EVIDENCE DOSSIER

Ambu® aScope™ Gastro and Ambu® aScope™ Gastro Large

Ambu

UPPER GI EVIDENCE DOSSIER

This document includes published peer-reviewed studies and conference abstracts on contamination, infectious outbreaks, organizational impact, performance and health economics issues associated with reusable gastroscopes and advantages of introducing single-use gastroscopes.

All included studies substantiate the reasoning behind introducing Ambu® aScope™ Gastro and Ambu® aScope™ Gastro Large single-use gastroscopes.

September 2023, 2nd edition

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ABBREVIATIONS

AER: Automatic Endoscope Reprocessor

ASC: Ambulatory Surgery Centres

CFU: Colony-Forming Units

CI: Confidence Interval

CLN: Colonoscopy

CPT: Common Procedural Technology

ECRI: Emergency Care Research Institute

ED: Emergency Department

E. coli: Escherichia Coli

EGD: Esophagogastroduodenoscopy

ERCP: Endoscopic Retrograde Cholangiopancreatography

ESGE: European Society Of Gastrointestinal Endoscopy

FDA: Food & Drug Administration

HCP: Health Care Professionals

HEMA: Health Economics And Market Access

HLD: High-Level Disinfection

ICU: Intensive Care Unit

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

UGIB: Upper Gastrointestinal bleeding

WGS: Whole Genome Sequencing

PREFACE

This dossier will help you get an overview of the clinical landscape related to Ambu® aScope™ Gastro, a single-use standard gastroscope, and to Ambu® aScope™ Gastro Large, a single-use therapeutic gastroscope. 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 published studies and conference abstracts published from January 2015 to August 2023 and related to contamination, infectious outbreaks, organizational impact, performance, health economics and environmental impact. The last section offers environmental initiatives and an introduction to the benefits of Ambu® aScope™ Gastro and Ambu® aScope™ Gastro Large.

Each study summary is true to the original publication, and a link to the original manuscript can be found in the references. Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an inquiry to the Ambu A/S global health economics and market access department (global_hema@ambu.com).

The study titles are taken from the publications as they appear in their original form, allowing the reader to make an accurate internet search if they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall evidence landscape concerning Ambu® aScope™ Gastro and Ambu® aScope™ Gastro Large 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, anaesthesia, 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 and quality products. As the world's leading supplier of single-use endoscopes, Ambu is committed to leading the way in sustainability for this area.

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

For more information, please visit ambu.com

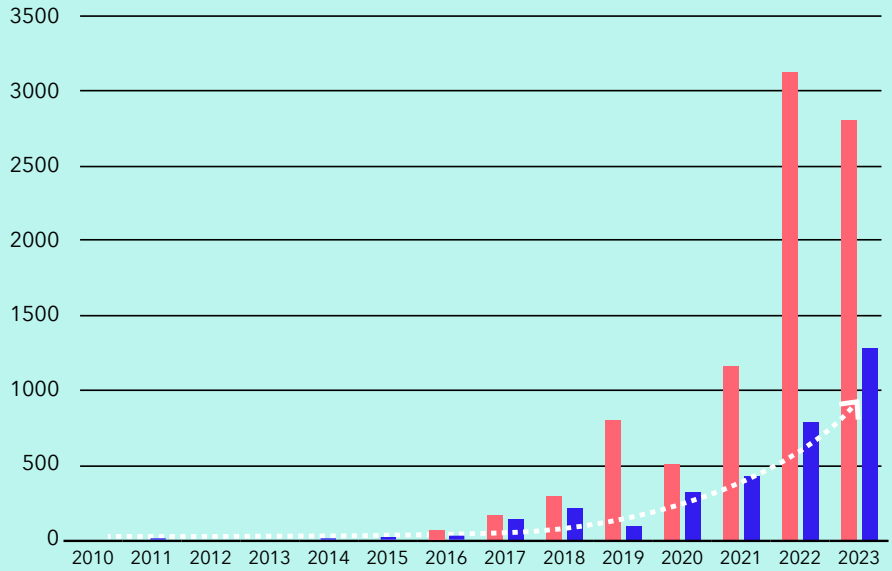
FDA MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) REPORTS

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 health care professionals, patients and consumers. MAUDE data represents 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 issues related to reprocessing error and contamination of reusable gastroscopes.

