	Aug. 14, 2002 *
Class I nonexempt	Feb. 14, 2002	Aug. 14, 2002

* Provided that the reprocessor:
1. submitted a pre-market notification by Aug. 14, 2001;
2. has not received a "not substantially equivalent" determination;
3. provides timely responses to FDA's requests for additional information.

Dates for Meeting Non-PMA Requirements

Registration and Listing	Aug. 14, 2001
Medical Device Reporting (MDR)	Aug. 14, 2002
Tracking	Aug. 14, 2002
Corrections and Removals	Aug. 14, 2002
Quality System Regulation	Aug. 14, 2002
Labeling	Aug. 14, 2002

Source: U.S. Food and Drug Administration, Rockville, MD.

Also, because the device is nonsterile, there will not be a subsequent sterilization process to kill any contaminants remaining on the device after cleaning/disinfection.

Q. *Since several extensions have been granted, what are the dates that hospital reprocessors of SUDs must meet?*

A. The chart **on p. 97** summarizes the regulatory requirements and the enforcement dates that apply to hospital reprocessors of SUDs.

[Editor's note: For questions regarding the use or interpretation of the FDA guidance, contact Lily Ng at the FDA at (301) 594-2812, or by e-mail to lxn@cdrh.fda.gov.] ■

CDC: Test HIV patients for hepatitis C virus

Co-infection complicates treatment efforts

In a move that may give voice to at least one key section of the "silent epidemic," infectious disease experts are recommending that HIV patients be offered testing for hepatitis C virus.

The new emphasize on HCV screening was added in recent HIV recommendations because the groups have some similar risk factors (e.g., injection-drug users and patients with hemophilia).[1]

In addition, knowledge of HCV status is critical for management of all HIV-infected patients in order to interpret and manage elevated liver-related tests. Screening should be performed by using enzyme immunoassays (EIAs) licensed for detection of antibody to HCV (anti-HCV) in blood.

Positive anti-HCV results should be verified with additional testing (i.e., recombinant immunoblot assay [RIBA] or reverse transcriptase-polymerase chain reaction [RT-PCR] for HCV RNA). The presence of HCV RNA in blood also might be assessed for HIV-infected persons with undetectable antibody but other evidence of chronic liver disease or when acute HCV infection is suspected.

National numbers are somewhat difficult to project, because any one HCV case can progress along several lines for years to end in benign infection or deadly liver cancer.

But like a balloon payment that is finally coming due, several projections see HCV worsening over time in a large group of those previously infected. Of the estimated 4 million Americans who have HCV antibodies, about 2.7 million have active infection. Most HCV cases are believed to have been contracted before 1990, but about 30,000 new cases still occur annually.

CE/CME questions

Save your monthly issues with the CE questions in order to take the two semester tests in the June and December issues. A Scantron sheet will be inserted in those issues, but the questions will not be repeated.

5. The first clinical strain of vancomycin-resistant *Staphylococcus aureus* (VRSA) occurred in a patient with which of the following clinical conditions?
   A. HIV infection
   B. a history of vancomycin-intermediate *S. aureus* (VISA) infections
   C. chronic renal failure
   D. all of the above

6. The Food and Drug Administration response to a needle safety petition stated the agency may ban a device if it finds a "substantial deception or an unreasonable and substantial risk of illness or injury."
   A. true
   B. false

7. Linezolid proved to be an effective alternative for vancomycin for certain types of methicillin-resistant *Staphylococcus aureus* (MRSA) infections. Which of the following type of infections were excluded from the comparative study?
   A. endocarditis
   B. decubitus ulcers associated with diabetes
   C. osteomyelitis
   D. all of the above

8. Addressing what has been called the "silent epidemic," infectious disease experts are recommended that all HIV patients be offered testing for:
   A. multidrug-resistant bacteria
   B. cryptosporidium
   C. hepatitis C virus
   D. cancer

Research indicates there was a large increase in the incidence of HCV infections from the late 1960s to the early 1980s. Annual incidence went from 45,000 infections to 380,000 infections a year in the 1980s. **(See *Hospital Infection Control*, January, October 2000, at *www.HIConline.com*.)**

HIV- and HCV-co-infected patients might experience HCV-associated liver disease in a shorter time course than patients infected with HCV alone and should be evaluated for chronic liver disease and the possible need for treatment. Limited data indicate that HCV treatment can be safely provided to patients co-infected with HIV and HCV.

