EVIDENCE DOSSIER

Ambu® aScope™ Gastro

Ambu

June 2022, 1st edition

This document includes published peer-reviewed studies and conference abstracts on contaminated gastroscopes, infectious outbreaks, and organizational impact issues associated with reusable gastroscopes.

All included studies substantiate the clinical or organizational reasoning behind introducing Ambu aScope Gastro single-use gastroscope.

CONTENTS

ABBREVIATIONS

AER: Automatic endoscope reprocessor

CFU: Colony-forming units

CI: Confidence interval

E. coli: Escherichia coli

EGD: Esophagogastroduodenoscopy

FDA: Food & Drug Administration

HLD: High-level disinfection

K. pneumoniae: Klebsiella pneumoniae

MAUDE: Manufacturer and User Facility Device Experience

OR: Odds ratio

P. aeruginosa: Pseudomonas aeruginosa

RCT: Randomized controlled trial

SHLD: Single high-level disinfection

WGS: Whole genome sequencing

PREFACE

This dossier will help you get an overview of the clinical landscape underpinning the need for Ambu aScope Gastro, a single-use gastroscope, and aBox and aView monitoring systems. The introduction summarizes data derived from FDA Manufacturer and User Facility Device Experience (MAUDE) reports concerning the risks of cross-contaminated reusable gastroscopes. The main section is comprised of relevant studies and conference abstracts, published from January 2010 to April 2021, related to contamination, infectious outbreaks, and organizational impact issues associated with reusable gastroscopes. The last section offers an introduction to the benefits of aScope Gastro and Ambu® aBox™ 2, the most innovative Ambu plug-and-play live imaging processor. aBox 2 is designed for use with single-use Ambu gastroscopes. Advanced image processing helps ensure continuous optimization of imaging.

Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an inquiry to U.S. Director of Health Economics and Market Access Christina Cool (ccool@ambu.com)

In an effort to include all known data, irrespective of the outcome, a systematic literature search was conducted for this dossier, giving the reader every opportunity to obtain a balanced overview of the clinical data. The study titles are taken from the publications as they appear in their original form, allowing the reader to make a perfectly accurate internet search should they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall clinical landscape, and need for introducing aScope Gastro, and assists you in your day-to-day evidence-based practice.

While every effort has been made to provide accurate information, we will be pleased to correct any errors or omissions brought to our notice in subsequent editions.

A HISTORY OF BREAKTHROUGH IDEAS

Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety, and performance of our single-use endoscopy, anesthesia, and patient monitoring & diagnostics solutions. The manifestations of our efforts have ranged from early innovations like the Ambu® Bag™ resuscitator and the Ambu® BlueSensor™ electrodes to our newest landmark solutions like Ambu aScope – the world's first single-use flexible endoscope. Moreover, we continuously look to the future with a commitment to deliver innovative quality products, like Ambu aScope Duodeno, which have a positive impact on your work. As the world's leading supplier of single-use endoscopes, Ambu leads by example offering a service to help you dispose of our endoscopes in the most cost-effective, risk-free and eco-friendly way possible.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,000 people in Europe, North America, and the Asia-Pacific region.

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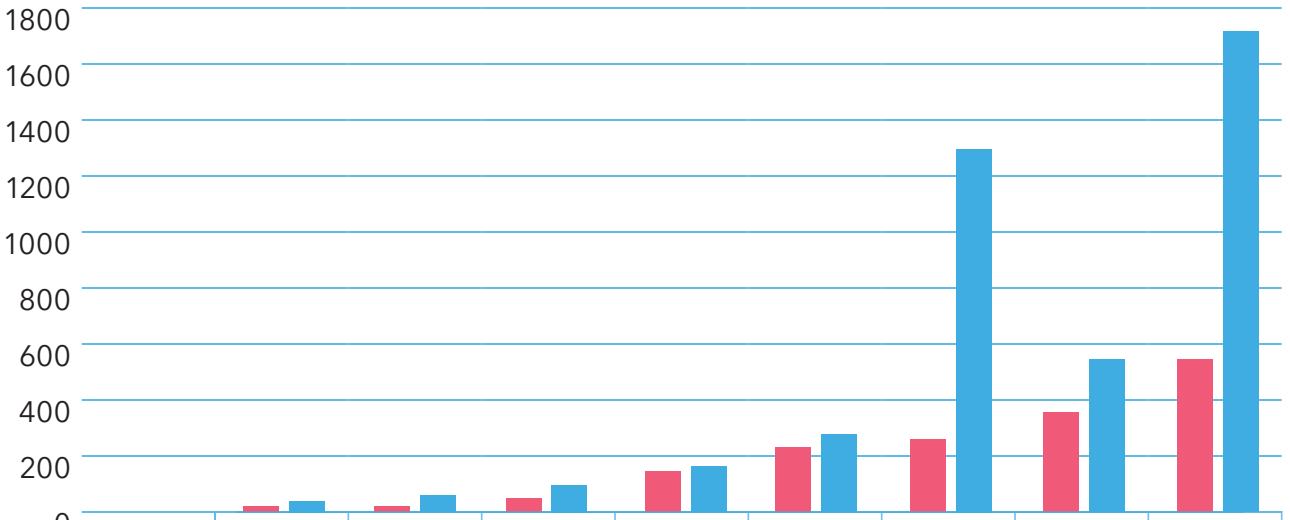
FDA MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) REPORTS

The FDA MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as healthcare professionals, patients and consumers. MAUDE data includes reports of adverse events involving medical devices.

MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. However, when looking at MAUDE reports submitted to the FDA concerning reusable gastroscopes, it is possible to get an indication of the increased awareness related to reprocessing errors and contamination of reusable gastroscopes.

The graph below shows all submitted MAUDE reports for reusable gastroscopes within the category "Malfunction." Within this category, it was possible to identify reports concerning "Device Reprocessing Problems," "Microbial Contamination of Device," "Device Contamination With Biological Material" and "Contamination/Decontamination Problems." [1]



	2014	2015	2016	2017	2018	2019	2020	2021
Reprocessing & Contamination Issues	4	4	49	131	228	251	353	535
Malfunction Total	16	18	78	156	269	1305	545	1695

Reprocessing & Contamination Issues Malfunction Total

"TOP 10 HEALTH TECHNOLOGY HAZARDS" BY ECRI FROM 2010 TO 2020

For the past 10 years, endoscope reprocessing has reached ECRI's top-10 list. ECRI writes in its report that sterile processing failures "can lead to surgical site infections, which have a 3% mortality rate and an associated annual cost of $3.3 billion".

Below is a table showing how endoscope reprocessing and cross-contamination have ranked on the ECRI top-10 list since 2010:

Years	Number on ERCI list	Headline of techonology hazard
2020	5	"Device Cleaning, Disinfection, and Sterilization"
2019	5	"Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections"
2018	2	"Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk"
2017	2	"Inadequate Cleaning of Complex Reusable Instruments Can lead to Infections"
2016	1	"Inadequate Cleaning Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens"
2015	4	"Inadequate Reprocessing of Endoscopes and Surgical Instruments"
2014	6	"Inadequate Reprocessing of Endoscopes and Surgical Instruments"
2013	8	"Inadequate Reprocessing of Endoscopic Devices and Surgical Instruments"
2012	4	"Cross-contamination from Flexible Endoscopes"
2011	3	"Cross-contamination from Flexible Endoscopes"
2010	1	"Cross-contamination from Flexible Endoscopes"

SUPPORTING EVIDENCE-BASED PRACTICE WITH BEST AVAILABLE EVIDENCE

Evidence-based decision making is key when purchasing new devices. The core principle of evidence-based practice is the hierarchy of evidence, which identifies the best available evidence for a given clinical question. This document will not go into detail with the different levels of evidence, but instead provide an easy overview that indicates the quality of the respective study based on the system below.

Studies rated as “low quality of evidence” include conference abstracts, editorials, commentaries, and case reports. Studies rated as “medium quality of evidence” include descriptive studies, cohort studies, case-controls, and meta-analyses based on non-RCT studies. Lastly, studies rated as “high quality of evidence” include RCT studies and meta-analyses based on RCT studies.

LOW QUALITY OF EVIDENCE

MEDIUM QUALITY OF EVIDENCE

HIGH QUALITY OF EVIDENCE

HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Three major scientific online databases, PubMed (MEDLINE), Embase and Web of Science, were searched for all relevant articles up to April 1, 2021. Articles published in the English language within the areas of infection control, performance and health economics were included. Commentaries, letters to the editor, book chapters, and publications with no clinical or economic relevance were excluded. This document only includes studies published after 2010, in order to provide the reader with the most up-to-date studies.

This evidence dossier includes summaries of eight published peer-reviewed studies and three conference abstracts related to esophagogastroduodenoscopy (EGD) procedures.

PEER-REVIEWED STUDIES AND CONFERENCE ABSTRACTS

Contaminated gastroscopes

★★☆ Infection Control Not open access

TAKEAWAY

From January 2008 to June 2015, microbiological tests of 762 gastrointestinal endoscopes were performed. A total of 264 endoscope tests (34.6%) showed a level of contamination higher than the target (<25 colony-forming units [CFUs]). To improve the detection of contaminated endoscopes, samples should be cultured for more than two days. Particular attention should be paid to endoscopes older than 2 years and to those that are not stored in storage cabinets.

