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JULY 2005
VOL. 32, NO. 7 • (pages 81-92)

Timing is everything: Delivering drug prophylaxis to prevent SSIs

Researchers find it is done right only half of the time

The chances that a surgical patient in a U.S. hospital will receive appropriate antibiotic prophylaxis — with drugs both administered and discontinued in a timely fashion — remains essentially a flip of the coin.

A recently published study of more than 30,000 patients found that the antimicrobial dose was administered appropriately within one hour of the surgical incision only 55.7% of the time.[1] Worse still, antimicrobial prophylaxis was discontinued appropriately within 24 hours after the surgery for only 40.7% of the patients.

The timely administration of antibiotics prior to a procedure has been shown to reduce subsequent surgical-site infections (SSIs). On the other hand, inappropriately prolonging antibiotics provides no prevention benefit, wastes resources, and increases the likelihood that any infection the patient develops will be of the drug-resistant variety. One of the first questions that arise is whether this matter of timing is a systems problem or an education problem.

"I think its both — that's a personal opinion," says **E. Patchen Dellinger**, MD, co-author of the study and chief of general surgery at the University of Washington in Seattle.

"But to say that it's a settled issue — I don't really know. There are many ways to do this, and I think what works in one hospital sometimes doesn't work in another hospital. You have to figure out what works in what setting. This is an issue that is very unsettled [regarding] why the stats are as bad as they are. There are a number of national projects going on to try and improve this," Dellinger explains.

Indeed, in an age of patient safety, timing of surgical antibiotic prophylaxis now is blinking brightly on the radar screen. As usual, infection control professionals and hospital epidemiologists find themselves with key roles in addressing the problem.

"Infection control practitioners often have the responsibility of doing

surveillance and are perhaps more knowledgeable about the infection rate postoperatively than anybody else in the hospital system," says **Dale Bratzler**, DO, MPH, lead author of the study and director of the health care quality improvement program at the Oklahoma Foundation for Medical Quality in Oklahoma City.

"They can't do it themselves, but they can bring together the groups of surgeons, pharmacists, nurses, and others to focus on practices that reduce infection rates. They have the opportunity to play a real leadership role in the hospital in terms of driving practices to reduce [SSIs]."

And there are plenty to reduce. Of the nearly 30 million operations in the United States each year, more than 2% are complicated by an SSI, the authors report. Mortality rates are two to three times higher in patients who develop an SSI, and hospital readmission rates are significantly increased.

Moreover, SSIs increase length of stay by an average of seven days and charges by approximately $3,000, they report.[2,3]

Lax compliance despite data

The effectiveness of antimicrobials administered shortly before skin incision for prevention of SSIs was established in the 1960s and has been demonstrated repeatedly since, the authors emphasize.

However, adherence remains poor despite evidence of effectiveness and the publication of guidelines for antimicrobial prophylaxis.

In 2002, the Centers for Medicare & Medicaid Services, in collaboration with the Centers for Disease Control and Prevention (CDC), implemented the National Surgical Infection Prevention Project.

The project promotes prophylactic practices that have been shown to reduce the risk of SSI, and thus reduce morbidity and mortality in the Medicare population. **(See recommendations, p. 85.)**

The aforementioned study describes the baseline results on the use of antimicrobial prophylaxis for a national sample of Medicare patients undergoing five types of major surgery during 2001.

The researchers conducted a systematic random sample of 34,133 Medicare inpatients undergoing coronary artery bypass grafting; other open-chest cardiac surgery; vascular surgery; general abdominal colorectal surgery; hip and knee total joint arthroplasty; and abdominal and vaginal hysterectomy. A total of 2,965 hospitals were involved in the effort to assess the baseline levels for antibiotic prophylaxis.

Overall, 55.7% of patients received prophylactic antimicrobials during the 60 minutes (120 minutes for vancomycin) before incision, the authors report.

Prior studies have demonstrated that timing is critical to the effectiveness of prophylaxis, and

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Statement of Financial Disclosure: To reveal any potential bias in this publication and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we disclose that Montgomery (editorial advisory board member) is on the speaker's bureau of Schering-Plough and Ball (board member) is a consultant and stockholder with the Steris Corp. and is on the speaker's bureau for the Association of periOperative Registered Nurses. Grant, Hedrick, Schaffner, and Tsivitis (board members) report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

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current guidelines recommend dosing within one hour before incision.

