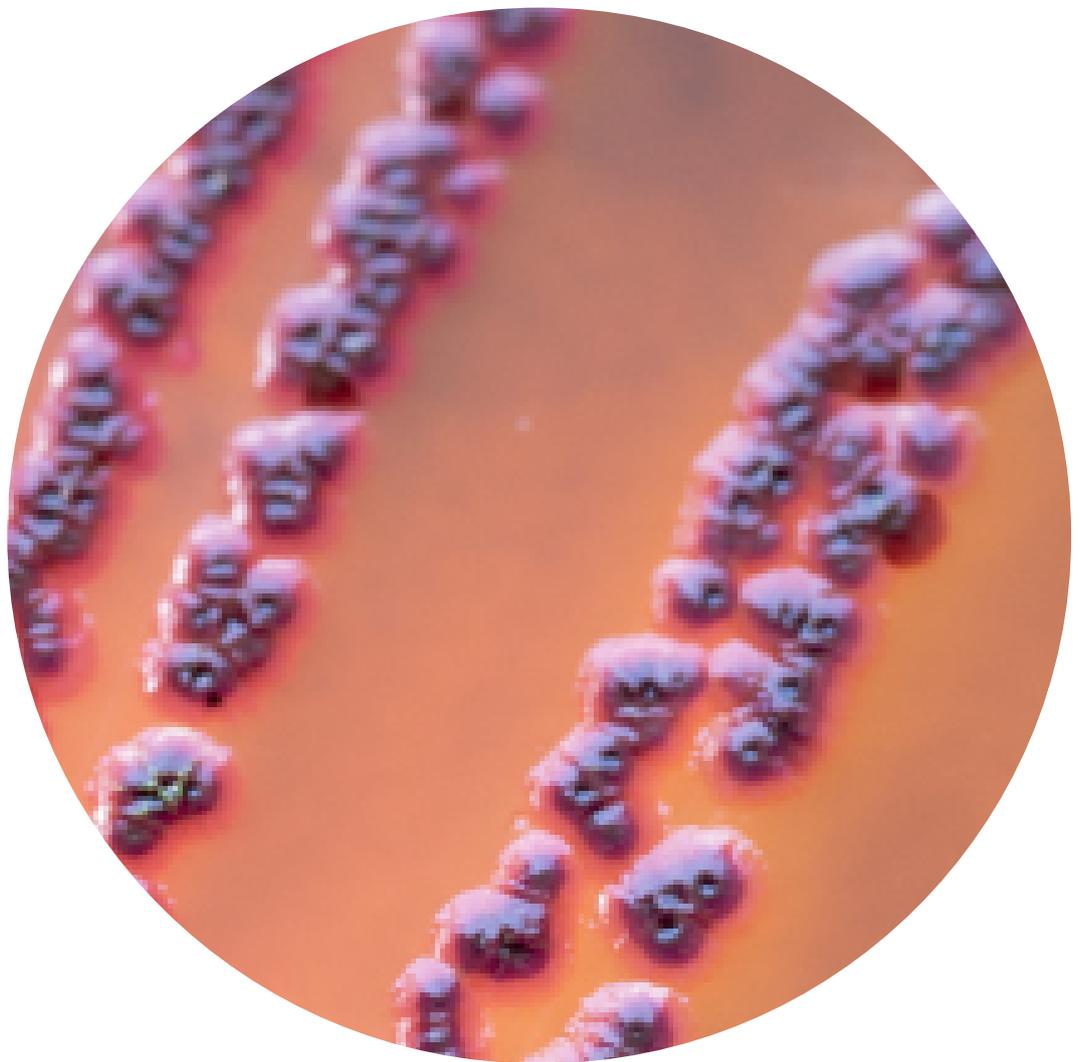


GI INFECTION CONTROL

e-Booklet



Ambu

TAKE AWAY

This is the first meta-analysis to estimate the contamination rate of patient-ready duodenoscopes used for ERCP. Based on the available literature, the analysis demonstrates that there is a 15.25% contamination rate of reprocessed patient-ready duodenoscopes. Additionally, the analysis indicates that dHLD and EtO reprocessing methods are superior to single HLD, but still not efficient in regard to cleaning the duodenoscopes properly.

