Four Patients Tested Positive For Drug-resistant *Klebsiella pneumonia* After Having Undergone ERCP, October 2017

A report in the FDA’s MAUDE database states that four patients tested positive for OXA-48 producing *Klebsiella pneumonia* after having undergone endoscopic retrograde cholangiography (ERCP) with an Olympus TJF-Q180V duodenoscope in a foreign healthcare facility. OXA-48 is an enzyme that breaks down carbapenem, one of the antibiotics used to treat multidrug-resistant bacterial infections. The duodenoscope had its forceps elevator replaced in 2016.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7027139&pc=F

An Olympus Colonovideoscope Linked to *Salmonella zanzibar* Infection, October 2017

A report in the FDA’s MAUDE database states that *Salmonella zanzibar* was found in fecal samples of all five patients who underwent colonoscopies with a particular Olympus colonovideoscope, model CF-HQ190I. Evaluation of the device showed no irregularities and the exact issue could not be determined.


An Endoscope With a ‘Design Issue’ Has Been Linked to Probable Transmission of a Colistin-Resistant Superbug, U.S, April 2017

A regulatory report filed by Pentax with the FDA reveals that an ED-3490TK duodenoscope was likely responsible for the transfer of a colistin-resistant strain of CRE from patient to patient. Colistin is an antibiotic known as the “last resort” antibiotic. This is the first known case of a colistin-resistant strain of CRE being linked to patient to patient transfer via duodenoscopy. As many as five patients may have been exposed to the contaminated duodenoscope.


Carbapenem-Resistant *Klebsiella pneumoniae* Cluster Associated with Gastroscope Exposure among Surgical Intensive Care Unit Patients at University of Pittsburgh Medical Center, Pennsylvania, October 2016
At the University of Pittsburgh medical center, an increase in carbapenem-resistant *Klebsiella pneumoniae* (CR KP) isolates was observed in the surgical intensive care unit. Three new cases were identified in one month compared with the average of 0.5 new cases/month from the previous year. Three additional cases were identified who had exposure to the surgical intensive care unit, but whose CR KP isolates were recovered in another unit. Review of the 6 cases found that all cases were exposed to the same OR gastroscope. Boroscopy revealed several deep scratches and luminal debris in the gastroscope. It then underwent channel replacement and cultured negative prior to going back into service. No further cases were identified.

http://ofid.oxfordjournals.org/content/3/suppl_1/248.full

### Nurse claims University of Cincinnati Health failed to stop infectious outbreak, Ohio, June 2016

A University of Cincinnati Health nurse filed a lawsuit against the health system, claiming it failed to prevent the spread of multidrug-resistant bacteria and covered up its role in the outbreak.

According to the report, as many as 100 patients may have developed an infection as a result of the care they received at UC Health. The lawsuit claims UC Health launched an investigation after recording a spike in the number of infections in patients who had undergone a bronchoscopy. Allegedly, the nurse suggested reaching out to an outside agency to investigate the medical devices and infections, but was told "no" because the organization didn't want an audit.

The news reported that the health system decided to simply deal with the patient infections rather than tackling the root of the problem, which were the bronchoscopes being used for the procedure.

The health system had stopped checking the bronchoscopes. By no longer checking the scopes the system wasn’t going to find any problems so there would be no need for an outside audit.


### CRE death linked to ERCP procedure at Lehigh Valley hospitals, Pennsylvania, April 2016

A patient at the Lehigh Valley hospital in PA underwent an ERCP procedure and soon thereafter was diagnosed with severe sepsis, septic shock and acidosis. She was admitted to the intensive care unit and, weeks after the procedure the doctor delivered the news that she had been infected with antibiotic resistant bacteria from a contaminated endoscope. She died a few weeks later.