Of particular concern, the authors found that 9.6% of the patients received their first antimicrobial dose *more than four hours after the incision* when little if any benefit would be expected based previously on published studies.[4-6]

The authors clarify that an explicit incision time was documented for only 11,220 patients (32.9%). Of those, the aforementioned 55.7% received an antimicrobial dose in the recommended time frame. What about the other two-thirds of patients?

To get at those data, the researchers randomly selected 1,728 cases for which an explicit incision time was missing. Using proxy times to approximate the incision time, they estimated that 54.3% of these patients received their antimicrobial dose within one hour before incision. So again, we're still in the range of a coin flip.

"I think it is a systems problem," says **Donald E. Fry**, MD, co-author of the paper and chairman of the department of surgery at the University of New Mexico in Albuquerque.

"It comes down to the fact that we set out schedules for our operating rooms, but sometimes I think they are only advisory — if you will," he continues.

"In the sense that things do not always happen on the exact time schedule that they are supposed to happen. Operations don't start exactly when we expect they do, and there is the error of drugs being given too soon."

Trying to create a new surgical culture

Patients awaiting surgery may be administered the antibiotics in a holding area in the hospital, but the critical one-hour time frame may tick away before they get under the OR lights.

There also is the issue that many surgeons have become accustomed to the antibiotics traditionally being given "on call on the floor," Fry says.

"So we are trying to create a new culture of people understanding better that if the drug is given too soon — or if the drug is forgotten and not given until after the incision, or God forbid, after the operation — it will have a potential consequence as far as outcomes," he says. "We have to overcome a culture of many decades, and we have to overcome some of the vagaries of operations being delayed," he adds.

Antibiotic prophylaxis decisions could be incorporated into a surgical timeout, with the timing of the dose being verified along with the correct surgical site and other important factors, Fry says.

"Re-identify the patient and confirm that antibiotics, if indicated, have in fact been given," he notes. "[That] hopefully is a systems approach to try and remedy the fact that in the past, the drugs were either given entirely too soon, were omitted, or started too late."

The researchers found that patients undergoing cardiac and orthopedic surgery were more likely to receive an antimicrobial dose within one hour before incision.

That may reflect the much more common use of pre-printed care plans or order forms (50% of patients undergoing hip or knee arthroplasty and 36.6% of patients undergoing cardiac surgery), which often included antimicrobial protocols, they report.

However, such pre-printed care plans or order forms were found in only 4% of colorectal surgery cases, 4.5% of hysterectomy cases, and 5.3% of vascular surgery cases.

"A lot of hospitals around the country now have created standard protocols for prophylaxis, which incorporate preoperative administration and limited postoperative doses," Bratzler says. "[They allow] less exceptions and opt-outs by surgeons."

Fry says he favors that approach, particularly because only 40.7% of the patients had their antimicrobial prophylaxis discontinued within 24 hours after the procedure.

Patients undergoing cardiac surgery (34.4%) and hip or knee arthroplasty (36.7%) were least likely to have antimicrobial prophylaxis discontinued. The median duration of antimicrobial prophylaxis was longest (57 hours) for patients undergoing colon surgery.

A counterintuitive decision

"I have been screaming about this subject for 25 years now, and I am actually convinced that perhaps the only solution is to protocol preventive antibiotics within the institution and do not allow it to be a free and independent decision of the surgeon," Fry explains.

"In some institutions, they have just adopted a protocol and taken that decision out of the hands of the individual surgeon. I think individual surgeons want the best for their patients. I truly believe that," he continues. "But [discontinuing

antibiotics] is a counterintuitive thing, so I don't think it is too surprising that there would be resistance to it."

The optimal duration of prophylaxis has been controversial, especially for cardiovascular and orthopedic surgery, where many surgeons prefer to continue prophylaxis until all drains and tubes have been removed, the researchers acknowledge.

"The antibiotic discontinuation [issue] is largely a function, I believe, of the surgeons," Bratzler says. "They control the orders about the antibiotics that are given postoperatively. Here we targeted a lot of our educational efforts toward making sure that surgeons understand there is really no data that support prolonged postoperative antibiotics, despite the way they may have been trained or the way they have always done it. We are trying to provide a lot of education on that point."