KEY FINDINGS

- **A total of 264 endoscope tests (34.6%) showed a level of contamination higher than the target (<25 CFU).**
- **After 2 days of incubation, contamination was apparent in only 55.5% of the endoscopes that were later shown to be contaminated (95% confidence interval [CI] 49.2 - 61.8).**
- **Multivariable analysis showed that the use of storage cabinets for heat-sensitive endoscopes significantly reduced the risk of endoscope contamination (odds ratio [OR] 0.23, 95% CI 0.09 - 0.54; P< 0.001).**
- **The use of endoscopes older than 4 years significantly increased this risk of contamination (OR > 6 vs. < 2 years 2.92, 95% CI 1.63 - 5.24; P< 0.001).**
- **Most of the contaminated endoscopes (n=225) reached the action level (> 100 CFU), and only 39 microbiological tests reached the alert level (25-100 CFU).**

Measures to improve microbial quality surveillance of gastrointestinal endoscopes, Endoscopy[2]

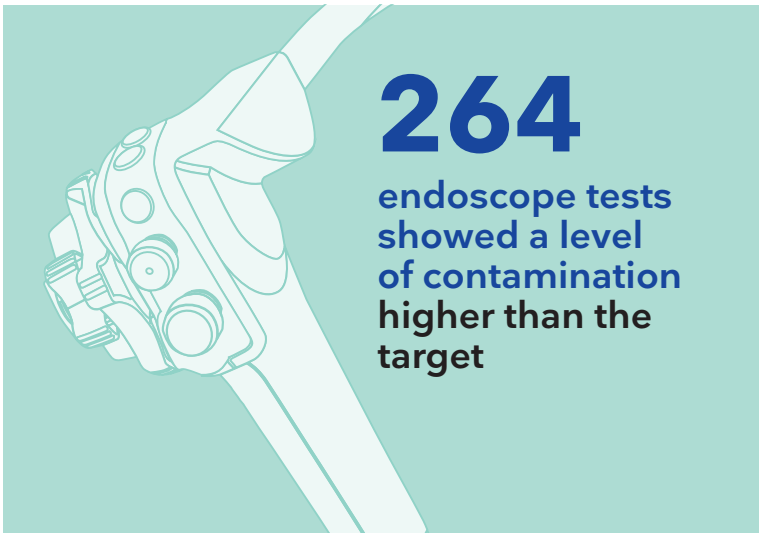
Saliou et al., 2015

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 microbial quality surveillance of gastrointestinal endoscopes.

METHODS

- The authors reviewed the results of all microbiological surveillance testing of gastrointestinal endoscopes and automatic endoscope reprocessors (AERs) performed at Brest Teaching Hospital from January 2008 to June 2015.
- The influence of the time of incubation on the rate of positive results was analysed. Risk factors for gastrointestinal endoscope contamination, such as the age of the endoscopes, were studied as well.
- The sampling included microbiological tests of gastrointestinal endoscopes and was performed: gastroscopes (n=271), colonoscopes (n=190), duodenoscopes (n=118), echoendoscopes (n=113), transnasal gastroscopes (n=48), enteroscopes (n=17), and choledoscopes (n=5).



★★☆ Infection Control Open access

TAKEAWAY

In phase I, 3 out of 107 (2.8%) samples from reprocessed gastroscopes were contaminated. In phase II, 4 out of 122 (3.3%) samples from reprocessed gastroscopes were contaminated. The authors concluded: "In the present study the contamination rate of endoscopes was low compared with results from other European countries, possibly due to the high quality of endoscope reprocessing, drying and storage".

KEY FINDINGS

- **29 of 36 (81%) endoscopy centers took part in the anonymous Tyrolean Endoscope Hygiene Surveillance study.**
- **In phase I, 107 gastroscopes and 51 AERs were investigated, and in phase II, 122 gastroscopes and 54 AERs were investigated.**
- **In phase I, 3 out of 107 (2.8%) samples from reprocessed gastroscopes were contaminated. Samples included the following bacteria: *Sphingomonas parasanguinis, Streptococcus viridans and Moraxella osloensis.***
- **In phase II, 4 out of 122 (3.3%) samples from reprocessed gastroscopes were contaminated. Samples included the following bacteria: *Pseudomonas oleovorans, Pseudomonas aeruginosa, Streptococcus sanguinis and Moraxella osloensis.***

High-quality endoscope reprocessing decreases endoscope contamination, CMI[3]

Decristoforo et al., 2018

STUDY AIM

The aim of this multicenter prospective study was to evaluate the hygiene quality of endoscopes and automated endoscope reprocessors (AERs) in Tyrol/Austria.

METHODS

- In 2015 and 2016, a total of 463 GI endoscopes and 105 AERs from 29 endoscopy centers were analysed by a routine and a combined routine and advanced (CRA) sampling procedure and investigated for microbial contamination by culture-based and molecular-based analyses.
- All participating centers reprocessed the endoscopes adhering to the complete reprocessing chain (pre-cleaning, manual cleaning, AER, storing) recommended by the Austrian Society for Sterile Supply (ÖGSV) guidelines. Reprocessing of endoscopes was done directly after the GI procedure, and enzymatic agents were used for pre-cleaning in 83% of study centers.
- In 6 of 52 AERs (11.5%), no regular thermal self-disinfection was performed. The disinfectant used in AERs of all study members was exclusively based on glutaraldehyde.
- All samples were obtained by two hygiene experts and processed under highly aseptic conditions. All specimens were stored on ice and immediately transferred for further analyses.