The graph below (Figure 1) 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”, showing an overall increase of 46% since 2010 and a 20% increase from last year up to date on reprocessing and contamination issues.[1]

MAUDE REPORTS TREND



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total Malfunction Category	2	15	6	3	14	23	75	171	293	801	512	1186	3117	2804
Reprocessing & contamination issues	1	2	1	1	4	3	33	143	219	102	318	428	795	1280

Figure 1: Increasing trend of contamination and reprocessing issues which have been reported to the FDA

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

In 1968, the tragic death of a young child in a Philadelphia emergency room due to a malfunctioning medical device led to the establishment of the Emergency Care Research Institute (ECRI[2]), a non-profit independent organization dedicated to enhancing healthcare safety, effectiveness and affordability. Since then, ECRI has conducted rigorous scientific research and pursued significant advancements in patient care, ultimately saving numerous lives. The organization maintains stringent conflict-of-interest regulations, setting a high standard within the healthcare industry.

ECRI is a global leader in healthcare technology and safety, conducting independent medical device evaluations worldwide, with North America and Asia-Pacific laboratories, providing expert analysis of adverse events data, a unique medical device evaluation lab, and access to clinical evidence to further empower healthcare leaders to improve quality, cut costs and make data-driven decisions for safer care. ECRI maintains the highest principles of integrity and transparency.

For the past 12 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." The table below shows where endoscope reprocessing and cross-contamination have been listed on ECRI's Top 10 list since 2010:

Years	Number on ERCI list	Techonology hazard
2022	8	Poor duodenoscope reprocessing ergonomics and workflows
2021	N/A	N/A
2020	5	Device cleaning, disinfection, and sterilization
2019	5	Mishandling flexible endoscopes after disinfection can lead to patient infections
2018	2	Endoscopes 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 depth 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 August 2023. Articles published in the English language within the areas of contamination, infection control, performance, organizational impact and health economics were included. Commentaries, letters to the editor, book chapters, and publications with no clinical or economical relevance were excluded. This document only includes studies published after 2015 to provide the reader with the most up-to-date studies.

This Evidence Dossier includes summaries of twelve published peer-reviewed studies and four conference abstracts related to esophagogastroduodenoscopy (EGD) procedures.

PEER-REVIEWED STUDIES AND CONFERENCE ABSTRACTS

PERFORMANCE

★★☆ Performance | Not open access

TAKE AWAY

Single-use gastroscopes is a viable option for urgent endoscopic evaluation and treatment of upper gastrointestinal bleeding (UGIB), with a high technical success rate and successful therapeutic interventions in cases requiring treatment. aScope Gastro can be used in the emergency setting, and in the intensive care unit, to successfully identify and treat a variety of bleeding sources with all endoscopic tools used in the study.

KEY FINDINGS

- **Twenty consecutive patients including 15 (75%) with melena. The median age was 69, with a median Glasgow-Blatchford score of 12 (range 4-18). Six patients were treated in the ICU.**
- **95% of cases achieved complete EGD with access to the second part of the duodenum using the single-use gastroscope.**
- **Successful therapeutic interventions with cap-mounted clips, adrenalin injections, haemostatic powder, hemoclip and variceal band ligation.**
- **No adverse events were reported**
- **The image quality, wheel functionality, air/water valve function, stability of the endoscope and overall user experience received satisfactory ratings on the Likert scale.**

One-Scope I: Evaluation of a single-use gastroscope in patients presenting with suspected upper gastrointestinal haemorrhage – a pilot feasibility study[3]

Ebigdo et al., 2023

STUDY AIM

The objective of this study was to evaluate the feasibility of using the single-use gastroscope aScope Gastro, assess the technical success rate and determine the efficacy of therapeutic interventions in patients with signs of UGIB.