The notion is dead wrong

Indeed, many could argue with apparent logic that keeping antibiotics in the bloodstream of a post-op patient is a good precaution against infection. But that notion is dead wrong for a number of reasons, according to Fry.

"Nearly 60% of patients [in our study] had their drugs extended beyond any period of time for which there would be any benefit to be derived from them," he says.

"The literature is very replete in showing that the critical time, the decisive time for having antibiotics present during an operation, is while it is being conducted. Extending the antibiotics for indefinite periods after the operation — there is just no evidence that that is of any value. On the other hand, it is counterintuitive for surgeons to accept that," Fry adds.

It is true that bacteria cause SSIs and antibiotics kill bacteria, but drugs administered after the surgical wound is closed cannot reach the site, he continues. The reason is fibrin, a protein involved in blood clotting that forms a barrier at the wound site that antibiotics cannot penetrate.

"The facts are that the bacteria that contaminate the surgical wound are embedded in a matrix of fibrin from the coagulation cascade during the onset of human inflammation," he points out.

"The antibiotics simply do not penetrate the fibrin. Secondly, when we close the surgical wound, the human inflammatory process continues, and we end up with increasing hydrostatic pressure in and about the wound following the wound closure from the natural and continued evolution of edema [swelling]," Fry notes. "The systemic drug does not get to the wound interface. It is a plain and simple issue."

Fry, for his part, says he sees no benefit in even the 24 post-op time frame, noting that it was something of a compromise in the quest toward eliminating post-op drug administration entirely.

"I am even more adamant in my personal feeling," he points out.

"I think any antibiotic given after wound closure has no benefit. So the surgical infection prevention project opted for 24 hours, feeling if we got everybody to a 24-hour standard that it would be a tremendous accomplishment. I believe that that is true. Maybe at some future time, we can get surgeons to ratchet down, hopefully, to reaching the day where there would be no re-dosing of the drug after the operation is over," Fry says.

No good and some harm

Not only does the post-op dosing of antibiotics do no good, it does harm in the form of selecting out resistant bacteria. There is clear evidence that prolonged antimicrobial administration can be harmful to patients by promoting antimicrobial-resistant bacteria and increasing the incidence of antibiotic-associated complications, the authors note.[7-10]

"There is no question that it contributes to resistance," Fry explains. "If you look at patients who have prolonged preventive antibiotics, who develop nosocomial infections, they always do so with organisms that are resistant to whatever the preventive drug that was used. The patient ends up having more resistant organisms with any infectious complications that occur in the wake of the procedure."

Toxicity and drug reactions are a concern as well, and blasting the system with antibiotics is an infamous prelude to a nasty *Clostridium difficile* infection. The *C. diff* already may be present, and wiping out the rest of the bacterial flora will give it ample room to grow and cause diarrhea and other problems.

"Then there is simply the issue of why are we continuing to waste resources [on practices] that are of no benefit," Fry adds.

"In a given patient, somebody may say, 'What

Use narrow window to start and stop surgical antibiotics

Consensus is one hour before, one day after

As part of the Medicare National Surgical Infection Prevention Project, a guideline working group was formed to develop consensus recommendations for surgical antimicrobial prophylaxis.[1] Key recommendations regarding the timing of antibiotic administration include the following:

1. Before surgery

On the basis of published evidence, the work group endorsed the national performance measure that infusion of the first antimicrobial dose should begin within 60 minutes before incision. However, when a fluoroquinolone or vancomycin is indicated, the infusion should begin within 120 minutes before incision to prevent antibiotic-associated reactions. Although research has demonstrated that administration of the antimicrobial at the time of anesthesia induction is safe and results in adequate serum and tissue drug levels at the time of incision, there was no consensus that the infusion must be completed before incision. When a proximal tourniquet is required, however, the entire antimicrobial dose should be administered before the tourniquet is inflated.

2. After surgery

The majority of published evidence demonstrates that antimicrobial prophylaxis after wound closure is unnecessary, and most studies comparing single-dose prophylaxis with multiple-dose prophylaxis have not shown the benefit of additional doses. Prolonged use of prophylactic antimicrobials is associated with emergence of resistant bacterial strains. For the majority of operations, prophylaxis should end within 24 hours after the operation.

