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CLEAR CONCERNS AMID MURKY DEBATE

PATENT DOCUMENTS RAISE QUESTIONS IN DISPUTE ON ENDOSCOPE INFECTION RISK

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Katie Anderson was just six months old when doctors snaked an endo scope through her mouth and throat into her stomach. She had such severe acid reflux that she had stopped eating, and doctors feared her esophagus might be damaged.

Within days of the procedure, however, the 15-pound infant developed a life-threatening infection - a type of strep that doesn't respond to penicillin and is typically found only in hospitals. Today, 10 years later, Katie's mother remains convinced the endoscope caused the infection. "I ran around telling everybody in the hospital that day," said Beth Anderson of Germantown, Md. "I kept saying, `You need to check those instruments. You need to clean them up.' "

Despite their suspicions, the Andersons don't believe their case was ever reported or investigated, making it impossible to determine whether the infection was caused by the endoscope.

It is amid such anecdotal accounts and a lack of scientific evidence that a heated debate has raged over the past decade on the safety of endoscopes.

That there is reason for concern seems clear. Patent records examined by the Globe suggest the world's leading maker of endoscopes was aware as early as 1993 of certain problems. In more than 40 patents, Tokyo's Olympus Optical Co. describes the difficulty of cleaning the devices or the need for improved instruments. In a patent filed in July 1993, the company writes that at times, "satisfactory cleaning can not be achieved." In another filed in March 1993, the company writes that "the disinfection process is too complicated to be completed."

David Barlow, director of technology assessment for Olympus America, the company's US division, said it has increasingly taken into account in recent years the difficulty of cleaning the devices when designing them. Some of the technologies outlined in the patents have been incorporated into the company's existing endoscopes to make them easier to clean, he said.

In other cases, however, the company decided the technologies didn't warrant development. For example, many of the patents describe ways of covering the endoscope with a disposable outer layer and making its internal channels disposable. Such a system has been marketed by a small Natick competitor, Vision Sciences Inc., for nearly a decade, Barlow said, and physicians have decided that there isn't enough scientific evidence that it reduces the risk of infection.

"These are delicate procedures," Barlow said. "They require fantastic optical systems and the ability to maneuver easily. The endoscope is a highly evolved and engineered instrument. When

you replace the precision of the reusable parts with cheap disposable parts, the operability declines."

Nearly 20 million patients nationwide are prodded with endo scopes each year. By reducing the complications of invasive surgery and helping doctors detect diseases at an early stage, the devices have probably saved millions of lives in the past decade. But precisely because they are complex instruments designed to detect diseases hidden in the body, they are difficult to clean.

They have fiber optics, air and water channels and a tube that allows doctors to thread instruments through the body to biopsy tumors and remove polyps. If they are not properly cleaned and disinfected, blood, tissue and other substances can become lodged inside the devices, harboring bacteria and viruses that can spread disease.

Olympus's harshest critics say the devices are virtually impossible to clean, and Olympus has done little to address concerns about infection risks. David Lewis, a microbiologist with the Environmental Protection Agency assigned to the University of Georgia, said one study showed that nearly a quarter of instruments cleaned and considered ready for use in patients have not been adequately disinfected.

The cleaning process is so elaborate - technicians wash the devices by hand, soak them in chemicals, and run them through a machine similar to a dishwasher - that it is prone to human and mechanical error, he said. Lewis estimates that 2.7 percent of patients who undergo endoscopic procedures contract an infection - a number he stands by despite criticism from the medical community.

Many of the infections may be minor, he said, but others, including tuberculosis and hepatitis C, are serious. He claims the risk is underestimated because infections can show up weeks or months later. Patients go to different doctors to be treated, and no one considers that an earlier endoscopy may be the possible cause. For every case that is reported, Lewis believes, many more are missed.

The revelation earlier this month by Johns Hopkins Hospital in Baltimore that faulty bronchoscopes may have exposed more than 400 patients to a potentially deadly bacteria has breathed new fervor into the decade-old maelstrom of accusations and recriminations. Every few years, it seems a new report of an infection suspected to be caused by contaminated endo scopes spurs the controversy, which then quietly fades leaving little changed in its wake.

The problem, industry insiders say, is that there is widespread disagreement about the actual risk and a deplorable lack of scientific evidence to support the claims. On one side, a prominent physicians' group claims the risk of infection from contaminated endoscopes is one in 1.8 million. On the other, Lewis, a scientist credited with changing standards for disinfecting dental instruments in the midst of the AIDS crisis, contends the risk is nearly 3 in 100.

Other industry insiders, regulators, and public health officials say the risk likely falls between the two estimates. And though most of them maintain that the risk of infection is low, they say there are no data available to accurately gauge the risk.

"The true infection rate is pretty fuzzy," said Timothy Ulatowski, the Food and Drug Administration's director of infection control for dental and hospital devices. "It does occur, but

it occurs at a low rate. Can the devices be satisfactorily cleaned? Yes. Are there problems with cleaning and disinfection? Yes."

The bronchoscopes at Johns Hopkins and nearly 4,700 others had been recalled by Olympus late last year after a nurse in a Tennessee hospital noticed an unusually high number of cultures performed on lung secretions collected from bronchoscopes were positive for bacteria called pseudomonas. Health officials traced the problem to the Olympus scopes, which appeared to be passing bacteria from one patient to the next.

Citing a manufacturing defect, the company recalled 15 models of scopes with a loose valvelike component called a port. Olympus's Barlow said it is not clear that the loose part contributed to the infections, and the matter is still under investigation. But a report by the Centers for Disease Control earlier this week concluded that the loose part was probably trapping bacteria in a spot the normal disinfecting process could not reach. Even if the CDC's contention proves true, Barlow said, the company has fixed the manufacturing flaw.

Still, more questions remain about the risk of infection carried by endoscopes. The devices were suspected of exposing patients to hepatitis C this summer after eight people treated at the same New York clinic were diagnosed with the disease. More than 700 patients were notified in November 2000 by a Michigan hospital that they may have been exposed to bacteria and viruses after the hospital discovered it was cleaning its scopes incorrectly. A New Jersey lawsuit alleges that 1,800 patients may have been exposed to bacteria at a surgical center where the machine used to clean endoscopes had been broken for nearly four months.

"They try to claim that the risk of infection is small, but I don't see how they can know that," said Jamie L. Sheller, a lawyer on the New Jersey case.

Lawrence Muscarella, an infection control specialist at Custom Ultrasonics, a company that makes the washing equipment, said the rate of infection is probably higher than 1 in 1.8 million - though he believes it is small. But, he said, the accusations by those who charge endoscopes pose serious risk of infection cause more harm than good.

When the existing standards are followed, he said, the cleaning and disinfecting of endoscopes is highly effective. In case after case where contaminated endoscopes are blamed for spreading infection, he said, there is a breakdown in the cleaning process. He blames much of that on the pressure placed on nurses and technicians as hospitals cut staff and costs. And though it is an elaborate process, he said, it is not an impossible task when the staffs are properly trained and supported.

Regulators and public health officials need to increase monitoring of hospitals and physicians offices, he said. They need to institute a system to more carefully track and follow patients for potential cases of infection. They need to put more pressure on manufacturers to make devices that can be easily cleaned. And claims, whether made by manufacturers, physicians or critics, need to be supported by solid scientific data.

"The science has to hold up," Muscarella said. "If there's a problem, you have to show it. It has to be studied methodically and without emotion. If there's a better solution, its benefits have to be proven."

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