



Microbiological surveillance post-reprocessing of flexible endoscopes used in digestive endoscopy: a national study

B. Casini^a, A.M. Spagnolo^{b,c,*}, M. Sartini^{b,c,*}, B. Tuvo^a, M. Scarpaci^a, M. Barchitta^d, A. Pan^e, A. Agodi^d, M.L. Cristina^{b,c}, on behalf of the Study Group[†]

^a Department of Translational Research, New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy

^b Department of Health Sciences, University of Genova, Genova, Italy

^c Operating Unit Hospital Hygiene, Galliera Hospital, Genoa, Italy

^d Department of Medical, Surgical and Advanced Technology Sciences "G.F. Ingrassia", University of Catania, Catania, Italy

^e Operating Unit of Infectious Diseases, ASST Cremona, Cremona, Italy

ARTICLE INFO

Article history:

Received 20 June 2022

Accepted 19 September 2022

Available online 13 October 2022

Keywords:

Duodenoscopes

Endoscope reprocessing

Microbiological surveillance

Survey



SUMMARY

Introduction: Microbiological surveillance of endoscopes is a safety measure for verifying the quality of reprocessing procedures and identifying contaminated devices, but duodenoscope-related outbreaks are still reported.

Aim: To assess the effectiveness of duodenoscope reprocessing procedures in Italy.

Methods: Between December 2019 and April 2020, data obtained from microbiological surveillance post-reprocessing in 15 Italian endoscopy units were collected. Sampling was carried out after reprocessing or during storage in a cabinet. In keeping with international guidelines and the Italian position paper, the micro-organisms were classified as high-concern organisms (HCOs) and low-concern organisms (LCOs).

Findings: In total, 144 samples were collected from 51 duodenoscopes. Of these, 36.81% were contaminated: 22.92% were contaminated with HCOs and 13.89% were contaminated with LCOs [2.08% with an LCO load of 11–100 colony-forming units (CFU)/device and 0.69% with an LCO load of >100 CFU/device]. The contamination rate was 27.5% in samples collected after reprocessing, 40% in samples collected during storage in a cabinet that was compliant with EN 16442:2015 (C-I), and 100% in samples collected during storage in a cabinet that was not compliant with EN 16442:2015 (NC-I). The respective HCO rates were 15.00%, 27.27% and 66.67%. Correlation between LCO contamination and storage time was demonstrated (Spearman's $\rho=0.3701$; $P=0.0026$). The Olympus duodenoscope TJFQ180V demonstrated the lowest rate of contamination (29.82%), although the contamination rate was 100% for duodenoscopes stored in an NC-I cabinet.

* Corresponding authors. Address: Department of Health Sciences, University of Genova, Via Pastore 1, Genova 16132, Italy.

E-mail addresses: am.spagnolo@unige.it (A.M. Spagnolo), sartini@unige.it (M. Sartini).

[†] Full details of the Study Group Collaborators provided in Appendix.

Conclusion: Microbiological surveillance, along with strict adherence to reprocessing protocols, may help to detect endoscope contamination at an early stage, and reduce the risk of duodenoscope-associated infections.

© 2022 The Authors. Published by Elsevier Ltd on behalf of The Healthcare Infection Society. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

After the first reported case cluster of duodenoscope-related carbapenem-resistant Enterobacteriales transmission in 2013 [1], the Centers for Disease Control and Prevention (CDC) reported an association between endoscopes and the transmission of multi-drug-resistant bacteria to the Food and Drug Administration (FDA) [2]. Since then, several similar outbreaks have been documented in the literature, which, despite low incidence, are of clinical significance given their severity [3–5]. These adverse events have raised serious concerns regarding current standards of care. Professional scientific associations have revised their existing guidelines for duodenoscope reprocessing techniques [2].

Reprocessing, which is used to prevent the transmission of micro-organisms, does not always guarantee adequate decontamination of duodenoscopes. Despite adherence to reprocessing guidelines, transmission and outbreaks have still been reported [6–8]. Endoscope reprocessing failures, reported as one of the 10 most significant threats to patient health by the Emergency Care Research Institute, can occur because of the complexity and multiplicity of the steps involved in this process [9]. As it is a complex process, reprocessing should be performed in an adequately cleaned workplace, with proper storage areas. Furthermore, as it involves different professional profiles, each phase should be performed in a standard way by adequately trained staff, and should be traceable [10,11].

The intrinsic complexity of endoscopes makes it difficult to control the risk of contamination, especially because of the formation of biofilm, which is frequently found in particular areas of the endoscope (e.g. microlesions in channels, valves, distal lenses, etc.), and is difficult to remove with standard procedures. It is in this context that microbiological surveillance comes into play: to prevent and reduce the risk of infection, accompanied by the implementation of corrective actions where necessary [12]. Although microbiological surveillance is recommended by guidelines, it is not always performed regularly or properly.

In 2015, FDA ordered three different manufacturers (Olympus, Fujifilm and Pentax) to conduct a post-marketing surveillance study on duodenoscopes to better understand how these devices are reprocessed in real-world settings, and the impact on the transmission of infection [13]. Following the improved safety measures and implementation of the reprocessing techniques, the surveillance study documented a decline in the number of medical device reports associated with patient infections between 2015 and 2017 [14].

However, after additional medical device reports associated with patient infections and device contamination in 2018 and 2019, FDA re-emphasized that, despite the improvements made and the decline in the number of medical device reports, it is still important to ensure adequate reprocessing procedures

to improve the safety of reprocessed duodenoscopes [15]. Given the ongoing reports of adverse events, the new European Medical Devices Regulation (MDR 2017/745) also advises post-marketing surveillance studies, which were not been conducted previously in Europe [16].

The importance of undertaking microbiological surveillance to guarantee the safe use of duodenoscopes is highlighted in a 2015 report by CDC and the American Society of Microbiology [2]. This was updated in 2018, suggesting the application of modified procedures for other types of flexible endoscope, as also recommended in Europe in the guidelines of the European Society of Gastrointestinal Endoscopy/European Society of Gastroenterology and Endoscopy Nurses and Associates [17].