KEY FINDINGS

- A total of 15 studies fulfilled the inclusion criteria, which included 925 contaminated duodenoscopes from 13,112 samples.
- The calculated total weighted contamination rate was 15.25% ± 0.018 (95% confidence interval [CI]: 11.74% - 18.75%).
- The contamination rate after only using HLD was 16.14% ± 0.019 (95% CI: 12.43% - 19.85%).
- After using either dHLD or EtO the contamination rate decreased to 9.20% ± 0.025 (95% CI: 4.30% - 14.10%).

Rate and impact of duodenoscope contamination: A systematic review and meta-analysis, *EClinicalMedicine*.¹

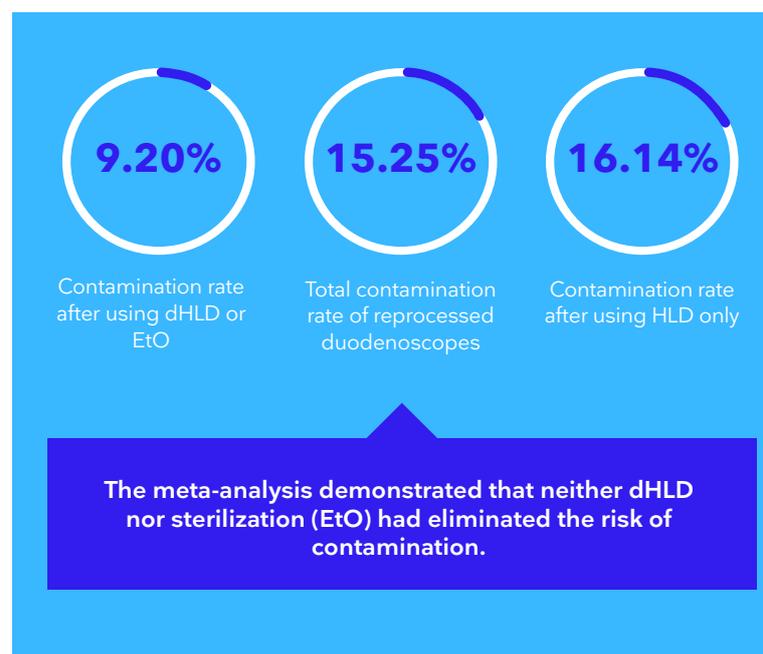
[Larsen et al., 2020](#)

STUDY AIM

This meta-analysis aimed to estimate the contamination rate of reprocessed patient-ready duodenoscopes for ERCP, based on currently available data.

METHODS

- PubMed and Embase databases were searched from January 1, 2010 until March 10, 2020 for citations investigating contamination rates of reprocessed patient-ready duodenoscopes.
- A random-effects model (REM) based on the proportion distribution was used to calculate the pooled total contamination rate of reprocessed patient-ready duodenoscopes.
- Subgroup analyses were carried out to assess contamination rates when using different reprocessing methods by comparing single high-level disinfection (HLD) with double HLD (dHLD) and ethylene oxide (EtO) gas sterilization.



TAKE AWAY

Duodenoscope and linear echoendoscope contamination was independent of age and usage. These results suggest that old and frequently used endoscopes, if maintained correctly, have a similar risk of contamination to new ones. The MGO contamination prevalence of ~15% was similarly high for duodenoscopes and linear echoendoscopes, rendering both patients undergoing ERCP as well as endoscopic ultrasound at risk for transmission of microorganisms.

