Discussions in Infection Control

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Endoscopy Patients at Vanderbilt Potentially Exposed to HIV and Hepatitis, County Officials Have Confirmed

By Lawrence F Muscarella PhD

NOV 26, 2024 #Colonoscopes, #Gastroscopes, #Hepatitis, #HIV, #Infections, #VUMC

November 26, 2024 (*by: Lawrence F Muscarella, PhD*) – Endoscopy patients at a medical center in Tennessee may have been exposed to bloodborne pathogens due to an acknowledged "inappropriate practice," local county health officials confirmed a few weeks ago.

Highlights

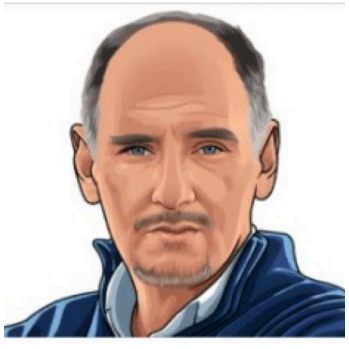
- Patients at Vanderbilt affected by an acknolwedged infecti0n control issue are now being notified of the potential for exposure to bloodborne pathogens during an endoscopic procedure.
- Nevertheless, the risk of infection due to this infection control breach is "very low," according to a statement by Vanderbilt.
- Few other details about this breach, including the number of affected endoscopy patients, have been made public.
- Published cases and analyzed FDA adverse event data suggest that the incidence of patient exposures to inadequately cleaned GI endoscopes potentially contaminated with infectious materials, including hepatitis and multidrug-resistant bacteria, may be appreciably higher than generally recognized.
- More than 10,000 adverse event reports submitted to FDA since January describe a gastroscope or colonoscope that was not cleaned adequately.* Improperly reprocessed endoscopes can expose patients to infectious materials and pose an increased infection risk.
- Some experts conclude that institutions have an ethical obligation to inform affected patients in a timely manner when a significant endoscope reprocessing breach occurs or an endoscope-related infection is suspected or confirmed.
- Recommendations are provided to reduce the risk of infection from HIV and the hepatitis B and C viruses during GI endoscopy.

"We recently discovered an issue in how a solution was administered through the scope during a limited number of endoscopy procedures at the Vanderbilt Clinic," the medical center acknowledged in a statement in October, according to news reports.

The statement emphasized that the Vanderbilt University Medical Center "immediately corrected" the misstep and reported it to the Tennessee Department of Health.

The medical center also announced in October that it is "in the process" of notifying the affected endoscopy patients of the risk of exposure to HIV and the hepatitis B and C viruses, news articles reported. (For clarity, a patient's exposure to a contaminated GI endoscope does not assure infection.)

The acknowledged exposure risk notwithstanding, few other details about Vanderbilt's infection control issue have been made public. According to some news reports, the lapse may have involved use of improperly sterilized endoscopic equipment.



When asked, Vanderbilt did not disclose the specific number of potentially exposed patients, according to news reports. Instead, the facility's October statement indicated that "less than 4% of endoscopy patients over the last six months" may be at risk.

> ***When such an infection control breach is identified, we generally want to know the details of what happened and how the error was corrected. With this information, endoscopy departments can then promptly inspect their own infection control and cleaning practices to ensure the same mistake isn't being repeated. — Lawrence F. Muscarella Ph.D.***

Whether 4% of the endoscopy patients said to be at risk, a seemingly low percentage, corresponds to only a few patients or possibly significantly more, as some news reports have suggested, has not been clarified.

The term "endoscopy" can refer to several different types of medical procedures, although all use an endoscope to examine structures inside a patient's body.

During colonoscopy, a colonoscope is inserted into the colon to diagnose and treat disorders of the lower bowel. Esophagogastro-duodenoscopy, which is another common type of gastrointestinal endoscopic procedure, is performed using a gastroscope to diagnose and treat disorders of the upper GI tract including the esophagus and stomach (as the procedure's name suggests).

A colonoscope is longer in length and usually wider in diameter than a gastroscope.

Hepatitis infection risk

While reports have linked GI endoscopic procedures to patient-to-patient transmission of both the hepatitis C and hepatitis B viruses, the risk has been reported to be small or low depending on the case's circumstances.