Given the clinical importance of multi-drug-resistant bacteria, a multi-society position paper on microbiological surveillance after reprocessing flexible endoscopes was published recently in Italy, which supported the quality of this process in order to ensure patient safety [18]. Only a small number of Italian studies to date have assessed endoscope contamination following reprocessing, and a national investigation has never been undertaken [19,20].

This study reports the results obtained during the first Italian nationwide cross-sectional study, conducted by members of the Italian Multidisciplinary Society for the Prevention of Healthcare-Associated Infections and the Italian Hospital Hygiene Study Group of the Italian Society of Hygiene, Preventive Medicine and Public Health, to verify the effectiveness of duodenoscope reprocessing procedures.

Materials and methods

Settings

This prospective nationwide cross-sectional study was performed in digestive endoscopy units where endoscopic retrograde cholangiopancreatography (ERCP) was performed on outpatients and inpatients. These operative units were distributed in nine Italian regions (seven units in northern Italy, four units in central Italy, and four units in southern Italy). Of the 21 operative units that initially agreed to take part in the study, 15 actually participated; six operative units withdrew due to the coronavirus disease 2019 pandemic.

A mean of 380.15 [standard deviation (SD) 359.34; range 73–1002] ERCP procedures are performed in these operative units each year. All of the operative units were enrolled in the study on a voluntary basis between 1st December 2019 and 30th April 2020. Duodenoscopes were eligible for sampling if they were reprocessed and ready for patient use following high-level disinfection or cabinet storage. Each operative unit was asked to complete a data collection form with the duodenoscope brand and model, sampling date, storage type and timing, and results of microbiological sampling performed during these periods. No patient data were included in this study,

meaning that there was no need for approval by the Medical Research Ethics Committee.

Microbiological surveillance was performed according to the protocol described in the 2018 CDC guideline [21]. The protocol was translated and shared with all of the operative units that participated in the project.

Sample collection

Sampling was carried out independently by local staff after reprocessing, during storage in a cabinet that was compliant with EN 16442:2015 (C-I), or during storage in a cabinet that was not compliant with EN 16442:2015 (NC-I). In the case of sampling during storage, the operative units were also asked to indicate the time between reprocessing and sampling.

In keeping with the CDC guideline sampling protocol, samples were obtained from the elevator recess and instrument channel, as well as the elevator wire channel when accessible. To facilitate aseptic sampling, a clean surface covered with an impervious sterile drape was used in conjunction with appropriate personal protective equipment, including sterile gloves. Two staff members were required to conduct aseptic sampling from the channels. Briefly, two samples were collected and combined: an instrument channel sample (biopsy port to distal end) taken using the 'flush, brush, flush' method, and an elevator recess sample obtained by flushing and brushing the elevator recess. The brushes used were those recommended by the device manufacturer, while the elution solution was 0.01M phosphate buffered saline with 0.02% Tween 80; if not available, the use of sterile de-ionized water was permitted as long as the subsequent analyses were carried out within 12 h. For duodenoscopes with an open elevator wire channel, a third sample was collected by flushing the elevator wire channel, which was then combined with the other two samples. A final volume of approximately 45 mL was obtained and collected in a container, and the same volume of Dey Engley neutralizing broth (Sigma Aldrich, Milan, Italy) was added in order to neutralize any trace of chemicals that might have restricted the detection of micro-organisms.

Microbiological analysis

The entire volume of the sample was filtered through a 0.45- μ m filter that was then placed on a plate of blood agar (VWR International PBI, Radnor, PA, USA) and incubated at 35–37 °C for 72 h. Colony-forming units (CFU) were counted, and each species was identified to distinguish between high-concern organisms (HCOs) and low-concern organisms (LCOs).

In keeping with international guidelines and the Italian position paper, the micro-organisms were classified as HCOs and LCOs. HCOs are most often associated with diseases, and their presence in any numbers indicates that there is a problem with the cleaning/disinfection process, with potential for cross-infection (e.g. *Staphylococcus aureus*, *Salmonella* spp., *Escherichia coli*, *Pseudomonas aeruginosa*, *Klebsiella* spp.). LCOs are less often associated with disease, and may arise from contamination during sampling, or may be due to insufficient drying of endoscope channels post-processing or improper storage conditions (e.g. coagulase-negative staphylococci, excluding *Staphylococcus lugdunensis*, *Bacillus* spp., diphtheroids). In this case, when the number of isolated organisms is low (<10 CFU/channel), the endoscope does not need to be

removed from patient use. When the number of isolated LCOs is >10 and <100 CFU/channel, it is recommended that reprocessing methods and sampling collection should be reviewed. However, if the number of organisms is >100 CFU/channel, the endoscope should be removed from use. In accordance with CDC guidelines, the decision to consider some of the isolated micro-organisms as HCOs was made on the basis of the epidemiology of the infections prevalent in the participating health facility, and on the basis of international guidelines, such as the Gastroenterological Society of Australia (GESA) Health Infection Control Service guidelines, which report micro-organisms of clinical interest for endoscopy-related infections [2,17,18,22].

Statistical analysis

Statistical analysis was carried out using STATA SE13TM (Stata Corp, College Station, TX, USA). The results were analysed in terms of descriptive statistics, and differences between groups were evaluated using the Kruskal–Wallis test, as appropriate. Possible correlation between LCO contamination and storage time was also evaluated by Spearman's correlation test. $P < 0.05$ was considered to indicate statistical significance.

Results

Each operative unit tested at least one duodenoscope, up to a maximum of seven at some operative units, with a total of 51 duodenoscopes included in the study. The most widely used model was the Olympus TJF Q180V (45.10%), followed by the TJF 160 (17.65%) and the TJF 145 (21.57%); other duodenoscope brands and models were sampled in 15.69% of cases.