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is an extra hundred bucks?' Well, an extra hundred dollars when there are 30 million operations performed annually in the United States comes to a staggering sum of money," he stresses. "There are a lot of reasons to stop the drugs within 24 hours. The patient benefits, wound infections will not be higher, and drug morbidity will be less."

The nation's major surgical societies are on board with the issue, though the Society for Thoracic Surgery originally suggested antibiotics be given for 48 hours rather than the 24-hour post-op limit, Fry says.

"There is no evidence that 48 is better than 24," he notes. "When you extend the drugs postoperatively, you buy a measure of risk with no measure of benefit. I think the surgical societies are working hard to try to bring up compliance."

Going to a standard protocol

The use of standard protocols is the way to go, Fry argues, noting that a study published way back in 1982 showed multiple benefits to taking the decision out of the surgeon's hands.[11]

"When they went to a protocol, they brought compliance with accepted standards in using preventive antibiotics from 30% to 40% up to almost 100%," he explains.

"And in a specialty like orthopedics, that actually showed that overall wound infection rates dropped by 80% and days of antibiotics dropped by 80%," Fry points out.

"Well, that's the best deal I know of: improving outcomes and reducing resource utilization. The hospitals [should] say, 'This is the way we are going to do it.' It makes for less cost and better results," he adds.

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Will emerging norovirus become nosocomial bug?

Problem for cruise ships, nursing homes

Emerging as the bane of cruise ships and nursing homes, norovirus — with its ability to cause severe gastroenteritis, persist in the environment, and spread via contaminated food or human contact — would seem to be the perfect candidate for a nosocomial pathogen of the most troublesome variety.

The question is, why isn't it?

"That is an extremely interesting question," says **Marc-Alain Widdowson**, DVM, a medical epidemiologist in the respiratory and enteric viruses branch at the Centers for Disease Control and Prevention (CDC).

"It is in certain countries. In the United Kingdom, for instance, and in Canada, they have a lot of problems with hospital outbreaks with norovirus in the winter.

"In the UK, they have to shut down hospitals regularly because of it. In the United States, we don't seem to hear about outbreaks as much," he explains.

Widdowson recently published an article in the CDC's *Emerging Infectious Diseases* journal, which argues the norovirus is an emerging pathogen.[1] Still, he cannot quite explain why noroviruses are not being reported in more nosocomial outbreaks in U.S. hospitals. Is it a surveillance artifact — a case of not finding something you're not looking for?

"We weren't quite sure whether this was because there is no reporting of nonfoodborne [gastroenteritis] outbreaks to CDC or whether it was actually a genuinely low incidence," he tells *Hospital Infection Control*.

"In the UK, for instance, if you have an outbreak in a hospital — because it is a national health [system] — it has to be reported. There is a reporting system for all outbreaks of gastroenteritis. In the U.S., there is only an official mechanism for foodborne [outbreaks of gastroenteritis]. So our concern was that there actually are hospital outbreaks, but we just don't hear about them, at least through formal channels," Widdowson notes.

But a CDC survey of hospitals in Georgia suggests the pathogen is not spreading in hospitals to the degree it has been found in other countries. "Sure, there were some [outbreaks] that haven't been reported to the state, but the general feeling was that there does seem to be fewer outbreaks of norovirus illness in U.S. hospitals than in the UK and Canada," he said.

Still, the CDC is concerned enough about noroviruses emerging as a nosocomial pathogen that it posted guidance for health care facilities on the web site of its Division of Healthcare Quality Promotion. **(See guidance, p. 87.)**

Noroviruses are highly contagious, with as few as 100 virus particles thought to be sufficient to cause infection.

Noroviruses are transmitted primarily through the fecal-oral route, either by direct person-to-person spread or fecally contaminated food or water.

In health care facilities, transmission additionally can occur through hand transfer of the virus to the oral mucosa via contact with materials, fomites, and environmental surfaces that have been contaminated with either feces or vomitus, the CDC advises.

Patients who have suspected norovirus infection should be managed with standard precautions with careful attention to hand hygiene practices.

However, contact precautions should be used when caring for diapered or incontinent people,

(Continued on page 88)

Use standard/contact iso, bleach to kill norovirus

CDC posts guidance of its DHQP site

The Centers for Disease Control and Prevention (CDC) has posted guidance on preventing the spread of norovirus in health care facilities. Key points are summarized as follows; the full text is available at www.cdc.gov/ncidod/hip/default.htm.

