Germ warfare

Vaccines, other products join a growing arsenal in fight against hospital-acquired infections

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Administrators don’t like to talk about it, but hospitals are breeding grounds for infections and an adverse dividend of many a patient’s stay.

No hospital is immune, and infection control understandably is a key priority at every institution. Approximately one in 10 hospitalized patients will acquire an infection after admission, according to the Centers for Disease Control and Prevention. That results in added treatment costs and extended hospital stays, and also could be life-threatening or, at the minimum, exacerbate a patient’s hospital experience. The annual economic costs of these so-called nosocomial infections are estimated to be a whopping $6.7 billion annually in the U.S., according to the CDC. Surgical-site infections alone—500,000 annually in the U.S., the CDC says—increase a hospital stay by an average of seven days and add more than $3,000 in costs.

Many hospital executives panicked in Pennsylvania last year when the Pennsylvania Health Care Cost Containment Council announced it would start requiring hospitals to report all hospital-acquired infections to the independent state agency and further raised the possibility that the information would be made publicly available. On Jan. 1, the council began collecting data on the four most serious types of hospital-acquired infections—bloodstream, surgical-site and urinary tract infections and ventilator-associated pneumonia—but it’s still “wrestling with the issues” of compliance and how to report the data, says Joe Martin, the council’s spokesman. The council believes that those four types account for 50% of all hospital-acquired infections.

Preliminary data from the first quarter of this year showed some interesting results after the council cross-checked what hospitals reported (1,861 patients suffering from 2,253 infections) with secondary infections (56,966) in the uniform billing data for the same period. The 1,881 patients racked up $66 million in extra charges and an added 7,716 days in the hospital, Martin says. But the council believes that the nearly 57,000 secondary infections extracted from the uniform billing data are closer to the actual number of infections, Martin says. Although it can’t be said with certainty that the infections found through the uniform billing data were hospital-acquired, the fact that they were secondary diagnoses increases the likelihood that they were, as the infection was not the principal reason for admission to the hospital, he explains.

Attacking the problem

A new class of software is giving hospitals the ability to track infection outbreaks,
but as yet there is no silver bullet for annihilating the cleverly persistent bacteria that plague all hospitals. But there are some advances afoot for containing the problem other than the traditional arsenal of antibiotics and infection-control processes.

Nabi Biopharmaceuticals, a publicly traded company in Boca Raton, Fla., is in the late stages of phase 3 trial testing a vaccine for Staphylococcus aureus, the cause of about 65% of all hospital-acquired infections, says Henrik Rasmussen, Nabi's senior vice president of clinical, medical and regulatory affairs.

The vaccine, called StaphVAX, is made from bacterial components and is designed to induce the immune system to fight the bacterial infection, Rasmussen explains. Studies so far indicate that the vaccine provides protection against 85% of all types of staph infections approximately 60% of the time or better. Nabi researchers believe it will probably be effective for up to 10 months before requiring a booster that would buy another year of partial immunity, he says.

The trial is focused on patients with end-stage renal disease—those at highest risk of such infections—and encompasses 400 dialysis units in the U.S. Nabi completed enrollment of 3,600 patients in mid-August and expects to wind up the trial in a year, filling an application with the Food and Drug Administration by the end of 2005, Rasmussen says. If everything goes according to plan, Nabi can anticipate FDA approval in 2006, he says.

Nabi estimates that 12 million patients in the U.S. and a similar number in Europe are at risk of developing staph infections. The company plans to eventually widen the indications for the vaccine. It also is working on developing other vaccines targeted at smothering a wider range of hospital-based bacteria, but those vaccines are in earlier stages of development, Rasmussen says. (Nabi also is developing a vaccine against nicotine addiction, and it has three approved drugs on the market, including an immunoglobin to prevent hepatitis B after exposure.)

Although Nabi hasn't yet priced StaphVAX, a good business case can nevertheless be made for it even if the vaccine turns out to cost as much as the most expensive vaccines on the market today—$300 for a four-shot regimen of the pneumonia vaccine, Rasmussen says. Consider that 5% of the 300,000 patients with end-stage renal disease in the U.S.—15,000 people—are at risk annually of acquiring a staph infection through dialysis. If the vaccine were 60% effective in preventing infection, 9,000 cases of staph infection would be avoided. Rasmussen says the societal cost of these infections is approximately $30,000 per year per case, adding up to $270 million in cost savings. In addition, 25% of these high-risk patients die from the infections, so avoiding 9,000 cases of staph infection would save 2,250 lives, he says.

"So you have a drug that is not only reducing pain and suffering but actually saving lives," Rasmussen says.