In total, 144 samples were collected from the 51 duodenoscopes analysed in the operative units. Eighty samples (55.56%) were collected after reprocessing, 55 (38.19%) samples were collected during storage in a C-I cabinet, and nine (6.25%) samples were collected during storage in an NC-I cabinet. The mean storage time before sampling was 27.8 (SD 27.44) h for C-I cabinets [range 2–120 h, median 16 h, interquartile range (IQR) 16–24 h] and 90.67 (SD 112.43) h for NC-I cabinets (range 24–360 h, median 24 h, IQR 24–96 h). Of the samples collected during storage in C-I and NC-I cabinets, 94.55% and 66.67%, respectively, were taken within 72 h of reprocessing.

Figure 1 shows the non-conformity rate of samples collected from the various duodenoscope models and the timing of sampling. Considering all the samples, regardless of the timing of sampling, 36.81% showed microbial contamination; of these, 13.89% were contaminated with LCOs and 22.92% were contaminated with HCOs. Specifically, 2.08% of the samples contaminated with LCOs had a microbial load of 11–100 CFU/duodenoscope, and 0.69% had a microbial load of >100 CFU/duodenoscope.

Considering the timing of sampling, the contamination rate was 27.50%, 40.00% and 100% for the samples collected after reprocessing, during storage in a C-I cabinet, and during storage in an NC-I cabinet, respectively. The rate of HCO contamination was 15.00%, 27.27% and 66.67%, respectively. Correlation between LCO contamination and storage time was observed, regardless of the cabinet type (obs=64; Spearman's rho=0.3701; $P=0.0026$).

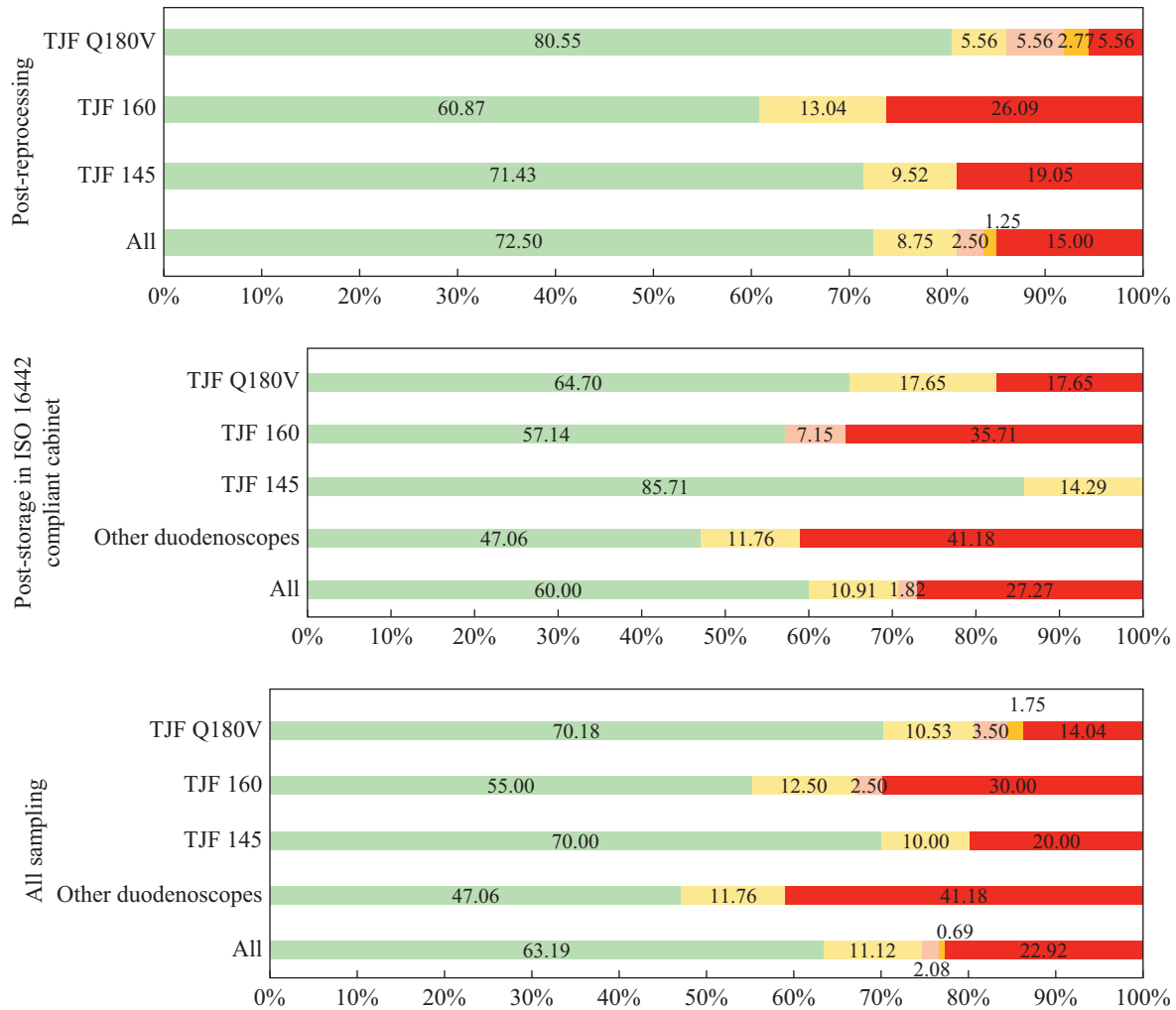


Figure 1. Compliance and non-compliance rates for high-concern organisms and low-concern organisms as a function of duodenoscope model and sampling time. Green bars, compliant; yellow bars, low-concern organisms <10 colony-forming units (CFU)/duodenoscope; light orange bars, low-concern organisms 11–100 CFU/duodenoscope; dark orange bars, low-concern organisms >100 CFU/duodenoscope; red bars, high-concern organisms.