The patient was one of as many as 350 patients at 41 medical facilities in the United States and worldwide who were infected or exposed to contaminated scopes from Jan. 1, 2010, to Oct. 31, 2015, according to a U.S. Food and Drug Administration document obtained by the House Committee on Oversight and Government Reform and made public in mid-April.
Multidrug-Resistant *E. coli* Infects Patients at University of Colorado Hospital, Colorado, January, 2016

Nine University of Colorado Hospital patients developed infections after undergoing surgeries with a duodenoscope. Three of the patients have died, although it is unclear what role these infections played in their deaths. The hospital has notified patients, families, and other patients who had undergone surgery with the same suspect endoscope. A visual inspection of the scope at Olympus found "the bending section adhesive was whitish in color and had open gaps at each side of the bending section cover, the glue around the nozzle had signs of cracks and gaps," and "the insertion tube had multiple buckles throughout the entire length." A microscopic inspection also discovered brown stains.


A study conducted involving the genetic marker, *clpK*, which increases the heat resistance of a strain of *Klebsiella pneumonia*, revolved around a recent outbreak in Norway. Five patients and one intubation endoscope were found to have the *clpK* marker at an intensive care unit in a secondary care hospital. The bacteria survived within the endoscope despite going through a chemothermal disinfection process in a decontaminator. The study found, through testing after heat treatment, the survival rate was strongly dependent upon the *clpK* marker. Due to the potential of heat resistance of certain strains of *K. pneumonia*, this is allows for possible spreading and infection to other areas of the hospital.


Psuedomonas outbreak at Huntington Hospital in Pasadena, California, August, 2015

On August 19th, 2015 Olympus contacted Huntington Hospital after a news report about patients being sickened after scope procedures at the hospital. The hospital informed Olympus that the patients had died. At least 3 patients are reported dead. It is not clear how many were exposed and whether only
three have passed. The report in the FDA database shows a different scope than the one recalled in January.


**E. coli outbreak at Hartford Hospital**, Connecticut, March, 2015

On March 4th, 2015 Hartford Hospital in Connecticut contacted 281 of their patients who could have been exposed to a strain of *Escherichia coli* (*E. coli*). Two scopes that could have infected 281 patients were removed from service in December. The hospital has been active, calling the patients to let them know and ask them to come in for screening. Dr. Rocco Orlando of Hartford Hospital stated that there is a defect in this particular scope that makes it nearly impossible to be completely disinfected and that the process for cleaning their endoscopes was followed. The medical device that was used was the same one that officials at Ronald Reagan UCLA medical center said was used when seven patients were infected by the “superbug”. Hartford hospital has notified the Department of Public Health and that they are monitoring the situation.


**CRE Outbreak at Cedars-Sinai in Los Angeles**, California, March, 2015

On March 4, 2015, health officials at Cedars-Sinai hospital in Los Angeles announced that 4 patients were infected with CRE (Carbapenem-Resistant Enterobacteriaceae) and that 67 additional patients might have been exposed as well. Investigators started testing for CRE after a similar outbreak occurred at UCLA Medical Center last month. A single ERCP (Endoscopic Retrograde Cholangiopancreatography) scope was identified as the source of the outbreak and was used from August 2014 – February 2015. Officials at Cedars have since removed the scope from use and have decided to increase the safety measures associated with all scopes. As with other cases across the country, health officials found no cleaning flaws and that the cleaning was performed according to the manufacturer’s directions.


In North Carolina on February 22, 2015, officials made a statement that two people died from CRE and infected a dozen others. So far this year, three people have acquired CRE at Carolinas Healthcare
System hospitals and additional 15 have come into hospitals with existing CRE infections. CRE affects sick patients who are in facilities for a long time or who use devices like ventilators, urinary catheters, and endoscopes. Carolinas HealthCare has changed how they clean their devices. Because of the increase, officials said that the Charlotte-based hospital systems have started screening patients who likely have CRE, once they are identified; these patients are isolated from other patients and once they are released, extra steps are being taken to decontaminate their rooms.


**CRE Outbreak at University of California, Los Angeles (UCLA), California, January 2015**

At UCLA’s Ronald Reagan Medical Center, five patients were infected with CRE and two others died from CRE infections. These infections are all associated with contaminated endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes. 179 other patients also received treatment with these scopes and may have been exposed to CRE. UCLA says that the dirty scopes were washed according to the directions provided by the manufacturer. UCLA has now implemented a new decontamination process for the scopes that “goes above and beyond the manufacturer and national standards.” The CDC is assisting the L.A. County Department of Public Health look into these infections at UCLA. According to the FDA, work is being done to prevent the spread of infections while still allowing these tools to be used.