That the reported risk of healthcare-associated transmissions of hepatitis B and C could under-estimate the actual risk due to under-reporting and limited surveillance, however, is a recognized possibility. According to Vanderbilt's October statement provided to reporters, the risk of infection due to the discovered breach is "very low."

Although unrelated to Vanderbilt's issue, the failure by medical staff to practice proper aseptic technique during the preparation, handling and administration of intravenous medications is another risk factor, in addition to a patient's exposure to a contaminated GI endoscope, for infection from a bloodborne virus during an endoscopic procedure.

Cases linking a contaminated GI endoscope to HIV infection have not been reported.

Infection Case Reviews, Forensic Analyses, Expert Guidance: *LFM-Healthcare Solutions, LLC* provides medical expertise for legal representatives, device manufacturers, and medical facilities specializing in healthcare-associated infections linked to contaminated reusable medical equipment.

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Vanderbilt patients notified of risk

While few other details about Vanderbilt's endoscopy error have been publicly revealed, the medical center's decision to notify the affected endoscopy patients of the exposure risk is notable, as the disclosure of the risk of infection from exposure to potentially contaminated medical equipment is often discretionary and neither a foregone outcome nor necessarily an established policy or law.

Experts have advised that disclosure of large-scale adverse events "should be the norm," that "disclosure is ethical even when the chance of harm is extremely low," and that "institutions have an ethical obligation to inform affected patients in a timely manner when a significant breach in reprocessing is discovered or an endoscope-associated infection is suspected." Nevertheless, cases have occurred when patients potentially exposed to a contaminated GI endoscope were not informed of the infection risk.

Other documented cases unrelated to Vanderbilt's issue, including many adverse event reports detailed in the FDA's device database, similarly raise questions about patient notification following exposures to potentially infectious materials during GI endoscopy.

For example, FDA received several reports in October linking a single GI endoscope at a U.S. facility to four (4) infections of multidrug-resistant bacteria, called carbapenem-resistant *Enterobacterales*, and at least one patient death. The reports state that, according to the facility, the implicated duodenoscope, used to perform ERCP, "might have caused a cross contamination between patients."

> ***While appreciating that exposure to a disease does not assure infection, FDA adverse event data and other evidence suggest that the incidence of patient exposures to inadequately cleaned GI endoscopes potentially contaminated with infectious materials may be markedly higher than generally thought or publicly reported. — Lawrence F. Muscarella Ph.D.***

According to these FDA reports, the implicated GI endoscope was found to have "a small tear within the inner sheath of the device," despite the device passing the leak test prior to the procedures. (This case's duodenoscope model was recalled in 2023 due to reports linking the device to "infections and positive cultures." Earlier that same year, FDA had questioned the quality of this same duodenoscope model's single-use detachable endcap.)

A third type of flexible GI endoscope, duodenoscopes are used during endoscopic retrograde cholangiopancreatography to diagnose and treat problems in the pancreas and bile ducts.

. /hether all of the patients exposed to the implicated duodenoscope described in these October FDA reports were notified about the potential infection risk, this apparent cluster of CRE infections, and the potential cause (*i.e.* endoscope damage) is unknown. Infections caused by CRE can have a mortality rate of 50% or higher.

Delayed notification?

The number of days from when a medical center discovers an infection control lapse to the time it notifies the affected patients of the potential infection risk (if patient notification occurs) is also not standardized and can vary considerably.

One Vanderbilt patient reportedly affected by the facility's "inappropriate practice" publicized in October told a news source she was notified of the infection risk "more than two months" after her colonoscopy.

Another Vanderbilt patient also reportedly affected by this same infection control issue told a different local news source that he received a telephone call from the medical center informing him of the infection risk "three months" after undergoing colonoscopy.

For some affected patients, it seems that the elapsed time from the day of their GI endoscopic procedure to when they were notified of the infection concern could have been longer, however, as a Vanderbilt spokesperson reportedly told a news reporter that the exposure risk occurred "over the past six months."

Related posts: Dr. Muscarella's related posts focusing on the risk of GI endoscopes transmitting infections include:

- "Improper Use and Reprocessing of a Gastrointestinal Endoscope's Auxiliary Water System" (*April 2013*)
- "How to Reprocess the MAJ-855 Water Tube and the GI Endoscope's Auxiliary Water Channel" (*December 2012*)
- "Tap Water Used for Irrigation during GI Endoscopy: A Recommendation and Assessment of the Infection Risk" (*May 2014*)

An earlier, unrelated incident?