- ✔ **Virology**: Noroviruses (genus *Norovirus*, family *Caliciviridae*) are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was approved recently as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses" (NLV).
- ✔ **Clinical manifestations**: The average incubation period for norovirus-associated gastroenteritis is 12 to 48 hours, with a median of approximately 33 hours. Illness is characterized by acute onset vomiting; watery, nonbloody diarrhea with abdominal cramps, and nausea. In addition, myalgia, malaise, and headache commonly are reported. Low-grade fever is present in about half of cases. Dehydration is the most common complication and may require intravenous replacement fluids. Symptoms usually last 24 to 60 hours. Volunteer studies suggest that up to 30% of infections may be asymptomatic.
- ✔ **Epidemiology of transmission:** Noroviruses are highly contagious, with as few as 100 virus particles thought to be sufficient to cause infection. Noroviruses are transmitted primarily through the fecal-oral route, either by direct person-to-person spread or fecally contaminated food or water. Noroviruses also can spread via a droplet route from vomitus. These viruses are relatively stable in the environment and can survive freezing and heating to 60° C (140° F). In health care facilities, transmission additionally can occur through hand transfer of the virus to the oral mucosa via contact with materials, fomites, and environmental surfaces that have been contaminated with either feces or vomitus.
- ✔ **Diagnosis:** Diagnosis of norovirus infection relies on the detection of viral RNA in the stools of affected persons, by use of reverse transcription-polymerase chain reaction (RT-PCR) assays. This technology is available at the CDC and most state public health laboratories and should be considered in the event of outbreaks of gastroenteritis in health care facilities. Identification of the virus can be best made from stool specimens taken within 48 to 72 hours after onset of symptoms, although good results can be obtained by using RT-PCR on samples taken as long as seven days after symptom onset. Other methods of diagnosis, usually only available in research settings, include electron microscopy and serologic assays for a rise in titer in paired sera collected at least three weeks apart. Commercial enzyme-linked immunoassays are available but are of relatively low sensitivity, so their use is limited to diagnosis of the etiology of outbreaks. Because of the limited availability of timely and routine laboratory diagnostic methods, a clinical diagnosis of norovirus infection often is used, especially when other agents of gastroenteritis have been ruled out.
- ✔ **Infection control:** Patients with suspected norovirus infection should be managed with standard precautions with careful attention to hand hygiene practices. However, contact precautions should be used when caring for diapered or incontinent people, during outbreaks in a facility, and when there is the possibility of splashes that might lead to contamination of clothing. People cleaning areas heavily contaminated with vomitus or feces should wear surgical masks as well. In an outbreak setting, it may be prudent to place patients with suspected norovirus in private rooms or to cohort such patients.
- ✔ **Environmental disinfection:** There are no hospital disinfectants registered by the Environmental Protection Agency that have specific claims for activity against noroviruses. In the absence of such products, the CDC recommends that chlorine bleach be applied to hard, nonporous, environmental surfaces in the event of a norovirus outbreak. A minimum concentration of 1,000 ppm (generally a dilution 1 part household bleach solution to 50 parts water) has been demonstrated in the laboratory to be effective against surrogate viruses with properties similar to those of norovirus. Health care facility staff should use appropriate personal protection equipment (e.g., gloves and goggles) when working with bleach. Quaternary ammonium compounds often are used for sanitizing food preparation surfaces or disinfecting large surfaces (e.g., countertops and floors). However, because noroviruses are nonenveloped, most quaternary ammonium compounds (which act by disrupting viral envelopes) do not have significant activity against them. Phenolic-based disinfectants have been shown to be active against noroviruses in the laboratory. However, this activity may require concentrations twofold to fourfold higher than manufacturer recommendations for routine use. ■

during outbreaks in a facility, and when there is the possibility of splashes that might lead to contamination of clothing, the CDC recommends.

No longer Norwalk

In 1972, noroviruses — previously called "Norwalk-like viruses" — were discovered as the first viruses definitively associated with acute gastroenteritis, Widdowson explains.

But for years, researchers were unable to easily detect the virus or to find the etiologic agents of nonbacterial gastroenteritis outbreaks and hospitalizations, he notes.