Of the Olympus duodenoscope models sampled, the TJF Q180V was found to have the lowest rate of contaminated samples (29.82%). When sampling during storage in an NC-I cabinet (N=9), with all samples collected from Olympus duodenoscopes, the contamination rate, regardless of the model,

was 100% (HCOs in 66.67% and LCOs <10 CFU/duodenoscope in 33.33% of samples). In terms of the contaminated samples, the mean concentration of HCOs was 159.12 (SD 251.91) CFU/duodenoscope, with a maximum microbial load of 1001 CFU/duodenoscope. Only one sample was found to be contaminated

Table I

Mean values of total microbial load, high-concern organisms (HCOs) and low-concern organisms (LCOs) [colony-forming units (CFU)/duodenoscope]

	Parameters	N	Mean (SD)	Range	Median	IQR
All sampling	Total microbial load	144	38.58 (136.76)	0–1001	0	0–5.5
	HCOs	144	36.53 (136.75)	0–1001	0	0–0
	LCOs	144	4.84 (28.96)	0–301	0	0–0
Contaminated sampling	Total microbial load ^a	37	148.19 (240.13)	2–1001	40	8–202
	HCOs	33	159.12 (251.91)	1–1001	80	7–202
	LCOs 11–100 CFU/duodenoscope	3	30.33 (15.88)	12–40	39	12–40
	LCOs >100 CFU/duodenoscope	1	137	137	137	137

SD, standard deviation; IQR, interquartile range.

^a Only samples with LCOs >10 CFU/duodenoscope or presence of just one HCO.

Table II

Mean values of total microbial load, high-concern organisms (HCOs) and low-concern organisms (LCOs) [colony-forming units (CFU)/duodenoscope] observed in the various duodenoscope models

			N	Mean (SD)	Range	Median	IQR
All sampling	Olympus TJF 145	Total microbial load	30	37.40 (77.09)	0–202	0	0–1
		HCOs	30	37.03 (77.25)	0–202	0	0–0
		LCOs	30	3.73 (18.44)	0–101	0	0–0
	Olympus TJF 160	Total microbial load	40	73.62 (230.31)	0–1001	0	0–10
		HCOs	40	71.90 (230.76)	0–1001	0	0–9
		LCOs	40	1.72 (6.54)	0–39	0	0–0
	Olympus TJF Q180V	Total microbial load	57	21.49 (77.41)	0–400	0	0–1
		HCOs	57	17.81 (75.97)	0–400	0	0–0
		LCOs	57	8.96 (43.63)	0–301	0	0–0
	Other duodenoscopes	Total microbial load	17	15.47 (38.20)	0–144	2	0–7
		HCOs	17	15.18 (38.31)	0–144	0	0–7
		LCOs	17	0.29 (0.85)	0–3	0	0–0
Contaminated sampling	Olympus TJF 145	Total microbial load ^a	6	160.00 (76.49)	9–202	202	101–202
		HCOs	6	185.17 (41.23)	101–202	202	202–202
		LCOs ^b	0	-	-	-	-
	Olympus TJF 160	Total microbial load ^a	13	194.47 (350.28)	1–1001	20	9–101
		HCOs	12	238.92 (381.19)	6–1001	60.5	9.5–300.5
		LCOs 11–100 CFU/duodenoscope	1	39	39	39	39
	Olympus TJF Q180V	Total microbial load ^a	11	82.61 (145.57)	1–400	5	2–40
		HCOs	8	126.87 (174.22)	1–400	4	2–301
		LCOs 11–100 CFU/duodenoscope	2	26.00 (19.80)	12–40	26	12–40
		LCOs >100 CFU/duodenoscope	1	137	137	137	137
	Other duodenoscopes	Total microbial load ^a	7	49.37 (61.72)	2–144	9	7–108.5
		HCOs	7	36.86 (54.61)	2–144	8	7–80
		LCOs ^b	0	-	-	-	-

SD, standard deviation; IQR, interquartile range.

^a Only samples with LCOs >10 CFU/duodenoscope or presence of just one HCO.

^b >10 CFU/duodenoscope.

with an LCO >100 CFU/duodenoscope (137 CFU/duodenoscope) (Table I). Table II shows the mean values for total microbial load, HCOs and LCOs for the duodenoscope models analysed.

This study did not find any significant differences between duodenoscope models. Of the Olympus duodenoscopes, the TJF Q180V model presented the lowest mean microbial load (82.61 CFU/duodenoscope), even when considering HCOs alone (126.87 CFU/duodenoscope). The most widely represented HCOs were *Pseudomonas* spp. (23.26%), *E. coli* (18.60%) and *P. aeruginosa* (13.95%). *Klebsiella pneumoniae* was found in 9.30% of samples (Figure 2).

Of the LCOs, coagulase-negative *Staphylococcus* spp. were found in 38.46% of samples, and *Micrococcus luteus* was found in 15.38% of samples (Figure 3). Of the 15 operative units participating in the study, five (33.33%) (OU 6, OU 7, OU 9, OU 10 and OU 12) recorded 100% non-contaminated samples, collected from a total of 13 duodenoscopes (one to four duodenoscopes analysed for each operative unit).

More than half of the operative units found contamination with HCOs within their duodenoscopes; only one operative unit had 100% contaminated samples with HCOs (OU 15: nine samples from three duodenoscopes) (Figure 4).

Discussion and conclusions

Endoscopic procedures are well established in gastrointestinal endoscopy, playing an integral part in the

prevention, diagnosis and treatment of gastrointestinal diseases [17]. Exposure to biological fluids, including blood and secretions, subjects flexible endoscopes to contamination [23]. Cleaning is a critical issue due to the internal complexity of endoscopes, characterized by narrow lumens and multiple internal channels. Endoscope reprocessing is a daunting task which includes manual cleaning and high-level disinfection, followed by rinsing and drying before appropriate storage. Due to the complex internal structure of endoscopes, and tenacious microbial contamination of the internal parts, biofilms can persist even when reprocessing is performed in accordance with international and manufacturer guidelines. Duodenoscopes are more difficult to reprocess than other flexible endoscopes. This is due to their more complex design, which includes a side viewing tip, forceps elevator and elevator channel [24]. The presence of multi-drug-resistant strains in devices used for endoscopy may have serious consequences for health.

