# Single-Use vs Reusable Duodenoscopes: How Infection Knowledge Gaps Are Driving Environmental Harm and What Can Be Done

More than 500,000 duodenoscopies are now performed annually in the United States.[1] Increased reports of duodenoscope-associated infections (DAIs) after endoscopic retrograde cholangiopancreatography (ERCP) over the past decade have sparked discussions about how to reduce the incidence of DAIs and have propelled the adoption of single-use duodenoscopes (SUDs) as an infection mitigation strategy. Meanwhile, potential downsides to SUDs, including increased environmental and public health impacts, costs, and supply chain risks, also warrant discussion, especially because the true benefits of these devices remain unclear. A better understanding of DAI incidence is essential for the rational use of SUDs.

To address key information gaps and potential next steps, this article highlights the environmental impact of SUDs and calls for the development of standard DAI case definitions and a reliable DAI data repository, similar to how case definitions have been developed to improve reporting and surveillance of ventilator-associated adverse events (VAEs).[2] An accurate reporting system and supporting an active surveillance infrastructure will enable evidence-informed discussions on how to weigh the risks and benefits of SUDs vs reusable duodenoscopes. Implementing value-based incentive programs, wherein health system reimbursement is linked to standardized DAI reporting, could advance measurement and quality improvement activities related to DAIs.

## Environmental Impact and Cost of SUDs

A recent life cycle assessment comparing environmental impacts of SUDs and reusable duodenoscopes found that SUDs generate 24–47 times more carbon dioxide emissions than reusable duodenoscopes on a per-use basis.[3] Switching to SUDs increases the net solid waste from ERCP by 40%–400%, with high-end estimates reflecting inclusion of ancillary supplies in the calculation.[4] In addition to a larger carbon footprint and solid waste generation, reliance on SUDs can increase supply chain vulnerability to manufacturing shortages, such as those experienced during the coronavirus disease 2019 pandemic.[5]

The US healthcare system is responsible for 8.5% of our country's greenhouse gas emissions and other toxic pollutants.[6] This connection between patient care and pollution is in direct tension with healthcare's responsibility to first, do no harm.[7] Gastrointestinal endoscopy is one of the highest waste-generating clinical specialties, behind perioperative services and intensive care,[8] highlighting the importance of sustainable practices in the gastroenterology community.[9] Thus, the growing concern stemming from increasing reliance on SUDs must be urgently addressed.

The financial viability of SUDs is also concerning. SUD costs have recently been estimated to range from $1995 to $4400 per procedure, depending on facility volume and negotiated procurement discounts,[10] whereas the cost of reusable duodenoscopes (including decontamination and refurbishment) ranges from $1110 to $2,685 per procedure.[11] Bang et al[12] estimated that a high-volume US-based center switching all their duodenoscopes to SUDs would incur a cost of $367,200 over a 3-year period, a 10-fold increase in cost per patient. Additionally, cost calculations for reusable duodenoscopes change based on the estimated rate of DAIs. For example, Bang et al[12] estimated that post-ERCP cholangitis added $125,000 in costs to patient care, so the cost of 1 ERCP using a reusable duodenoscope rose $600 to $1400 assuming a DAI rates of 0.4% and 1.0%, respectively. A different study by Das et al[13] showed that reusable duodenoscope costs are also affected by the reprocessing technique, with high-level disinfection being less costly than culture-and-quarantine and ethylene oxide sterilization methods. The performance characteristics of various reprocessing measures for duodenoscopes are still not fully understood, further complicating the cost discussion.[1]

## Uncertainty of the Actual Rate of DAIs

Concern for DAIs is the cornerstone of the movement toward SUDs. However, there is great uncertainty regarding the true rate of infections after ERCP, suggesting current risk-to-benefit calculations are insufficiently supported.[14] Early estimates ranged from 1 infection per 1,800,000 ERCPs to 1 infection per 276,000 ERCPs: This variability arose from inconsistencies in defining the number of infections (ie, the numerator) and the number of procedures that occur (ie, the denominator).[15] It is commonly theorized that the actual rates of DAIs are higher than reported in the literature, because existing studies typically rely on case reports. A recent study of the Dutch health system estimated DAI rates to be 1 infection per 10,000 ERCPs (0.01%), a much higher rate than previously reported.[16] Understanding the number of ERCPs performed annually is challenging given that in the United States, the estimated annual number of endoscopies performed varies by a factor of 7 depending on whether the estimate came from a government agency or an endoscopy society.[14] In the absence of a national health registry, denominator numbers will continue to remain elusive. Adding to the confusion, many cost-assessment studies use a DAI rate of 1% for their

