

Physician pioneers groundbreaking infection treatment

By Lori Houston, Editor



Santa Rosa physician Barry Silberg has developed a new treatment for soft tissue infections, including MRSA, currently in Phase 2 FDA clinical trials.

FOR THE FIRST TIME IN DECADES, the number of patients who develop secondary infections in U.S. hospitals or health care facilities has declined, according to a December 2010 report from the Centers for Disease Control. This is significant because hospital-acquired infections rank in the top 10 leading causes of death in the United States. At the moment, about 1.7 million patients—one in 20—contract such infections annually and 99,000 of those die as a result. The most common infections are surgical site, bloodstream, urinary tract, and pneumonia. Collectively, these infections account for as much as \$33 billion dollars in *preventable* health care costs every year in the U.S.

Patients facing weeks or months of intravenous antibiotics are being treated and discharged in days.

Surgical site infections contribute to increased hospital stays, delay patients' return to previous level of physical ability, cause increased pain, and increase the risk of death as a result of sepsis and multi-system organ failure. More than 600,000 surgical site infections occur annually. Open abdominal surgeries such as colon or gastrointestinal have the highest infection rates.

The latest statistics seem to indicate that stepped up infection prevention practices in health care settings—centered around establishing safeguards and best practices and driven by a national action plan to ultimately eliminate hospital-acquired infections altogether—are beginning to make a difference.

But until such time that infections can be completely prevented, what else can be done for patients at risk or those who already suffer from hospital-acquired infections? Many of them wind up hospitalized for extended periods of time for treatment and affected by the infection's aftermath for the rest of their lives in the severest cases. Soft tissue infections have become a major global health issue.

Santa Rosa physician Barry Silberg has pioneered a highly safe and effective, yet relatively low-cost solution to prevent infection and treat chronic conditions caused by infection, derived from his own groundbreaking discovery as a plastic surgeon.

Anxious to prevent post-surgical dehydration and swelling for his liposuction patients, Dr. Silberg modified an ultrasound device so that he could infuse the layers of tissue surrounding surgical sites with saline, essentially "super hydrating" them. He decided to apply this same method to deliver pre-surgery antibiotics to his patients, and found that by doing so, he could safely apply much higher concentrations of antibiotic directly to surgical wounds. When he used this method of subcutaneously infusing antibiotics for several outpatient procedures, Dr. Silberg found that not only were his patients nearly pain free afterwards, but the incidence of infection all but completely disappeared.

Recognizing this method could also be applied to prevent inpatient surgical site infections, Dr. Silberg went to the surgical review board at Santa Rosa Memorial Hospital, where he performs most of his procedures. The board also recognized the huge potential of Dr. Silberg's method and gave approval for its use in hospital

surgeries on the basis of signed patient consent, with the added condition that he would seek federal Food and Drug Administration approval. In the world of medicine, any new uses for drugs—even medications already approved by the FDA—are considered "off label" and must undergo intensive studies and trials before they can be adopted as protocol. In the case of Dr. Silberg's treatment, the drug is Cefazolin, an FDA-approved, broad-spectrum antibiotic first discovered in 1948 and widely used today. Cefazolin is considered very safe for intravenous use with virtually no side effects. Dr. Silberg's patented method of subcutaneous delivery enables Cefazolin to be infused directly into body tissues in much higher concentrations than can be given intravenously.

Standard, accepted medical protocol currently is to give antibiotics orally or intravenously before and after hospital surgeries to prevent infection. Antibiotics are also commonly used to irrigate wounds during surgery. This protocol has evolved in response to decades of research and surgical outcomes. Still, in numerous major studies on surgical site infections to date, notes Dr. Silberg, the most statistically significant cause of infection is not the timing or dosage of antibiotics but rather the length of surgery. For every hour of surgery, the complication rate doubles. Dr. Silberg's theory is that the longer a surgical site is open, the greater the exposure of fatty tissues to dehydration and bacteria. Irrigating surgical sites with antibiotics under these circumstances appears to be "meaningless" because antibiotics are ineffective for damaged or dead tissue.