Also reported locally in October, a woman told a news source she received a letter from Vanderbilt, dated June 27, 2024, stating that her 5-year-old daughter might have been exposed to HIV and the hepatitis B and C viruses during a colonoscopy.

According to the details in that news report, however, the risk was apparently due to a different incident unrelated to the previously described lapse involving how a solution was administered through the endoscope at the Vanderbilt Clinic.

As stated in this June letter, Vanderbilt had "identified a discrepancy in sterilization documentation relating to the scope" used during the child's endoscopic procedure. The medical center reported this misstep, too, to the Tennessee Department of Health.

While acknowledging that improperly sterilized endoscopes "could potentially expose a patient to viruses such as Hepatitis B or C or HIV," Vanderbilt's letter states that "we believe the exposure risk to your child is is extremely low." The letter also highlights that "we found no evidence of infection that could be traced to these scopes."

The 5-year-old child's colonoscopy was performed seven months earlier on November 17, 2023, according to Vanderbilt's June letter.

> ***Because hepatitis B and C can mutate relatively quickly, prompt testing of patients for the virus can prove important to evaluating genetic relatedness and epidemiologically linking infected patients to a common source or event. — Lawrence F. Muscarella, Ph.D.***

Other cases have been reported similarly describing a discrepancy in documentation or in the records associated with the disinfection or sterilization of GI endoscopes.

In 2004, for example, 177 patients at a Long Island hospital were notified of the risk of exposure to bloodborne pathogens due to the potential, over a 12-day period, for the concentration of the solution used to disinfect GI endoscopes to have become too low to prevent infections.

Because the genomes of both the hepatitis B and C viruses have relatively high mutation rates, prompt notification and testing of patients has been recommended, among other reasons, to help investigators epidemiologically link infected patients to one another and to a common source or infection control lapse.

What might have happened at Vanderbilt?

As news articles explained, Vanderbilt's issue reportedly affecting "less than 4% of endoscopy patients" involved how a type of solution was administered through the GI endoscope.

Little more about what exactly happened at Vanderbilt, including the ingredients of this administered solution — for example, whether it was a disinfectant, another type of chemical, or possibly even tap water, — has been publicly reported, leaving some questions unanswered.

A recently performed on-line search, however, did not identify any news reports or health department notices directly linking an infection to Vanderbilt's "inappropriate practice" or to the reported discrepancy in sterilization documentation. (The failure of investigators to epidemiologically link an infection to a medical center's infection control breach does not confirm no transmissions occurred.)

Other bloodborne pathogen exposure cases

Many other cases in past years described the potential for patients to be exposed to bloodborne pathogens and other infectious agents during GI endoscopy due to a confirmed infection control misstep.

A salient case highlighting the importance of following published guidelines to prevent endoscopic cross-infection, Bronowicki et al. (1997) reported transmission of the hepatitis C virus during colonoscopy from an infected person to two other patients. These authors reported that failure to clean the colonoscope's biopsy-suction channel using a brush as published endoscope reprocessing instructions advise, may have contributed to the virus's transmission.

In another case, Birnie et al. (1983) reported hepatitis B infection "almost certainly acquired at endoscopy" from an instrument used the previous day "on a patient with bleeding oesophageal varices who was incubating type B viral hepatitis."

In December 2008, staff at a Veterans Administration medical facility in Murfreesboro (TN) observed blood in tubing that is part of the colonoscope's auxiliary water system. An investigation determined that, among other errors, this tubing mistakenly had not been fitted with a one-way internal valve designed to prevent the backflow of bodily fluids from the patient (via the colonoscope) into this tubing.

This auxiliary water system, which includes the GI endoscope's internal auxiliary water channel, tubing and an external water source, provides a controlled stream of water for irrigation and to remove mucus, blood, and debris from the lining of the GI tract for improved image clarity during the procedure.

