A deadly superbug was hiding in plain sight

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The hunt for a deadly superbug that sickened 22 patients at a Dutch hospital began just before noon on a spring day in 2012.

Inside a lab in the tiny hamlet of Zoeterwoude, a technician carefully peeled back the tip of a state-of-the art medical scope. Watching him intently was a small group of hospital officials and executives from Olympus Corp., maker of the device.

The Olympus technician found trouble right away. He spotted a brown, grimy film inside parts of the flexible scope - parts that were supposed to be sealed. A rubber ring designed to keep bacteria out was cracked and worn. The same bacteria that had sickened the patients were found on the scope.

An investigator hired by Olympus and the hospital concluded that the scope's design could allow blood and tissue to become trapped, spreading bacteria from one patient to another. In his report, he called on Olympus to conduct a worldwide investigation and recall all its scopes if similar problems turned up.

Over the next three years, 21 people died and at least two dozen more became ill from infections related to scopes in Pittsburgh, Seattle and Los Angeles. An unknown number of other patients have been infected. The U.S. Food and Drug Administration has identified 10 outbreaks, seven of which involve Olympus scopes.

Even as patients died and others were put at risk, Olympus continued to sell the device and failed to warn U.S. hospitals that the scopes were tied to dangerous infections, according to interviews with dozens of hospital officials, doctors, regulators and former Olympus employees.

After each outbreak, Olympus contended that its scopes did not cause the infections and blamed the hospitals for not cleaning them properly. The company treated each case as an isolated incident, not telling the U.S. hospitals that they there were others.

"Olympus' silence on this important issue was unethical, irresponsible and dangerous," said Dr. Andrew Ross, chief of gastroenterology at Virginia Mason Medical Center in Seattle, where 18 patients sickened by tainted scopes died and 21 other were infected.

Olympus controls 85 percent of the multibillion-dollar U.S. market for gastrointestinal scopes. U.S. prosecutors and congressional investigators are looking into how Olympus and two smaller scope manufacturers responded to the superbug outbreaks.

The investigations were launched after the Los Angeles Times reported in February about an outbreak that killed three people at UCLA Ronald Reagan Medical Center.

Regulators have warned all U.S. hospitals that an increasing number of infections across the country might be related to the design of the scopes.

Olympus declined to answer specific questions about the scope's role in patient infections and its handling of the outbreaks.

Many people think of cameras when they hear the name Olympus. Doctors know it as a medical device giant, one with a reputation for

engineering expertise and a close working relationship with medical professionals.

Medical devices today account for nearly 75 percent of the Tokyo company's $7 billion in annual revenue. Sales of its scopes surged 18 percent to $1.4 billion in the six months ending in September, and overall company profit rose 60 percent, to $294 million.

Olympus worked with doctors to invent the device called a duodenoscope more than four decades ago. It is used in a procedure known as ERCP, or endoscopic retrograde cholangiopancreatography. Doctors thread the flexible scope down a patient's throat and into the digestive tract, where cancers, gallstones and other conditions can be diagnosed and treated, without the complications of more invasive surgery.

Physicians perform nearly 700,000 of those procedures annually in the U.S., and 2 million worldwide, Olympus said. Many of those patients have serious illnesses, making them more vulnerable to infection.

By 2010, two Olympus rivals, Pentax and Fujifilm, were selling a redesigned scope that they said was easier to clean because a crucial section of the device was sealed to keep bacteria out.

Olympus introduced a similar model, known as the TJF-Q180V. The company said the $40,000 scope was a technical triumph designed to give doctors the ability to perform more complex procedures.

The Olympus sales force also pitched its new scope as being easier to clean. That appealed to hospitals, where nurses and staff were under pressure to quickly disinfect the devices, which could take as long as an hour.

But the redesign had created a new problem.

The 2012 outbreak in the Netherlands, at Erasmus University Medical Center in Rotterdam, was the first sign of trouble.

"You only need one bacteria to get inside and multiply," said the Dutch investigator, Arjo Loeve, a mechanical engineer at Delft University of Technology. "You shouldn't find anything on the inside."

After Loeve's report linked the bacterial outbreak to its scope, Olympus alerted European hospitals about potential contamination. But it didn't issue a similar warning in the United States, its biggest market.

A few months later, patients at the University of Pittsburgh Medical Center began testing positive for a superbug known as CRE. That superbug is so resistant to antibiotics that health officials call it the "nightmare bacteria." As many as half of infected patients die.

The Pittsburgh hospital found that many patients infected with the superbug had been treated with an Olympus scope. The hospital quickly stopped using its Olympus devices, alerted the company and tested them for the bacteria.