KEY FINDINGS

- Of all Dutch centres, 97% participated in one of the studies, sampling 309 duodenoscopes and 64 linear echoendoscopes.
- In total, 54 (17%) duodenoscopes and 8 (13%) linear echoendoscopes were contaminated according to the AM20 definition.
- MGO were detected on 47 (15%) duodenoscopes and 9 (14%) linear echoendoscopes.
- Contamination was not age or usage-dependent (all p-values ≥ 0.27), nor was it shown to differ between the reprocessing characteristics (all p-values ≥ 0.01).

Nationwide risk analysis of duodenoscope and linear echoendoscope contamination, *Gastrointest Endosc.*²

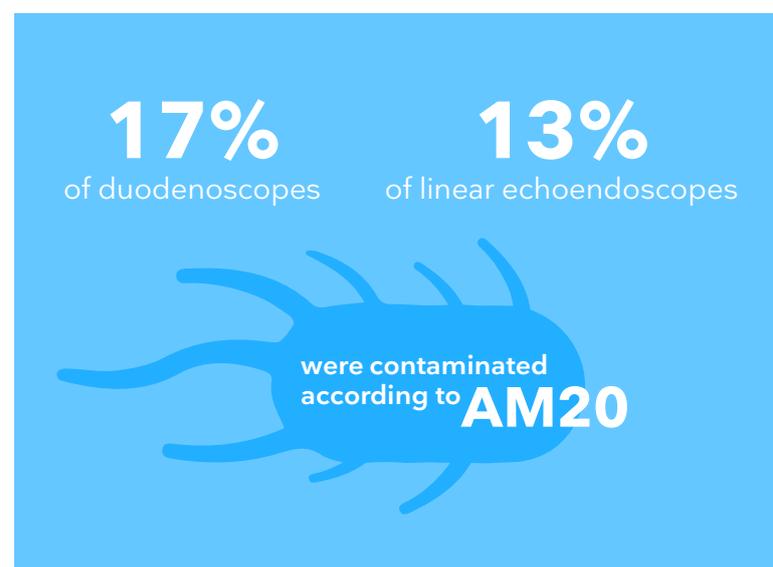
[Rauwers et al., 2020](#)

STUDY AIM

Contaminated duodenoscopes and linear echoendoscopes (DLEs) pose a risk of infectious outbreaks. To identify DLE and reprocessing risk factors, the nationwide study combined the data of the previously published nationwide cross-sectional study¹ (PROCESS 1) with the follow-up study (PROCESS 2).

METHODS

- The investigators invited 74 Dutch DLE centres to sample >2 duodenoscopes during PROCESS 1, and all duodenoscopes and linear echoendoscopes during PROCESS 2. The studies took place in two consecutive years.
- Local staff sampled each DLE at >6 sites according to uniform methods explained by online videos.
- **The study used two contamination definitions:**
 - **AM20:** any microorganism with >20 colony-forming units (CFU)/20 mL
 - **MGO:** presence of microorganisms with gastrointestinal or oral origin, independent of CFU count.



¹Rauwers AW, Voor in 't holt AF, Buijs JG, et al., High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study; *Gut* 2018;67:1637-1645.



Not open access

Contaminated duodenoscopes

TAKE AWAY

A total of 34.7% of the duodenoscope samples reached the action level (>100 CFU/endoscope). The findings of this study may support revision of guidance issued by governmental agencies and professional associations. These elements may be useful for redaction of guidelines to improve microbiological quality surveillance of gastrointestinal endoscopes, and to prevent outbreaks linked to these devices.

KEY FINDINGS

- A total of 118 microbiological tests were performed on duodenoscopes.
- Six out of 118 (5.1%) samples reached the alert level (25-100 CFU/endoscope).
- 41 samples (34.7%) reached the action level (≥100 CFU/endoscope).
- 71 samples (60.2%) were within the target level defined as <25 CFU/endoscope.
- Gram-positive and gram-negative bacteria, fungi, and yeast were all isolated from endoscope samples.
- Microbial contamination was linked to the age of the endoscope. The more the endoscope is used, the higher the risk of damage.
- The use and disinfection of gastrointestinal endoscopes can lead to damage of the channels and to the formation of biofilms that are difficult to remove.