> ***Deciding whether to notify affected patients of an infection control breach is based, in part, on an assessment of the infection risk. However, citing codes of transparency and public health principles, experts have advised that disclosure of large-scale adverse events 'should be the norm' and that "disclosure is ethical even when the chance of harm is extremely low." — Lawrence F. Muscarella, Ph.D.***

In addition to the increased infection risk due to the tubing's missing one-way valve and blood contamination, investigators determined that this tubing, more formally known as the "auxiliary water tube," was being cleaned and disinfected only once at the end of the day, not after every patient procedure as the manufacturer's instructions require to prevent cross-

fections.

Providing a second function along with irrigation, the auxiliary water tube is used during reprocessing to clean and disinfect the GI endoscope's auxiliary water channel. (Not every colonoscope and gastroscope model features an auxiliary water channel.)

After a risk assessment and calculation to determine the number of patients affected by these tubing missteps, the Murfreesboro's VA facility, two months later in February (2009), advised 6,387 colonoscopy patients of the risk of exposure to bloodborne viral diseases.

Similarly, almost 7,000 patients who underwent endoscopy between 2002 and 2011 at a Canadian endoscopy clinic were notified by mail in 2011 of the risk of infection from HIV, hepatitis B virus and the hepatitis C virus due to "significant deficiencies in the cleaning and disinfection of the endoscopes."

More recently, as many as 4,000 veterans at a VA medical center in Dublin (GA) were notified, in 2022, of potential exposure to bloodborne viruses during endoscopy along with other types of medical procedures due to "concerns about reprocessing reusable medical equipment."

This past April, a manufacturer submitted to FDA two seemingly related adverse event reports, one for gastroscopes and one for colonoscopes, stating that the facility had not been properly using the auxiliary water tube to flush the GI endoscope's auxiliary water channel, as instructed by the manufacturer, to prevent cross-infection.

An under-recognized safety concern?

While the risk of a patient being exposed to an infectious agent during GI endoscopy is difficult to estimate — and notably this risk is significantly higher than the that of contracting an endoscope-related infection — an analysis of FDA adverse event reports, along with other published data, suggest that the incidence of patient exposures to inadequately cleaned GI endoscopes potentially contaminated with infectious materials, including bloodborne viruses and multidrug-resistant bacteria, may be markedly higher than generally acknowledged or publicly reported.

That the reported risk of infectious transmissions during an endoscopic procedure could significantly underestimate the actual risk has been acknowledged.

More than 10,000 adverse event reports submitted to FDA just since January (of this year) describe a gastroscope or colonoscope that was not cleaned adequately, posing an increased infection risk.* (See footnote, below).

One report submitted to FDA in October, for instance, states that a gastroscope's air/water nozzle, which is located at the device's distal end, was not adequately cleaned and found to be clogged with "foreign material."

While no infections were reported, improper cleaning and reprocessing of a GI endoscope, including the air/water nozzle, can expose patients to infectious materials and pose an increased infection risk.

The air/water nozzle, unlike the auxiliary water channel, is used both to wash the GI endoscope's viewing lens with water and to feed air into the patient's body to improve visualization during the procedure.

Another October report stated that a colonoscope tested positive for *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Escherichia coli*. Although no infections were reported, if resistant to carbapenem antibiotics, these bacteria would be CRE.

Of these more than 10,000 analyzed reports submitted to FDA in 2024, however, fewer than two dozen reports link the colonoscope or gastroscope to confirmed or possible infection. Whether more infection occurred but were not reported or detected is unknown.

One of these FDA reports, which the agency received in February, linked a single gastroscope device in a U.S. facility to four (4) infections of CRE. According to the report, however, "no lapses in endoscope cleaning were identified and there was no report of technical issues with the endoscope."

Another report submitted to FDA in July states that five (5) patients have been infected since April after colonoscopy with biopsy. Among other identified reprocessing lapses, the report states that the adapter used to clean the colonoscope's air/water channel was not being reprocessed after each use.

In agreement with Vanderbilt's assessment, however, a national society of gastrointestinal physicians published in 2018 that the risk of a GI endoscope infecting a patient is "extremely low."

Other Vanderbilt questions that remain

Some other questions remain about Vanderbilt's improper practice (and sterilization discrepancy) impacting endoscopy patients, including the number of elapsed days from when the infection-control lapse began to when it was discovered (and then corrected). The approximate number of endoscopy patients potentially exposed during this time period also remains unclear.

