Dirty Surgical Instruments a Growing Problem in OR

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Literature Review

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Today Investigates: Dirty Surgical Instruments a Growing Problem in the OR

A new report suggests doctors across the country are using surgical tools contaminated with blood and other debris and because the FDA doesn't require hospitals to report it, many incidents are unknown. NBC's chief medical editor Dr. Nancy Snyderman reports.

By Stacey Naggiar and Kerri Zimmer
NBC News

When John Harrison checked into a Texas hospital in 2009 for rotator cuff surgery, he thought that after a six week recovery period, he'd be as good as new. But two weeks after the operation, the 63 year-old was experiencing severe discomfort and swelling in his shoulder and knew something was terribly wrong.

During an emergency visit to the hospital, doctors told him that **he had been infected during surgery with a deadly bacteria called P. aeruginosa.** And Harrison wasn't the only one -- **six other patients who had undergone surgery at the same hospital had contracted potentially lethal infections as well.**

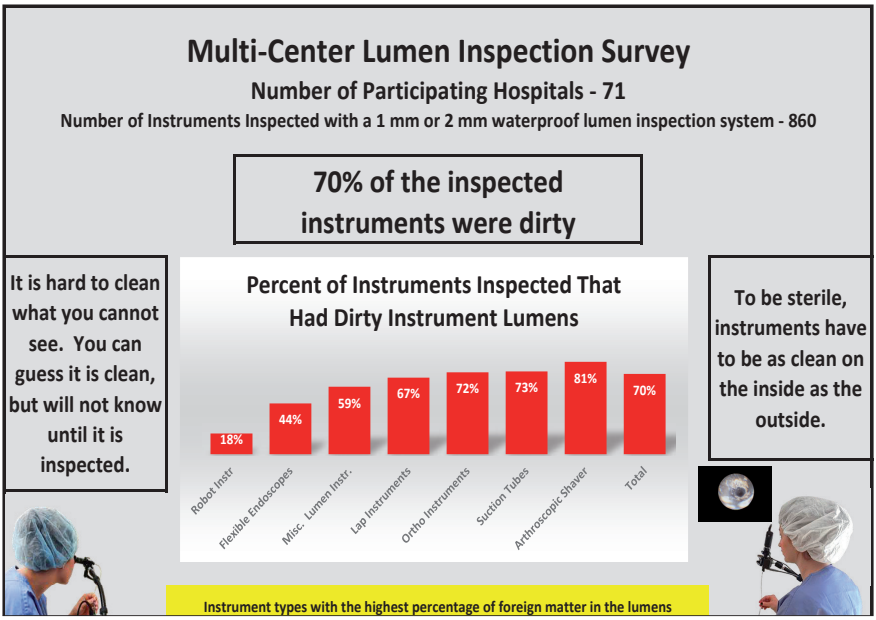
The hospital, along with the Centers for Disease Control and Prevention, launched an investigation and closed operating rooms for two weeks. Surgery was cancelled while they searched for clues and they found some, **in something called an arthroscopic shaver**. Somehow potentially deadly bacteria had survived the sterilization process and infected Harrison's shoulder.

And the problem isn't isolated. Other investigations in hospitals across the country have revealed the use of other dirty surgical instruments, such as endoscopes used for colonoscopies, have led to infection outbreaks.
Investigative reporter Joe Eaton of the Center for Public Integrity, a Washington, D.C., nonprofit that focuses on ethics and public service, tackled the issue head on. As a result of the CPI investigation, NBC News Chief Medical Editor Dr. Nancy Snyderman took a closer look at the wide range of instruments used during surgical procedures and the care with which they are handled. Who is in charge of cleaning the instruments? How are they sterilized? And how is the process regulated?

What NBC found suggests that the handling of the increasingly high-tech instruments can be a weak link in hospitals' patient safety net.