Five of the hospital's 31 scopes tested came back positive for bacteria - even after being scrubbed by hand and machine-washed with a powerful disinfectant, the hospital said. One device contaminated with CRE was originally linked to 18 sick patients. The hospital later said it could definitively tie only one case to the Olympus scope because some patients underwent procedures at other hospitals.

An Olympus representative who reviewed the test results told doctors that the scopes might not be getting completely cleaned because the hospital was using the wrong type of automatic washer, the hospital said.

The representative persuaded the hospital to replace its cleaning machine with an Olympus model, which can cost about $25,000.

But another scope tested positive for bacteria even after it was cleaned in the new machine. The medical center began sterilizing scopes with a toxic gas, a costly, more time-consuming method. Because of the longer cleaning time, Pittsburgh ordered more scopes from Olympus, doubling its supply.

A few months later, in October 2013, patients undergoing operations with Olympus scopes at Virginia Mason Medical Center in Seattle began to develop serious infections. Eighteen of those infected died.

Hospital officials summoned Olympus.

A company service representative watched hospital employees wash the scopes and raised no concerns, said Dr. Andrew Ross, the hospital's chief of gastroenterology. Over the next several weeks, Virginia Mason sent its eight scopes back to Olympus, one by one, for inspections. Olympus never told the hospital about the Rotterdam and Pittsburgh infections, he said.

In 2014, nearly a year later, Olympus told the Food and Drug Administration that no Virginia Mason devices were returned for evaluation. The company also said that it had offered an on-site visit but that the hospital declined.

That account was at odds with that of the hospital, and Virginia Mason is suing Olympus for fraud, arguing that it "deceptively concealed ... the risks and flaws of the scopes." Olympus denies the allegation, contending that the hospital failed to follow the instructions for cleaning the scope.

An investigation by federal, state and county officials concluded this year that the hospital followed proper cleaning procedures and that the Olympus cleanings were insufficient. In a report, the health officials called that "disturbing."

When doctors at UCLA's Ronald Reagan Medical Center began to suspect that they had tainted scopes in December 2014, they called their Olympus salesman, Vincent Hernandez.

Hernandez was one of the company's top salesmen; he boasted on LinkedIn about securing $14.6 million in new business in 2014. He had spent much of that summer with UCLA doctors and administrators, wrapping up a major sale of Olympus scopes.

Hernandez and Olympus technicians visited the hospital. Company representatives watched UCLA employees clean the scopes. None of them raised concerns about the cleaning or mentioned the previous outbreaks, according to UCLA officials involved in the investigation.

Olympus told the FDA, though, that one of its employees had noted "inconsistencies" in the hospital's cleaning practices. In court filings, Hernandez and two other employees said they couldn't have warned UCLA about outbreaks linked to the scopes in the Netherlands, Pittsburgh or Seattle because they weren't aware of them.

By late January of this year, the relationship between Olympus and UCLA had grown testy. University doctors had taken two scopes linked to patient infections out of service and asked Olympus to lend them two more. Olympus asked for the scopes to be returned before replacements would be sent. UCLA declined.

The hospital soon had a shortage of scopes because new cleaning methods were taking longer. When the university asked about buying

more scopes, Olympus said the price had increased since the hospital had purchased scopes a few months earlier, according to hospital officials. The company also said it couldn't promise when the devices would arrive because the outbreaks had increased demand.

Dr. Raman Muthusamy, UCLA's director of endoscopy, said he hadn't been aware of the Netherlands case while his hospital was investigating the infections. When he read the Dutch investigator's report, he was struck by the similarities.

"Pittsburgh was established. We had Virginia Mason. We had Rotterdam," he said. "You wonder, why didn't they get on this earlier? I had no inkling this was an issue."

The family of 11-year-old Jeffrey Hughes of Santa Monica says they deserved to know about the potential risks. Jeffrey, who had been fighting cancer for three years, was treated with an Olympus scope at UCLA during the outbreak and developed an infection. He died a month later.

His parents have sued Olympus in federal court in Los Angeles, blaming the scope.

"To put something in him that could risk his life - yeah, I would have wanted to know that," said his mother, Annie Hughes. "Olympus knew about this in 2012. At least tell us."

Olympus has denied liability in the boy's death, saying it could have been caused by pre-existing conditions.

Although Olympus did not alert U.S. hospitals to previous outbreaks, it was required to file reports to federal regulators. Most of those reports suggested culprits other than its scope, including poor cleaning

procedures.