Whether the types of implicated GI endoscopes at Vanderbilt could have possibly included duodenoscopes, which are generally associated with a higher infection risk than colonoscopes and gastroscopes, was not addressed in any of the news reports reviewed for this article.

Nor did any of the reviewed news reports discussing Vanderbilt's incident provide a clear rationale for focusing exclusively on the risk of infections from HIV and the hepatitis B and C viruses, although health officials in past investigations have stated that bacterial infections routinely occur within days of endoscopic transmission in contrast to viral infections, which can take months or longer to appear following transmission.

Recommendations, summary

Published data suggest that patient exposures to inadequately cleaned GI endoscopes potentially contaminated with infectious materials, including hepatitis and multidrug-resistant bacteria, may occur appreciably more often than generally thought or publicly reported.

These exposures notwithstanding, Vanderbilt's October statement to reporters indicated that the risk of a bloodborne viral infection due to its publicized breach is "very low."

When a significant breach in reprocessing a GI endoscope is identified or an endoscope-associated infection is suspected or confirmed, experts advise that the affected patients be advised and in a timely manner.

Few other details about Vanderbilt's breach publicized in October are known, limiting the publication of focused guidance. Nevertheless, several recommendations are provided to reduce the risk of infection from HIV and the hepatitis B and C viruses during GI endoscopy.

While this guidance is provided in the context of Vanderbilt's publicized issue, some recommendations are included for educational purposes and are not necessarily relevant to this medical center's concerns publicized in October:

1. Confirm the GI endoscope is being cleaned and high-level disinfected (or sterilized) in accordance with the manufacturer's instructions.
    - Ensure proper reprocessing of all of the GI endoscope's internal channels and external surfaces, including the auxiliary water channel and air/water nozzle, after each patient procedure.
2. Depending on the GI endoscope model, confirm that the auxiliary water system's auxiliary water tube is being reprocessed as frequently as the instructions require (*e.g.*, after every patient procedure) to prevent infections.
    - Verify that the auxiliary water tube is fitted with the correct valve to prevent the backflow of potentially infectious fluids during the GI endoscopic procedure.
3. Ensure no discrepancies and that a reused disinfectant is tested according to manufacturer instructions to ensure its concentration is sufficient to prevent the GI endoscope from transmitting infections.
    - Confirm these test results are properly recorded.

4. Click here to view a 20-minute, on-line interview of this article's author discussing Vanderbilt's incident that was reported in the news in October.
5. For additional infection prevention guidance, consider reading the following five (5) peer-reviewed articles that focus on reducing the risk of transmission of bloodborne viruses and multidrug-resistant bacteria during GI endoscopy:
    - Muscarella LF. (2019): "Use of ethylene-oxide gas sterilisation to terminate multidrug-resistant bacterial outbreaks linked to duodenoscopes." *BMJ Open Gastro* 2019;6:e000282. (*A free download*)
    - Muscarella LF. (2014): "Risk of transmission of carbapenem-resistant *Enterobacteriaceae* and related "superbugs" during gastrointestinal endoscopy." *World J Gastrointest Endosc* 2014 Oct 16;6(10):457–474. (*A free download*)
    - Muscarella LF. (2010): "The study of a contaminated colonoscope." *Clin Gastroenterol Hepatol* 2010;8:577–580. (*A free download*)
    - Muscarella LF. (2004): "Infection control and its application to the administration of intravenous medications during gastrointestinal endoscopy." *Am J Infect Control* 2004;32:282-6. (*A free download*)
    - Muscarella LF. (2001): "Recommendations for Preventing Hepatitis C Virus Infection Analysis of a Brooklyn Endoscopy Clinic's Outbreak."

Footnote: * A focused search of the FDA's MAUDE database identified more than 10,000 adverse event reports, from January through October (2024), that: (*i*) involved a colonoscope (*Product Code* of "FDF") or gastroscope (*Product Code* of "FDS") and (*ii*) listed "Failure to Clean Adequately" or "Microbial Contamination of Device" as the report's *Product Problem*. This number of FDA reports (> 10,000) would have been higher if the search had been more complete and also included each of the following additional *Product Problem* choices associated with endoscope reprocessing: "Device Reprocessing Problem," "Obstruction of Flow," and " Partial Blockage," among other valid choices.

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