Several infections and outbreaks caused by multi-drug-resistant micro-organisms following endoscopic procedures (e.g. ERCP) have been reported [25–30]. Aumeran et al. [26] reported a duodenoscope-associated outbreak with extended-spectrum beta lactamase (ESBL)-producing *K. pneumoniae*. Similarly, Bajolet et al. [27] reported an outbreak at a hospital in Reims, France in 2011, which was traced to a single endoscope contaminated with ESBL-producing *P. aeruginosa*. Epstein et al. reported a cluster of New Delhi metallo-β-lactamase-producing *E. coli* infections associated with ERCP [11].

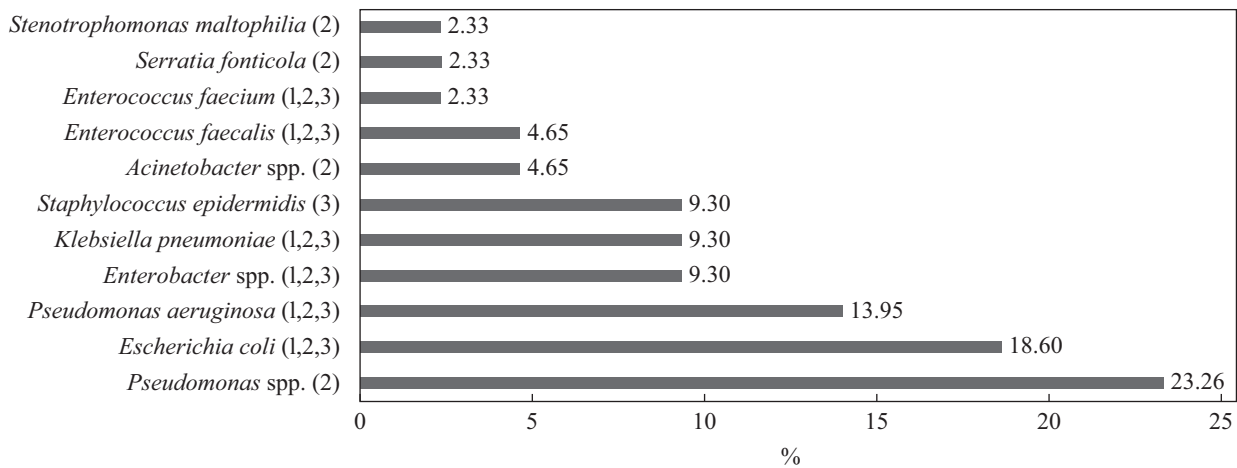


Figure 2. Percentage distribution of high-concern organisms. 1, Centers for Disease Control and Prevention; 2, Gastroenterological Society of Australia—Gastroenterological Nurses College of Australia; 3, European Society of Gastroenterology and Endoscopy Nurses and Associates.

The present study on the microbiological surveillance of duodenoscopes, performed on a national scale, involved 15 digestive endoscopy units and a total of 51 sampled duodenoscopes, mainly Olympus models (TJF Q180V, TJF 160 and TJF 145), with a few duodenoscopes from other manufacturers (15.69%). Monitoring was performed after reprocessing (55.56% of samples) or during storage in a cabinet (mostly compliant with EN 16442:2015). Considering all of the samples collected ($N=144$) and regardless of the timing of sampling, 36.81% of the samples analysed were positive for at least one HCO/LCO. Greater levels of contamination were observed in a study conducted by Ribeiro *et al.* [31], which evaluated contamination in reprocessed endoscopes (gastrosopes and colonoscopes). Contamination was detected in 71.8% (28/39) of the samples obtained from the air/water channels of colonoscopes, and in 70% (42/60) of the samples from the air/water channels of gastrosopes.

The CDC protocol states that microbiological non-conformity of duodenoscopes corresponds with the presence of any HCOs,

or any microbial load ≥ 10 CFU/duodenoscope of LCOs [21]. Action is needed if any HCOs are present or if LCOs exceed 100 CFU/duodenoscope as this is indicative of inadequate reprocessing and/or damage to the endoscope. In the present study, the reasons for taking corrective action were mainly due to HCOs. Indeed, only one sample showed LCO contamination >100 CFU/duodenoscope (137 CFU/duodenoscope), while HCOs were found in 33 samples with a mean concentration of 159.12 (SD 251.91) CFU/duodenoscope (maximum 1001 CFU/duodenoscope).

A previous study by the present authors involved post-reprocessing microbiological surveillance of duodenoscopes in the operative unit of an Italian hospital over a 3-year period [32]. Samples displayed contamination with *P. aeruginosa*, *K. pneumoniae*, *K. oxytoca*, *S. maltophilia*, *A. baumannii*, *E. coli* and other micro-organisms. The highest levels of contamination detected were *P. aeruginosa* (2500 CFU/duodenoscope), *K. pneumoniae* (2580 CFU/duodenoscope) and *A. baumannii* (2600 CFU/duodenoscope). The contaminated devices were sent

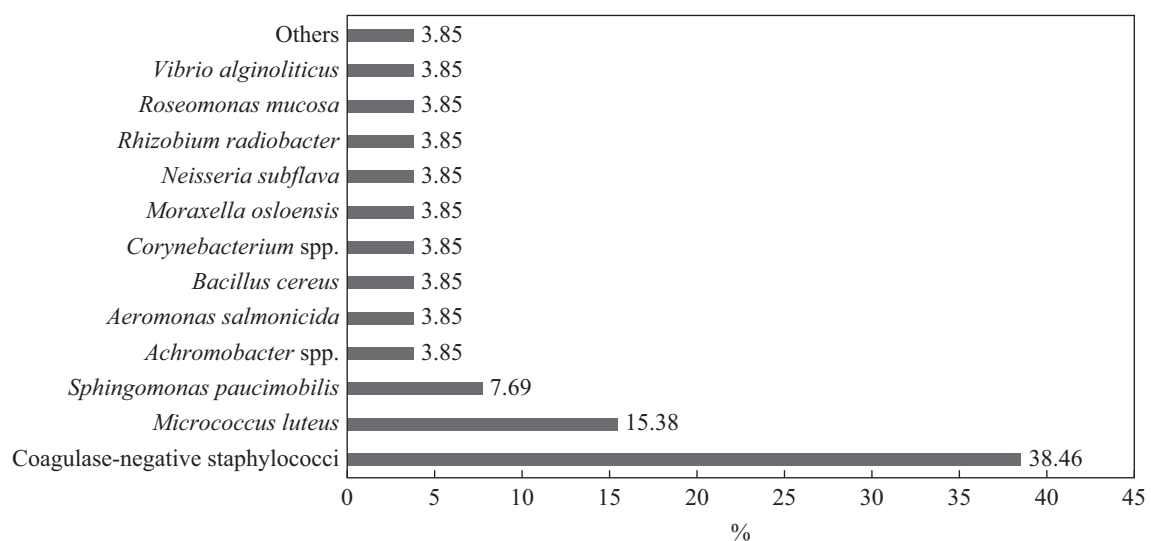


Figure 3. Percentage distribution of low-concern organisms.