"Here's the analogy I like to use. When you've got a fly in a room there are two ways to get rid of it: swat it with a fly swatter or fumigate the entire room. Giving antibiotics intravenously amounts to fumigating the entire body," explains Dr. Silberg. "What we demonstrated in our Phase I study is that it is possible to get 1,000 times higher concentration of antibiotic into tissues using direct ultrasonic delivery than can be achieved by giving the same antibiotic intravenously."

To produce the scientific data needed to seek FDA approval, Dr. Silberg sought out a laboratory to conduct a tissue analysis with Cefazolin. He could find only one such laboratory in the entire country: the Center for Anti-Infective Research



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and Development at Hartford Hospital in Hartford, Connecticut. The director of this center, Dr. David Nicolau, is also the research coordinator for the hospital's Department of Medicine, Division of Infectious Diseases and Pharmacy.

The initial analysis focused on one of the most persistent infection control issues for in-patient health care facilities: MRSA (Methicillin-Resistant Staphylococcus Aureus), a bacterium that has become extremely resistant to many antibiotics, making it a particularly dangerous threat to physically vulnerable patients and extremely hard to treat.

"We tested these higher concentrations against bacteria that were previously thought to be resistant to antibiotics and we discovered that the key to effectiveness is concentration," Dr. Silberg says.

The Phase I pilot study confirmed that Cephalosporin antibiotics (such as Cefazolin) are effective against MRSA infections in high enough concentration. And since Cephalosporins are not toxic to local tissues, a much higher concentration than what is

routinely administered before surgery can be given without fear of tissue damage.

The results were so compelling that Dr. Nicolau joined the board of directors of Dr. Silberg's nonprofit organization formed in 2008, Santa Rosa Antibiotic Effectiveness Project, Inc. Other board members include Santa Rosa surgeons Joseph Cohn and James Harwood, and Dr. Laurel Warner, an internist and infectious disease specialist.

As word of Dr. Silberg's research and treatment spread, other physicians began referring their patients with surgical site or chronic wound infections. Dr. Guy Delorefice, a hospitalist at Santa Rosa Memorial, has worked with Dr. Silberg on numerous patients.

"Dr. Silberg has developed an ingenious technique," Dr. Delorefice says. "I can personally testify that I have not yet witnessed a negative outcome in a single patient where this technique has been performed. The benefits have been tremendous. The result tends to be one of rapid improvement in the infection leading to better patient outcomes. In a single case, I believe Dr. Silberg's antibiotic infusion technique ... saved a limb I thought was lost."

Long-time Santa Rosa orthopedic surgeon Dr. Roger Klein observed that one of his post-surgical knee patients with a MRSA infection had "an incredibly rapid and complete response" to Dr. Silberg's surgical treatment, noting that the patient had no pain and no residual redness, swelling, or tenderness. "It is my opinion that Dr. Silberg's study should be continued and expanded because it has great potential for patient treatment and cost savings," Dr. Klein concluded.

Since June 2011, Dr. Silberg has treated more than 100 patients successfully for chronic and acute MRSA infections, many with extensive skin loss, using direct antibiotic delivery into the infected tissues. In addition, this method can be used to treat diabetic patients with ulcers who have decreased blood supply to their legs because antibiotic infusion is independent of blood supply.

This past March, the FDA gave approval for Dr. Silberg to conduct Phase II clinical trials of the treatment, focusing on the technique of delivering Cephalosporin antibiotics directly to targeted tissues to treat



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specific, persistent infections. To date, there have been no negative side effects from the treatment and only one patient failed to respond. Predominantly, the treatment has dramatically and quickly resolved infections and enabled patients with skin loss to undergo skin grafting. Many of these people had suffered for years with wound infections. Suzanne Drake, manager of Santa Rosa Memorial Hospital's Wound Care Clinic, has seen several long-term, chronic wound patients respond to Dr. Silberg's treatment after failing to respond to more conventional wound care procedures. "My staff and I are excited for our patients to get relief after long sieges of pain and non-healing, despite our best efforts," she says.

