Article Highlights:

- *FDA reports submitted in December describe the exposure of 17 patients at a U.S. medical facility to a colonoscope contaminated with Salmonella bacteria*
- *Exposure to Salmonella can result in infection, including gastroenteritis, bacteremia, and septicemia. Those strains resistant to "last-resort" carbapenem antibiotics are the feared "CRE" superbug*
- *Salmonella can be transmitted from patient-to-patient, or to a person from the environment including contaminated food*
- *A supplemental review identified approximately 650 adverse event reports submitted to FDA in December, including the Salmonella cases, describing ineffective reprocessing of a colonoscope*
- *Recommendations are provided to reduce the risk of a colonoscope transmitting Salmonella and other infectious organisms*
- *Efforts to improve public awareness about the risk of a colonoscope remaining contaminated and transmitting infections are recommended*

January 24, 2024 (*by: Lawrence F Muscarella, PhD*) – Just weeks ago, 17 patients at a U.S. medical facility were exposed to a colonoscope contaminated with *Salmonella*, several FDA reports submitted in December reveal.

The reports suggest the colonoscope became contaminated with the bacteria when it was used on a prior patient to perform diagnostic colonoscopy for suspected colitis.

That patient, described in these FDA reports as the "original" or "initial" patient, was discharged on the same day as the procedure, but then visited the emergency room the next day for "continual pain." The patient had surgery and was diagnosed with *Salmonella*.

Salmonellosis is an infection that can be transmitted from patient-to-patient by the fecal-oral route. The organism can be found in human intestines, raising concerns that an improperly cleaned colonoscope could cross-infect patients with the bacteria.

After use on this initial patient, the colonoscope was high-level disinfected "per the facility's cleaning protocols which follow (the colonoscope manufacturer's) instructions for use," according to these FDA reports, which the device's manufacturer submitted to FDA. (The accuracy of this claim that the facility adhered to the manufacturer's reprocessing instructions could not be independently verified.)

I have reviewed every adverse event report submitted to FDA in December (2023) involving ineffective reprocessing of a colonoscope and identified hundreds of reports just in this one month, raising the question whether patient exposure to a contaminated colonoscope may be more common than previously recognized. -- Lawrence F Muscarella, PhD

The same colonoscope was then (unwittingly) used to perform colonoscopy on 17 other patients before the facility's infection control team learned of the initial patient's *Salmonella* diagnosis.

In response to the cross-infection risk, the facility cultured (and quarantined) the suspect colonoscope and found it to be positive for *Salmonella* "even though the endoscope had been used and reprocessed with (high-level disinfection) 17 times since the original (patient's) colonoscopy," the FDA reports claim. (The accuracy of this claim, too, could not be independently verified.)

Cases describing patient exposures to a colonoscope harboring *Salmonella* are notable in part because they are infrequently reported. Those strains displaying resistance to "last-resort" carbapenem antibiotics are the feared "CRE" superbug.

As their name indicates, colonoscopes are used to perform colonoscopy, which is a procedure that examines the inside of the colon, and is used for screening and to diagnose gastrointestinal diseases, such as inflammatory bowel disease and colon cancer.

Exposure limited to 17 patients? The information in the FDA's December reports raises a reasonable question about whether the actual number of patients exposed to the colonoscope harboring *Salmonella* was limited to 17.

The timeline and details in several reviewed FDA reports describing this case do not appear to exclude the possibility that the initial patient, rather than being the original *source* of the *Salmonella* that contaminated the colonoscope, might instead have been infected by the colonoscope already contaminated with the bacteria.

If additional records and evidence cannot rule out this possibility, then it could be that the number of patients potentially exposed to the *Salmonella* – namely, additional patients who underwent colonoscopy using the same device *prior* to the initial patient – is higher than 17. (It is certainly possible that the facts in the case not provided in these FDA reports rule out this scenario.)

Several factors could have contributed to these 17 patients being potentially exposed to the *Salmonella* bacteria, including undetected damage to the colonoscope's working channel; the formation of an inaccessible biofilm inside the colonoscope; or the failure to maintain and service the colonoscope according to manufacturer instructions. – Lawrence F Muscarella, PhD

All affected patients notified? The FDA's December reports do not clearly indicate whether all 17 affected patients were notified of the potential for *Salmonella* exposure and infection. These reports note, however, that "the awareness date for the 17 additional patient cases" was December 15, 2023, and that only the original patient was confirmed to have the *Salmonella*.