Because the optimal means of treating co-infected patients has not been established and certain HIV-infected patients have conditions that complicate therapy (e.g., depression), this care should occur during a clinical trial or be coordinated by health care providers with experience treating both HIV and HCV infections.

People co-infected with HIV and HCV should be advised not to drink excessive amounts of alcohol. Avoiding alcohol altogether might be prudent because even occasional alcohol use may increase the incidence of cirrhosis among HCV-infected people.

In addition, patients with chronic HCV should be vaccinated against hepatitis A virus to decrease the risk for fulminant hepatitis associated with HAV. The HAV vaccine is safe for HIV-infected persons, but only about 66% to 75% of patients experience protective antibody responses. Patients should also be vaccinated for hepatitis B virus if they are susceptible.

Antiretroviral-associated liver enzyme elevations may increase among patients co-infected with HIV and HCV. Such increases might not require treatment modifications. Thus, although liver enzymes should be carefully monitored, highly active antiretroviral therapies (HAART) should not be routinely withheld from patients co-infected with HIV and HCV. However, co-infected patients initiating HAART might have an inflammatory reaction that mimics an exacerbation of underlying liver disease. In this situation, careful monitoring of liver function is required.

If the serum HCV RNA level becomes undetectable during HCV therapy and remains undetectable for six months after HCV therapy is stopped (i.e., sustained virologic response), more than 90% of HIV-uninfected patients with HCV will remain HCV RNA-negative for more than five years and have improved liver histology.

For HIV- and HCV-co-infected patients, durability of treatment response and requirement for maintenance therapy are unknown.

Reference

1. U.S. Public Health Service and the Infectious Diseases Society of America. Guidelines for preventing opportunistic infections among HIV-infected persons — 2002. *MMWR* 2002; 51(RRO8); 1-46. ■

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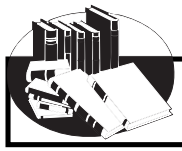

JOURNAL REVIEW

Poor work climate, high workloads = needlesticks

Looking at the intangibles of needle safety

Clarke SP, Rocket JL, Sloane DM, et al. **Organizational climate, staffing, and safety equipment as predictors of needlestick injuries and near-misses in hospital nurses.** *Am J Infect Control* 2002; 30:207-216

Nurse staffing and organizational climate are key determinants of needlestick risk and must be considered with the adoption of safety equipment to effectively reduce sharps injuries, the authors emphasize.

Recently passed federal legislation requires institutions to adopt safety equipment to prevent needlesticks, but there is little empirical evidence of the effectiveness of specific types of safety devices or the contribution of safety devices to reducing needlesticks relative to the contributions of staffing, organizational climate, and clinicians' experience, the authors note.

Staffing, organizational climate examined

They surveyed 2,287 medical-surgical unit nurses in 22 U.S. hospitals in regard to staffing and organizational climate in their hospitals and about patient and nurse outcomes, including needlestick injuries.

Hospitals provided information about available protective devices at the time of the survey (1998). The authors looked at the relationship between nurse and hospital characteristics, protective equipment, and the likelihood of needlestick injuries and 'near-miss' incidents.

"Poor organizational climate and high workloads were associated with 50% to twofold increases in the likelihood of needlestick injuries and near misses to hospital nurses," the authors concluded.

"Capless-valve secondary intravenous set systems and use of any type of protective equipment for IV starts or blood draws were associated with 20% to 30% lowered risks of both event types." ■

CE/CME 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. ■

Healthcare Infection
PREVENTION™
A Bimonthly Supplement on Infection Control Issues Across the Continuum of Care

While more procedures move beyond hospitals, most physician offices remain unaccredited, free of oversight

Only 7% of ambulatory areas accredited nationally

The vast majority of physician offices and ambulatory centers — where an increasing array of invasive procedures is being performed — have virtually no accreditation oversight and little systemized tracking of infections and other adverse events, *Healthcare Infection Prevention* has learned.