METHODS

- Patients recruited from October to November 2022 at the University Hospital of Augsburg.
- The primary aim of the study was to evaluate the technical success rate of the single-use gastroscope in accessing the descending duodenum and assessing the upper gastrointestinal tract for bleeding sites.
- Secondary aims included assessing the clinical success of primary hemostasis, 7-day rebleeding rate, adverse events, user satisfaction, and the crossover rate to a standard gastroscope.

★★☆ Performance Open access

TAKE AWAY

Single-use endoscopes offer a solution to counter-balance the bacterial growth that can be fostered in reusable endoscopes due to cleaning challenges, and the risk of cross-infection which has been reported. The case report also shows successful endoscopic submucosal dissection (ESD) for early gastric cancer using the single-use gastroscope Ambu aScope Gastro, showcasing its potential as an alternative to reusable endoscopes.

KEY FINDINGS

- **Effective Imaging and Manoeuvrability:** The endoscope's imaging and manoeuvrability were suitable for performing mucosal incision and submucosal dissection.
- **Successful Application of Techniques:** The clip-and-line traction method using the 2.8-mm working channel was successfully employed.
- **Bleeding Point Identification:** The water-jet function of the device aided in identifying the bleeding point.
- **Complete Resection and Pathological Finding:** The tumour was fully resected with no significant complications. Pathologically, it was an adenocarcinoma of fundic gland type, classified as SM1, Ly0, V0, HM0 and VM0, indicating a curative resection.
- **Single-Use Scope Success:** This case exemplifies a successful gastric ESD using aScope Gastro single-use gastroscope, proving its potential as an alternative to reusable endoscopes.

Endoscopic submucosal dissection for early gastric cancer, using a disposable endoscope[4]

Okimoto et al., 2023

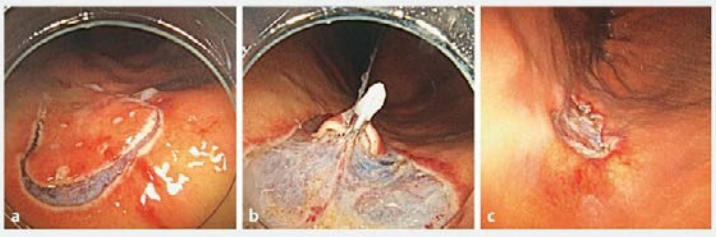
STUDY AIM

Present a case of early gastric cancer resected by means of ESD, using the aScope Gastro single-use gastroscope.

METHODS

- A 70-year-old woman with early gastric cancer underwent endoscopic submucosal dissection (ESD). The tumour measured 5mm and was classified as 0-IIc, situated on the anterior wall of the greater curvature in the middle of the stomach.
- After marking using NBI, the procedure transitioned to the single-use disposable endoscope Ambu aScope Gastro for the ESD, which was successfully carried out.

After marking had been done, gastric endoscopic submuscosal dissection (EDS) was performed employing the aScope Gastro.



a Muscosal incision.
b Clip-and-line traction was successfully applied.
c The tumor was completely removed.

HEALTH ECONOMICS

★☆☆ Health economics | Not open access

TAKE AWAY

This case study highlights the positive outcomes of using a single-use endoscope, including favourable perceptions of quality and functionality. It resulted in significant cost savings of approximately $126 per procedure, totalling almost $38,000 per year. Furthermore, the adoption of the single-use gastroscope from Ambu aScope Gastro was projected to potentially accommodate an extra bariatric surgery weekly, contributing to an annual total of 52 additional surgeries.