Salmonella exposure can result in infection, including gastroenteritis, bacteremia, and septicemia. The mortality rate of *Salmonella* infection is relatively low, however. While millions of people are infected with *Salmonella* annually in the U.S, only a few hundred reportedly die.

Further, these December reports state that "no species identification was performed." Confirmation that an implicated endoscope was contaminated with the same (or a genetically related) organism as an infected patient, however, is often important to understanding the chain of transmission.

Forensic Case Reviews, Infection Investigations: *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.

The cause: The reviewed FDA reports do not identify the specific error or missteps that may have caused or contributed to these patients being exposed to the single colonoscope harboring *Salmonella*.

Possible factors that may have contributed to the apparent ineffective reprocessing of this colonoscope include (but are not limited to):

- faulty cleaning and/or high-level disinfection of one of the colonoscope's internal channels or the air/water nozzle (notwithstanding the FDA reports' indication to the contrary);
- damage to the colonoscope (e.g., a tear inside working channel, or a device defect);
- an inaccessible biofilm forming inside the colonoscope;
- the high-level disinfectant (if reusable) was below its minimum effective concentration;
- failure to maintain, service and repair the colonoscope according to the manufacturer's recommendations
- an unqualified third party repairing the colonoscope using uncertified parts;
- mishandling the colonoscope, or using it in a contaminated environment; and
- though quite unlikely, use of contaminated water to rinse the colonoscope after high-level disinfection.

(Other factors could also be responsible for the colonoscope remaining contaminated with *Salmonella* despite reprocessing. This list is provided as an informative guide, not as a conclusion of cause.)

Other *Salmonella* cases: Reports linking colonoscopy to *Salmonella* infections are uncommon. Cases have been published, however, substantiating the risk.

Dwyer et al. (1987), for example, linked an outbreak of *Salmonella newport* to colonoscopy. The endoscopic equipment most likely became contaminated when an initial patient diagnosed with acute *Salmonella newport* gastroenteritis underwent colonoscopy, the report concluded.

The report further explained that: "Inadequate disinfection of the equipment allowed the organism to survive and possibly to cross-contaminate other colonoscopes, and the organism was then transmitted to other patients by use of the contaminated colonoscopes or the contaminated biopsy forceps."

More recently, FDA received a report in 2021 describing a patient diagnosed with *Salmonella* infection two days after undergoing colonoscopy. Although stains and a tear mark were visually identified inside the endoscope's biopsy channel suggesting the potential for inadequate cleaning and damage, the colonoscope tested negative for *Salmonella*.

FDA reports submitted four years earlier, in 2017, describe the fecal samples of five (5) colonoscopy patients testing positive for *Salmonella zanzibar*. Each of these patients was exposed to a single colonoscope, although the device was sampled and tested negative for the bacteria.

While contaminated GI endoscopes and other types of medical instruments can transmit *Salmonella* from patient-to-patient in the healthcare setting, contaminated food and water are the most common modes for salmonellosis transmission among humans.

Additional reading: The author of this article discussing these 17 cases (Dr. Muscarella) has previously published in the peer-reviewed literature on the risk of contaminated colonoscopes transmitting bacteria:

1. "The Study of a Contaminated Colonoscope" (Muscarella LF, 2010)
2. "Risk of transmission of carbapenem-resistant *Enterobacteriaceae* and related 'superbugs' during gastrointestinal endoscopy" (Muscarella LF, 2014)
3. "Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy" (Nelson DB, Muscarella LF, 2006) (The article specifically addresses the risk of a colonoscope transmitting *Salmonella*)

An underestimated infection risk? Accurate assessments of the risk of infection following colonoscopy, including from a contaminated device, are difficult to calculate in part because the infection data necessary for such an accounting are incomplete due to underreporting, among other factors. Nonetheless, estimates have been published.

In previous years, the risk of a GI endoscope transmitting disease to a patient was estimated to be much less frequent, or 1 in 1.8 million. Similarly, Deb et al. (2022) and other researchers reported the incidence of infection following lower gastrointestinal endoscopic procedures (*i.e.,* colonoscopy) to be low (*e.g.*, less than 0.1%).