"Until the mid-1990s, most of the diagnoses were based on complicated tests [such as] electron microscopy," Widdowson continues. "So lab confirmation was rare before the mid-1990s."

Not unlike the old diagnosis of exclusion for non-A, non-B hepatitis (before it was identified as hepatitis C), norovirus was identified by epidemiological clues and the absence of a bacterial agent.

"A lot of the diagnosis was based on epidemiological and clinical criteria, like if you have more than 50% of people vomiting, a certain incubation period, a certain duration of illness, and no bacteria are found, then you can attribute the infection to norovirus," Widdowson explains.

"For many years, that is what people used. Beginning in the mid-1990s [diagnostics improved so] that we were able to say for sure that this outbreak was due to norovirus because we actually detected it," he adds.

Indeed, of more than 2,500 foodborne outbreaks reported to the CDC from 1993 to 1997, less than 1% were attributed to noroviruses, and 68% were listed as "unknown etiology," Widdowson found.

"Over the last 10 years, there has been an expansion in the use of [new diagnostics], and more and more state public health authorities are using this technology," he says. "More and more specimens are being tested at the local level."

Common cause of gastroenteritis

As a result, noroviruses now are recognized as the most common cause of infectious gastroenteritis among people of all ages, Widdowson notes in his paper.

They are responsible for around 50% of all foodborne gastroenteritis outbreaks in the United States, a major contributor to illness in nursing homes and — to a less extent — hospitals.

Norovirus infection has put apparently healthy people in intensive care and has been associated with chronic diarrhea among transplant patients, he explains.

But is it truly an emerging pathogen or merely one that has been an elusive etiologic agent? Widdowson points to the fact that there are myriad strains of norovirus, which have been classified into five genogroups.

The diversity "represents a dramatic increase from the single calicivirus strain discovered more than 30 years ago," he writes in the article.

In addition, the viruses are being found in an expanding array of animal hosts including mice, cows, and pigs. Antibodies to bovine strains have been found in humans, raising speculation that some zoonotic transmission may be occurring, Widdowson points out.

Another important factor is the emergence of predominant norovirus strains. The so-called Farmington Hills strain plagued cruise ships in 2002 and 2003 with the grim persistence of water rising up through the decks of the *Titanic*.

"What we find in cruse ships — and often with nursing homes and hospitals — is that you can close down, you can dry-dock a cruise ship for a week, put a whole bunch of new passengers on it, and the infection will still be on board," he says.

"Somehow it is in the environment. The new cohort of passengers will get sick. Similarly, with nursing homes, the virus is very persistent in the environment and can stay around for one to two weeks and act as a source of infection," adds Widdowson.

Hard to kill

The ability of the viruses to persist in the environment is explained in part by the fact that it is not phased by some commonly used disinfectants. The CDC reports, for example, that because noroviruses are nonenveloped, most quaternary ammonium compounds (which act by disrupting viral envelopes) do not have significant activity against them.

With no U.S. disinfectant approved as having specific activity against the virus, the CDC currently advises the use of chlorine bleach (1 part household bleach diluted with 50 parts water) for cleaning environmental surfaces during a norovirus outbreak. Another factor is that the viruses may become so pervasive in the environment during an outbreak that small reservoirs persist despite cleaning.

"If you have viral contamination everywhere on lots of surfaces, it is extremely difficult to make sure that you have cleaned all of the surfaces that people are going to touch," Widdowson says.

Though an obvious cause of morbidity, another unknown is to what degree norovirus infections actually may lead to attributable mortality in nursing homes.

"We haven't really been able to nail down mortality in nursing homes, but it is something we are interested in doing by looking at hospital discharge dates and looking at gastroenteritis in the elderly," he says.

"Most gastroenteritis in the elderly, I suspect, would be due to norovirus. So it would be interesting to look at deaths and hospitalizations due to norovirus in the elderly," Widdowson explains.

He points out that if noroviruses are an increasingly common cause of infectious gastroenteritis — with some cases resulting in diarrhea-related deaths and hospitalizations — then substantially greater investments are required in their diagnosis.

Increased use of diagnostics along with improved surveillance, such as in sentinel sites, will permit identification of new strains and shifts in the epidemiology of norovirus disease, Widdowson argues in his paper.

The development of easy-to-use, sensitive assays for use by clinical and public health laboratories also should have a high priority, he urges.