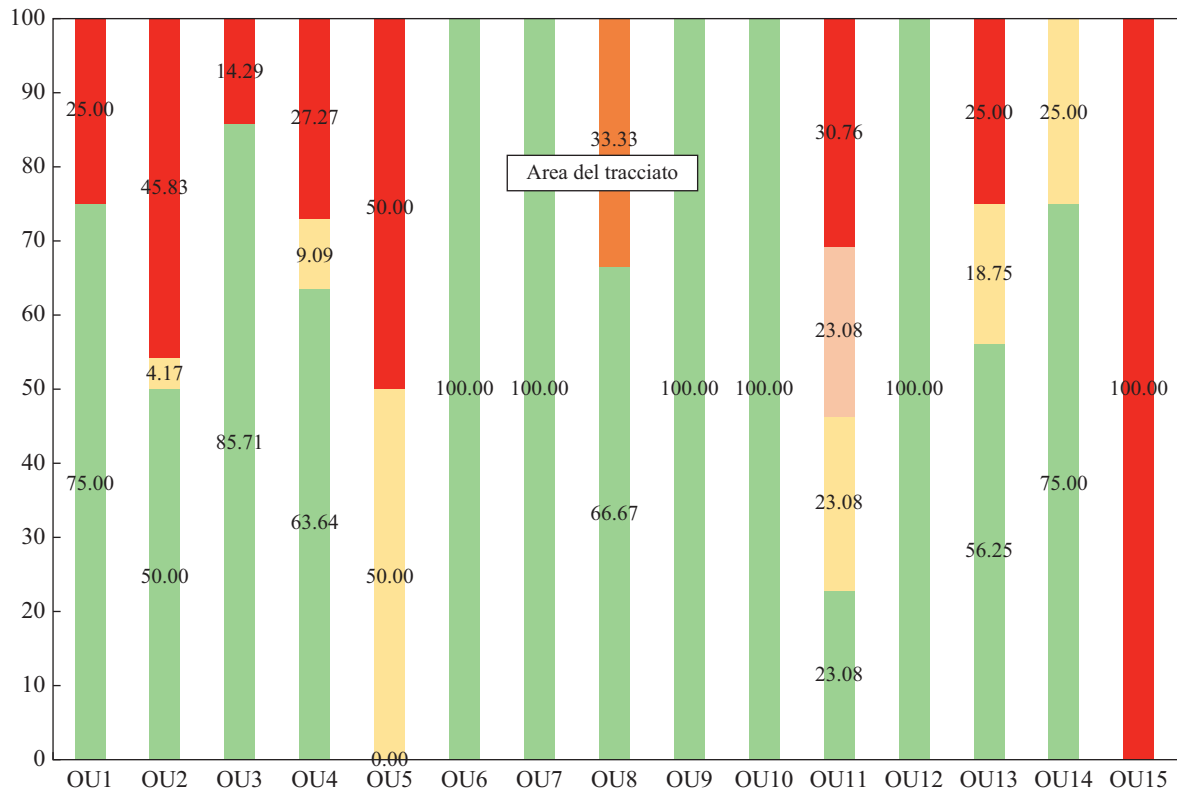


Figure 4. Conformity and non-conformity rates of high-concern organisms and low-concern organisms in the operative units (OUs). Green bars, compliant; yellow bars, low-concern organisms <10 colony-forming units (CFU)/duodenoscope; light orange bar, low-concern organisms 11–100 CFU/duodenoscope; dark orange bar, low-concern organisms >100 CFU/duodenoscope; red bars, high-concern organisms.

to the manufacturer for evaluation. Audits were carried out with the personnel responsible for reprocessing, with the aim of optimizing the procedures used. Subsequently, only one case of non-conformity was found, confirming the importance of staff training.

In addition to reprocessing, other factors can contribute to microbial contamination of duodenoscopes, including appropriate storage in dedicated cabinets in accordance with EN 16442:2015. In the present study, the percentages of contaminated samples were 27.50%, 40.00% and 100% for samples taken after reprocessing, during storage in a C-I cabinet, and during storage in an NC-I cabinet, respectively. The percentages of HCOs were 15.00%, 27.27% and 66.67%, respectively. Concerning the possible effect of storage time on microbial contamination, the Italian Association for Endoscopy Technical Operators and the National Association of Gastroenterology and Associated Nurses suggest reprocessing the devices as a precaution after 72 h of storage [33]. However, there is currently an ongoing debate about the real need to reprocess endoscopes after 72 h of storage. According to the American Society for Gastrointestinal Endoscopy, the available data suggest that contamination during appropriate storage for intervals of 7–14 days is negligible, is not associated with duration, occurs only on the exterior of instruments, and only involves common skin organisms rather than significant pathogens [34]. A systematic review identified 10 studies investigating hang time for flexible endoscopes, with no change in the rate of contamination over the hang time duration studied (at least 2–7 days, including up

to 56 days) [35,36]. Furthermore, Cottarelli *et al.* [37] found no significant association between longer storage times and the risk of detection of pathogens. In the present study, endoscopes were stored for a time ranging from a few hours to 15 days. Correlation was only found between LCO contamination and storage time (obs=64; Spearman's rho=0.3701; $P=0.0026$).