Measures to improve microbial quality surveillance of gastrointestinal endoscopes, Endoscopy.³

[Saliou et al., 2016](#)

STUDY AIM

Infectious outbreaks associated with the use of gastrointestinal endoscopes have increased in line with the spread of highly resistant bacteria. The aim of this study was to determine the measures required to improve microbiological quality surveillance of gastrointestinal endoscopes.

METHODS

- Results of all microbiological surveillance testing of gastrointestinal endoscopes performed at Brest Teaching Hospital from January 1, 2008 to June 1, 2015 were reviewed.
- When microbiological testing failed to comply with the target level, the endoscope was subjected to a double manual reprocessing before being retested.
- The target level was defined as total flora <25 CFU/endoscope and absence of indicator microorganisms.
- Alert level was defined as total flora 25-100 CFU/endoscope and absence of indicator microorganisms.
- Action level was defined as total flora ≥100 CFU/endoscope or presence of indicator microorganisms.

118

microbiological tests were performed on duodenoscopes

5.1%

samples reached the alert level (25-100 CFU/endoscope)

34.7%

reached the action level (>100 CFU/endoscope)

60.2%

were within the target level defined as <25 CFU/endoscope

Both gram-positive, gram-negative, fungi, and yeast were isolated from endoscope samples

TAKE AWAY

Duodenoscope design modifications may compromise microbiological safety, as illustrated by this outbreak. Extensive pre-marketing validation of the reprocessability of any new endoscope design and stringent post-marketing surveillance are therefore mandatory. Twenty-two patients got infected during this outbreak.

KEY FINDINGS

- From January to April 2012, 30 patients with a VIM-2-positive *P. aeruginosa* were identified, of whom 22 had undergone an ERCP using a specific duodenoscope, the TJF-Q180V.
- In total, 251 patients had undergone ERCP using the same duodenoscope, and 22 patients became infected with VIM-2-positive *P. aeruginosa*.
- This was a significant increase compared with the hospital-wide baseline level of two to three cases per month.
- Clonal relatedness of the VIM-2 *P. aeruginosa* was confirmed for all 22 cases and for the VIM-2 strain isolated from the recess under the forceps elevator of the duodenoscope.
- An investigational study of the new modified design, including the dismantling of the duodenoscope tip, revealed that the fixed distal cap hampered cleaning and disinfection, and that the O-ring might not seal the forceps elevator axis sufficiently.
- The high monthly number of cases decreased below the pre-existing baseline level following withdrawal of the TJF-Q180V device from clinical use.

Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*, Endoscopy.⁴

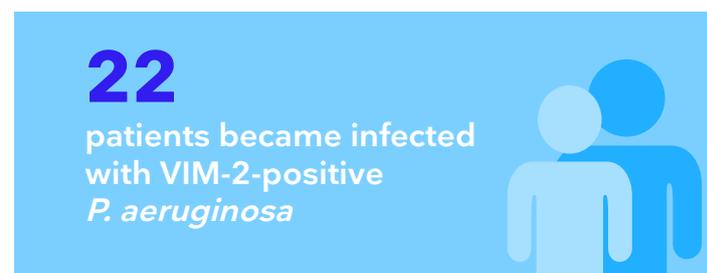
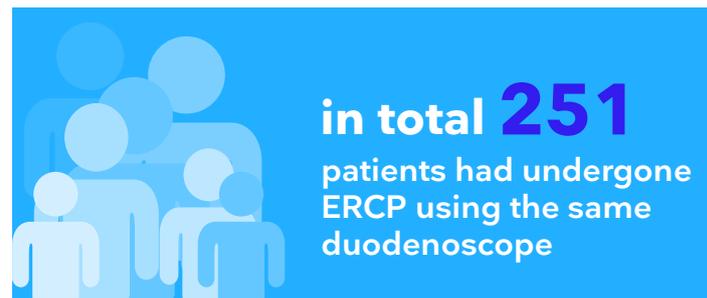
[Verfaillie et al., 2015](#)

STUDY AIM

This study reports a large outbreak of VIM-2-producing *Pseudomonas aeruginosa* that was linked to the use of a recently introduced duodenoscope with a specifically modified design (Olympus TJF-Q180V).