KEY FINDINGS

Cost Savings from Single-Use Gastroscopes:

- **aScope Gastro resulted in a cost reduction of $126.23 per procedure, equating to annual savings of $37,867.**
- **The breakdown included additional equipment costs of $137.93 per procedure, offset by savings in reprocessing ($147.12) and repairs ($117.04).**

Increased Workflow Efficiencies and Additional Bariatric Surgeries:

- **The facility anticipated workflow improvements due to the modality of aScope Gastro, enabling an increase in bariatric surgeries performed.**
- **The analysis projected the potential for one additional bariatric surgery per week, totalling 52 surgeries annually.**

Enhanced Reimbursement Potential:

- **With an average reimbursement of $15,500 per bariatric surgery, the facility could gain an extra $806,000 in yearly reimbursement.**
- **The additional reimbursement would come at a cost of $23,400, presenting a favourable financial scenario.**

Single-use gastroscope usage and implications in a high procedure volume facility: a case study[5]

NB: This study is a conference abstract presented at DDW 2023

Hoffman and Cool 2023

STUDY AIM

Evaluate the cost implications of adopting aScope Gastro for procedures at a high-volume hospital in the south-eastern United States, prompted by the need to address malfunctioning automated endoscope reprocessors (AERs) and maintain procedural schedules for a dozen patients.

METHODS

- Endoscope-related data was collected from the facility, including procedure volume, gastroscope quantity and cost, reprocessing equipment expenses, reprocessing method and repair costs.
- Data was used to calculate the cost per use of gastroscopes for the facility. Additional reimbursement and costs were calculated given the additional projected bariatric surgeries, and a final financial impact was calculated for a transition to the single-use gastroscopes.

Savings of $126 per procedure.

Totaling $38,000 per year

aScope Gastro can potentially accommodate 52 additional surgeries annually

CONTAMINATED GASTROSCOPES

★★☆ Contaminated gastroscopes Open access

Endoscope reprocessing: Retrospective analysis of 90,311 samples[6]

Pineau Lionel, 2023

STUDY AIM

The study aimed to analyse the results of 90,311 endoscope samples collected between 2004 and 2021 in 490 private or public hospitals in France.

METHODS

- The sampling method follows French guidelines from 2007 and 2018. In a retrospective study, endoscopes are sampled at least 6 hours after reprocessing. This involves flushing endoscope channels with 10 to 40 mL of sampling solution NPD + thiosulfate using sterile connectors and purging channels with air, collecting the sampling solution in a sterile container. Samples are stored at 5°C ± 3°C for a maximum of 24 hours before analysis. The analysis employs the membrane filtration method with 0.45-µm membrane filters, which are then incubated at 30°C ± 2°C on Plate Count Agar for further assessment.

TAKE AWAY

The study highlighted the presence of various microorganisms in endoscope channels, with environmental microorganisms such as fungi and Bacillus species being frequently isolated, along with Coagulase-negative Staphylococcus and Micrococcus species. Waterborne bacteria like Pseudomonas sp. were also found in endoscope channels.

13% of the endoscopes should have been quarantined (at the action level), and 21.1% of the endoscopes present a contamination rate in unsafe conditions.

The microbiological quality of reusable endoscopes is currently inadequate, with reprocessing procedures falling short when ensuring thorough sterilization. This poses a heightened risk of infection transmission during endoscopy procedures due to increased bacterial contamination. Given the limitations of current microbiological testing protocols, which covers only a subset of endoscopes, endoscope sampling emerges as the primary means for verification. Standardized methods and clear threshold limits should be established to ensure effective quality control in endoscope reprocessing.