Other investigators, however, including Wang et al. (2018) reported that infections following colonoscopy (performed in ambulatory surgery centers) "are more common than previously thought" (*e.g.*, 1-2 infecitons per 1,000 procedures). In another study, Lin et al. (2017) reported that colonoscopy patients had almost a 10-fold risk of infection compared with the control group.

These latter studies suggest, therefore, that the true infection risk associated with colonoscopy today is significantly higher than generaly recognized. Post-endoscopy surveillance of patients for disease transmissions is not routinely performed in the U.S., and when practiced these monitoring systems may not be sufficiently sensitive or adequate designed to detect and count all bacterial (and viral) transmissions.

Need guidance investigating the cause (and prevention) of a healthcare-associated infection or outbreak? *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.

An FDA database analysis: An analysis was performed for this article that reviewed FDA reports submitted in December (2023) describing ineffective reprocessing of a colonoscope, including this *Salmonella* case.

This analysis identified approximately *650 reports* (just in this one month) describing ineffective reprocessing (e.g., faulty cleaning, a clogged channel) of a colonoscope. Almost 100 of these identify “microbial contamination” of the colonoscope (including with *Salmonella*) as the reportable adverse event.

These findings suggest that, in general agreement with Wang et al. (2018), the number of patient exposures to a contaminated colonscope, with and without documented infection, may occur considerably more often than previously recognized.

I recommend increasing public awareness about the risk of colonoscopes remaining contaminated and exposing patients to infectious bacteria -- for example, through published FDA alerts -- to improve patient safety, enhance quality, and prevent infections.– Lawrence F Muscarella, PhD

Based on this number of FDA reports filed in December, thousands of reports (*e.g.*, 7,800) could be filed in the next year describing the ineffective reprocessing of a colonoscope. And this number could be even higher. Kim et al. (2019) reported that "the actual incidence of colonoscopy-related adverse events may be higher than reported."

By any reasonable measure, this concerning number of FDA reports argues for the prompt adoption of enhanced measures and corrective actions to improve colonoscope safety, including greater public awareness of the risk.

FDA safety alerts: The author of this article has previously recommended (to date, unsuccessfully) that FDA consider advising the public about the risk of "reprocessed" colonoscopes (and gastroscopes) remaining contaminated and potentially exposing patients to bacteria, including multidrug-resistant organisms.

This alert could be modeled after the FDA's recently published safety alerts and communications discussing reports of "reprocessed" bronchoscopes, duodenoscopes, and urological endoscopes remaining persistently contaminated despite their being cleaned and high-level disinfected (or sterilized) in accordance with manufacturer recommendations.

Publication of safety alerts that increase public awareness about the risk of "reprocessed" colonoscopes, too, remaining contaminated with bacteria is recommended to improve patient safety.

Recommendations: Other recommendations designed to reduce the risk of patient exposure to a colonoscope contaminated with *Salmonella* and other infectious organisms include:

- reprocessing the colonoscope in accordance with manufacturer instructions
- properly maintaining, serving and repairing the colonoscope
- leak testing and visually inspecting the colonoscope to detect defects or other types of damage
- properly handling and storing the colonoscope
- having in place a comprehensive quality assurance program that ensures the colonoscope's reliable and effective cleaning and high-level disinfection
- if the technology is available, consider using a sterilized colonoscope when feasible

Study limitations: Adverse event reports submitted to FDA have two notable limitations.

First, a report linking or associating a colonoscope or other type of flexible endoscope with an infection does not confirm the endoscope transmitted or otherwise caused the infection, as one or more other factors could be, in part or solely, responsible. Additional data would be required to conclude more definitively that the endoscope caused the infection.

Second, adverse event reports listed in the FDA's "MAUDE" database, according to FDA, have not been independently reviewed and could potentially be "inaccurate, untimely, unverified, or biased," Nor, according to FDA, are adverse-event reports "by themselves, definitive evidence of a faulty or defective medical device, and cannot be used to establish or compare rates of event occurrence."

Nevertheless, FDA routinely uses the MAUDE database to monitor the safety of medical devices and specifically flexible endoscopes (*e.g.*, bronchoscopes, duodenoscopes and urological endoscopes), and to develop important recommendations to reduce the risk of patient harms.

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Sponsorship: *The research and writing of this article was sponsored, in part, by AMBU, which received FDA clearance in 2023 for a sterile, single-use, flexible colonoscope.*

Services: Details about the quality and expert services Dr. Muscarella provides healthcare facilities, patients, device manufacturers and legal representatives are available here.