METHODS

- Epidemiological investigations and molecular typing were executed in order to identify the source of the outbreak.
- Audits on implementation of infection control measures were performed. Additional infection control strategies were implemented to prevent further transmission.
- The design and the ability to clean and disinfect the duodenoscope were evaluated, and the distal tip was dismantled.



TAKE AWAY

Carbapenemase-producing *Klebsiella pneumoniae* were identified in five patients who underwent an endoscopy with the same duodenoscope. The duodenoscope was the only factor linking the patients. The duodenoscope had previously been used in an infected patient, which is thought to be the origin of the contamination.

KEY FINDINGS

- A total of five cases of Carbapenemase-producing *K. pneumoniae* colonization were identified from patients who received an ERCP with the same duodenoscope over a short period in October 2015.
- The duodenoscope was the only epidemiological link between these cases.
- The investigators strongly suggest that this duodenoscope has become transiently contaminated, following its use for known CPE carriers of a previous outbreak.

Duodenoscopy: an amplifier of cross-transmission during a carbapenemase-producing Enterobacteriaceae outbreak in a gastroenterology pathway, J Hosp Infect.⁵

[Bourigault et al., 2018](#)

STUDY AIM

Carbapenemase-producing *K. pneumoniae* were identified in five patients who underwent ERCP with the same duodenoscope. The duodenoscope was the only epidemiological link between these cases. This study reports the epidemiological and microbiological investigations conducted to determine the origin of contamination of these patients.

METHODS

- Between December 2014 and October 2015, 61 patients underwent ERCP with the same duodenoscope. Forty-one patients were readmitted after exposure and screened.
- Five out of the 41 readmitted patients had become infected with CRE after undergoing ERCP with the same duodenoscope.
- The outbreak was identified at the Nantes University Hospital, France. Reprocessing of endoscopes has been centralized on one site that performs around 100 disinfections per day, and it is carried out in accordance with the French guidelines.
- A multidisciplinary team, comprising endoscopy physicians, bacteriologists, infection control specialists, biomedical engineers, and staff of the endoscope reprocessing unit, coordinated the epidemiological and microbiological investigations.



5 OUT OF 41

readmitted patients were infected with CRE after undergoing ERCP with the same duodenoscope. The duodenoscope was the only factor linking the patients

REFERENCES

1. Larsen S, Russell RV, Ockert LK, et al. Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. *EClinicalMedicine*. 2020;0(0):100451. doi:10.1016/j.eclinm.2020.100451
2. Rauwers AW, Voor in 't holt AF, Buijs JG, et al. Nationwide risk analysis of duodenoscope and linear echoendoscope contamination. *Gastrointest Endosc*. 2020;0(0). doi:10.1016/j.gie.2020.05.030
3. Saliou P, Le Bars H, Payan C, et al. Measures to improve microbial quality surveillance of gastrointestinal endoscopes. *Endoscopy*. 2016;48(8):704-710. doi:10.1055/s-0042-107591
4. Verfaillie CJ, Bruno MJ, Voor in 't Holt AF, et al. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*. *Endoscopy*. 2015;47(6):493-502. doi:10.1055/s-0034-1391886
5. Bourigault C, Le Gallou F, Bodet N, et al. Duodenoscopy: an amplifier of cross-transmission during a carbapenemase-producing Enterobacteriaceae outbreak in a gastroenterology pathway. *J Hosp Infect*. 2018;99(4):422-426. doi:10.1016/j.jhin.2018.04.015 LK