While Dr. Silberg has attracted interest and support from many health care colleagues, he has also encountered some resistance. As with many industries and disciplines, breakthrough developments are regarded initially with suspicion and considered disruptive because of their potential threat to the status quo. In this case, ultrasonic dispersion of antibiotics represents potentially huge cost savings for hospitals by preventing infections and reducing length of stay for surgical patients, as well as alleviating readmissions and treatments for patients with chronic infections. The treatment also appears to have the potential to reduce the need for many current infection control measures and to eclipse the prolonged use of antibiotics. In some segments of health care, those kinds of changes represent loss of revenue and/or jobs.

For this reason, Dr. Silberg chose to form a nonprofit and avoid any pharmaceutical industry funding of the research and approval process for antibiotic infusion. In this way he can maintain some control over what does, or does not, happen with his important discovery.

"This represents an entirely new method of treatment. So far we have treated patients with severe infections, some of whom have had open wounds for years and others who would have faced amputation. Patients who faced weeks or months of intravenous antibiotics have been able to be treated and discharged from the hospital in *days*," Dr. Silberg says. "I'm interested in getting people well."

For more information, visit antibioticresearch.org 

One patient's story: 'This just makes sense'



Cappie Garrett

When Cappie Garrett learned she needed to have a couple of skin cancers removed on her leg last September, facing that diagnosis was distressing enough. She was relieved to be able to undergo the procedure in the doctor's office right away, minimizing her down time as a busy professional who runs her own architectural design firm and is highly engaged in community work.

She went home to rest and recover, following her doctor's instructions to the letter so that she could heal as quickly as possible. The next morning, however, one of her incisions had become reddened and "angry looking" and felt hot. She phoned her physician right away, who thought it might be too soon to be infected but prescribed an antibiotic at Cappie's request.

But instead of responding to the antibiotic, the wound grew worse and she became unable to walk or drive. Her doctor took a culture for a lab analysis, but in the span of time needed to grow the culture, Cappie's entire leg became swollen, turning scarlet from her ankle to her groin. That's when her husband, Dr. Tom Garrett, took her to the emergency room.

"When they tell you that you might lose your leg, that's something nobody ever wants to hear."

Cappie wound up hospitalized for six days, dosed continuously with antibiotics and painkillers intravenously to fight the infection. When the results of the culture indicated a staph infection rather than highly contagious MRSA (Methicillin-Resistant Staphylococcus Aureus), she was released to go home and given a prescription for more antibiotics.

She was in the hospital parking lot with her husband helping her into the car when Dr. Barry Silberg walked up. As a longtime personal acquaintance who knew Cappie to be a very active person, he was stunned to see her in a wheelchair. Reluctantly, Cappie allowed him to look at her leg. Dr. Silberg recognized immediately that the wound had abscessed and told her he could help her. He came to the Garrett's home later that day to tell them about his antibiotic infusion treatment and research project, showing them before and after photos of patient wound infections he had treated successfully.

"I looked at my husband and said, 'I don't want to mess around with this for a year. I want to do this now, even if I have to pay for it myself,'" Cappie recalls.

She was able to have the surgical procedure right away. Dr. Silberg re-opened the wound site, removed the abscess, cleaned up the margins of the surgical site, and then infused the tissues with antibiotic using ultrasound dispersion.

"I started getting better immediately. It was really amazing," Cappie says. "Before, I was on antibiotics for weeks. This was a one-time treatment and I was not in the OR for very long. Within three days, I was walking again and everything was getting better."

Her leg is completely healed now.

Even though she admits she "felt like somewhat of a guinea pig" giving her consent for a brand new procedure, it seemed like the best course of action.

"When they tell you in the ER that you might lose your leg, that's something nobody ever wants to hear. That's how serious the infection was," she says. "This treatment should be the first line of attack for an infection like that. This would save patients from all the unnecessary antibiotics I was given initially that didn't do much good. Direct infusion kills the 'bug' at its source, which just makes sense. I am a total advocate."