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INSIDE

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HIV, hepatitis tests urged for thousands after stunning admission of needle reuse

Lab worker also had difficulty drawing blood in prior hospital job

Some 3,600 people have been advised to be tested for bloodborne viruses after a phlebotomist in a Palo Alto, CA, clinical laboratory recently shocked health officials and outraged patients by admitting to an infection control breach of striking severity: reusing needles to draw blood.

The admission and several other potentially significant findings about the case were documented in court records obtained by *Hospital Infection Control*, including reports by public health officials who investigated the case and submitted "declarations" in support of a court order temporarily barring the phlebotomist from doing any other patient care or blood work. The documents in the injunction application were filed in the state Superior Court of San Mateo County in Redwood City, CA, on April 29, 1999. The phlebotomist has not been charged with a crime. **(See related story on court action, p. 76.)**

The case is under criminal investigation by **Dale Sanderson**, JD, Santa Clara County deputy district attorney in San Jose. Sanderson declined to comment regarding which criminal statutes might be used to prosecute the phlebotomist. "It is an ongoing criminal investigation," he tells *HIC*. "It is by no means complete." Efforts to reach the phlebotomist by phone were not successful. Her attorney in the civil case, **James Lenninger**, JD, in San Jose, tells *HIC*, "Until such time as we are clear of any criminal investigation, there isn't going to be any comment on it." The considerable fallout from the case includes a class action lawsuit against the lab's operator, SmithKline Beecham Clinical Laboratories in Philadelphia; a separate lawsuit by a patient who claims to have been infected with hepatitis C virus at the lab; and a proposed new state law to toughen phlebotomy training and oversight in California. **(See related stories, pp. 77-78.)**

Public health officials are at a loss to explain such a gross violation of standard medical practice, particularly because the 52-year-old female phlebotomist had been working in the field as a certified blood-drawer since 1994.

"She had a lot more training than most, and she had been working as a phlebotomist for several years," says **Sara H. Cody**, MD, who interviewed the phlebotomist and filed a court report as communicable disease control officer for the Santa Clara County Public Health Department in San Jose. "In her case, I don't think that training was the issue. We are all just absolutely stunned — jaws on the floor — and really do not know [why she did it]. It is so bizarre."

According to court documents, a co-worker who blew the whistle in the case reported the phlebotomist allegedly said she was cleaning and reusing "expensive" butterfly phlebotomy needles at the SmithKline Patient Service Center lab to avoid any "problems" with the company. Butterfly phlebotomy needles, which are available in conventional and safety designs to prevent needlesticks, often are selected for more difficult blood draws because they have tabs that ease grip and placement. SmithKline adamantly denies that any cost or supply problems were an issue in such a flagrant violation of its basic infection control policies. The court documents also indicate that the phlebotomist had a record of "termination" from a previous hospital job after some six weeks for problems that included making "numerous errors" and having "extraordinary difficulty" doing blood draws. There was no indication of needle reuse at that site.

Phlebotomist cited supply concerns

According to court records, the lab co-worker who tipped off authorities about the case reported seeing a white plastic basket containing butterfly needles that were soiled with visible blood. When the co-worker asked the phlebotomist whether she should dispose of the needles in a sharps container, the co-worker reported that the phlebotomist allegedly said the butterfly needles could be reused two or three times, according to the court report filed by **Donald Newbold**, MT, a laboratory field services examiner for the state Department of Health Services (DHS) in Berkeley. The court reports do not imply any reuse of needles by the co-worker, a temporary employment service worker who reported the reuse incidents to her employer and subsequently described the lab practices to public health investigators.

In her comments to investigators, the phlebotomist who confessed to reusing single-use needles cited supply concerns as her rationale. When asked why she didn't simply call another lab or her supervisor regarding her concerns about running short of the needles, "she responded that she just didn't. She said the butterflies were 'like gold,' which I understood to mean that they were highly prized," Newbold reported in court documents. Newbold declined through a department spokesman to be interviewed for this report.

A SmithKline Beecham spokesman denied that any supply problems or cost pressures contributed to the phlebotomist's actions. Though such butterfly designs can cost an estimated 50 cents each as compared to conventional equipment in the range of 10 cents apiece, cost would not have been a roadblock to her simply ordering more of the needles, says **Thomas Johnson**, spokesman for SmithKline.

"She has stated that she was concerned about running out of needles and that is why she was reusing them," Johnson tells *HIC*. "But there are no restrictions on any of our phlebotomists for ordering or using supplies when it comes to collecting blood samples. So there is really no rational explanation for why she did what she did."

According to court records, the phlebotomist admitted to Cody and another investigator that she reused approximately five butterfly needles during the first week or two of March 1999. She also admitted to Newbold that she reused butterfly needles on five to 10 patients during a two-week period when she claimed she could not get butterfly needles because of a supply disruption due to the supply department moving. However, state health investigators and prosecutors in the civil case concluded in the court documents that her "reason for reusing butterfly needles is not substantiated, nor is her report of her frequency of reusing needles."

Some 3,600 patients visited the lab while the phlebotomist worked there from June 1, 1997, to March 22, 1999, after which her employers suspended and then fired her. Because she was the primary phlebotomist at the lab, it is thought that the majority of the blood draws done at the lab during that period were done by her with the exception of sick days, vacations, and periods when other workers joined her in the lab, says **Ken August**, spokesman for the state DHS in Sacramento. As a result, SmithKline sent certified letters offering free testing and follow-up for HIV and hepatitis B and C for all 3,600 patients. They also sent letters to patients' physicians of record and set up a hotline for patients to seek information on the case. The lab drew patients from a

variety of sources, including referrals from internal medicine physicians, obstetricians, and surgeons. Additional patients came on research protocols from Stanford University, Cody adds.

In admitting to reusing the needles in limited instances, the phlebotomist described a "disinfection" and repackaging method that was recorded in court documents as follows:

"To 'disinfect' the needle she placed it immediately in the sink behind her after removing it from the patient. She stated that she then took a small disposable cup, filled it halfway with water and added a small amount of hydrogen peroxide. She then placed the needle and tubing in the cup, and used a vacutainer to clear the solution. She said that both the needle and tubing were very clean when she was done. She stated that she slid the plastic protective cover back up over the bevel of the needle, wrapped up the tubing and placed the needle and tubing back in the original wrapping," the court report states.