KEY FINDINGS

- **Between 2004 and 2021, a total of 90,311 endoscope samples were collected from 490 private or public hospitals in France. The number of endoscopes sampled per year varied from 223 in 2004 to 18,288 in 2021.**
- **The non-compliance rate of the gastroscopes was 10.2-19.2%; for ultrasound gastroscopes it was 11.2-22.8%.**
- **In 2021, 13.0% of the endoscopes should have been quarantined, based on French guidelines due to contamination, and 8.1% were at the alert level. This means that the contamination level of 21.1% of the endoscopes exceeded the defined maximum acceptable value.**
- **Pseudomonas aeruginosa, a major endoscope contaminant, was found in 13% of samples.**

The non-compliance rate of the gastroscopes*

* Overall 90,311 endoscope samples

★★☆ Contaminated gastroscopes Not open access

TAKE AWAY

Bacterial contamination was detected on reprocessed flexible gastroscopes (FG) stored in non-Forced-Air Drying (FAD) cabinets overnight (12h) and increased with longer storage time (60 h). The contamination source is likely to be bacteria in biofilm which multiply in the absence of FAD. Evidence-based criteria should be available for storage time according to the cabinet available.

KEY FINDINGS

- **Bacterial contamination in FG channels increased significantly after storage in a cabinet without FAD.**
- **Contamination was detected after 12 hours of storage (Time 1) and increased further after 60 hours (Time 2) compared to immediate post-reprocessing (Time zero). Contamination in "Time 1" and "Time 2" was 5.9 and 16.1 times greater than in "Time zero", respectively.**
- **The number of positive cultures in media with and without neutralizer was similar in Times 1 and 2, but media with neutralizer produced more positive cultures in Time zero.**
- **In Time 2, most isolated bacteria were Gram-negative rods (52.3%) and showed resistance to one or more antibiotics (65%).**
- **The findings emphasize the need for evidence-based criteria for endoscope storage time based on the available cabinet type to mitigate contamination risks and ensure patient safety.**

Significant increased bacterial contamination with endoscope overnight and weekend storage times[7]

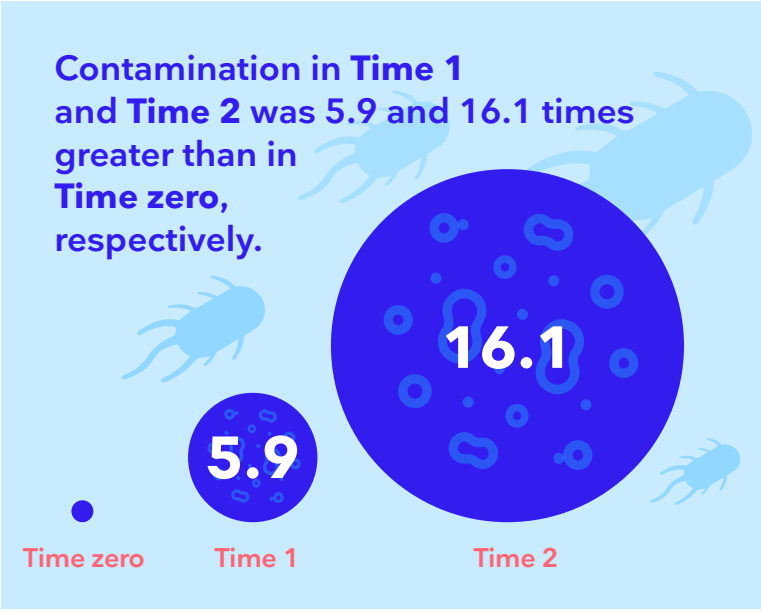
Guadagnin SVT et al., 2023

STUDY AIM

Determine bacterial contamination in flexible gastroscopes channels after storage, in a cabinet with filtered air and UV lights, but without FAD.

METHODS

- The study involved sampling 8 FG that were in clinical use at a large Brazilian hospital.
- Three sampling time points were selected: Immediately after reprocessing ("Time zero," N = 50); 12 hours after reprocessing ("Time 1," N = 25); and 60 hours after reprocessing ("Time 2," N = 25).
- For each sampling, the channels of the FG were flushed with a flush-brush-flush technique. A total of 40 mL of sterile water and 3 cm of the brush were collected from each FG. Each collected sample was divided into two portions, and each portion was filtered onto 0.22-µm membranes. The filtered samples were then incubated in media, some with a disinfectant neutralizer and others without. An automated method was used for the identification and antibiotic resistance testing of the isolated bacteria.