"Putting it bluntly, it is an appeal for resources to try and address it," Widdowson tells *HIC*. "Particularly, I think one thing I tried to address in the article is control measures.

"Person-to-person outbreaks are extremely difficult to control. The virus, unlike influenza, will [not only] spread from person to person but also stay in the environment. It is extremely difficult to get rid of when you have an outbreak that is ongoing," he adds.

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1. Widdowson M-A, Monroe SS, Glass RI. Are noroviruses emerging? *Emerg Infect Dis* [serial on the Internet]. May 2005. Web site: www.cdc.gov/ncidod/EID/vol11no05/04-1090.htm. ■

New needleless valves leading to spike in BSIs

Solving one problem and creating another

Health care epidemiologists are reporting an increase in bloodstream infections (BSIs) due to the use of needleless mechanical valve devices that connect to central venous catheters.

Originally intended to prevent needlesticks and protect health care workers from bloodborne infections, the devices now appear to be increasing the risk of BSIs in patients.

Trend uncovered at SHEA

Several studies documenting the trend were described recently in Los Angeles at the annual meeting of the Society for Healthcare Epidemiology of America (SHEA).

"We are now aware of over 20 institutions that have recognized this problem," said **William Jarvis**, MD, a former investigator at the Centers for Disease Control and Prevention (CDC) and now a private infection control consultant in Hilton Head, SC.

Jarvis provided a sweeping overview of the emerging problem, noting that it first came to light at the 2004 SHEA meeting in Philadelphia.

"The first report of this was actually at the SHEA meeting last year, and I don't know that it got a great deal of attention by those of us attending the meeting," he said.

In that study, investigators at the University of Virginia (UVA) in Charlottesville saw an increase in BSIs associated with the introduction of mechanical valves.[1]

"The mechanical valves were introduced in May 2002, and by June, they had seen literally a 61% increase in BSIs," Jarvis pointed out.

"Between January-May 2002 vs. May-December 2002, their BSI rate went from 2.2 to 3.5 per 1,000 patient days, which was statistically significant," he explained.

Looking at the types of pathogens associated with the mechanical valve device, the UVA investigators found a 3.7-fold increase in contamination of blood cultures in general; a 2.5-fold increase in catheter-related BSIs with common skin organisms; and a 1.8-fold increase in non-skin organisms, Jarvis told SHEA attendees.

"[They] felt this increase was really related to the introduction of mechanical valves," he said.

"The decision at the hospital to change to mechanical valves was not made by infection control — was not even known by infection control. It was made by occupational health for reduction of needlestick injuries, even though after the introduction of the needless device, there were no data that showed that needlestick injuries were changed at all," Jarvis noted.

Those findings were reinforced by two similar papers presented at the 2005 SHEA meeting, including one describing a similar problem at Johns Hopkins University Hospital in Baltimore.[2]

"[They] noticed from Quarter 1 to Quarter 4 of 2004, the BSI rate went up from 4.1 to 17.3 BSIs per thousand CVC days," Jarvis said.

"Interestingly, 40% of the BSIs were caused by candida species, [and] 20% of them were polymicrobial — both relatively unusual events," he added.

The surge in infections was linked to the introduction of a new positive-placement mechanical valve.

"Nurses reported leaking and cracking when they were using these mechanical valves, and they returned to the previous mechanical valve," he said. "Their BSI rate went up after [originally] changing the mechanical valves then decreased very rapidly after they moved back to the previous mechanical valve."

Disinfection problems cited

The third report was presented by epidemiologists at Wake Forest University School of Medicine in Winston-Salem, NC.[3]

"It gives us some insight into what might be the problem here," Jarvis explained at SHEA.

Quantitative blood cultures of blood from intensive care unit (ICU) patients were drawn through the needleless mechanical valve port. Blood was obtained from the initial syringe pullback, which is normally discarded.

"[That] first blood drawback is normally discarded and then you obtain the blood for blood culture," Jarvis said.

"But they took that initial blood and cultured it to see what was the rate of contamination in these mechanical valves. They had 226 discards from 83 patients and found that 39 of 226 or 17% of them were culture-positive," he noted.