"This is an absolutely inadequate method," Cody tells *HIC*. "It is not sterilization, it is not disinfection, and it's barely cleaning. To be honest, when she described what she did, there was some internal consistency in her story. So if she really believed hydrogen peroxide was an adequate disinfectant, maybe she was trying to do right, to do good. I don't know whether the whole story was constructed after some thinking, or whether she really felt that way. I am not sure how someone could have such a grave misunderstanding about infection control."

Though some flushing of pathogens may have been accomplished with the diluted antiseptic, even needles designed for reuse must be thoroughly cleaned and then heat-sterilized, according to guidelines by the Centers for Disease Control and Prevention. More to the point, any attempt to reprocess single-use needles "may not sterilize the internal surfaces and may compromise the integrity of the device," the CDC states.[1] Indeed, Newbold noted in his report that upon examining some of the repackaged devices, "a reddish substance that appeared to be blood" was visible to the naked eye on several of the butterflies on the end of the tubing and on the needle that is inserted into the vacutainer.

At least some of the butterfly needles at the lab were a winged steel design that uses a safety shield that locks in place after use to prevent needlesticks, Newbold found. But investigators did not report that the worker's actions were motivated by a desire to protect herself from injuries and exposures. Instead, the court documents cite a "cavalier" attitude toward basic asepsis that included rarely wearing gloves, according to the co-worker's account. Butterfly needles also are generally used for more challenging blood draws, Johnson says.

"They are used for patients that are more difficult to draw, either the very young or very old, or patients with veins that are difficult to draw from," he says.

Johnson says he was not aware of the phlebotomist having any difficulty with blood draws, but notes that she may have had a "preference" to use the devices.

Questions of competence

However, considerable evidence that the phlebotomist had past difficulties in collecting blood specimens was cited in hospital records and public health interviews with the phlebotomist's former supervisors at Mills-Peninsula Health Services in Burlingame, CA. She worked at the hospital "from Sept. 3, 1996 until her termination on Oct. 15, 1996," Newbold reported. Dated that same day, a hospital letter explaining the action to the phlebotomist said, "You have made numerous errors, such as misdrawing patients, leaving orders uncollected, [and] creating or drawing specimens that need to be recollected due to poor quality," according to court documents.

Another supervisor at the same facility told the investigator that the phlebotomist "had extraordinary difficulty getting patients' blood. Sometimes, [she] would be unable to obtain the blood specimen and would not tell the laboratory. The laboratory would learn of the problem when the physician would call for the test results." The reason given for the termination was "work performance not up to established standards regarding phlebotomy."

Margie O'Clare, director of communications at Mills-Peninsula, confirmed that the phlebotomist worked on the aforementioned dates in a probationary status. She did not "successfully complete" her probation, which is normally six months. Regarding questions about alerting subsequent employers to the action, O'Clare says hospital policy permits only release of employee dates of service. Regardless, court records reveal that the phlebotomist worked for a temporary service that found her a job at another SmithKline lab in San

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Court order granted to bar HCW from medical work

State cites 'cavalier disregard' of precautions

In successfully seeking a temporary restraining order to prohibit a laboratory phlebotomist in Palo Alto, CA, from continuing any blood-drawing or patient care duties after she admitted to reusing needles, state prosecutors outlined a series of findings from public health investigators.

The documents were filed by Elizabeth Edwards, JD, state deputy attorney general, on April 29, 1999, in the Superior Court of San Mateo County. The application for a temporary restraining order cites findings that were based on interviews with the phlebotomist and other principals in the case by public health investigators that included Sara H. Cody, MD, communicable disease control officer for the Santa Clara County Public Health Department, and Donald Newbold, MT, a laboratory field services examiner for the state Department of Health Services. The temporary restraining order was granted on April 29, 1999, barring the phlebotomist from blood drawing, patient care, and related activities. At a subsequent hearing on May 14, the court extended the order indefinitely, pending trial on the case for a permanent injunction. The findings by the health investigators and allegations by state prosecutors presented in the court documents are summarized as follows:

• Defendant admits that she knowingly and willfully reused needles on multiple patients while working as a phlebotomist at a SmithKline Patient Service Center (PSC) in Palo Alto in February or March 1999. Defendant admitted to two investigators that she reused approximately five butterfly needles during the first week or two of March 1999. However, defendant admitted to another investigator that she reused butterfly needles on five to 10 patients during a two-week period when she could not get more butterfly needles because the SmithKline supply department was moving.

• An investigator later confirmed that the defendant's PSC in Palo Alto received shipments of butterfly needles on Jan. 14, 1999, and March 2, 1999. The supply department's relocation took place over three days on Feb. 3-5, 1999. Supplies were delivered within two to three days of receipt of the order, but at most within five to six days if they had to be ordered from the vendor. Accordingly, defendant's stated reason for reusing butterfly needles is not substantiated, nor is her report of her frequency of reusing needles. For example, defendant ordered butterfly needles on Feb. 24, 1999, and defendant's PSC received the shipment of butterfly needles on March 2, 1999. Yet SmithKline supervisors located defendant's basket of used and "washed" butterfly needles three weeks later on March 23, 1999. The needles had been placed back into their original packaging, and some contained visible blood deposits. This was more than six weeks after the supply department had relocated.

• There also is evidence that defendant allegedly intentionally mislabeled blood specimens to cover up mistakes and to avoid recalling patients for further blood drawing. There is further evidence that defendant allegedly used the same pipette to pipette blood between specimens from several different patients, causing cross-contamination; used the same pipette to transfer both blood and urine; and rarely wore gloves. Defendant appeared to be cavalier in her disregard of the most basic precautions designed to protect patients from harm.

• There is evidence that defendant allegedly substituted her own judgment for that of referring physicians when patients presented at the PSC without requisition forms or when patients asked defendant for their test results. There is evidence that defendant allegedly provided patients with test results that were only to be given by physicians.

• Defendant's report of the reasons why she reused needles, her claims regarding the number of patients upon whom she reused needles, and the frequency with which she reused needles appears at this point to be inconsistent with the facts the department has gathered. The additional evidence indicating further wrongdoing would, among other concerns, cause false laboratory results, thereby causing additional potential harm to patients. Approximately 3,600 patients have been notified that they may want to be tested for bloodborne diseases. Defendant's actions have clearly caused widespread anxiety. ■

Carlos in 1995. Mills-Peninsula records also indicate she was reportedly an "on-call" employee for SmithKline at the time of the probationary hire, O'Clare says. The phlebotomist had three certificates of training and a recommendation, she says. Johnson says he is not sure specifically what referral and background information SmithKline had on the worker when she went to the Palo Alto lab, "but I can say for certain that if the company had received any information indicating that she was not fit to perform her duties as a phlebotomist, then she would not have been hired."