He notes that the same compelling economic argument can't be made for other patient populations with less risk of acquiring infections, but that doesn't negate the significance of the adverse medical events that the vaccine potentially prevents.

"Society needs to figure out how much it is willing to pay to avoid that kind of stuff from happening," Rasmussen says.

Another product far less costly but with as-yet-undetermined effectiveness is just now being rolled out by Medline Industries, Mundelein, Ill., a manufacturer and distributor of medical supplies. The company is treating bed linens with HaloShield, a patented technology first developed for high-end water filtration systems that uses chlorine-based sanitizers to kill infection-causing microbes, including those commonly found in hospitals such as staph. Medline licenses the technology from Vanson HaloSource, Redmond, Wash., and has exclusive rights to distribute HaloShield-treated linens in North and South America.

Using the sheets will cost a typical hospital a nickel per bed per day, says Ron Barth, division president for Medline's textile group.
Citing the CDC, Barth says the average hospital is the setting for 430 hospital-acquired infections each year at a cost of more than $6 million per facility. "We’re not suggesting that HaloShield is a cure-all or that linens are even the predominant reason (for nosocomial infections). But there is substantial evidence that linens do play a role, and if the sheets can prevent just one infection, they would pay for themselves more than four times over," Barth says.

Working much like Velcro for chlorine molecules, HaloShield is a coating that, between washings, prolongs and enhances the antimicrobial properties of chlorine sanitizers, Barth says. The germ-fighting properties of the chlorine typically used in hospital laundries is renewed each time the HaloShield linen is laundered. A typical sheet treated with the HaloShield coating lasts about 75 washings—the normal lifetime of a hospital sheet. The linens might even last a bit longer than typical as the treatment helps prevent material degradation, he says.

No one is certain that hospital linens are even a source of nosocomial infections let alone how frequently that happens. Still, it's common wisdom that soiled linens compromise a patient's safety. "There are a lot of preventive measures" hospitals take to fight infection such as putting germicides into floor cleaners, wearing face masks and filtration systems—none of which can be directly attributable to diminishing hospital-acquired infections, notes Mike McMahon, vice president of marketing in Medline’s textile group. "We’re trying to add one more tool to the toolbox."

An independent study commissioned by Medline found that after exposing linen to a variety of bacteria commonly found in hospitals, the HaloShield-treated sheets had killed 99.97% of the organisms versus none by the untreated sheets, Barth says.

Medline, which sells $300 million per year in traditional textile products with a better than 30% share of the hospital market, has enough manufacturing capacity to supply every hospital in the country, Barth says. The company plans to broaden the HaloShield product line beyond sheets to other linens such as gowns and scrubs.

Establishing guidelines

Reaching a consensus in the medical community on the best way to prevent nosocomial infections is no minor feat, judging by the experience of a work group that recently published guidelines on the use of antibiotics to prevent surgical-site infections. Representatives from leading medical organizations, physicians and hospitals published the guidelines in the June 15 issue of the journal Clinical Infectious Diseases.

The work group tackled three issues: which antibiotic to use before surgery, when to start administering it and when to stop. The panel eventually recommended that antibiotics should be given one hour before surgery and should not be used for more than 24 hours after the end of the operation. Before development of the guidelines, antibiotics were continued for an average of 40 hours after a surgical procedure.

When to stop treatment was the most controversial of the guidelines, says John Hitt, vice president of clinical improvement for hospital cooperative VHA. Hitt, who served on the work group, says the reasons for stopping treatment sooner rather than later were compelling. A longer duration can lead to more drug-resistant organisms and can increase the risk of allergies or side effects such as diarrhea. Meanwhile, there is little clinical evidence that giving more antibiotics produces better outcomes, he says.

There was a financial upside to a shorter duration of antibiotic treatment as well. Though the savings, including nursing time, might be as little as $100 per case for a simple antibiotic, such savings can add up to real money if thousands of surgeries are performed in a hospital each year, Hitt says.

Regardless, the medical community still has no idea what an "acceptable" rate of infection would be if hospitals did everything within their power to prevent them, Hitt
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says. There are a lot of technologies to prevent infections out there—everything from warming up patients after surgery to hand-washing "that are incredibly effective," Hitt says. Yet a recent survey by VHA of a small sample of hospitals found that only 60% of all healthcare workers appropriately wash their hands before patient contact.

"If there were one nonantibiotic thing we could do, it is washing hands," Hitt says. "It seems silly, but it's true."

This is the second of two stories on infection-control efforts at hospitals. The first, "Debugging hospitals," published in the April 26 issue, focused on using information technology to track outbreaks and the unreimbursed costs of fighting them. Read the story in the Technology section of this website.