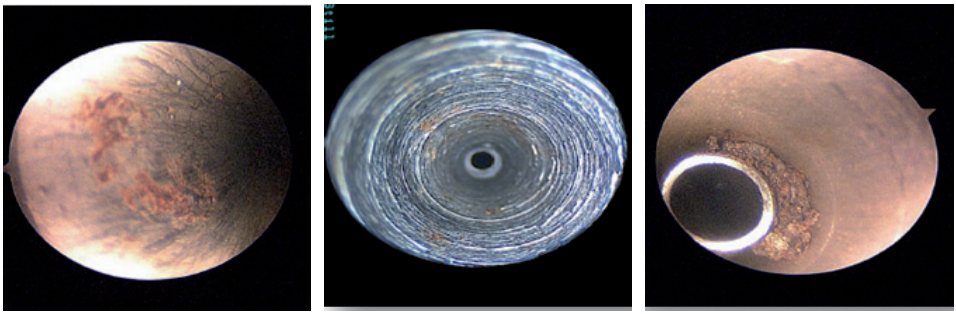
Multi-Center Lumen Inspection Survey, Poster presented at the 2015 IAHCSMM National Convention

- Number of Participating Hospitals - 71
- Number of Instruments Inspected with a 1 mm or 2 mm waterproof lumen inspection system - 860
- Outcome: 7 out of 10 of the inspected instrument lumens were still dirty after decontamination
- NUMBER 1 position : Arthroscopic shavers



Unclean Surgical Instruments CANNOT be Sterilized

As medical instruments have become more intricate, the same features that enable a surgeon to perform a minimally invasive procedure cause a nightmare for Central Sterile Technicians. Narrow lumens, bends, changing diameters, and other features common in modern surgical tools create barriers for manual brushing. Bioburden (including blood and other human residue) may become packed inside of instrumentation, creating a risk for infection and cross-contamination between patients. Although the instrument will be sterilized, the sterilization process is ineffective if bioburden is present.



These images show the interior lumens of surgical instrument AFTER they had been manually brushed and sterilized per the manufactures' instructions. Often times, a sterile crust is formed over the live bioburden and can be peeled away or re-moistened; thereby exposing live bacteria.

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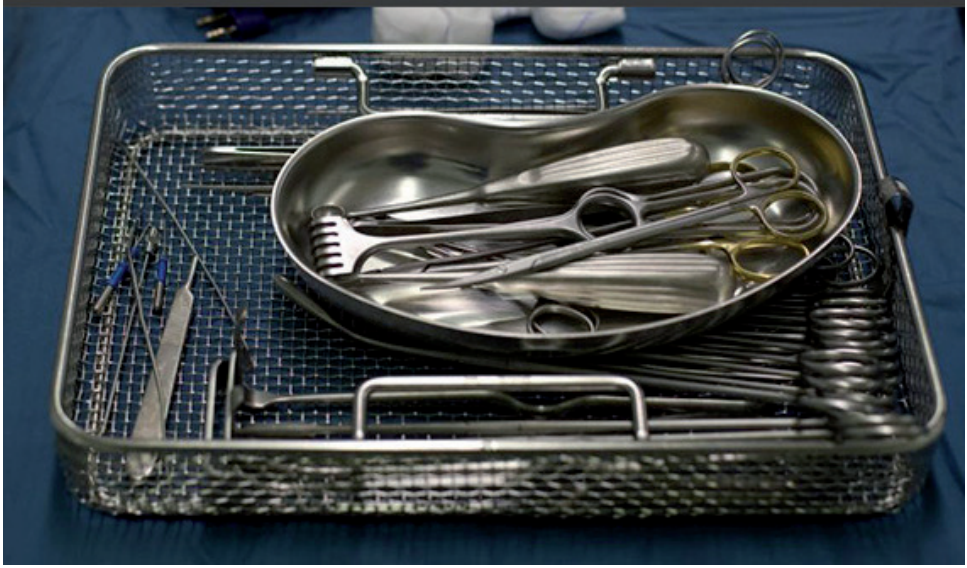

On the medical device known as an endoscope, a tiny camera sits at the end of a long black tube. In routine medical procedures like endoscopies and colonoscopies, the camera peeks into cavities in internal organs, checking for growths and spotting potential problems. But lately it's the scope itself that seems to be the problem amid recent reports of germs getting stuck on them and transferring infections between patients.