Mills-Peninsula sent letters offering free follow-up testing to 272 patients who may have had "contact" with the phlebotomist. Needle reuse is considered unlikely because she was closely supervised as a probationary employee at the facility, according to a hospital statement. The DHS is investigating other job sites where the phlebotomist worked to try to identify any other infection control breaches, August says. The department also is investigating allegations in the court documents that the phlebotomist reused lab equipment such as pipettes and mislabeled blood samples at the Palo Alto facility, he adds.

Still, there was no indication of criminal intent when the phlebotomist was questioned about reusing the needles, he notes. "In talking with investigators from the Santa Clara County Health Department and representatives from SmithKline, they [all] said that she did not show any malice or any ill intent," August says. Nevertheless, as part of the aforementioned criminal investigation, Palo Alto police have set up a "tip line" seeking information from any of the patients who specifically saw a staff worker reuse a needle to conduct a blood draw at the lab. In addition, they are seeking additional information from all patients who report that they tested positive for a disease they didn't have prior to having their blood drawn at the lab.

Cody reported in her court statement that the phlebotomist "knows the practice was wrong and that she should not have done it. She admitted that she made a mistake. She was directly asked if she had done anything like this before and she emphatically denied ever having re-used needles, except for this instance."

Such blatant violations of basic asepsis are rare but not unprecedented. The CDC took the unusual step of reiterating the aforementioned guidelines for proper use of needles and syringes in 1993 after a physician administering group immunizations was observed wiping the needle with an alcohol swab and using it on the next patient.[1] Though uncommonly reported, reuse of needles has resulted in patient-to-patient transmission of HIV.[2,3] Indeed, Cody concluded the phlebotomist's actions constituted a threat to public health, and Newbold recommended that she be barred for life from working in the laboratory sector of health care. While the state has regulatory authority over labs and could take action against the Palo Alto facility, no larger program of inspection or oversight of state clinical labs is currently planned, August says. "To our recollection," he says, "this is unique."

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Two lawsuits filed in wake of needle reuse admission

Class action for those 'scared out of their wits'

A class-action lawsuit and a separate suit by a patient claiming infection with hepatitis C virus have been filed in the wake of a phlebotomist's court-documented admission to reusing needles in a clinical lab in Palo Alto, CA. The lawsuits were filed against the phlebotomist and the lab's operator, SmithKline Beecham Clinical Laboratories in Philadelphia.

SmithKline spokesman **Thomas Johnson** says the company does not comment on cases under litigation. The class action suit was filed by Stephen L. Blick of the firm of Hawkins & Blick on April 30, 1999, in the state Superior Court of Santa Clara County in San Jose, CA. The suit's numerous damage claims include lack of informed consent to reuse the needles, battery, intentional infliction of emotional distress, negligence, and breach of contract and implied warranty. The suit also cites the prolonged fear — familiar to health care workers who have suffered needlesticks — that seroconversion from a bloodborne virus could occur months after the exposure.

Proposed law would beef up phlebotomy training

Training can't prevent irresponsibility

As a result of the court-documented admission of reuse of needles by a lab phlebotomist in Palo Alto, CA, Assemblywoman **Carole Migden** (D-San Francisco) is proposing a new state law that would require more rigorous infection control training for health care workers who draw blood.

Migden successfully spearheaded passage of a landmark law last year requiring medical facilities in California to purchase needle safety devices to protect health care workers from acquiring bloodborne infections from patients.

"The actions of the woman in Palo Alto appear to be very irresponsible, and no amount of training will prevent irresponsibility," Migden tells *Hospital Infection Control*. "But what my bill will do is to allow the state to prevent such people from doing it again. By requiring all phlebotomists be certified by the state, the state can prohibit irresponsible people from working in this field. This case has undoubtedly raised the priority of a policy that has long been neglected."

Nonetheless, a lack of training does not necessarily explain the Palo Alto case, because even the minimal current requirements that Migden is trying to upgrade would cover such a basic breach as reusing needles. State law currently requires a minimum of 10 hours of training and a demonstration of three blood draws for phlebotomy certification.

"Based on that training, [the phlebotomist] should have known that reusing needles or any other lab equipment is a serious breach of standard medical practice," says **Ken August**, spokesman for the state Department of Health Services in Sacramento.

If approved as drafted, beginning Jan. 1, 2001, phlebotomists must hold a valid, current certification issued by a national accreditation agency approved by state officials. The state will establish guidelines for approving certification training programs and national accreditation agencies to administer examinations and tests. In addition, phlebotomists will have to complete education, training, and experience requirements that include:

- 40 hours of didactic instruction;
- 40 hours of practical instruction;
- at least 100 venipunctures;
- three hours per year or six hours every two years of continuing education or training. ■

"The class action we have filed is basically for the people who have been scared out of their wits by this lady," says **Charles Hawkins**, JD, a partner in the firm. "There is an expressed, direct, contractual and actual relationship between SmithKline and each of these patients. There is an implied warranty that you are going to perform these medical tasks in a manner consistent with the standard of care and good medical practice. They breached that."

Hawkins' wife, Linda, who claims in the suit to have had blood drawn at the clinic several times by the phlebotomist, is listed in the suit as the initial plaintiff. "You just need one plaintiff to certify the class if the plaintiff is representative, but you have to show the judge that it is a kind of action that is amenable to class-action work," Hawkins says.

The suit could grow to include many of the 3,600 patients contacted by SmithKline if it is awarded class-action status by the court. The firm already has received 600 phone calls from patients who were notified by SmithKline to consider testing in light of the incident. In order to certify the class as "representative," those who actually claim to have been infected with a bloodborne disease at the lab will be referred to their own attorneys to pursue separate action, Hawkins says.

In that regard, another lawsuit claiming an actual infection at the SmithKline lab in Palo Alto was filed on May 4, 1999, in the state Superior Court of Santa Clara County in San Jose, CA, by attorney Richard Alexander, JD. A woman identified only as "Jane Doe" in the suit claims she tested positive for HCV on or about Oct. 29, 1997. She claims she had her blood drawn by the phlebotomist the prior June, July, and September at the Palo Alto lab while participating in a research program at Stanford University.

"That's the only likely association," Alexander tells *HIC*. "She doesn't have any history of transfusion or drugs [or any other risk factors]."