★★☆ Contaminated gastroscopes Open access

Gastrointestinal endoscope contamination rates – elevators are not only to blame: a systematic review and meta-analysis[8]

Goyal et al., 2022

TAKE AWAY

Approximately 20% of reprocessed gastrointestinal endoscopes may be contaminated when used in patients. This contamination rate varies across different types of endoscopes, geographies and colony-forming unit (CFU) thresholds. The study emphasizes that the elevator mechanism is not the only source of contamination, and guidelines should include more surveillance of the endoscope channels during reprocessing.

KEY FINDINGS

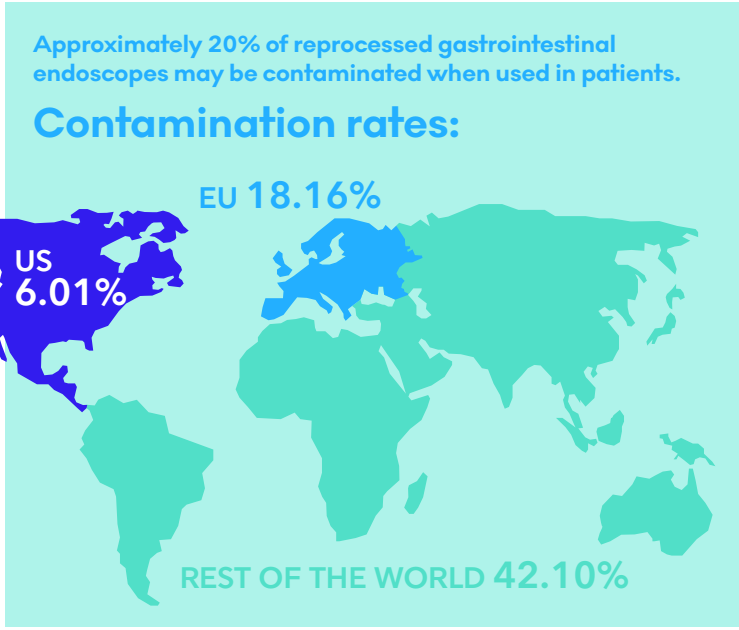
- **85% of the studies used high-level disinfection (HLD) as the reprocessing method. 10% tested a combination of HLD, double HLD (dHLD) and ethylene oxide (EtO) sterilization, while 5% compared dHLD and HLD. 65% of the studies reported a CFU threshold, with 30% setting the threshold >20 CFU and 35% setting it <20 CFU.**
- **The meta-analysis revealed a pooled contamination rate beyond the elevator of gastrointestinal endoscopes at 19.98% ± 0.024%.**
- **Gastroscope-specific samples (n=6) showed a contamination rate of 28.22%±0.076.**
- **Meta-analysis in North America (USA and Canada, n=7) showed a contamination rate of 6.01% ± 0.011%, while European countries (n=7) had a higher contamination rate of 18.16% ± 0.053%. The Rest of the World (RoW, n=6) had the highest contamination rate of 42.10% ± 0.011%.**
- **Meta-analysis of studies using a CFU threshold >20 (n=6) showed a contamination rate of 30.36% ± 0.094%, while studies using a CFU threshold <20 (n=8) had a lower contamination rate of 11% ± 0.026% (95% CI: 5.94%-16.06%; I2 = 95.3%). Egger's regression test indicated significant publication bias for studies using a CFU threshold >20 (P = 0.026).**

STUDY AIM

Estimate the contamination rate beyond the elevator of various gastrointestinal endoscopes, including duodenoscopes, echoendoscopes, gastroscopes and colonoscopes, due to poor reprocessing and using available data.

METHODS

- Studies included ranged from 1 January 2010 to 10 October 2020. Of 1,914 peer-reviewed studies, 20 studies fulfilled all inclusion criteria for the final meta-analysis, including 1,059 positive cultures out of 7,903 cultures sampled from various gastrointestinal endoscope channels and areas beyond the elevator.
- 30% of studies were conducted in the United States, 35% in Europe, 25% in Asia, 5% in Canada and 5% in Brazil. A random effects model was used due to anticipated heterogeneity in sample size and outcomes.