The latest outbreak of CRE, or carbapenem-resistant Enterobacteriaceae, infections from not-fully-disinfected endoscopes in U.S. hospitals appears to be just the most recent instance of unclean medical instruments passing infections from one patient to another. Contaminated medical tools and lab equipment used to manufacture drugs have also been responsible in recent years for spreading infections such as hepatitis and meningitis. Endoscopes are complex medical instruments that are extremely difficult to clean and disinfect, but the growing numbers of outbreaks associated with dirty medical equipment has raised questions about the cleanliness of U.S. hospitals and the degree to which patients are at risk.

Health officials in North Carolina announced Monday that two residents had died from CRE in recent months and three had been infected with the highly resistant bacteria in Carolinas HealthCare System hospitals. Last week, at Ronald Reagan UCLA Medical Center in California, two patients passed away after being infected and 179 people may have been exposed to the bacteria after undergoing routine procedures with endoscopes.

"We now have the most stringent process for sterilizing scopes, which undergo gas sterilization with Ethylene oxide after the FDA recommended high level disinfection," UCLA spokeswoman Dale Tate said in an email, adding that the hospital had "a robust infection prevention infrastructure that does ongoing surveillance looking for problems," in order to reduce the possibility of more shared pathogens. Asked whether the hospital was concerned about a second outbreak of CRE, Tate said, "We are always vigilant, but not concerned since we believe we have an extremely safe process in place for sterilizing scopes

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Ongoing Safety Review of Arthroscopic Shavers: FDA Safety Communication

FDA has become aware of instances in which pieces of tissue have remained within certain arthroscopic shavers, a device used in some orthopedic surgical procedures, even after the cleaning process was believed to have been completed according to the manufacturer's instructions. Reports submitted to FDA suggested that the tissue retained was not evident to the naked eye. Multiple manufacturers of these devices recently informed their customers of this situation and reiterated the importance of proper cleaning procedures.

We are concerned about this because retained tissue in these devices can compromise the entire sterilization process. We are actively working with the manufacturers of these devices to gather more data about this situation and to understand its potential public health impact. As the FDA obtains more information that better defines the situation and determines whether there are specific risks, we will provide that information to facilities, health care providers and the public.

The FDA encourages facilities that use any of these types of devices to evaluate the adequacy of their cleaning procedures. Hospitals should consider taking the following steps to minimize any potential risk to patients:

- Be sure that all personnel responsible for device cleaning and sterilization at your facility are aware of and comply with all steps in the manufacturer's instructions for thoroughly cleaning these devices prior to sterilization. Please refer to the specific instructions provided in the labeling or user manual for each brand and/or model of shaver your facility uses.
- Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a 3mm video scope to inspect the channels of the shaver handpiece.

If you discover retained tissue in arthroscopic shavers at your facility after following the manufacturer-recommended cleaning procedures, you may file a **voluntary report (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)** with

MedWatch, the FDA Safety Information and Adverse Event Reporting program (OMB Approval No. 0910-0291). You can report directly to MedWatch by phone at 1-800-FDA-1088, or obtain the **fillable form online (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)**, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787. These voluntary reports will help us gather additional information related to this problem and assess its public health impact.

This reflects FDA's current analysis of available information concerning these devices, in keeping with our commitment to inform the public about its ongoing safety reviews of devices. The nature, magnitude and possible public health impact of this situation are not yet clear, and at this point FDA is not recommending that healthcare professionals stop using the device. FDA is considering, but has not reached a conclusion about whether future regulatory action may be warranted. We will update this document when additional information or analyses become available.

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at **DSMICA@CDRH.FDA.GOV (mailto:DSMICA@CDRH.FDA.GOV)** or 800-638-2041.

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