The woman gave birth in March of 1997, and there was no evidence of any HCV in the testings and evaluations prior to delivery, he adds. Her husband is HCV-negative, he notes. ■

Nosocomial outbreaks linked to staff shortages

Investigators find fewer staff may mean more staph

Health care staffing fluctuations, increasingly common in the managed care era, can spark nosocomial outbreaks if rising patient census or acuity outstrip nursing resources, clinical investigators are reporting.

As health care delivery changes continue, nosocomial infection rates in general may rise as patient severity of illness increases and all but the sickest patients are rapidly discharged.[1-3] But clinicians — including several recently in San Francisco at the Society of Healthcare Epidemiology of America (SHEA) Conference — also are increasingly tracing nosocomial infections to staff problems caused by department mergers or addition of new services, spikes in census, cutbacks in nursing, or increased use of "pool" and agency nurses.

Though it can be difficult to establish a clear epidemiological link between such conditions and subsequent infections, the general consensus is that staffing problems — particularly if they occur in conjunction with an increase in patient acuity — may undermine aseptic technique, catheter care, and hand washing compliance by harried health care workers.[4] **(See *Hospital Infection Control*, June 1996, pp. 69-72.)** *HIC* asked **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University in Nashville, TN, to review some of the SHEA findings on the emerging trend.

"When we have difficulties in our surgical and trauma ICUs, it is when the personnel are stressed with more admissions and sicker patients," says Schaffner. "Obviously, there has to be a certain degree of flexibility in staffing, but when you reach the upper limits of that, [our nurses] are absolutely convinced — just by their observations — that health care personnel cut corners. They just have so much to do and they stop washing their hands, or they may be gloved but they go from patient to patient with the [same] gloves. Lots of little things like that begin to frazzle."

If so, current conditions generally ascribed to restructuring under managed care — higher inpatient acuity and tight-fisted budgets for nursing staff — would seem to be a virtual recipe for such problems to occur. But the link between staffing problems and subsequent infections is not a newly reported phenomena, as evidenced by studies reporting the problem in the early 1980s.[5] In one such study, Schaffner and colleagues linked an outbreak of multiresistant *Klebsiella pneumoniae* infections in an intensive care nursery to inadequate nurse-to-patient staff ratios.[6]

"Clearly, the *Klebsiella* was being spread from person to person, and we think that it was on the hands of caregivers," he says. "Staffing ratios appeared to play a very important role."

While it is extremely difficult to tease out the variables in such studies to clearly ascribe the infections to staff changes as opposed to an increase in severity of patient illness, efforts to document the elusive connection may be used to sway administration from making staff cuts, he adds.

"It's important to publish these because [ICPs] can take them to their administrators kind of 'prophylactically' as reductions in force are anticipated," he says. "They can educate them that at some point, these reductions in force can have direct adverse consequences on the patients."

Latest findings presented at SHEA

In that regard, the latest wave of research on the issue was reported at the annual SHEA conference.

In one study, a staffing shortfall during a period of increased patient census was linked to an outbreak of *Staphylococcus aureus* in a neonatal intensive care unit at University Hospital in Cincinnati, reports **Amy Beth Kressel**, MD, director of infection control at the facility.[7] Last year, the hospital became a referral center for high-risk pregnant women within its multihospital group. As a result, the census of the NICU increased and staffing fell below optimum levels. During the period of May 14-31, five infections with *S. aureus* occurred in the NICU. Four of the five infected neonates were in the same area of the NICU, and four of five infected babies were intubated.

"Usually, we have fewer than two infections per month, and they had five that were in close temporal association with each other," Kressel says. "When we looked at where the beds were [of] the infected neonates, four of them were in close proximity to each other — actually adjacent beds in one pod."

Given the close proximity of the cases, an initial theory was that a colonized health care worker was spreading the pathogen from patient to patient. Nurses were typically assigned to certain patients or pods of neonates on various shifts.

"But when we actually tried to find out who had been taking care of the babies, the nurses told us that they had a nursing shortage and in reality people were helping each other out, and even in rare instances they were going into other pods," she says. "So we really can't say who specifically took care of these babies because there was a lot of cross-coverage. We also found that a disproportionate number of the infected neonates were intubated, so we [also investigated] respiratory therapy. We found that in both areas — respiratory therapy and nursing — there was a staff shortage."

Increase in census, acuity

Both overall census and the respiratory acuity index had increased approximately two weeks prior to the outbreak, and the ratio of patients to nurses grew beyond recommended levels. As a result, evaluation of nursing care revealed deficiencies in hand washing technique and glove use, use of nonstandard soaps, and inconsistencies separating clean and dirty areas. Four of the five infected patients had staph with the same DNA fingerprint pattern. Efforts that successfully stopped the outbreak included presentations to administration on the importance of adequate staffing and education of nurses and respiratory therapists on infection control techniques, especially hand washing.

"We concluded that overall decreased staffing had probably played a role," she says. "There had been a spike in our census just before all of this happened, and that seemed to support this as well. Our staffing levels have improved, and we have not had recurrent problems with *Staph aureus* in the NICU."

In another MRSA outbreak reported at the SHEA conference, **Robert Cunney**, MB, a research fellow at McMaster University Medical Center in Hamilton, Ontario, Canada, examined the impact of nursing and environmental staffing levels on a busy general surgical ward over a six-month period during July to December 1998.[8] There were 29 nosocomial acquisitions of MRSA by patients on the ward during the time period. A marked increase in the incidence of new cases of colonization was noted shortly after a cost-saving cutback reduced the number of environmental cleaning personnel on the ward. The cleaning duties affected included terminal room cleaning after patient discharge and routine cleaning on a day-to-day basis in the ward. There also was a prior increase in the use of temporary "agency" nursing staff on the ward.

"While there wasn't a reduction in the overall nurse staffing levels, there was an increase in the use of temporary staff brought in from outside agencies," he tells *HIC*. "There was also some transfer of staff from other units in the hospital. So our impression was because it wasn't the same stable nursing base in this particular ward, that this may have accounted for the increases in nosocomial MRSA acquisition."

On regression analysis, the use of agency staff was significantly associated with MRSA acquisition rates, though overall nursing and environmental staff levels were not. However, both the use of extra nursing staff (i.e., outside of those normally scheduled to work on that ward) and the number of hours of environmental cleaning carried out each week were found to be linked to MRSA acquisition rates on covariance analysis. Cunney concluded that ICPs should pay attention to nursing and environmental cleaning staffing levels on wards where MRSA is a potential problem. Environmental cleaning hours have been increased since the findings, and a similar effort will be made with administration regarding the nursing staff issues, he notes.