PHASE 1

3 out of 107 samples from reprocessed gastroscopes were contaminated

Samples included the following bacteria: *Sphingomonas parasanguinis, Streptococcus viridans, and Moraxella osloensis*

PHASE 2

4 out of 122 samples from reprocessed gastroscopes were contaminated

Samples included the following bacteria: *Pseudomonas oleovorans, Pseudomonas aeruginosa, Streptococcus sanguinis, and Moraxella osloensis*

★★☆ Infection Control Not open access

TAKEAWAY

3 out of 29 (10.4%) samples from reprocessed gastroscopes were contaminated after having been stored for 48 hours over the weekend. Due to the length and the narrow lumen of the air/water channels, more bacteria were isolated from these channels compared with suction/biopsy channels.

KEY FINDINGS

- **Samples were collected from 20 flexible GI endoscopes (5 gastroscopes) in the endoscopy clinic on early Monday morning on 8 different dates between December 2005 and June 2006.**
- **Out of 160 potential scope tests over the course of the study, 19 could not be performed because of the unavailability of endoscopes.**
- **3 out of 29 (10.4%) samples from reprocessed gastroscopes were contaminated.**
- **The culturing method used in this study was not able to identify viruses, anaerobes or atypical bacteria.**
- **Bacteria and fungi were isolated from more air/water channels than suction/biopsy channels. Because the air/water channel is the longest channel and has a relatively narrow lumen, it is more difficult to properly dry, and improper drying increases the risk of microbial replication.**

Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes, AJIC[4]

Alfa et al., 2012

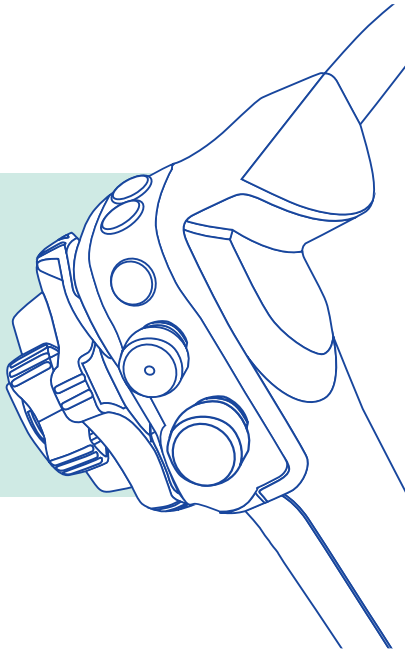
STUDY AIM

The primary aims of the study were to assess the bioburden level in routinely reprocessed flexible GI endoscopes that were stored over the weekend (for 48 hours), and to define a realistic benchmark for residual microbial levels.

METHODS

- All channels from 20 flexible GI endoscopes (5 gastroscopes, 9 colonoscopes and 6 duodenoscopes) used at St Boniface General Hospital's endoscopy clinic were tested periodically between December 2005 and June 2006.
- Endoscope channels were tested early Monday mornings on patient-ready scopes that had been stored unused in a closet over the weekend.
- Samples from air/water channels and suction/biopsy channels were collected into a sterile container by flushing 10 mL of sterile reverse-osmosis water, followed by 20 mL of air, through the entire length of each channel (from the light-guide end to the distal end of the insertion tube).

3 OUT OF 29
samples from reprocessed gastroscopes were contaminated



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TAKEAWAY

36 out of 72 (50%) samples from reprocessed gastroscopes were contaminated. However, the authors state that "We think that our findings are representative of China's endoscope reprocessing procedures."

KEY FINDINGS

- **36 out of 72 (50%) samples from reprocessed gastroscopes were contaminated.**
- ***Pseudomonas aeruginosa, Escherichia coli, Acinetobacter lwoffii and Stenotrophomonas maltophilia* were the most common bacteria detected.**
- **Many endoscopes failed to meet the national standard for microbial culture after reprocessing. These results suggest that using a pump-assisted method could increase the sensitivity of the test.**
- **China started late in the verification of endoscope reprocessing and has not yet established a systematic verification system.**

Microbiologic assessment of flexible gastrointestinal endoscope reprocessing using a pump-assisted sampling technique: an investigation involving all endoscopy units in Tianjin, China, AJIC[5]

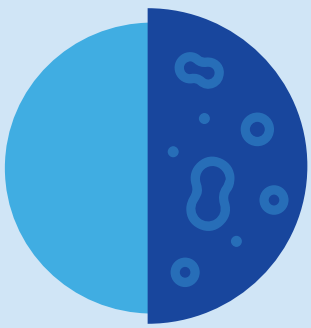
Ji et al., 2018

STUDY AIM

This study aimed to evaluate the contamination level and prevalence of bacteria of post-reprocessing endoscopes, and to access whether using a pump-assisted sampling method (PASM) improves the sensitivity of culture.

METHODS

- A total of 59 hospitals, located in all 16 districts of Tianjin, China, all of which perform gastrointestinal endoscope examination and treatment, were included in this study.
- 238 gastroscopes and 149 colonoscopes were distributed over these 59 endoscopy units.
- Sampling and testing were conducted according to the Hygienic Standard for Disinfection in Hospital, which is the Chinese national standard promulgated by the Chinese National Health and Family Planning Commission.
- 2 sampling techniques were used to sample flexible gastrointestinal endoscopes: (1) the conventional flushing sampling method, and (2) the pump-assisted sampling method.



