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Special Report

The Dirty Truth about Hospitals

The surgeons may be skilled, the nurses prepared. But if their tools are contaminated, a world of hell awaits. So how good is the cleanup crew at your hospital?

BY LAURA BEIL

AFTER THE FIFTH SOLDIER TURNED UP WITH a post-op knee infection, the staff at Madigan Army Medical Center in Tacoma, Washington, halted all anterior cruciate ligament surgeries. Something was very wrong, but no one could say what. In a little more than 3 months during 2003, the men had undergone routine reconstruction of ligaments torn when knees had twisted under 100-pound pack loads or ankle ligaments snapped during pickup basketball games. It's usually a safe procedure, and infections are rare (though not unheard of). In 4 years of repairing ACLs, doctors could recall just one other infection. Now five?

The hospital gathered a team of surgeons, nurses, infectious-disease specialists, and even medical supply personnel to scrutinize every aspect of its technique. The team eventually zeroed in on a new handheld device called a hex driver, which is used to turn a small screw that fastens the ligament in place during the operation. The center is hollow, which allows surgeons to guide the driver into place along a thin wire. The canal, called a cannula, is tiny—so tiny that apparently the sterilization staff didn't notice it or, if they did, they didn't have a brush small enough to scrub it clean.

Trapped inside the hex driver was "a mixture of bone and blood and saline from the arthroscopy," notes Captain Stephen Parada, M.D., a Madigan orthopedic surgeon who's now deployed in Afghanistan. Doctors swiped cannula contaminants into a petri dish and bacteria bloomed, just as it had in the knees of the five soldiers. "Interestingly, other studies have found that this 'dried sludge' in other cannulated instruments was sterile," Dr. Parada says. "But our findings showed it was not."

Medical devices are becoming smaller and more sophisticated, speeding recovery times, lowering complications from surgery, and allowing doctors a view into the body's hidden cavities. Without the revolution in arthroscopy, you wouldn't be heading home an hour or two after the surgeon patches up your damaged joint. But in between you and the guy who just left the table, someone has to clean the bodily gunk out of the equipment.

It's called reprocessing. Most of the time, that job is handled by technicians who, depending on the hospital and state they work in, might not have formal certification for what they do. They might have a copy of the cleaning instructions, or they might not. They may be trying to make sense of dozens of sets of instructions, which can differ from manufacturer to manufacturer for the same kind of instrument.

You probably have never thought about the people in those instrument cleanup crews, but one day your life may depend on one of them.

"My staffers are all certified and many have stayed with me for 20-plus years," says Sue Klacik, who oversees reprocessing at St. Elizabeth Health Center in Youngstown, Ohio. But she notes that reprocessing jobs throughout the country tend to have high turnover because of the pressure and technical demands. Though official figures on turnover aren't available, Jerzy Kaczor of Soyring Consulting, a company that helps hospitals manage reprocessing, notes that he recently worked with one hospital in which half the techs left after a few years. In other places, he says, turnover is even higher.

The concern isn't just that reprocessing is handled by a workforce that could earn almost as much money as groundskeepers but with less stress and a lower "yuck" factor. These workers must also face challenges presented by the new breed of devices themselves, many of which have minuscule channels and crevices that can be impossible to see and difficult to access. "When you use artificial materials, all kinds of proteins and bacteria stick to the surface," says Christopher Jobe, M.D., a professor of orthopedic surgery at Loma Linda University. Case in point: Dr. Jobe's 2006 study found protein remnants on the tiny bone shavers commonly used in orthopedics.

"Picture yourself washing dishes while wearing Playtex gloves, and trying to disassemble something that has very small moving parts," says Ramona Conner, M.S.N., of the Association of Perioperative Registered Nurses.

Even the most dedicated technicians scratch their heads as they attempt to follow cleaning guides that can be either too detailed or not detailed enough. "There is a large variability in the instructions from the different manufacturers for very similar devices," says Linda Condon, R.N., the educator for the reprocessing department at Johns Hopkins Hospital in Baltimore. And sometimes, she says, cleanability seems like an afterthought to design. Surgeons at Condon's hospital recently bought a remote control for some of their arthroscopic instruments. "The cleaning instruction for the remote was one sentence: 'Use a neutral detergent and wipe it clean.' So I was like, 'Wow, okay, can I submerge it? Can I soak

it? Can I scrub it?' It took me 30 days to get an answer from the manufacturer."