"It may well have been that these two changes were almost synergistic," he says. "That when you combined extra use of agency staff — who perhaps were not as familiar with the patients, who were generally working overtime and may not have the same skills base — with a reduction in environmental cleaning, they seem to translate into a marked increase in our MRSA rates."

Inadequate hand washing may have again been a factor, because patients who were acquiring MRSA on the ward appeared to be the ones who required the most handling, he added.

A similar finding regarding use of pool nurses was reported in another SHEA study on central venous catheter-related bloodstream infections (CVC-BSIs) presented by **Robert Duncan**, MD, epidemiologist at Lahey Clinic in Burlington, MA.[9]

Nursing workload not a factor in VRE outbreak

Antibiotic use emerged as risk factor for VRE

The emerging link between infection rates and nursing staff changes may make it tempting to conclude that increases in nursing workload in general will lead to increased patient colonization with nosocomial pathogens. But an epidemiologist who explored this issue found that only prior administration of antibiotics — not nursing workload intensity — was a statistically significant risk factor for subsequent patient colonization with vancomycin-resistant enterococci.[1] **(See related story, p. 79.)**

Mark Loeb, MD, MSc, FRCPC, microbiologist and infectious disease consultant at McMaster University in Hamilton, Ontario, conducted a case-control study to determine whether potentially modifiable risk factors such as antibiotic use and nursing workload intensity were associated with VRE colonization during a 1998 hospital outbreak. The study was reported recently in San Francisco at the annual conference of the Society for Healthcare Epidemiology of America.

"The assumption is that if nurses are working too hard, they can't pay attention to infection control measures," he tells *Hospital Infection Control*. "Everyone, the media, says we are getting so much VRE because the nurses are overworked. So we did a study to say, is this true or not? We didn't find it was true in this study."

Case patients in the study were those who acquired VRE nosocomially (at least 48 hours after admission) during the outbreak period and had at least one negative surveillance swab prior to detection of VRE. Control patients were randomly selected from among patients who did not acquire VRE in the units where VRE was detected. Antibiotic use was determined for up to a 12-week period prior to VRE detection for cases, and for up to a 12-week interval between the first and last negative rectal swabs for controls. Nursing workload intensity was determined daily using the GRASP system, in which standardized nursing time requirements are assigned to nursing interventions as a way to measure workload intensity.[2] Only cephalosporin use was independently associated with subsequent VRE colonization in a statistical analysis.

"We found that the nursing workload was not an independent risk factor for VRE," Loeb says. "The point estimate of the odds ratio did show an increased workload in cases as compared to controls, but it wasn't statistically significant."

A possible reason is that the threshold of workload intensity that would result in increased VRE transmission was not reached, says Loeb, who has submitted the study for publication to a peer-reviewed journal. "The bottom line is that this is not the end of the story," he says. "We need more studies looking at nursing workload and multiresistant organisms, and we need to assess different tools for looking at them as well."

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Duncan and colleagues studied factors affecting CVC-BSIs after services were altered in a surgical intensive care unit (SICU). SICU infection rates had remained stable from 1993 until 1997, but then rates of BSIs and CVC-BSIs increased significantly. CVC-BSI rates rose most dramatically (by 3.1-fold). This coincided with facility changes that included incorporation in February 1997 of a Level II trauma center and establishment of a separate five-bed cardiothoracic surgery post-anesthesia care unit (PACU). Intensity of daily nursing care requirements remained steady, but average length of stay doubled (from three to six days) at the same time the hospital ran into a shortage of nurses.

"We had unanticipated change in nursing staffing," he told SHEA attendees. "We had

expected with the new five-bed cardiothoracic PACU that we were going to have empty beds in the surgical ICU. Suddenly we were scrambling for nurses in a fairly tight, competitive market for nursing staffing."

More staff were drawn from overtime and nursing pools in an effort to keep the nurse-patient ratio steady, he noted. However, make-up staffing by nurses less familiar with the SICU adversely affected CVC care and infection rates. With additional hiring in 1998, BSIs dropped 22%, from 18.16 per 1,000 critical care days to 14.08, and CVC-BSIs dropped 41%. During the peak of infection problems, the typical 7% level of pool nursing staff had nearly doubled to 13%, but as infections subsided with the hiring of new staff, the level of pool workers dropped back to 8%. The CVC-BSI rate may be a sensitive indicator of costly adverse outcomes related to overburdened nursing staff, he noted.

"We had a significant increase in the number of polymicrobial catheter infections, which I take as an indicator of sloppy line care," Duncan told SHEA attendees.

Such links between infection rates and staffing would seem to suggest that increases in nursing workload in general — without staff reductions or skill-level fluctuations — would contribute to increased patient colonization with nosocomial pathogens. But another SHEA study that explored the same issue found that only prior administration of antibiotics — not nursing workload intensity — was a statistically significant risk factor for subsequent patient colonization with vancomycin-resistant enterococci. **(See related story, p. 81.)**

"It may well be that certain pathogens are more likely spread under these circumstances than are others," Schaffner says. "The literature has a principal interest in staphylococci, and as we get into other organisms — VRE, for example — it may be that the threshold for that as your indicator organism is indeed higher. It may also depend on whether you look at certain site-specific infections as opposed to all nosocomial infections."

Indeed, because it can be difficult to account for all such possibilities, it will be important to see the complete presentation of data and methods of the aforementioned SHEA studies if they are published in the peer-reviewed medical literature, he notes.

"The questions that these investigators are trying to address are very important because hospitals are seeing an increase in severity of illness, trying to shorten hospital stays, and they are looking very carefully at personnel," Schaffner says. "Lots of hospitals are undergoing staff reductions of various kinds. The possible relationship of those circumstances to nosocomial infections clearly needs to be looked at. Based on the literature and these [SHEA] observations, one suspects that at least under certain circumstances the two are related. The devil is in the details."

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Paradigm shift: Rethinking IC and rising patient acuity

Novel catheters; isolation of high-risk patients

Technological advances like antiseptic-coated catheters and other intravascular devices designed for infection prevention may become increasingly important clinical weapons as inpatient acuity increases, **Dennis Maki**, MD, emphasized recently in San Francisco at the annual conference of the Society for Healthcare Epidemiology of America.