36 OUT OF 72
samples from reprocessed gastroscopes were contaminated

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TAKEAWAY

32 out of 300 (10.7%) samples obtained from the biopsy channels of gastroscopes were positive. This was significantly higher than that obtained from AERs used to reprocess the gastroscopes (2.0%, 6/300). Therefore, findings from this study suggest that culturing rinse samples from biopsy channels can better indicate the effectiveness of decontamination of GI endoscopes after HLD than culturing swab samples from AERs, which can only indicate whether AERs are free from microbial contamination.

KEY FINDINGS

- **32 out of 300 (10.7%) samples obtained from the biopsy channels of gastroscopes were positive. This was significantly higher than that obtained from AERs used to reprocess the gastroscopes (2.0%, 6/300).**
- **Yeast-like bacteria were present in the swab samples obtained from the AERs used to reprocess gastroscopes but were absent from the samples obtained from the biopsy channels.**
- **Most of the aerobic bacteria present in the samples collected from the biopsy channels of gastroscopes (75.0% [24/32]) were glucose non-fermenting Gram-negative.**
- **The authors state: "... 100% decontamination of all GI endoscopes after HLD reprocessing may be impossible..."**

Surveillance cultures of samples obtained from biopsy channels and automated endoscope reprocessors after high-level disinfection of gastrointestinal endoscopes, BMC Gastroenterology[6]

Chiu et al., 2012

STUDY AIM

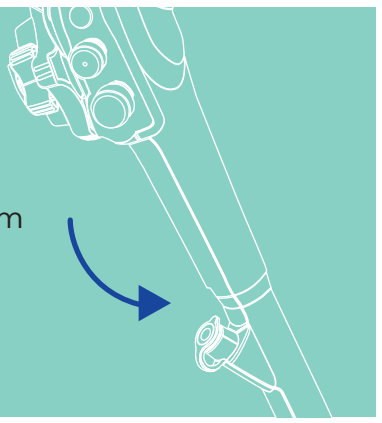
This study aimed to assess the effectiveness of decontamination using reprocessors after HLD by comparing the cultured samples obtained from biopsy channels of GI endoscopes and the internal surfaces of AERs.

METHODS

- This 5-year (February 2006–January 2011) prospective study was performed at Chang Gung Memorial Hospital, Kaohsiung Medical Centre, Taiwan.
- Random swab and biopsy channel samples were collected monthly from 7 AERs and 5 reprocessed gastroscopes.
- 300 rinse and swab samples were collected from biopsy channels of gastroscopes.
- Samples were collected by flushing the biopsy channels with sterile distilled water and swabbing the residual water from the AERs after reprocessing. These samples were cultured to detect the presence of aerobic and anaerobic bacteria and mycobacteria.

32 OUT OF 300

samples obtained from the biopsy channels of gastroscopes were positive



★★☆ Infection Control | Not open access

TAKEAWAY

Microorganism growth was detected in 70% (42 of 60) of the samples collected in the air/water channels of gastroscopes. These findings indicate that many air/water channels were still contaminated after reprocessing, representing a risk of cross-transmission of microorganisms among patients undergoing gastrointestinal endoscopic examinations.

KEY FINDINGS

- **Microorganism growth was detected in 70% (42 of 60) of the samples collected in the air/water channels of gastroscopes.**
- **Gram-negative microorganisms were detected in 38 samples (71.7%) collected from the air/water channels, mainly *P. aeruginosa (26.4%), Escherichia coli (18.9%), A. baumannii (9.4%) and K. pneumoniae (5.7%).***
- **In addition to the Gram-negative microorganisms, fungi (*Candida glabrata* and *Aspergillus spp.*) and mycobacteria (*Mycobacterium fortuitum*) were also detected in two samples (3.7%).**
- **Colonies were counted in 85.5% (36 of 42) of the samples obtained from the air/water channels of gastroscopes.**
- **The median microbial load in these channels was 750 CFU/mL (range: 100-33,000 CFU/mL).**
- **Contamination of the channels was most likely related to the lack of brushing of air/water channels during the cleaning process, or the failure to inject cleaning solution, disinfectant and water within the channels using manufacturer-recommended adaptors.**

Analysis of the air/water channels of gastrointestinal endoscopies as a risk factor for the transmission of microorganisms among patients, AJIC[7]

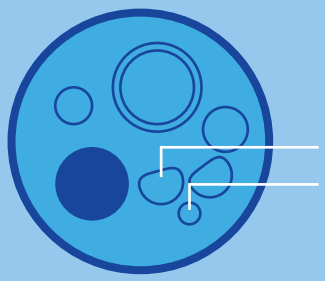
Ribeiro et al., 2012

STUDY AIM

The aim of the present study was to evaluate whether or not the air/water channels of gastrointestinal endoscopes represent a risk factor for the transmission of microorganisms in patients undergoing endoscopic procedures.