Colony-forming units were very low in some cases, but some pathogens were present in sufficient numbers to pose potential problems. A nursing practice survey revealed that 31% of the

CE/CME *questions*

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1. A recently published study of more than 30,000 patients found that the antimicrobial dose was appropriately administered within one hour of the surgical incision a surprising 75% of the time.
   A. true
   B. false

2. Not only does the prolonged post-op dosing of antibiotics do no good, it may do harm in the form of:
   A. selecting out resistant bacteria
   B. drug reactions
   C. toxicity
   D. all of the above

3. Noroviruses are transmitted primarily through which route?
   A. airborne
   B. bloodborne
   C. fecal-oral
   D. all of the above

4. Health care epidemiologists are reporting an increase in bloodstream infections due to the use of needleless mechanical valve devices that connect to central venous catheters. According to William Jarvis, MD, increased BSI rates associated with mechanical valves may be caused by:
   A. inadequate infection control practices
   B. the devices themselves
   C. a combination of both
   D. all of the above

CE/CME instructions

Physicians and nurses participate in this CE/CME program by reading the issue, using the provided references for further research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to answer key to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing the semester's activity, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a certificate of completion. ■

nurses did not disinfect the needleless valve port before accessing the system.

"Those of us who are clinicians don't really understand these products very well," Jarvis said.

"We don't understand how they work. We don't understand the internal mechanisms, and we don't understand how we need to disinfect them," he explained.

"Oftentimes, the same can be said of the sales staff who are selling you these devices. They don't understand how you are using them or misusing them and can't really educate you very well," Jarvis continued.

If the mechanical valves are not disinfected properly, then bacteria can set up within the nooks and crannies of the device. "[That] can lead to contamination of the fluid path," Jarvis said.

"You can have gaps around the plunger that harbor bacteria. And the gaps may not be accessible for disinfection. That again can lead to fluid contamination. That can especially occur if you are having multiple breaks in the system, uses of syringes, and repeated flushing," he continued.

Look alike, sound alike

The products look alike and often sound alike, but may have different procedures for use and disinfection, Jarvis added.

"I can tell you that many of the hospital epidemiologists and infection control professionals who I have talked to that are at hospitals and are noticing an increase in BSIs — when I ask them which valve they use, they often cannot tell me," he said.

"It may be familiar to the people in purchasing, or it may be to the people in the ICU, but oftentimes infection control is completely unaware of it," Jarvis added.

The mechanical valve devices have been introduced in recent years to replace the original split-septum needleless ports introduced in the 1990s. The idea apparently was to maintain the needlestick prevention aspect while reducing occlusion or clotting.

"Split septum were initially introduced to reduce health care worker needlestick injuries," Jarvis said.

"We accomplished that with the split septum. Initially, the split septums were associated with BSI outbreaks, but it wasn't just a device problem — but rather the device plus the infection control practices. As the infection control practices improved, the BSI rates with these devices went down," he noted.

The unanswered question is whether the new generation of mechanical devices causes more problems then they actually solve.

"We now have the mechanical valves introduced to not only reduce needlestick injuries but also to presumably reduce catheter occlusion," Jarvis explained. "The data are out as to whether that is really the case or not. We need to understand whether changing from one to another really has any effect on needlestick injuries and occlusion," he stressed.

"If it doesn't, then you may use different criteria for selecting which kind of device you are going to use. The increased BSI [rates] associated with mechanical valves may be caused by inadequate infection control practices, they may be caused by the device, or they may be caused by both," Jarvis added.

References

1. Hall KK, Geffers C, Giannetta E, et al. Outbreak of bloodstream infections temporally associated with a new needleless IV infusion system. Abstract 285. Presented at the Society for Healthcare Epidemiology of America annual conference. Philadelphia; April 2004.
2. Cosgrove SE, Bradley K, Mckee C, et al. Increase in catheter related bloodstream infections (CR-BSI) in pediatric intensive care units temporally associated with a change in the needleless intravenous port. Abstract 26. Presented at the Society for Healthcare Epidemiology of America annual conference. Los Angeles; April 2005.
3. Karchmer TB, Cook EM, Palavencino E, et al. Needleless valve ports may be associated with a high rate of catheter-related bloodstream infection. Abstract 307. Presented at the Society for Healthcare Epidemiology of America annual conference. Los Angeles; April 2005. ■

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CE/CME answers

1. B **2. D** **3. D** **4. D**

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- 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. ■