The Joint Commission on Accreditation of Healthcare Organizations is trying to address the gap with new standards and programs, but currently is only "in the foothills of these mountains," notes **Robert Wise**, MD, vice president for standards in the Joint Commission's division of research.

"One of the problems with these settings is that they have such minimal administrative infrastructure that we are not finding any data being collected systemically," he says.

"What you're finding are the sentinel events that pop up in the newspaper. Most of this stuff is anecdotal. In these settings, there is no one collecting the data, there is no one aggregating the data, and there is no one saying these are the changes that we need," Wise adds.

The issue arose again recently when endoscopy clinicians warned that an increasing number of gastrointestinal procedures are being performed in physician's offices and outpatient clinics without adequate assurance of appropriate infection control measures.

They noted that federal reimbursement actually favors doing endoscopy in such settings, though the infection control oversight found in a hospital is often lacking. **(See *Hospital Infection Control*, July 2002, under archives at *www.HIConline.com*.)**

"The trend is that more and more kinds of [procedures] are leaving the hospital," Wise says. "And actually, we are now seeing a large percentage of doctors who are not even seeking hospital privileges anymore. It is becoming more common that doctors not even associate themselves with a hospital — [and with] what they view as the rigidity and bureaucracy of being part of a hospital."

Physician offices and ambulatory settings are eligible for Joint Commission accreditation, but thus far, only a small percentage has pursued the matter. A program launched in January 2001 aimed at office-based surgical practice has resulted thus far in some 60 accredited offices, says **Michael Kulczycki**, MBA, executive director of ambulatory accreditation.

In addition, the Joint Commission currently accredits some 1,300 ambulatory settings. While these facilities must meet Joint Commission standards for infection control and other areas, they remain a striking minority nationally. **(See standards, p. 2.)**

"The ambulatory care universe — ambulatory, not just office-based surgical practice — is 60,000 facilities," Kulczycki says. "And between us and other accreditation programs, the level of accredited organizations is 6% to 7%."

Hospitals have incentives to seek accreditation, he notes, including using the Joint Commission process to ensure Medicare certification. That is less of an issue in ambulatory care, so the primary drivers for accreditation are managed care

contracts, local competition, and a desire for a quality seal of approval, he notes.

"They want to demonstrate to their medical community and the patients that they serve that they focus on providing safe and quality care," Kulczycki says.

Anesthesia problems first to surface

The highest profile adverse events occurring in offices and ambulatory settings have centered on anesthesia and sedation problems, some which have resulted in patient deaths, Wise says.

As the situation draws more attention, some states are starting to require accreditation from the Joint Commission or other organizations if the institution is going to be conducting anesthesia or moderate sedations, he says.

"Those 'drivers' are still very slow in growing," Wise says. "But because this problem still exists, we would expect more states and possibly the federal government to take a stance that accreditation is going to be required."

Infection control is not as prominent on the radar screen, but that may be a by-product of little surveillance and reporting.

"To my knowledge, problems with infection control have not popped up," he adds. "But [there is] a difference between somebody having a cardiac arrest because of improper sedation and anesthesia vs. somebody having an infection that could take days to show up. And then they may not even return to the same practitioner.

"You have a much more difficult data collection problem. Clearly one of the areas of our interest is infection control. It takes a good amount of skill, surveillance, and the collection of data. It would be one of the areas that could become weak as these settings grow," Wise points out.

Rather than requiring ICP involvement — as is done in the hospital — the Joint Commission will make infection control a focus of the survey process, he says. "We would be expecting certain data collection, certain evidence of processes in place; all of those together would decide whether the current infection control program is sufficient."

The other major push for more oversight in the expanding continuum of care has been physician credentialing and privileging issues, he adds. "A license to practice medicine allows you to do anything [medically]," Wise says.

"In a hospital setting, you have well-established processes to look at things such as privileging. It is almost unheard of, for instance, for a dermatologist to be doing liposuction in a hospital. They probably wouldn't get the privileges to do that. It's possible that they could, but there would be a lot more scrutiny. While in fact, pretty much anybody can do anything they want in the office-based setting," he adds.