**A Genetic and Epidemiological Analysis of Antibiotic-Resistant Enterobacteria Identifies an Endoscope as the Possible Source of an Outbreak, France, 2012-2014**

A genetic investigation of OXA-204, an enzyme that breaks down carbapenem, lead researchers to trace the origin of an outbreak. Carbapenem is an antibiotic that is prescribed to treat patients with multidrug-resistant bacterial infections. Bacteria with the gene that produces OXA-204 are resistant to carbapenem. Isolates of bacteria with OXA-204 were sent to the National Reference Center for Antibiotic Resistance during 2012-2014. Seventeen patients that had bacteria with the OXA-204 gene isolated from them had direct contact with a specific endoscope. In February 2014, the endoscope was retired from use and colonization of patients by the bacteria in question stopped. No bacteria with OXA-204 were recovered from the device, but gram-negative bacteria were cultured.


**CRE Outbreak at Seattle Hospital, Washington, 2012-2014**

The Virginia Mason Medical Center in Seattle, Washington blames the contaminated endoscopic ERCP duodenoscopes for the infection of at least 35 patients. These dirty scopes may also have contributed to the death of 11 people. The outbreak occurred between 2012 and 2014. Officials at Virginia Mason did not believe it was necessary to notify the patients. Investigators say the scopes had been properly
sterilized according to the manufacturers’ Instructions for Use. Virginia Mason now quarantines all reprocessed scopes 48 hours prior to scheduled procedure to ensure that there is no bacterial contamination.


CRE Outbreak at Lutheran General Hospital in Park Ridge, Illinois, December 2013

243 patients underwent the Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure, which is a specific procedure looking at bile ducts and pancreas were screened for potentially being exposed to the bacteria CRE. 105 of 243 patients who may be infected have come in contact with the hospital for screening. The ERCPs involve a process of high-grade disinfectants and brushes in order to effectively clean them. The hospital has since permanently moved to the use of gas sterilization for better cleaning efficacy.


Outbreak of Hospital Infection from Biofilm-embedded Pan Drug-resistant Pseudomonas aeruginosa, Due to a Contaminated Bronchoscope, Turkey, October 2013

An outbreak of colistin-resistant Pseudomonas aeruginosa occurred at a hospital in Ankara, Turkey on October 13, 2013. Fifteen patients were infected after undergoing bronchoscopy. P. aeruginosa was isolated from the bronchoscope. The hospital’s disinfection and cleaning protocols were modified, but infections still occurred. Ethylene oxide sterilization was introduced to the disinfection protocol, and infections stopped. Scanning election microscopy was used to confirm the presence of biofilm in the bronchoscopes taken out of use.


Gram-Negative Pneumonia Death Linked to Contaminated Scope, Washington, February, 2013

A lawsuit over the death of a retired Navy chief petty officer was filed in November 2015. The lawsuit claims that Veteran Affairs Puget Sound Health Care System contributed to his death by failing to properly sterilize bronchoscopes. The suit claims that the veteran underwent at least two procedures with bronchoscopes from 2009 to 2012 that had not been disinfected according to the manufacturer’s instructions. A nurse, Barbara Deymonaz, who worked at the Puget Sound VA from 2012 to 2013 said that she complained many times about lapses in procedures that may have potentially put patients at risk. The amended lawsuit mentions that the VA used scope-washing machines manufactured by Custom Ultrasonics.

**CRE Outbreak at University of Pittsburgh Medical Center,** Pennsylvania, November 2012

In November 2012, an investigation was started at UPMC Presbyterian after multiple patients tested positive for CRE. None of the patients died as a direct result of the infection. As a result of the investigation, 18 patients had matching cultures to an infected scope used in ERCP procedure. During the investigation, UPMC realized that due to a new design, disinfectant was unable to reach all parts of the scope. They have started using ethylene oxide gas sterilization as a new way to clean all gastrointestinal scopes.