The company's reports didn't suggest a link among the cases; instead, they were each reported as separate, unconnected incidents.

The FDA issued no warnings based on those reports. Following federal rules, it didn't publicly identify the hospitals.

Olympus waited until 2015 to file a detailed report on the 2012 Netherlands outbreak. In it, the company again contended that the hospital may have not cleaned the scope properly.

"The cause of the patient infection could not be conclusively determined," Olympus concluded.

In February 2015, immediately after the UCLA outbreak was reported, Olympus sent an alert to customers. It disclosed, for the first time, that it was aware of 95 complaints tying its scope to patient infections.

A former top Olympus executive familiar with the inner workings of the company said the previous scope models logged far fewer complaints.

"This rash of incidents couldn't be explained away," this former official said on the condition of anonymity for fear it would damage career prospects in the medical industry. "They should have pulled the scope."

In May, the FDA convened a panel of medical experts at its headquarters outside Washington to examine the scope-related infections.

Doctors from Rotterdam, Seattle and Los Angeles gathered for the two-day hearing. One by one, they described how their outbreaks unfolded.

Dr. Margreet Vos, an infectious diseases doctor at the Rotterdam

medical center, showed regulators and medical experts the photos taken inside the Olympus lab after the Dutch outbreak three years earlier.

She pointed to the brownish debris that Olympus employees had found behind the glass cover of the scope's camera - an area closed off from cleaning.

She put an image of the rubber seal on a giant screen. It was worn down with rough edges and a tear on the bottom left side.

"A solution must be found in changing the design," Vos said. "I think many transmissions will occur ... . This is the tip of the iceberg."

Then FDA officials invited the public to speak.

Carla Warner of North Carolina said her 55-year-old husband, Bill, was treated with an Olympus scope at Carolinas Medical Center in Charlotte. He died of an infection in November 2013.

His family sued Olympus, alleging wrongful death, in federal court last month in Philadelphia.

"Olympus knew of the risk and hid the infections," Warner said.. "My husband should be alive today."

Olympus executives sat in the back of the room. None of them rose to speak.

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Times researcher Scott Wilson contributed to this report.

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Timeline of scope-related outbreaks

2010

August: Japanese device maker Olympus Corp. introduces its TJF-Q180V duodenoscope.

2012

April 23: An Olympus employee dismantles a duodenoscope suspected of infecting 22 patients at a Netherlands hospital.

June 27: An independent expert's report on the Netherlands outbreak calls on Olympus to conduct a worldwide investigation and possibly recall the scopes if more contaminated devices are found.

Dec. 4: Olympus visits the University of Pittsburgh Medical Center after being alerted to apparent scope-related infections.

2013

January: Olympus issues "important safety advice" in Europe for the TJF-Q180V duodenoscope after infections in the Netherlands. There's no notification in the U.S.

November: Olympus visits Virginia Mason Medical Center to review the Seattle hospital's scope cleaning practices; an outbreak is later confirmed.

2014

August: Olympus sends a second safety alert in Europe after receiving complaints about tainted scopes.

Oct. 3: A UCLA patient carrying the CRE superbug undergoes a scope procedure with an Olympus device; the instrument remains contaminated after cleaning.

Dec. 14: UCLA begins investigating a superbug infection in a female patient who was treated with an Olympus scope.

2015

Jan. 28: UCLA ties patient infections to the Olympus devices, temporarily halts use of the scope.

Feb. 18: Los Angeles Times first reports the UCLA outbreak.

Feb. 19: The Food and Drug Administration warns U.S. hospitals about scopes spreading deadly bacteria.

March 4: Cedars-Sinai Medical Center reports four patients who had been infected by Olympus scopes.

March 26: Olympus issues new cleaning instructions to U.S. customers, similar to its European guidelines in 2013.

May 8: The U.S. Justice Department is investigating Olympus' role in outbreaks, the company confirms.

May 15: An FDA panel says that duodenoscopes are unsafe but that they should remain in use because no alternative is available.

June 9: Sen. Patty Murray, D-Wash., demands details from Olympus on its response to infection reports, as part of a congressional investigation.

Aug. 17: The FDA cites Olympus and two other scope manufacturers for

safety violations, including the failure to report potential injuries and deaths within 30 days.

Aug. 19: The Times reports that Huntington Memorial Hospital in Pasadena is investigating several patient infections tied to Olympus scopes.

Sept. 17: The FDA expands its warning, saying contaminated bronchoscopes made by Olympus and other companies may pose a risk to patients.

Sources: Olympus, Los Angeles Times reporting, hospitals