(Editor's note: Lest we paint with too broad a brush, it is important to remind that some same-day surgery centers are so proficient at infection control that they are focusing on areas usually associated with advanced hospital practice — eliminating rituals. ***See story, p. 3.)*** ■

Infection control key to MD office accreditation

Practice must take measures to reduce risk

The Joint Commission on Accreditation for Healthcare Organization's requirements for physician offices and ambulatory settings that practice invasive procedures, which involve sedation, include the following areas of emphasis:

Ambulatory accreditation under the office-based surgery standards is intended for providers performing operative or invasive procedures in an office setting. Organizations licensed as ambulatory surgery centers (ASCs) are surveyed under the *Comprehensive Accreditation Manual for Ambulatory Care* (*CAMAC*).

Organizations seeking Medicare certification through Joint Commission accreditation must be surveyed under the *CAMAC*. Organizations that may recover more than one patient overnight at a time must be surveyed under the CAMAC. Hospital-based organizations are surveyed under the *Comprehensive Accreditation Manual for Hospitals*.

Practices must meet all the following criteria to be eligible for accreditation under the office-based surgery standards:

- The organization or practice is composed of three or fewer surgeons (physician, dentist, or podiatrist) performing operative or invasive procedures.
- The organization or practice must be surgeon-owned or operated, for example, a professional services corporation, private physician office, or small group practice.
- Invasive procedures are provided to patients.

(Practices only providing procedures such as excisions of skin lesions, moles, and warts and abscess drainage limited to the skin and subcutaneous tissue are not typically surveyed under office-based surgery standards.)
- Local anesthesia, minimal sedation, conscious sedation, or general anesthesia are administered. Office-based surgery practices that render four or more patients incapable of self-preservation at the same time are required to meet the provisions of the Life Safety Code. Practices may work with the Joint Commission to identify equivalencies to meet these requirements.

Other key practice standards

PC.6: The practice takes action to prevent or reduce the risk of nosocomial infection in patients, staff, and visitors.

PC.6.1: The practice takes action to control outbreaks of nosocomial infections when they are identified.

Intent of PC.6 and PC.6.1

Infection control processes and procedures are designed based on current scientific knowledge, accepted practice guidelines, and law and regulation.

At a minimum, defined protocols and schedules for infection control in the procedure and recovery areas include the following:
- Only authorized and properly attired staff are allowed in procedure areas.
- Suitable equipment and cleaning agents are provided for regular cleaning of all interior surfaces.
- Suitable equipment is available for rapid and routine sterilization of procedure room materials.
- Sterilized materials are packaged and labeled in a consistent manner to maintain sterility.
- Anesthetic apparatus is inspected and tested before each use by the practitioner who will administer the anesthetic. If found defective, the equipment is not used until the fault is repaired; repair of the equipment is documented.
- All individuals in procedure areas use acceptable aseptic techniques.
- Appropriate ventilation and humidity control are provided to minimize the risk of infection and provide for the patient's safety.
- Procedure areas are appropriately cleaned after each procedure.
- Provision is made for use of isolation precautions or, when indicated, for immediate transfer when patients are known or suspected to have an infectious disease.
- Temperature control for sterilizers, refrigerators, and other machines are monitored.
- A preventive maintenance schedule is established and maintained that includes periodic calibration, cleaning, and adjustment of all equipment, as appropriate. ■

Surgery centers herd out old sacred cows

Shoe covers, blade changes, and other rituals

It is not an easy thing to change operating room practices that have been in place since your "older" nurses were trained, says **Hilda Guevara**, RN, BSN, facility administrator of Central Park Surgery Center in Austin, TX.

"It helps to understand why we have been performing certain rituals and what has changed in the past few years," Guevara says. "Understanding where we've been and why we can change eliminates much of the reluctance a same-day surgery manager might encounter.,"

According to Guevara, the rituals that are most commonly undergoing evaluation or changes, are:

• **Cover gowns.** In the past, cover gowns were required any time you left the OR, Guevara says. There were two reasons, she says.