Contamination due to the structural complexity of these devices can differ according to brand and model. In 2015, FDA ordered all duodenoscope manufacturers to conduct post-market surveillance studies to assess duodenoscope contamination rates following high-level disinfection, and to identify the factors causing duodenoscope contamination [38]. In the present study, of the Olympus duodenoscopes sampled, the TJF Q180V model presented the lowest rate of contaminated samples (29.82%) and the lowest mean total microbial load [82.61 (SD 145.57) CFU/duodenoscope] and HCO load [126.87 (SD 174.22) CFU/duodenoscope], although these contamination levels are still high and concerning. However, analysis of the data, using all the samples, showed that the differences between various duodenoscope models were not significant. In a similar study by Rauwers *et al.* [24] that analysed duodenoscopes of different brands and models, contamination was not found to be type-dependent ($P>0.05$).

The results provided by the 15 participating operative units showed a highly diverse conformity rate among the analysed duodenoscopes. Five operative units reported 100% compliance, corresponding to 13 sampled duodenoscopes, while in other operative units, high rates of non-compliance were

observed, which were also associated with HCO contamination (OU 15 had 100% of samples contaminated with HCOs). These results suggest a possible difference in the effectiveness of reprocessing and/or storage procedures in the various operative units.

In conclusion, the high percentage (36.81%) of contaminated samples observed in this study highlights the potential risk of pathogen transmission via duodenoscopes. In order to reduce the risk of patient infection, FDA recommended the use of disposable components (endcaps) or fully disposable duodenoscopes in August 2019 [39]. However, the cost of disposable parts will be high, and the large amount of medical waste generated each year will have a negative impact on the environment [38]. Therefore, duodenoscope surveillance by microbiological culturing, along with strict adherence to reprocessing protocols, may help to detect endoscope contamination at an early stage and reduce the risk of transmission of duodenoscope-associated infections.

Conflict of interest statement

None declared.

Funding sources

None.

Appendix

Study Group Collaborators: L. Baroncelli (Ospedali Riuniti di Livorno); P. Castiglia (Università di Sassari); M. De Giusti (A.O. Universitaria Policlinico Umberto I, Roma); M.M. Distefano, A.M. Longhitano (A.O. Cannizzaro, Catania); P. Laganà (Università di Messina); B. Mentore (ASL4 Lavagna, Genova); F. Canale, F. Mantero, M. Opezzi (E.O. Ospedali Galliera, Genova); E. Marciano, L. Zurlo (A.O.U. Pisana), A. Segata (APSS Trento); I. Torre (Università di Napoli "Federico II"); D. Vay (Azienda Sanitaria Ospedaliera S.S. Antonio e Biagio e C. Arrigo, Alessandria); E. Vecchi (A.O. Universitaria di Modena); S. Vincenti (Fondazione Policlinico Universitario Agostino Gemelli, Roma)

References

- [1] Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. *World J Gastrointest Endosc* 2014;6:457–74.
- [2] Centers for Disease Control and Prevention. Interim protocol for healthcare facilities regarding surveillance for bacterial contamination of duodenoscopes after reprocessing. Atlanta, GA: CDC; 2015. Available at: <https://www.orangecountygov.com/DocumentCenter/View/246/Interim-Protocol-for-Healthcare-Facilities-Regarding-Surveillance-for-Bacterial-Contamination-of-Duodenoscopes-after-Reprocessing-PDF> [last accessed April 2022].
- [3] Rubin ZA, Murthy RK. Outbreaks associated with duodenoscopes: new challenges and controversies. *Curr Opin Infect Dis* 2016;29:407–41.
- [4] US Senate. Health, Education, Labor and Pensions Committee. Preventable tragedies: superbugs and how ineffective monitoring of medical device safety fails patients. Washington, DC: US Senate; 2016. Available at: <https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf> [last accessed April 2022].
- [5] Petersen BT, Koch J, Ginsberg GG. Infection using ERCP endoscopes. *Gastroenterology* 2016;151:46–50.
- [6] Ross AS, Baliga C, Verma P, Duchin J, Gluck M. A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant *Escherichia coli*. *Gastrointest Endosc* 2015;82:477–83.
- [7] Verfaillie CJ, Bruno MJ, Voor in 't Holt AF, Buijs JG, Poley JW, Loeve AJ, et al. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*. *Endoscopy* 2015;47:493–502.
- [8] Kovaleva J, Meessen NE, Peters FT, Been MH, Arends JP, Borgers RP, et al. Is bacteriologic surveillance in endoscope reprocessing stringent enough? *Endoscopy* 2009;41:913–6.
- [9] Emergency Care Research Institute. Top 10 health technology hazards for 2018: executive brief. Elkins Park, PA: ECRI; 2018. Available at: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_18.pdf [last accessed April 2022].
- [10] Archibald LK, Jarvis WR. Health care-associated infection outbreak investigations by the Centers for Disease Control and Prevention, 1946–2005. *Am J Epidemiol* 2011;174:S47–64.
- [11] Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, et al. New Delhi metallo- β -lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA* 2014;312:1447–55.
- [12] Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterol Nurs* 2010;33:304–11.
- [13] US Food and Drug Administration. FDA warns duodenoscope manufacturers about failure to comply with required postmarket surveillance studies to assess contamination risk. Silver Spring, MD: FDA; 2018. Available at: <https://www.fda.gov/news-events/press-announcements/fda-warns-duodenoscope-manufacturers-about-failure-comply-required-postmarket-surveillance-studies#:~:text=As%20part%20of%20an%20ongoing,healthcare%20facilities%20were%20able%20to> [last accessed April 2022].
- [14] US Food and Drug Administration. Updated status of Pentax medical duodenoscope model ED-3490tk: FDA safety communication. Silver Spring, MD: FDA; 2018. Available at: <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-clears-design-changes-pentax-duodenoscope-improve-cleaning-and-disinfection-voluntary> [last accessed May 2022].
- [15] US Food and Drug Administration. The FDA continues to remind facilities of the importance of following duodenoscope reprocessing instructions: FDA Safety Communication. Silver Spring, MD: FDA; 2019. Available at: <https://www.fda.gov/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda> [last accessed April 2022].
- [16] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
- [17] Beilenhoff U, Biering H, Blum R, Brljak J, Cimbro M, Dumonceau JM, et al. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – update 2018. *Endoscopy* 2018;50:1205–34.
- [18] Casini B, Pan A, Guarini A, Rivara C, Zullo A, Monica F, et al. Multisocieties position paper: microbiological surveillance on flexible endoscopes. *Dig Liver Dis* 2021;53:1105–11.
- [19] Marchese V, Di Carlo D, Fazio G, Gioè SM, Luca A, Alduino R, et al. Microbiological surveillance of endoscopes in a southern Italian transplantation hospital: a retrospective study from 2016 to 2019. *Int J Environ Res Public Health* 2021;18:3057.