METHODS

- This study investigated gastrointestinal endoscopy services in Belo Horizonte, the capital of the state of Minas Gerais, Brazil, between August 2010 and March 2011.
- An invitation to participate in this study was delivered in person to all institutions performing gastrointestinal endoscopy services listed in the National Register of Health Services. 37 (61.7%) of these services agreed to participate in the study.
- Samples for analysis were collected from the air/water channels of endoscopes using sterile technique immediately after completion of the reprocessing procedures.
- The study opted for the "flush, brush, flush" method rather than the "flush" method for reprocessing, because of the former's greater sensitivity.
- For the air/water channels of Olympus and Fujinon endoscopes, the flush method was adopted because of the impossibility of achieving friction within these channels.



Microorganism growth was detected in

70%

of the samples collected in the air/water channels of gastroscopes

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TAKEAWAY

This meta-analysis demonstrates that 18.16% of patient-ready GI endoscopes may be contaminated when used in patients. These findings highlight that the elevator mechanism is not the only obstacle when reprocessing flexible reusable GI endoscopes. Additionally, these findings indicate that contamination issues are present in European health care settings, despite less acknowledgement compared to the United States. However, high heterogeneity and significant publication bias should be considered when interpreting these results.

KEY FINDINGS

- **Based on the inclusion criteria, the study identified seven European studies including 383 positive cultures from a total of 1,834 samples.**
- **The total weighted contamination rate was 18.16% ± 0.053 (95% confidence interval [CI]: 7.75% - 28.57%).**
- **I^2 indicated high heterogeneity (98.1%). Egger's regression test indicated significant publication bias (Egger's test of publication bias: p=0.0025).**

Gastrointestinal Endoscope Contamination Rate Beyond The Elevator: A Systematic Review And Meta-Analysis Based On European Data, Endoscopy[8]

Larsen et al., 2021

This study is a conference abstract presented at ESGE Days 2021.

STUDY AIM

The elevator has been suggested as a key factor in multiple European outbreaks associated with contaminated reusable patient-ready duodenoscopes. The outbreaks have led to increased focus on contamination of the elevator. However, numerous studies have documented microbes in gastrointestinal (GI) endoscopes without an elevator, and in the channels of both duodenoscopes and linear echoendoscopes. This study aimed to estimate the contamination rate beyond the elevator of GI endoscopes, based on currently available European data.

METHODS

- The electronic databases PubMed, Web of Science and Embase were searched from Jan. 1, 2010, until Oct. 10, 2020, for European studies investigating contamination rates of patient-ready GI endoscopes.
- Analysis and inclusion criteria were based on the PRISMA guidelines.
- A random-effects model based on the proportion distribution was used to calculate the total weighted contamination rate beyond the elevator of patient-ready GI endoscopes.
- Heterogeneity between the included studies was analyzed using the inconsistency index (I2) statistics. Publication bias was assessed using funnel plot and Egger's regression test.

The total weighted contamination rate was

18.16%

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TAKEAWAY

These study findings indicate that contamination issues of gastroscopes are acknowledged among European GI endoscopists. The average stated contamination rate across countries was 10.2% for gastroscopes. A total of 25.9% of the endoscopists were unaware of the reprocessing setup at their endoscopy unit.

KEY FINDINGS

- **Across all five countries, the average stated contamination rate was 10.2% for reusable gastroscopes.**
- **Italian GI endoscopists reported the highest contamination rate for gastroscopes (12.7%), whereas GI endoscopists from the UK reported the lowest contamination rate for gastroscopes (7.2%).**
- **The majority used HLD (31.2%) followed by double HLD (25.7%), whereas 25.9% of the respondents were unaware of the reprocessing setup at their endoscopy unit.**
- **There were no significant differences between the stated contamination rate and reprocessing method (p=0.2293).**
- **Endoscopists from the UK were most often unaware of the reprocessing method used (59.0%) followed by endoscopists from France (23.3%).**
- **There were no significant differences between stated contamination rates and annual procedure volume (p=0.0602).**

Stated Contamination Rates Associated With Reusable Colonoscopes And Gastroscopes Amongst European Endoscopists: A Survey-Based Investigation, Endoscopy[9]

Larsen et al., 2021

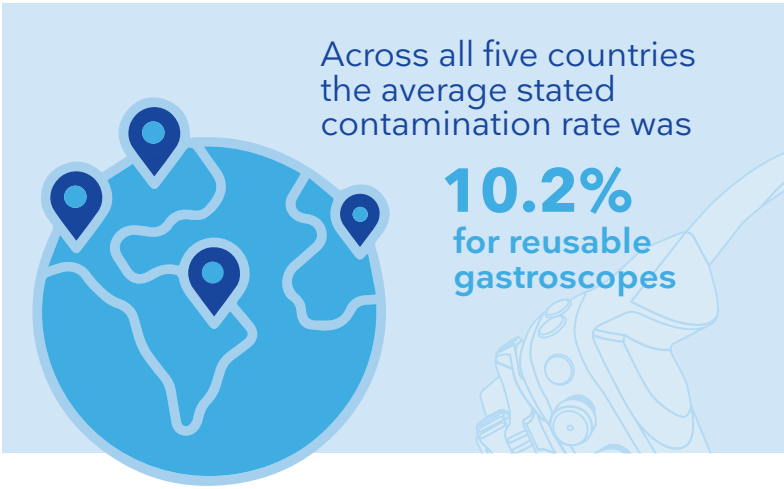
This study is a conference abstract presented at ESGE Days 2021.