Maki, the chief of infectious diseases at the University of Wisconsin Hospital and Clinics in Madison, delivered the SHEA lecture, one of the conference's keynote addresses. Surveying a health care landscape marked by spiraling inpatient acuity, Maki said new infection control approaches must be embraced because the old paradigms are failing.

"There has been a tremendous trend in acute care hospitals over the last 15 years towards an intensification of care," Maki said. "The severity of illness of patients in hospitals is striking. In my own ICU where I have been doing research and have been attending for almost 25 years, the average Apache II score has increased from about 12, 15 to 20 years ago, to 16 to 18 now, which is a tremendous increase in terms of risk for the patient."

Such severely ill patients may well survive due to the medical skills and devices that can be brought to bear in today's ICUs, but all the while they face increased risk of nosocomial infections, he added.

"The price we pay is a great increase in risk of infection, and I think that we are starting to lose the battle in terms of nosocomial infection," he said. "I think that rates of bloodstream infections and pneumonias are increasing. It's very clear that certain organisms, such as nosocomial fungi, have increased almost tenfold over the last 15 years. We've lost the battle against MRSA, and we are losing the battle against vancomycin-resistant enterococcus [VRE]."

Infection surveillance may suffer under trends toward increased acuity of care and decreased staffing per patient, especially bedside nurses in ICUs, he added.

"Our databases in individual hospitals are shrinking because we're being asked to do more and more with less and less. There are less resources targeted toward surveillance," Maki told SHEA attendees. "I'm not sure we really fully understand what's happening in our hospitals. The challenge to simply hold the line is formidable. What can we expect [to achieve] in terms of trying to further modify health care workers' behavior to try to reduce the risk of infection? I would submit this is the old paradigm, and I think it's failing."

But a new paradigm may be emerging in light of epidemiologic research underscoring advances in infection prevention technology, he said. Such advances may provide a new avenue to infection prevention in light of the continuing struggles to improve health care worker compliance with aseptic measures in the care of catheters and invasive lines.

"Trying to whip people to comply more is not the direction we ought to be going in," he said. "I think the yield is going to be extremely [low] and it's going to [do] nothing but engender more frustration."

The greatest advances have been made with intravascular devices such as catheters. For example, catheters coated with silver sulfadiazine chlorhexidine have been shown to reduce the risk of infections — particularly those caused by multiresistant organisms — by about 50% in some dozen studies. Catheter-related infections may occur when microorganisms invade the implanted portion of the device and then colonize the surface in a biofilm. But strategies to make the device's surface less conducive to formation of a biofilm are starting to pay off, he said.

"I think it's a very exciting time to be working in nosocomial infection control, because only in the last 10 years there has been an explosion of good research identifying technologies that hold much promise for substantially reducing the risk of infection independent of whether or not the care that that device gets is what we would like to see," Maki said.

Still, only about 25% of ICU patients with central lines — the highest-risk population — are currently being treated with antiseptic or antimicrobial catheters, he said.

Addressing other topics in his wide-ranging speech, Maki said the emerging data on antibiotic

resistance continue to prove that new drug development will not solve the problem. For example, some of the patients treated with Synercid for VRE infection have developed strains of the pathogen resistant to the new streptogramin compound.

"If new antibiotics were the answer, we shouldn't be drowning in resistant organisms because we've had many, many new antibiotics introduced over the last 20 years," Maki said. ". . . The answer is reduced antibiotic pressure and improving infection control."

Yet even a national moratorium on vancomycin use would not solve current resistance problems with that critical antibiotic, he noted. That is because antibiotic use can arise from "cross resistance," in which overuse of one agent inadvertently renders another less effective.

"It turns out that MRSA has certainly not been driven by heavy use of methicillin or semisynthetic penicillins," Maki said. "It has been cephalosporins and other betalactams. VRE has been driven probably more by the use of cephalosporins and anaerobic drugs than vancomycin. Fully 30% of the patients we see in our hospital [with] VRE never saw vancomycin."

Maki recommended more widespread implementation of the kind of computer-assisted antibiotic management programs that have been used in some centers to improve antibiotic use on a broad scale by reducing susceptibility mismatches and excess dosing. With regard to infection control precautions, Maki called for the routine use of barrier precautions on all ICU patients and others at high risk of infection with nosocomial pathogens due to prior heavy exposures to antibiotics or the presence of invasive devices.

"Our current paradigm is, we wait until the lab calls us up and they say, 'you've got MRSA in that sputum or *C. diff* in that stool,' and then we . . . scurry and run to put the patient in isolation," he said. "By that time, they have been handled and manipulated by a dozen or two dozen or three dozen [health care workers], and the resistant organism has probably been spread to two or three other people. All we've got to do is look at our rates of resistant infection. This is failing dismally."

Emphasizing that greater use of vaccines can have a downstream effect on nosocomial infection prevention, Maki cited "appalling" national data that only about two-thirds of patients over the age of 65 were immunized for influenza last year and only about half received the pneumococcal vaccine.

"It's very clear that giving the flu vaccine to high-risk patients reduces hospitalizations about 40%," he said. "By a program of assuring that every high-risk patient gets a flu vaccine in your catchment area, in your hospital, in your outpatient clinics, you are going to implicitly reduce nosocomial infections because these patients aren't going to be admitted to your ICU." ■