- [20] Cristina ML, Valeriani F, Casini B, Agodi A, D'Errico MM, Gianfranceschi G, et al. Procedures in endoscope reprocessing and monitoring: an Italian survey. *Ann Ig* 2018;30:45–63.
- [21] Centers for Disease Control and Prevention. Duodenoscope surveillance sampling and culturing protocols. Atlanta, GA: CDC; 2018. Available at: <https://www.fda.gov/media/111081/download> [last accessed April 2022].
- [22] Gastroenterological Society of Australia. Microbiological testing of endoscopes clinical guideline. Adelaide: GESA; 2017. Available at: https://www.sahealth.sa.gov.au/wps/wcm/connect/d7ba9e80412adf23ba45bee8f09fe17d/Microbiological+Testing+of+Endoscopes+Clinical+Guideline__14.06.2017.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-d7ba9e80412adf23ba45bee8f09fe17d-nzp23WY [last accessed May 2022].
- [23] Valeriani F, Agodi A, Casini B, Cristina ML, D'Errico MM, Gianfranceschi G, et al. Potential testing of reprocessing procedures by real-time polymerase chain reaction: a multicenter study of colonoscopy devices. *Am J Infect Control* 2018;46:159–64.
- [24] Rauwers AW, Voor In 't Holt AF, Buijs JG, de Groot W, Hansen BE, Bruno MJ, et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut* 2018;67:1637.
- [25] Gastmeier P, Vonberg RP. *Klebsiella* spp. in endoscopy-associated infections: we may only be seeing the tip of the iceberg. *Infection* 2014;42:15–21.
- [26] Aumeran C, Poincloux L, Souweine B, Robin F, Laurichesse H, Baud O, et al. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy* 2010;42:895–9.
- [27] Bajolet O, Ciocan D, Vallet C, de Champs C, Vernet-Garnier V, Guillard T, et al. Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing *Pseudomonas aeruginosa*. *J Hosp Infect* 2013;83:341–3.
- [28] Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, et al. Independent root-cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to investigate an outbreak of multidrug-resistant *Klebsiella pneumoniae*. *Gastrointest Endosc* 2019;90:793–804.
- [29] Cristina ML, Sartini M, Ottria G, Schinca E, Cenderello N, Crisalli MP, et al. Epidemiology and biomolecular characterization of carbapenem-resistant *Klebsiella pneumoniae* in an Italian hospital. *J Prev Med Hyg* 2016;57:E149–56.
- [30] Cristina ML, Spagnolo AM, Cenderello N, Fabbri P, Sartini M, Ottria G, et al. Multidrug-resistant *Acinetobacter baumannii* outbreak: an investigation of the possible routes of transmission. *Public Health* 2013;127:386–91.
- [31] Ribeiro MM, de Oliveira AC. Analysis of the air/water channels of gastrointestinal endoscopies as a risk factor for the transmission of microorganisms among patients. *Am J Infect Control* 2012;40:913–6.
- [32] Cristina ML, Sartini M, Schinca E, Ottria G, Dupont C, Bova P, et al. Is post-reprocessing microbiological surveillance of duodenoscopes effective in reducing the potential risk in transmitting pathogens? *Int J Environ Res Public Health* 2020;17:140.
- [33] Italian Association for Endoscopy Technical Operators, National Association of Gastroenterology and Associated Nurses. Linee guida pulizia e disinfezione in endoscopia – update 2011. ANOTE, ALIGEA; 2011. Available at: <https://www.aocosenza.it/files/storage/LINEE%20GUIDA%20DOCUMENTALE/DIPARTIMENTO%20CARDIO-TORACO-VASCOLARE/UOSD%20BRONCOSCOPIA%20INTERVENTISTICA/2011%20linee-guida-Reprocessing%20strumenti%20endoscopici.pdf> [last accessed April 2022].
- [34] American Society for Gastrointestinal Endoscopy Quality Assurance in Endoscopy Committee, Petersen BT, Chennat J, Cohen J, Cotton PB, Greenwald DA, et al. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. *Gastrointest Endosc* 2011;73:1075–84.
- [35] Heroux R, Sheppard M, Wright SB, Sawhney M, Hirsch EB, Kalaidjian R, et al. Duodenoscope hang time does not correlate with risk of bacterial contamination. *Am J Infect Control* 2017;45:360–4.
- [36] Schmelzer M, Daniels G, Hough H. Safe storage time for reprocessed flexible endoscopes: a systematic review. *JBI Database System Rev Implement Rep* 2015;13:187–243.
- [37] Cottarelli A, De Giusti M, Solimini AG, Venuto G, Palazzo C, Del Cimmuto A, et al. Microbiological surveillance of endoscopes and implications for current reprocessing procedures adopted by an Italian teaching hospital. *Ann Ig* 2020;32:166–77.
- [38] Okamoto N, Sczaniecka A, Hirano M, Benedict M, Baba S, Horino Y, et al. A prospective, multicenter, clinical study of duodenoscope contamination after reprocessing. *Infect Control Hosp Epidemiol* 2022. <https://doi.org/10.1017/ice.2021.525>.
- [39] US Food and Drug Administration. FDA recommends healthcare facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection. Silver Spring, MD: FDA; 2019. Available at: <https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable> [last accessed April 2022].