What all this means about your next doctor's visit is hard to say. Cleaning lapses are not so rampant and dangerous that you should avoid surgery you need or cancel your next appointment. Experts say the risk of infection from a dirty medical instrument is low. Consider the context: A hospital with a few hundred beds probably turns around 10,000 to 13,000 instruments a day. Condon estimates that a large teaching center like hers may handle more than double that number. The FDA, which oversees medical devices, noted in a written statement that "harder to clean does not mean a device cannot be cleaned." (The agency declined a request for an interview.)

The trouble is that no one knows how often soiled instruments make their way to patients. No statistics exist because hospitals aren't required to notify the government when they discover a dirty device; also, they may feel pressure to hide the problem for fear of bad hospital ratings, bad publicity, and lawsuits.

"How frequently are lapses in reprocessing occurring? Honestly, we really don't know," says the CDC's Melissa Schaefer, M.D. "The reports that we hear about are potentially the tip of the iceberg."

In Dr. Schaefer's 2010 study, published in the *Journal of the American Medical Association*, 28 percent of the ambulatory surgical centers studied had strayed from their cleaning protocol to some degree. And a new University of Michigan study that analyzed the cleanliness of 350 suction tips (which are used to vacuum up fluids during surgery) found that 95 percent of them still contained debris after routine decontamination. The researchers noted that "debris was found where debris should not be, and the manufacturer's recommended cleaning methods—the current practices—were not effective."

The Pennsylvania Patient Safety Authority collects reports when tools unwrapped during surgery are noticeably contaminated. According to one hospital's report, "When placing the tissue protector on the drill, old dried blood and tissue came out." Another noted that a triple trocar, used to place a pin into bone, "was full of dried blood and smelled foul."

The risks to patients may be low, but they're not merely theoretical. In 2009, seven people who had knee or shoulder arthroscopy at Methodist Hospital in Houston contracted surgical-site bacterial infections. One man had at least seven subsequent surgeries and has still not regained full use of his shoulder. Another, a 38-year-old father of two, became so distraught over the complications from his knee infection that he took his own life.

In a CDC study of the Methodist Hospital outbreak, investigators discovered that the arthroscopic shavers that were used for these procedures harbored residual bits of tissue. Perhaps most disturbing was the fact that the hospital staff was following proper cleaning instructions. "[It] suggests that this problem is not specific to this institution or to a specific manufacturer," the investigators reported in last December's *Infection Control and Hospital Epidemiology*.

But perhaps nothing worries the infection-control experts more than an endoscope, the slender tube with a lens and a light source that doctors use to look down your nose or up into your large intestine. An estimated 20 million GI endoscopies are performed each year, most of them in the hunt for colon polyps and cancer. The instrument—picture a bundle of rubbery tubes—can be as long as 6 feet, with interconnected narrow channels inside so physicians can thread tools and cameras into deep-body spaces, or spray a jet of water or air to remove obstructions.

But where there are interconnections, there are gaps and crevices. "That's where material can accumulate and be difficult to clean, and for that matter be difficult to verify that it has been cleaned," says Chris Lavanchy, health devices engineering director of the ECRI Institute, a nonprofit organization that functions as a kind of *Consumer Reports* for medical equipment. "You can't actually go inside and look at the channel to see that it's free of debris." ECRI consistently ranks endoscopes among the top infection risks of medical technology.

"Because they're delicate, they can't be sterilized in the traditional way, which is to put them in a steam sterilizer," Lavanchy says. "Most endoscopes can't tolerate that heat and moisture." Plus, aggressive handling can damage them, so technicians must clean them gently: An endoscopic surgical system costs about as much as an Audi.

The biggest concern is that the insides of the tubes, if not correctly cleaned, can collect biofilms, the type of damp, stubborn slime that builds up in your shower drain or along the sides of the dog's water dish. Endoscope biofilms can't be washed away; they have to be physically broken up with a brush and chemicals. In a 2004 Australian study published in the *Journal of Hospital Infection*, researchers examined the tubing from 13 endoscopes under an electron microscope and found goo inside almost all of them. "The presence of soil and biofilms suggests that current cleaning and disinfection processing of endoscopes are inadequate," the authors wrote.