"Members of the public would see surgical scrubs and wonder what you might have on them that could contaminate them or the food on the salad bar," she says.

Although OR staff members always change into clean scrubs if they should get something on them during surgery, it was a matter of perception, she says.

"We also wore cover gowns to keep our scrubs clean when we left the OR," she adds. Now, 75% of OR managers no longer require cover gowns,[1] Guevara says. "Guidelines have been changed to reflect the myriad infection control studies that show no higher risk to the patient if cover gowns are not used," she explains.

• **Shoe covers.** Although many same-day surgery managers no longer require shoe covers, Guevara points out that this is a policy that can

change depending on the situation.

"One reason to wear shoe covers is to protect your shoes during surgery. The other reason is to avoid tracking dirt from the outside into the OR," Guevara explains.

Since many surgery staff members now keep a pair of "OR" shoes and a pair of outside shoes with them, the need for covers isn't as great, she says. If someone doesn't have separate shoes for inside and outside, common sense should determine if covers are needed, she says.

• **Event-related expiration date.** "We used to pull trays of instruments we had sterilized and wrapped after they had been on the shelf for three or six months and send them back to be sterilized again," Guevara says.

"Now, we realize that once it's sterile, it stays sterile as long as the packaging isn't damaged."

For this reason, it is common to leave trays on the shelf until needed unless the wrapping is damaged, she says.

• **Hand scrub.** A 10-minute initial surgical hand scrub with three to five minute scrubs between cases is one ritual that is still alive, says Guevara. "Although new scrubs, even some that don't require brushes, do eliminate the need for lengthy scrubs,[2] this is one ritual many OR staff members are reluctant to give up," she says.

At Guevara's facility, staff are given the option of reducing the initial scrub to five minutes with a three-minute scrub between cases. "Although some of the new surgical hand-scrub products are more costly, shorter scrub times are not as hard on the skin," she says. Shorter times help staff avoid various skin conditions such as eczema and rashes that result from constant scrubbing.

• **Knife blade changes.** Another ritual that may continue, depending on the surgeon's preference, is the use of two knife blades, Guevara says. "Most surgeons have always used one knife for the initial incision and another for any other dissection."

Some surgeons choose to do so because they believe that making the initial incision dulls the knife's edge, and they want a sharp blade for the rest of the procedure, she explains.

Other surgeons believe the use of two blades is better from an infection control perspective, she adds. "There are data that show that there is no increased risk with the continued use of the first knife because the microbes on the knife are the patient's own microbes."[3]

The best course of action for this ritual is to let the surgeon decide, Guevara adds.

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2. Larson EL. APIC guidelines for handwashing and handwashing antisepsis in healthcare settings. *Am J Infect Control* 1995; 23:251-269.

3. Hill R, Blair S, Neely J, et al. Changing knives a wasteful and unnecessary ritual. *Ann R Coll Surg Engl* 1985; 67: 149-151. ■

Patient safety standards coming for LTC in 2003

Joint Commission urging residents to 'speak up'

Taking its national patient safety campaign to long-term care facilities, the Joint Commission on Accreditation of Healthcare Organizations is adding new standards for 2003 and will urge all residents to "speak up" about medical errors.

Under the new "speak up" campaign, residents in nursing homes and assisted-living facilities will be urged to become active, involved, and informed participants of the health care team. Accredited health care organizations will be receiving information about the campaign and samples of the campaign brochure and buttons. The brochures are being tailored to specific organizations, including long-term care and assisted-living facilities. The brochure has a blank panel, which will permit an organization to add information about its commitment to resident safety and its logo. The new standards — similar to those implemented for hospitals last year — go into effect Jan. 1, 2003. The standards require:

- Long-term care leadership to create an environment that encourages risk- and error identification.
- Active engagement by the organization in proactive systems analysis and improvement.
- Training throughout the organization that focuses on teamwork, avoidance of adverse events and error identification, analysis, and prevention.
- The use of available knowledge to guide safety improvement and reduce errors.
- The need to inform the resident, and when appropriate, his or her family, of unanticipated outcomes of care.
- Solicitation of input from the resident and his or her family on steps that could be taken to enhance safety and reduce errors. ■