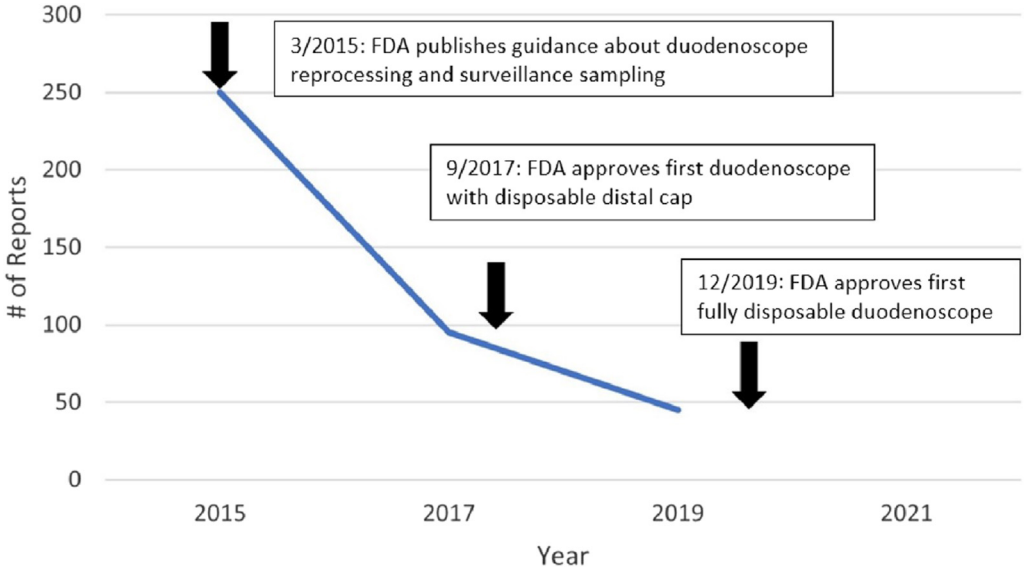


**Figure 1.** Duodenoscope-associated infection reports received by the FDA through MedWatch over time.

estimates, a 100-fold higher rate than supported by current literature. Even when considering the possible 7-fold variation in procedures performed, this leads to a potential bias toward overestimating the cost of reusable endoscopes.[10,12]

## Current State of Reporting DAIs

To understand why DAI rates are poorly understood, we must examine the history of DAI reporting in the United States. Before 1990, 281 reported episodes of pathogen transmission from general endoscopy were found in the scientific literature.[17] Most of these healthcare-associated infections were attributable to inadequate cleaning, insufficient decontamination standards, and equipment malfunction.[18] In 1990 the US Food and Drug Administration (FDA) gained oversight of medical device adverse event reporting in the United States. Before this, there was no standard definition of DAIs. Subsequently, a device-related adverse event was defined as any undesirable experience associated with the use of a medical product in a patient.[19] DAI is now 1 of many types of device-related adverse events that are reportable to the FDA.

There are hundreds of thousands of medical device–associated events reported each year through the FDA MedWatch reporting website, of which only a small portion are related to duodenoscopes. These data are publicly available and downloadable through the FDA Manufacturer and User Facility Device Experience database.[20] Per the FDA, event reporting is mandatory for both device manufacturers and facilities (including hospitals, outpatient diagnostic/treatment facilities, and ambulatory surgical facilities). A critical limitation of the FDA's medical device reporting system is that it is passive and lacks oversight to ensure the completeness of reports. This means the actual incidence of events is unknown, because many events likely go unreported given that facilities have no incentive to report. Also, limited information is provided in these reports, and their accuracy is unvalidated, so it is difficult to obtain meaningful clinical information about presumed cause and effect.

DAI incidence rates were not investigated for many years given the challenges in obtaining reliable data from the Manufacturer and User Facility Device Experience database. In the 2010s, reports of DAI outbreaks emerged from large-volume endoscopy centers.[21] In 2015, the FDA issued an advisory about the risk of duodenoscope contamination related to design issues involving parts of duodenoscopes that were difficult to clean.[22] They subsequently published guidance in collaboration with the Centers for Disease Control and Prevention (CDC) regarding reprocessing procedures. This guideline, which includes details about disinfection, sterilization, and cleaning, serves as a cornerstone of DAI mitigation. In addition, the CDC has published surveillance sampling and culture protocols.[23] Since these documents were published, the FDA has noted an 82% decrease in DAI reports (Figure 1), from a peak of 250 reports in 2015 down to 45 reports in 2019, suggesting that the FDA guidance was effective at significantly reducing the incidence of DAIs.[24] Notably, the downward trend started before the recent push toward SUDs over reusable duodenoscopes, as the first fully disposable duodenoscope was approved by the FDA in December 2019.[25]