**CRE Outbreak National Institute of Health (NIH),** Maryland, June 2011

In June 2011 staff members at the Nation Institutes of Health’s Clinical Center started a 6 month fight with antibiotic-resistant *Klebsiella pneumoniae* that eventually infected 17 patients. The staff attempted to contain the infection after they noticed the first patient became sick, but a few months later a second, third and fourth patient became ill with the same strain of bacteria. After the second round of infections occurred, the infection prevention staff implemented extreme measures including monitoring every patient, swabbing all surfaces, implementing an extreme hand hygiene policy and even disposing reusable equipment after one use. The staff struggled to treat the infected as well. The bacteria quickly developed resistance to experimental antibiotics as well as antibiotics that were thought to be too harmful to the patients. After six months, the infection-control finally caught up to the infections, and the spread of the bacteria was stopped. Ultimately, the most important aspect to stopping outbreaks in hospitals is surveillance.

*Vastag, B. (2012, August 22). 'Superbug' stalked NIH hospital last year, killing six.*

**Emergence of Glutaraldehyde-Resistant Pseudomonas aeruginosa,** Switzerland, November 2009

In November 2009, at the University Hospital of Basel in Basel, Switzerland, staff conducted a routine sampling of endoscopes. The routine sampling was to monitor the efficiency of the endoscope-cleaning procedure at the hospital. During this procedure *Pseudomonas aeruginosa* (gram negative) was detected. From 40 tested endoscopes in November 2009, 23 of 73 samples detected *P. aeruginosa*. In the following samples from November through December 2009, *P. aeruginosa* was detected in 29 of the 99 samples. It was found in the rinsing water and in the drain of 1 of the automated endoscope reproprocessors. 2 distinct *P. aeruginosa* strains were revealed, one in each reprocessor. The glutaraldehyde- based disinfectant showed no activity against the 2 pseudo outbreak strains when it was used in the recommended concentration under standard conditions. 63 patients who underwent endoscopic procedures from April through November 2009 tested positive for *P. aeruginosa*. The epidemiologic investigations failed to find a relation in 20 of 63 patients. After medical chart review by
2 infectious disease specialists, lower respiratory tract and bloodstream infections possibly caused by the pseudo outbreak strain were detected in 6 patients. The surveillance of the endoscopes were increased by sampling the rinsing water from the automated reprocessors twice weekly and sampling endoscopes twice monthly.


**Multidrug-resistant Klebsiella pneumonia outbreak after ERCP**, France, December 2008 – August 2009

Gram negative bacteria: *Klebsiella pneumonia* was the culprit producing extended-spectrum beta-lactamase outbreak. The investigators reviewed all medical data associated with patients and collected microbiological data from environmental sources and duodenoscopes. The investigators identified 16 patients that were colonized with *Klebsiella pneumonia* that produced extended-spectrum beta-lactamase type CTX-M-15. All 16 of these patients had previously undergone ERCP between December 2008 and August 2009 at Hospital G. Montpied in France. The ultimate source for the infection was identified as one duodenoscope. Audits show that the cleaning and drying was insufficiently performed. After strictly following the cleaning guidelines, the outbreak ended.


**Early Identification and control of carbapenemase-producing Klebsiella pneumoniae, originating from contaminated endoscopic equipment**, June 2008 - January 2009

A total of seven patients became infected with *Klebsiella pneumoniae* at two hospitals between June 2008 and January 2009. All seven patients had previously received ERCP within the past two months. Infection control measures were implemented to help prevent the transmission to other patients. There appears to be a link between all seven patients. They all had ERCP done at the same endoscopy center. It was discovered that there was an inadequate cleaning step at the endoscopy center. Investigators found bioburden in the elevator channel of the implicated scope. After identifying this flaw, 46 patients were invited for testing and an extra three patients were identified to be colonized with carbapenemase-producing organisms. The identification of the problem, the source of the problem and implementing infection control measures led to the prevention of an outbreak.