Like crusty dishes left in the sink overnight, endoscopes can be a challenge to clean if they sit around—which they sometimes do. Last year, a gastroenterologist complained in the journal *Gastrointestinal Endoscopy* that "delays in reprocessing usually occur when endoscopies are performed at night or over a weekend and the endoscopes are left for proper reprocessing by regular staff the next business day." Another obvious problem: a busy day at the endoscopy center. According to a 2010 study published in *Gastroenterology Nursing*, three out of four reprocessing employees said they felt pressured to get the endoscopes out quickly; it was common to skip steps in or rush cleaning.

But what are the consequences of a dirty scope? It might not cause an infection, or if it did, the symptoms could be so mild the victim wouldn't notice. The FDA received reports of 596 potentially endoscope-related infections between 2007 and mid-2010. That may sound tiny, but consider that hospitals and clinics don't have to notify the FDA if they find that a device has cleaning

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problems, or even if a patient gets sick. Only if a hospital suspects someone has actually died as a result of a dirty device does it need to file a report. (Manufacturers are supposed to alert the government if they receive reports of device-related harm.) If the cases aren't part of a recognized outbreak, they might escape notice altogether.

Douglas Cooper certainly did notice, however. In 2008, he saw a doctor near his upstate New York home because he was having problems urinating after an outpatient surgery. Before the doctor inserted a catheter, he slid a cystoscope—an endoscope for urology—into Cooper's penis. Two weeks later, Cooper was suddenly seized by a fever and chills. He was diagnosed with a severe bladder infection, his first in all his 65 years. Even more unusual, it was caused by *pseudomonas*, a pathogen often blamed for infections associated with health care. (And the diagnosis was not far-fetched for cystoscopy patients. In early 2007, at least seven men in New Mexico picked up *pseudomonas* infections from a dirty cystoscope after a urologist had probed their bladders.)

That turned out not to be Cooper's biggest problem. A week after his bladder infection, Cooper noticed "a very painful something on the tip of my penis, just below the opening." He had contracted genital herpes, which he believes came from the cystoscope. His doctor disagreed. "You cannot possibly prove that for 25 years you were faithful to your wife," says Cooper, "but for 25 years I have been."

Perhaps the most high-profile endoscope-cleaning breakdown came in 2009, when the U.S. Department of Veterans Affairs notified more than 11,000 patients about improperly cleaned endoscopes. They'd had appointments at four VA medical centers. One man who received the news was Robert Metzler of Coral Gables, Florida; he now has hepatitis C. It's up to a judge to decide whether Metzler has enough evidence to show that his illness came from the colonoscopy he underwent in 2007, at his physician's urging. ("She was so nice, I just didn't want to disappoint her," he stated in court documents.)

Metzler had had a negative hepatitis C test the year before the colonoscopy, which attorney Ervin Gonzalez hopes will convince the judge that the virus came from the endoscope. The VA cases were unusual, Gonzalez says, in that administrators notified all patients who could have been at risk; this is something a private hospital may be less inclined to do. "A lot of times people who develop injuries or diseases are not able to relate them to the scoping event," Gonzalez says, "not knowing that the instrument wasn't properly cleaned."

Given the many high-profile cleaning screwups, reprocessing is finally getting its due. The FDA is working with manufacturers of arthroscopic shavers to address the debris problem. And last year, the FDA and the Association for the Advancement of Medical Instrumentation held a summit to discuss improvements in reprocessing. The International Association of Healthcare Central Service Materiel Management, which represents reprocessing professionals, wants more states to require certification for techs. (Only New Jersey now has such a requirement; legislation is pending elsewhere.) Both organizations are working with the government and industry to establish some kind of consistency in cleaning instructions.

Major manufacturers, such as Olympus America, which sells 70 percent of the country's endoscopes, say they are engineering devices to be easier to clean, with fewer chances for human error in reprocessing. "In the past, reprocessing was not a focus of the design process," says Mary Ann Drosnock, M.S., who heads infection control for the company. "That's not true any longer."

Adam Higman, from Soyring, urges anyone planning to go in for any kind of procedure to do some homework. Ask how the equipment is cleaned, and check on the infection rates. It may take time, and the doctor may be surprised that you're even asking.

"If I have a choice between doing 2 hours of research or getting an infection," he says, "I'll go with the research." ■