## Future Desired State of Reporting DAIs

### *Standardizing and Expanding Definitions to Facilitate Accurate Reporting*

The most feared form of DAI is a highly drug-resistant organism transmitted from an inadequately reprocessed duodenoscope; however, DAIs can arise from the external environment or from disruption of the patient's endogenous flora during the procedure. Postprocedural infections include bloodstream infections, hepatobiliary infections, and intra-

abdominal infections, typically defined as occurring within 30 days after the procedure. In addition, a patient can become colonized with exogenous flora after ERCP with a contaminated duodenoscope. Colonization, although usually benign, can result in delayed infections, which are difficult to link to the procedure. Risk factors unique to DAIs include complex device design, biofilm formation on duodenoscopes, and suboptimal duodenoscope disinfection,[26] in addition to common risk factors including poor hand hygiene (with or without gloves) and weakened host immune health status.[5]

Proving that a postprocedural infection was secondary to a contaminated duodenoscope is challenging. Definitive proof of DAIs uses molecular epidemiology, comparing the DNA of the bacteria causing the infection with bacteria present on the duodenoscope and proceduralist staff before the procedure. In addition, there should be evidence that the patient was not already colonized with the offending organism before the procedure. In practice, this resource-intensive investigation is not feasible, so alternative means of culture and surveillance are suggested by the CDC, including liquid culture and/or standard plating methods and duodenoscope surveillance sampling protocols postprocedure.[23] However, many institutions do not perform duodenoscope sampling postprocedure because of costs and the burden of complying with challenging decontamination protocols, and only half of centers perform routine cultures after high-level disinfection (preproceduralist handling).[27] Moreover, culture methods and definitions of contamination are widely varying, and current duodenoscope culture techniques may fail to grow a pathogen even when a duodenoscope is highly implicated as the source of an outbreak.[28] Of note, no formal grading system of DAI currently exists.

The challenge of understanding device-related infections is not unique to gastroenterology. Pulmonologists struggle to adequately categorize and define infections arising from intubated patients and for many years described this condition as ventilator-associated pneumonia. Over time, however, it was recognized that etiologies of poor health outcomes related to intubation were heterogeneous, and the ventilator-associated pneumonia label was too narrow. This led to the development of a new framework in 2012, with ventilator-associated pneumonia broadened to VAEs. The VAE framework is more nuanced, with additional criteria for ventilator-associated conditions, including infection-related factors, and a distinct category of ventilator-associated pneumonia, which is subcategorized as possible and probable.[2] With these expanded criteria, physicians have the flexibility to better categorize infectious and noninfectious risk factors of respiratory failure. Furthermore, reporting is now streamlined because the definitions are based on standardized, objective data.

DAIs could benefit from a similar attribution approach to better account for vulnerability and associated risks. The creation of a "duodenoscope-associated adverse event" framework could serve to differentiate infectious and noninfectious contributors and parse out device-related events. Noninfectious contributors could include pancreatitis, bleeding, perforation, and other known postprocedural complications. Infections could be subcategorized as probable DAI, possible DAI, postprocedural infection unrelated to duodenoscope contamination, and duodenoscope-associated contamination (an event where postprocedural surveillance reveals duodenoscope contamination).

The VAE framework culminated from a multiyear interdisciplinary workgroup process, including stakeholders from pulmonary, critical care, and infectious diseases societies.[2] Similarly, a comprehensive framework and definitions of DAI will require collaboration between leading organizations in gastroenterology and infectious diseases, such as the American Gastroenterological Association, American College of Gastroenterology, American Society for Gastrointestinal Endoscopy, Infectious Disease Society of America, Association for Professionals in Infection Control and Epidemiology, Society for Healthcare Epidemiology of America, and the CDC.

## *Improving and Mandating Reporting*

There are several current structural obstacles to effective DAI reporting. Insufficient personnel available to do contact tracing as well as a lack of front-line clinician familiarity with the FDA MedWatch reporting infrastructure may hamper the initial detection and reporting of infections. Inadequate and unclear case definitions further impede outbreak investigations. The FDA MedWatch reporting requirement itself is minimal—presently, the only mandatory submission information is the product name and an event description that is entered in an unstructured free text box.[29] Thus, there are multiple reasons why a DAI might not be reported or might be reported inaccurately or with missing information.