AHA: Hospitals doubt Y2K will hurt critical areas

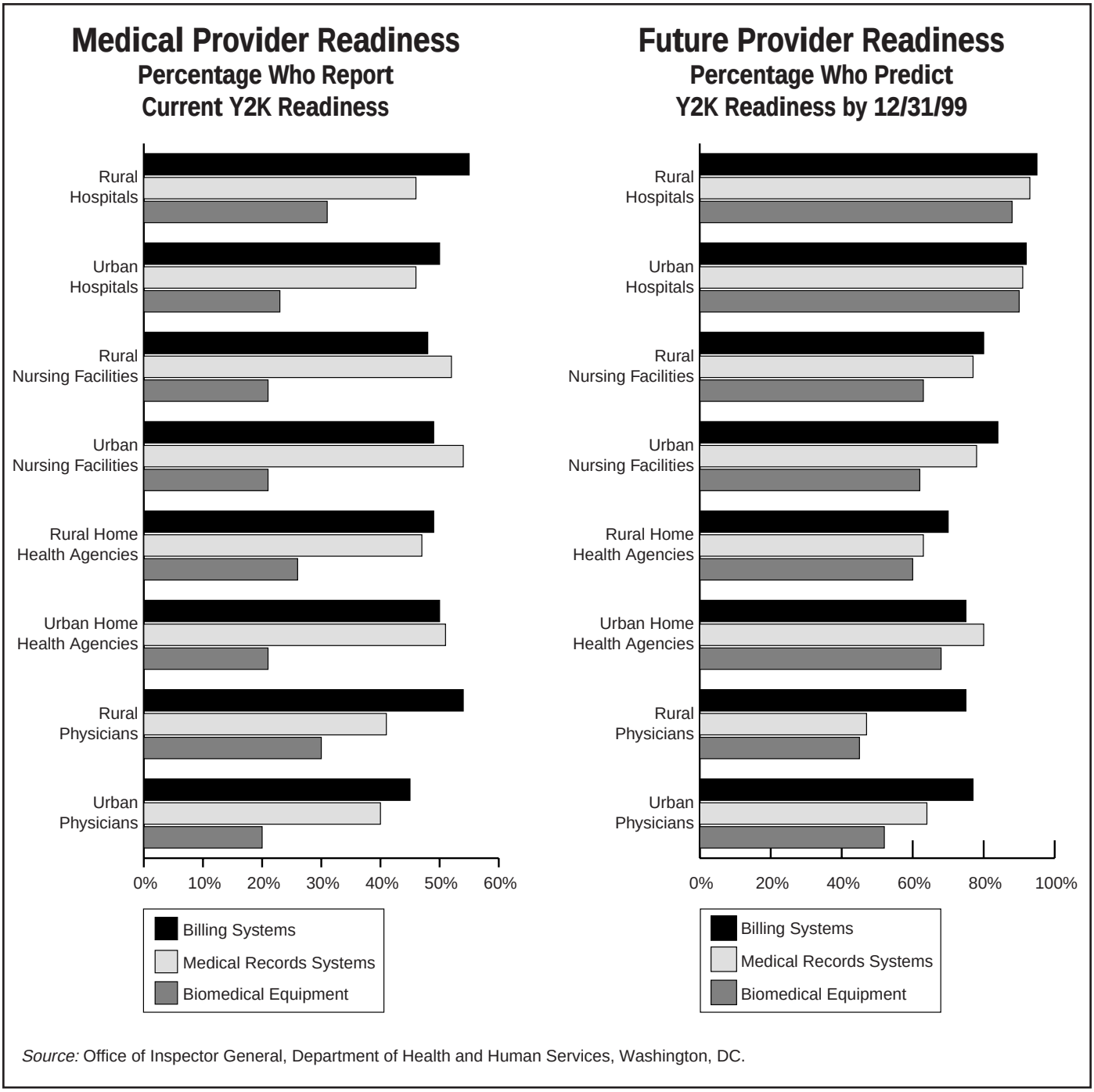
But many expect noncompliant data systems

On the heels of a U.S. Senate report about the woeful state of Y2K preparedness in health care, the American Hospital Association is reporting that even facilities that do not expect to be completely ready for the computer bug are projecting little impact on critical operations.

In the area of information systems readiness — which includes clinical data that may be most important to infection control programs — an AHA survey found that almost a third of the hospitals surveyed do not expect to be totally compliant by the end of the year, but are "expecting no adverse effect on critical operations." However, in assessing their current situation, 5.8% reported slow progress and difficulties in coming into compliance. Still, only 0.5% responded that they are expecting to be noncompliant with possible adverse effect on critical operations. **(See charts, p. 86.)** The survey did not ask respondents to be specific regarding which departments are considered critical operations.

"We've been hearing from our members that they have to prioritize in terms of their Y2K preparation," says AHA spokeswoman **Dionne Dougal** in Washington, DC. "They identify those areas which they consider mission-critical. Those are the areas that directly relate to patient care. Those may [also include] information systems, obviously medical devices, and also infrastructure. But that was pretty much left up to them."

The problem in part is that old two-digit software dating systems in many computers may not



Source: Office of Inspector General, Department of Health and Human Services, Washington, DC.

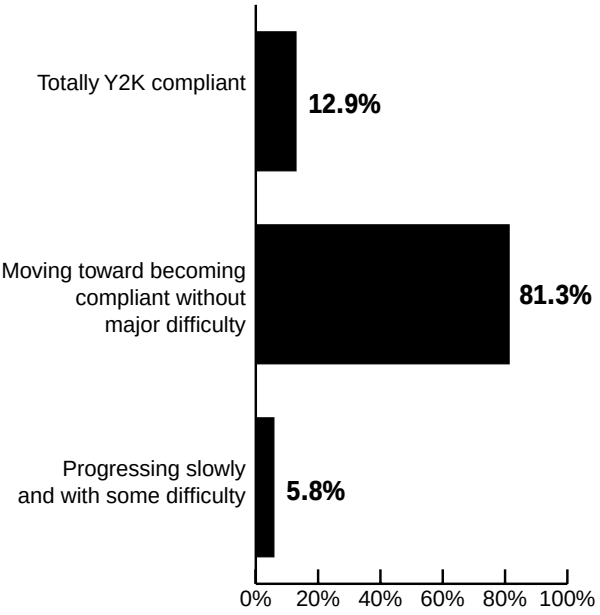
read year 2000 data correctly. That could set off potential equipment failures in computers and biomedical devices, creating a domino effect throughout interconnected systems. Y2K analysts have noted that even infection control departments with fully updated office computer systems may be impacted if, for example, the data systems they draw from for patient surveillance and lab reports are affected. In addition, the U.S. Senate report found that many hospitals are relying solely on producers of medical devices to certify their Y2K compliance, and that overall the health care industry lags significantly in its Y2K preparations compared to other key economic sectors. **(See *Hospital Infection Control,* May 1999, pp. 57-62 .)**

Indeed, lack of information from suppliers was listed as the No. 1 barrier to Y2K readiness in the AHA survey, with 62% of respondents reporting the problem. Other reported barriers to compliance cited by AHA survey respondents included lack of human resources (32%), not enough time (22%), and lack of funding (21%).