*Pseudomonas aeruginosa* outbreak in The Netherlands, 2008
In 2008, an outbreak of multidrug-resistant *Pseudomonas aeruginosa* occurred at the University Medical Centre Groningen at the University of Groningen in The Netherlands. Three patients became infected with this bacterium after undergoing ERCP procedures. Using both microbiological and epidemiological techniques, the investigators found the source of the infection: one individual ERCP scope. They found no bacterial contamination in the washer-disinfectors, tubing, or anywhere else in the hospital. The isolates found infecting the patients were linked to the isolates from the scope through molecular characterization. Luckily the routine screening of both patients and scopes prevented this outbreak from becoming a larger problem. The surveillance protocol needs to be tightened up to prevent all cases and prevent cross contamination between patients who underwent ERCP.


**Outbreak of Pseudomonas aeruginosa Infection Associated with Contamination of a Flexible Bronchoscope,** Georgia, June – July 2007

There was a small outbreak of *Pseudomonas aeruginosa* infections in June and July of 2007 at Grady Memorial Hospital in Atlanta, Georgia. Isolates were obtained from respiratory cultures of 12 patients. All of the cultures had the same unique antibiogram pattern. The investigators cultured all bronchoscopes at the hospital, and identified one as the source of the infection. As soon as this bronchoscope was identified as the source, it was removed from use. After removal of the bronchoscope, there were no more cases of *Pseudomonas aeruginosa*. 55% of patients exposed to that specific bronchoscope during those two months developed an infection, as opposed to 2% of patients exposed to other bronchoscopes in the same time period. The bronchoscope was evaluated, and there was visible damage to the bronchoscope that prevented effective high-level disinfection. It was determined that the occasional inspection for damage might be required in order to ensure effective high-level disinfection.


**An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor,** Japan, May - June 2003

In May and June 2003 an outbreak of *Pseudomonas aeruginosa* occurred after thoracic surgeries in Kyushu University Hospital in Fukuoka, Japan. Seven patients were reviewed and it was revealed that the bronchoscopes were used during endotracheal intubation for one-lung ventilation in most patients. *P. aeruginosa* was recovered from the sputum of these patients at a very early stage after the operation. Samples from the bronchoscopes and an automated endoscope reprocessor were cultured and *P. aeruginosa* was recovered from all the samples obtained. The sterilization cycles of the bronchoscopes were inspected and it revealed unsuitable management of bronchoscopes and a flaw in the AER. The detergent tank was contaminated and once it is contaminated it was not possible to disinfect it.

Unusual implication of biopsy forceps in outbreaks of Pseudomonas aeruginosa infections and pseudo-infections related to bronchoscopy, France, January – April 2003

Between January and April 2003, it was observed at the University Teaching Hospital of Montpellier, France an increase in positive respiratory tract samples for Pseudomonas aeruginosa. The samples were cultured from patients who had a bronchoscopic procedure. 61 bronchoscopic procedures were performed in 36 patients with two different bronchoscopes. 16 patients became infected and the infections were traced back to two bronchoscopes. After inspecting the bronchoscopes damage to the internal channel was observed. This damage was caused by defective biopsy forceps and prevented proper cleaning and disinfection of the bronchoscopes. The outbreaks stopped after the inner channels were replaced and the hospital switched to disposable biopsy forceps.


Multidrug-Resistant Pseudomonas aeruginosa Cholangitis after ERCP, Illinois, July 2002

In July 2002, three patients developed sepsis due to a Pseudomonas aeruginosa infection at Northwestern University Feinberg School of Medicine in Chicago, Illinois. All three patients had previously received ERCP treatment. This small outbreak was surprising because Northwestern is diligent about routine surveillance of their endoscopes. The infection control investigators believed that all three patients had received their ERCP treatment with the same scope. They confirmed that hypothesis by testing all of the available scopes, and linked the isolates from the patients to the isolates from one scope. This scope had been cultured about a month prior, and the culture was negative for bacterial growth. With that being said, it is possible that infections can still occur even if the surveillance cultures are negative. The screening and surveillance processes have to become more stringent to prevent infections from occurring.