Our present understanding of DAI is based on case reports in the medical literature. Many of these reports lack any standardized DAI definitions or case descriptions, lack description of contact tracing methods, and fail to examine potential breaches in cleaning and reprocessing of the device.[30,31] Reports from the early 2010s typically relied solely on patient and device cultures without gene sequencing.[32,33] Multiple reviews on DAI outbreaks have been published in the past several years, and these reviews highlight the heterogeneity of case outbreak reporting that makes meta-analysis impractical.[21,26,34]

A more comprehensive reporting system, shown in Table 1, would greatly expand our understanding of DAIs. Taking lessons from VAEs, a joint task force consisting of appointees from the American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, CDC, Infectious Disease Society of America, Association for Professionals in Infection Control and Epidemiology, and Society for Healthcare Epidemiology of America could work together to develop expert consensus on necessary components of device-related definitions and a reporting system. This could provide a foundation for a new centralized data repository for researching DAI prevention and guide development of best practices.

**Table 1.** Components of an Ideal Reporting System for DAIs and Their Presence or Absence in Existing Systems

| Suggested data inputs of an ideal reporting system | Mandatory in MedWatch reporting? | Included in outbreak/case series reporting? |
|---|---|---|
| Background | | |
| Location | Yes | Yes |
| Date of positive culture | Yes | Yes |
| Date of procedure | No | Yes |
| Demographics (eg, age, sex, race) | Yes | Yes |
| Duodenoscope | | |
| Manufacturer | Yes | Variable |
| Type of instrument (eg, single-use vs reusable, reposable; disposable elevator component) | No | Variable |
| Pre-existing damage? If yes, where? | No | Variable |
| Pathogen | | |
| Organism name | No | Yes |
| Isolated from patient? | No | Yes |
| Isolated from duodenoscope? | No | Variable |
| Type of infection (eg, cholangitis, bloodstream infection) | No | Variable |
| Patient outcome (eg, readmission, 30-day survival) | No | Yes |
| Epidemiology | | |
| Number of infected patients | No | Yes |
| Number of patients exposed to contaminated duodenoscope | No | Yes |
| Attack rate (infected and/or exposed) | No | Yes |
| Facility | | |
| Use of duodenoscope surveillance cultures? | No | Variable |
| Compliance with reprocessing measures? | No | Variable |
| Cause of contamination identified? | No | Variable |
| Corrective measures taken? | No | Variable |

Mandatory reporting would help ensure the ability to quantify and reduce healthcare-associated infections. Central line–associated bloodstream infections and catheter-associated urinary tract infections demonstrated a 35%–55% reduction in the decades following mandatory reporting because of the development of infection control measures and value-based incentive programs.[35] A similar program for DAIs could inform an evidence-based approach to DAI prevention and assist in determining the optimal circumstances when reusable duodenoscopes vs SUDs should be considered. The ideal initiative would balance patient safety with resource conservation, decrease healthcare costs, and minimize the negative environmental impact of health care.

## Conclusion

SUDs vs reusable duodenoscopes have sparked widespread discussion in the gastroenterology community, but progress has been slow because of significant information gaps surrounding DAIs. Obtaining reliable information about DAI epidemiology is vital. Clear case definitions are needed to appropriately categorize adverse events after ERCP, and accurate surveillance methods help to identify these events. These processes require interdisciplinary collaborations for their development. DAI reporting should be standardized, mandatory, and involve the use of a centralized database, similar to reporting of other healthcare-associated infections to the CDC's National Healthcare Safety Network. To ensure data are sufficiently complete, mandatory reporting would need to be incentivized, akin to value-based incentive programs of central line–associated bloodstream infections and catheter-associated urinary tract infections where health system reimbursement is linked to DAI numbers. This approach would allow a more accurate analysis and provide evidence for enhancing DAI prevention and developing best practices around appropriate use of alternative devices. Adoption of SUDs harms environmental health, increases costs, and increases supply chain vulnerability, so we must first understand DAIs to appropriately compare the benefits and harms of alternative ERCP devices.

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**Received September 28, 2023. Accepted February 27, 2024.**

**Conflicts of interest**

These authors disclose the following: Jodi D. Sherman is partially supported by the Commonwealth Fund and the Canadian Institute of Health Research. Hardeep Singh is partially supported by the Houston Veterans Affairs Health Services Research and Development Service Center for Innovations in Quality, Effectiveness and Safety (CIN 13–413) and the Agency for Healthcare Research and Quality. The remaining authors disclose no conflicts.

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**0016-5085/$36.00**
**https://doi.org/10.1053/j.gastro.2024.02.040**