STUDY AIM

Studies have demonstrated contamination rates of reusable colonoscopes and gastroscopes, which have led to several updates of reprocessing guidelines. This study aimed to investigate the contamination rate of colonoscopes and gastroscopes stated amongst gastrointestinal (GI) endoscopists in five European countries.

METHODS

- Between Sept. 24, 2020, and Oct. 12, 2020, a total of 459 GI endoscopists from the UK (n=100), France (n=90), Germany (n=72), Italy (n=99) and Spain (n=99) answered an electronic survey concerning perceived contamination rates and reprocessing setups.
- Data were collected using QuestionPro and analysed using Microsoft Excel.



Infectious outbreaks

★★☆ Infection Control Not open access

TAKEAWAY

Whole genome sequencing (WGS) surveillance combined with a machine-learning algorithm of the health record reviews identified a previously undetected outbreak of gastroscope-associated P. aeruginosa infections. Three infections could have been prevented if the machine-learning algorithm had been running in real time.

KEY FINDINGS

- **The study identified a cluster of six genetically related P. aeruginosa cases that occurred during a seven-month period. It is the first study to link infection to contaminated gastroscopes.**
- **The machine-learning algorithm identified gastroscopy as a potential transmission route for 4 of the 6 patients.**
- **Manual electronic health record review confirmed gastroscopy as the most likely route for five patients.**
- **This transmission route was confirmed by identification of a genetically related *P. aeruginosa*, incidentally cultured from a gastroscope used on four of the five patients.**
- **Three infections, 2 of which were blood stream infections, could have been prevented if the machine-learning algorithm had been running in real time.**

Outbreak of Pseudomonas aeruginosa Infections from a Contaminated Gastroscope Detected by Whole Genome Sequencing Surveillance, Clinical Infectious Diseases[10]

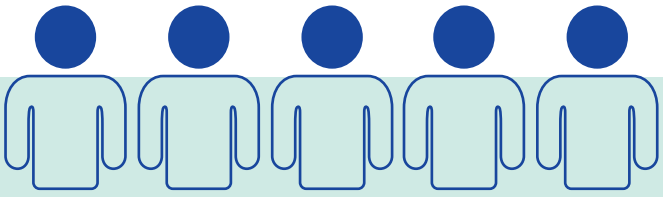
Sundermann et al., 2020

STUDY AIM

Traditional methods of outbreak investigations utilize reactive WGS to confirm or refute an outbreak. This study implemented WGS surveillance and a machine-learning algorithm for the electronic health records to retrospectively detect previously unidentified outbreaks and determine the responsible transmission routes.

METHODS

- This study was conducted at the University of Pittsburgh Medical Centre Presbyterian Hospital, an adult medical/surgical tertiary care hospital with 758 total beds.
- WGS surveillance was performed to identify and characterize clusters of genetically related Pseudomonas aeruginosa infections during a 24-month period.
- Machine learning of the electronic health records was used to identify potential transmission routes.
- A manual review of the electronic health records was performed by an infection preventionist to determine the most likely route, and results were compared to the machine-learning algorithm.



5 patients infected due to a contaminated gastroscope

and identified using a machine learning algorithm

3 out of 5 infections could have been prevented with the machine learning algorithm

★★☆ Infection Control Open access

TAKEAWAY

This is the first study to investigate infection rates after colonoscopy and EGD in free-standing and hospital-based ASCs. The rates of post-endoscopic infection per 1000 procedures within 7 days were 1.1 for screening colonoscopy, 1.6 for non-screening colonoscopy and 3.0 for EGD; all were higher than screening mammography (0.6).

KEY FINDINGS

- **Rates of post-endoscopic all-cause infection for colonoscopy are 1/1,000, and rates for esophagogastroduodenoscopy (EGDs) are 3/1,000. This is two to five times higher than rates of post-procedure infection rates with mammography.**
- **Low volume of procedures at ambulatory surgery centers (ASCs) constitutes a higher risk than high volume of procedures at ASCs. It is the strongest predictor for setting/facility. This correlates with longer hang times of endoscopes having increased bacterial presence.**
- **If patients have been hospitalized in the previous 30 days to the procedure, they are at a five times greater risk of developing post-procedure infection than those who have not.**

Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centers in the USA, Gut[11]