Fraser, T. (2013). Multidrug-Resistant Pseudomonas aeruginosa Cholangitis After Endoscopic Retrograde Cholangiopancreatography: Failure of Routine Endoscope Cultures to Prevent an Outbreak. Infection Control and Hospital Epidemiology, 25(10), 856-859.

Outbreak of Pseudomonas aeruginosa Infections Associated with Flexible Bronchoscopes, Maryland, June 2001 – January 2002

At Johns Hopkins Hospital in Baltimore, approximately 1000 flexible bronchoscopic procedures are
performed yearly. More than half of the procedures include bronchoalveolar lavage, where sterile saline is instilled in the lower airways and then extracted to obtain samples. Between June 2001 and January 2002, the rate of isolation of *P. aeruginosa* from bronchoalveolar-lavage samples was three times higher than the usual rate. 414 patients had a bronchoscopy during the outbreak. It involved 48 infections of the upper and lower respiratory tracts and bloodstream among 39 of the 414 patients. In 66.7% of these infections *P. aeruginosa* was found. The contaminated bronchoscopes might have been related to a loose biopsy-port cap which could have had a part in the death of three patients.


**An outbreak of multidrug-resistant *Pseudomonas aeruginosa* infection associated with contamination of bronchoscopes and an endoscope washer-disinfector**, England, October – November 1998

In the course of a two-month period at the St Thomas Hospital in London between October and November 1998, two strains of *P. aeruginosa* were isolated from eight patients on the intensive care unit and three patients from other units. 11 patient’s cultures came from respiratory samples and eight of the patients had a bronchoscopy. The possible cause of the outbreak appeared that the hospital purchased automated, closed washer-disinfectors due to the health and safety concerns over the use of open-trough glutaraldehyde. The machine had lime scale and biofilm deposits on its internal plumbing. 20 out of 21 samples from the washer-disinfector showed various bacterial contaminants including *Pseudomonas*. 1 specimen grew *P. aeruginosa*. Once the washer-disinfector was removed from service and the bronchoscopes had been cleaned, there was no patient cultures identified with ceftazidime- and azlocillin-resistant *P. aeruginosa*.


**Nosocomial Transmission of *Pseudomonas aeruginosa* Following Bronchoscopy Associated With Improper Connection to the STERIS SYSTEM 1 Processor**, New York, August - October 1998

This paper discusses the outbreak of Imipenem-Resistant *P. aeruginosa* (IRPA) after bronchoscopy procedures in the New York Hospital Medical Center of Queens in August, September, and October of 1998. IRPA was found in 18 patients total. Using traditional and molecular techniques, the investigators cultured multiple spots on bronchoscopes, cleaning equipment, and tubing. The results show that there was no direct patient-to-patient transmission. The likely cause of the infections was endoscopes used for the bronchoscopy procedure. The investigators linked the outbreak to poor training on new AERs for the disinfection staff as well as the similar yet different connectors found on the new AERs compared to the old AERs.

**Pseudo-Outbreak of *Mycobacterium chelonae* and *Methylobacterium mesophilicum* caused by Contamination of an Automated Endoscopy Washer, July – October 1998**

Medical equipment pieces like fiber-optic scopes cannot withstand high temperatures; it then becomes hard to accomplish high-level disinfection or sterilization. Automated washers using 2% glutaraldehyde to reach high-level disinfection are commonly used to clean fiber-optic scopes. These washers can be contaminated with atypical mycobacteria, including *Mycobacterium chelonae*. In August of 1998, the microbiology laboratory reported an unusual number of acid-fast bacilli and pink bacteria identified as *M. chelonae* and *M. mesophilicum* during the cultures obtained during bronchoscopy. Between July 21st and October 2nd 1998, 26 of 131 fungal cultures obtained by bronchoscopy grew *M. chelonae*. The 26 cultures obtained came from 22 patients. Two of the 22 cases were not thought to be part of the outbreak. The automated washers were the result of the contaminations. The washers then contaminated the endoscopes and the bronchoscopes that were used to decontaminate. As a result, the medical center purchased new endoscopes and a new paracetic acid sterilization system.