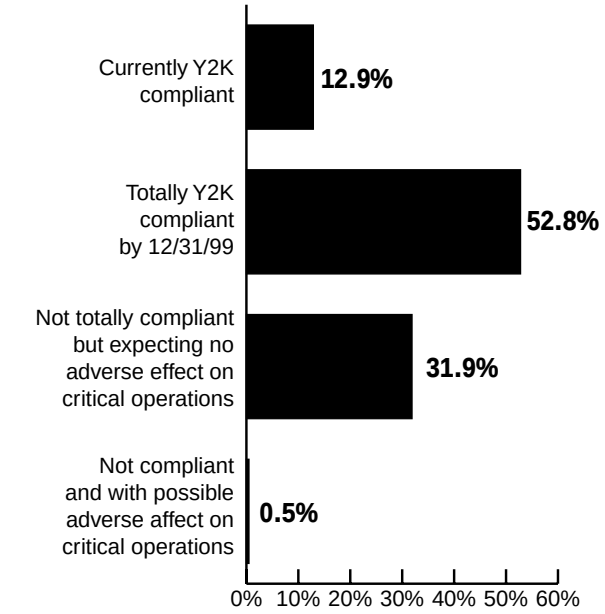
While the survey reflects overall confidence that major problems will not ensue as a result of the computer glitch, the AHA is concerned about the

Information Systems Readiness

Current Readiness



Predicted Readiness at Year End



Source: American Hospital Association, Chicago.

few hospitals anticipating problems or reporting difficulty in coming into compliance.

"That's a major concern for us, and that just means we've got to step up our activities and try to pinpoint exactly what area it is that either they've identified or that we can surmise where they need extra help," Dougal tells *HIC*.

The Senate report was based in part on hearings conducted in July and October 1998 and on an independently commissioned health care survey the same year. The AHA survey reflects a more current picture of the situation, Dougal says, because it was conducted in February 1999. The AHA surveyed a nationally representative sample of hospital and health system CEOs. The survey measured respondents' current and future Year 2000 readiness in the areas of information systems, medical devices, and physical plant and infrastructure. The survey defines Y2K compliance as an institution's performance and / or functionality not being affected by dates prior to, during, and after the year 2000. A total of 583 surveys were returned, which, based on standard survey methodology, means an accuracy rate of plus or minus 5%.

Most expect medical devices to be compliant

In findings on medical device readiness, 57.9% of those surveyed expect to be Y2K-compliant by the end of the year. Another 38.2% of respondents are projecting that their medical devices will not be totally compliant, but are expecting no adverse effect on critical operations. Again, only 0.5% projected noncompliance with possible adverse effects on critical operations, but 6.7% said their current efforts were progressing slowly.

A somewhat similar trend of current struggles and relatively high compliance projections by year's end was found in another report recently issued on health care Y2K preparedness by the U.S. Office of Inspector General.[1] **(See charts, p. 85.)** In December 1998, the survey was sent to a total of 5,000 hospitals, nursing facilities, home

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health agencies, durable medical equipment suppliers, and physicians. Survey responses were accepted through early February 1999. The report includes the following key findings regarding year 2000 readiness for the U.S. health care system:

• **Billing and financial systems:** About half of all respondents reported their billing and financial systems were Y2K ready. Of the respondents who were not ready, more than 90% of hospitals responded they will be ready by Dec. 31, 1999. Only 70% to 84% of the other provider groups responded that their billing and financial systems will be ready by this date.

• **Clinical and medical record systems:** About half of respondents indicated that their clinical and medical records systems were Y2K-ready. For most provider groups, at least three-quarters of those not ready reported that they will be ready by the year 2000. However, rural physicians (47%), urban physicians (64%), and rural home health agencies (63%) were less likely than other providers to have these systems ready by that date.

• **Biomedical equipment:** Fewer than one-third of respondents reported that their biomedical equipment was Y2K compliant. Overall, respondents seemed less confident in the Y2K compliance of their biomedical equipment than they did in the Y2K readiness of their computer systems.

• **Systems testing:** Fewer than two-thirds of respondents had renovated or replaced their computer systems for Y2K compliance. More than half of these respondents had tested the systems. Fewer than half of respondents renovated or replaced biomedical equipment. Testing of this equipment ranged from 36% to 80%.

• **Contingency planning:** Fewer than half of respondents had developed a contingency plan in preparation for possible Y2K-related failures. Of the respondents who have not yet developed a contingency plan, almost all hospitals plan to develop one, while about half of physicians intend to develop one.

[Editor's note: The complete AHA survey results are available on the association's Internet home page at http://www.aha.org. To obtain copies of the Inspector General's report, go to www.dhhs.gov/progorg/oei or call (800) 531-9562.]

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JOURNAL REVIEWS

Cordero L, Sananes M, Ayers LW. **Bloodstream infections in a neonatal intensive-care unit: 12 years' experience with an antibiotic control program.** *Infect Control Hosp Epidemiol* 1999; 20:242-246.

Antibiotic policies based on drug susceptibility information from individual hospital units may prove more effective than those that use data from the hospital at large or from national antibiotic resistance data, the authors report.

"Focused microbiological surveillance by hospital units is more valuable, because hospital-wide data may suggest antibiotic resistance where there is none or mask severe resistance problems unique to some care units," they conclude.

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They assessed the prevalence of gram-positive coccal, gram-negative bacillary, and fungal bloodstream infections (BSIs) during a 12-year period in which a consistent antibiotic treatment protocol was in place in a neonatal intensive care unit (NICU).

Over the study period, *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae,* and *Pseudomonas aeruginosa* isolated from the newborn intensive care unit (unlike those strains from other hospital units) remained fully susceptible to ceftazidime and gentamicin. While hospitalwide prevalence of methicillin-resistant *Staphylococcus aureus* increased, all 17 newborn BSI cases were due to methicillin-sensitive strains. Prevalence of methicillin-resistant coagulase-negative *Staphylococcus* increased, although all strains remained vancomycin-susceptible, as did the 16 *Enterococcus faecalis* isolates. All fungi recovered (from 48 patients) were susceptible to amphotericin.

The combination of ampicillin and gentamicin for suspected early-onset BSI and vancomycin and gentamicin for suspected late-onset BSI has not resulted in antimicrobial resistance in the NICU. Successful treatment of individual BSI cases was facilitated by the preservation of antimicrobial susceptibilities, the authors found.

"Our controlled antibiotic program limited the empirical use of cephalosporins in treatment of early- and late-onset sepsis and avoided resistance to this class of antimicrobials," they note. "The absence of serious outbreaks or epidemics highlights the usefulness of controlled antibiotic programs and the need for periodic reevaluations of antimicrobial resistance based on individual care units and not on hospital-wide or national data." ■

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

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- 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. ■