Wang et al., 2018

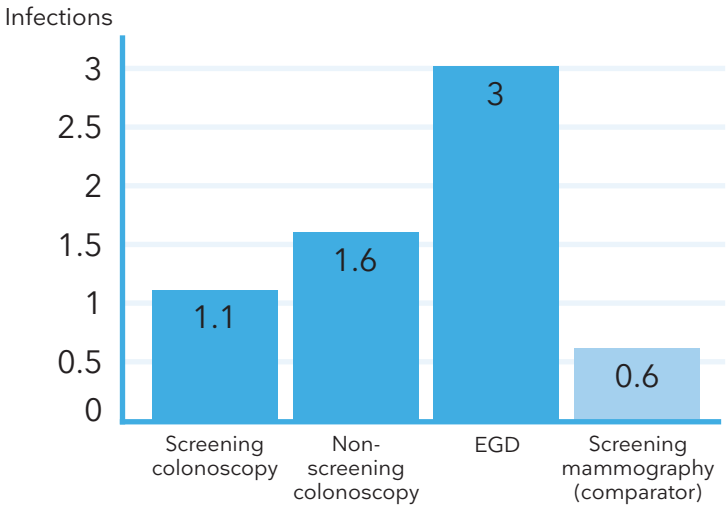
STUDY AIM

Over 15 million colonoscopies and 7 million esophagogastroduodenoscopies (EGDs) are performed annually in the USA. The study aimed to investigate infection rates 7 and 30 days after endoscopic procedures in ASCs.

METHODS

- This study used Common Procedural Technology (CPT) claims associated with colonoscopy or EGD from 6 different states at ASCs and in-patient locations.
- Emergency department (ED) visits, used for hospitalization admissions, were linked to endoscopic procedures.
- Infection rates at 7 and 30 days after procedure were tracked from the ED.
- Mammography and prostate-screening patients were used as controls, because they provided an infection rate baseline in a healthy population.

Rates of post-endoscopic infection per 1,000 procedures within 7 days



Organizational impact

★☆☆ Organizational impact | Open access

TAKEAWAY

13 percent of European gastrointestinal endoscopists often had to wait for a gastroscope to become available prior to a procedure. High-volume centers were not significantly more likely to experience availability issues.

KEY FINDINGS

- **Among the 5 European countries, 13% of the respondents "often" had to wait for a gastroscope to become available before a procedure.**
- **Reportedly, 1% "always" had to wait for a reusable gastroscope to become available.**
- **Availability issues were predominant in Italy and Spain, where 3% of the respondents "always" had to wait for a reusable gastroscope to become available. Only 5% "never" experienced availability issues.**
- **High-volume centers were not significantly more likely to experience availability issues (p=0.2677).**
- **16% of the respondents "often" experienced degradation of their reusable gastroscopes. Only 1% "never" experienced issues with degrading.**
- **There were no significant differences among high-volume centers and the experience of endoscope degradation (p=0.8682).**

Survey-Based Investigation Of Potential Organizational Issues Associated With Reusable Colonoscopes And Gastroscopes in Europe, Endoscopy[12]

Larsen et al., 2021

This study is a conference abstract presented at ESGE Days 2021.

STUDY AIM

Disposable endoscopes are entering the market as an attempt to ease potential availability, portability and degradation issues associated with reusable colonoscopes and gastroscopes. This study aimed to identify potential organizational issues associated with reusable colonoscopes and gastroscopes.

METHODS

- Between Sept. 24, 2020, and Oct. 12, 2020, a total of 459 gastrointestinal (GI) endoscopists from the UK (n=100), France (n=90), Germany (n=72), Italy (n=99) and Spain (n=99) answered an electronic survey about potential organizational issues they experience at their endoscopy unit.
- Data were collected using QuestionPro and analysed using Microsoft Excel.

Ambu aScope Gastro

Ambu aScope Gastro is a sterile single-use endoscope used for a variety of diagnostic and therapeutic procedures in the upper digestive tract. It works with the Ambu aBox 2 unit with built-in touchscreen monitor. The Ambu aScope Gastro solution offers a fast track to an efficient work scenario where endoscopes are available when you need them, provide consistent quality, and offer complete cost transparency.

STERILE STRAIGHT FROM THE PACK

The combination of difficult-to-reach areas and deterioration due to routine use makes reusable gastroscopes susceptible to harbouring microbes. aScope Gastro is sterile straight from the pack, so you can assure each patient that you are using a new sterile gastroscope just for them.

A GASTROSCOPE WHENEVER AND WHEREVER YOU NEED IT

The simplicity of the single-use concept makes it ideal for unscheduled, urgent and night-shift situations – or any scenario where time, location and availability are of the essence.

NO HANDLING, ZERO REPROCESSING AND NOTHING TO REPAIR

With the single-use aScope Gastro, you eliminate reprocessing and the more than 100 complex steps required of your staff. There is no need for pre-cleaning, leak-testing, manual cleaning, visual inspection, high-level disinfection, storage or documentation of adherence. Just discard the used endoscope after a procedure, unpack a new one, and you are ready for the next patient. As for aBox 2, you can simply clean and disinfect it with germicidal wipes.

KEY FEATURES

- Compact, lightweight, portable and convenient solution, making endoscopy available at all times and in any setting
- Innovative plug-and-play live imaging system
- Sterile straight from the pack, eliminating the risk of endoscope-related cross-contamination
- Cost-effective: no need for reprocessing or repair, which streamlines your daily workflow
- Performs reliably: no deterioration of mechanical performance
- Minimal upfront investment. Offers complete cost transparency: one gastroscope, one price

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Ambu Inc.
6721 Columbia Gateway Drive
Suite 200
Columbia, MD 21046
Tel. 800 262 8462
Fax 800 262 8673
ambuUSA.com