★★☆ Contaminated gastroscopes Open access

Cleaning of in-hospital flexible endoscopes: Limitations and challenges[9]

Madureira RADS, Oliveira AC. 2022

TAKE AWAY

There are significant gaps in the reprocessing stages of gastroscopes, colonoscopes and duodenoscopes in in-hospital health services. For gastroscopes a contamination rate of 18.7% and 25% was found from stored and after reprocessing, respectively, leading to the presence of protein residues and the growth of potentially harmful microorganisms. This highlights safety limitations in the endoscope reprocessing procedures, which may compromise disinfection processes and the safe use of endoscopes in patients.

KEY FINDINGS

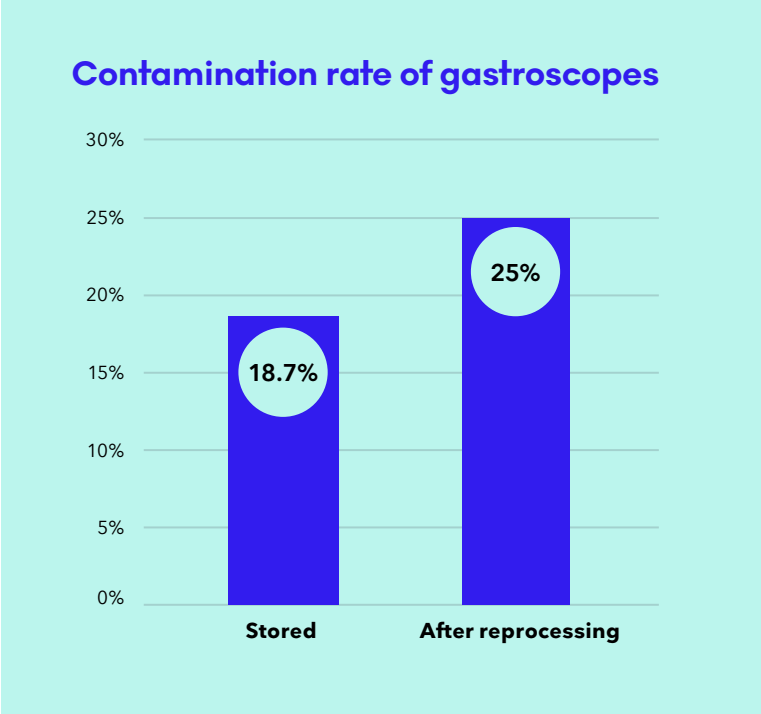
- **The reprocessing of 22 endoscopes was monitored with microbiological analysis for 60 channels. (Two collection times)**
- **32% of samples after reprocessing and 25% samples from the stored equipment, were positive for growth of microorganisms.**
- **Specifically, for gastroscopes a contamination rate of 18.7% and 25% was found from stored and after reprocessing, respectively.**
- **In 77% (17/22) of cases, the endoscope was incompletely immersed in the detergent solution, which can jeopardize efficiency for further cleaning.**
- **Standardization of filling the channels was lacking in 63.6% (14/22) of cases.**

STUDY AIM

This study aimed to assess and analyse the cleaning process of gastroscopes, colonoscopes and duodenoscopes within eight in-hospital health services.

METHODS

- Cross-sectional study with 22 endoscopes (8 gastroscopes, 8 colonoscopes and 6 duodenoscopes).
- Microbiological analysis was performed in 60 samples from air/water channels (all endoscopes) and elevators (duodenoscopes), along with protein testing.
- Data analysis involved descriptive statistics, including frequencies and central tendency measures.



★☆☆ Contaminated gastroscopes Open access

TAKE AWAY

These study findings indicate that contamination issues of gastroscopes are acknowledged amongst 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[10]

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

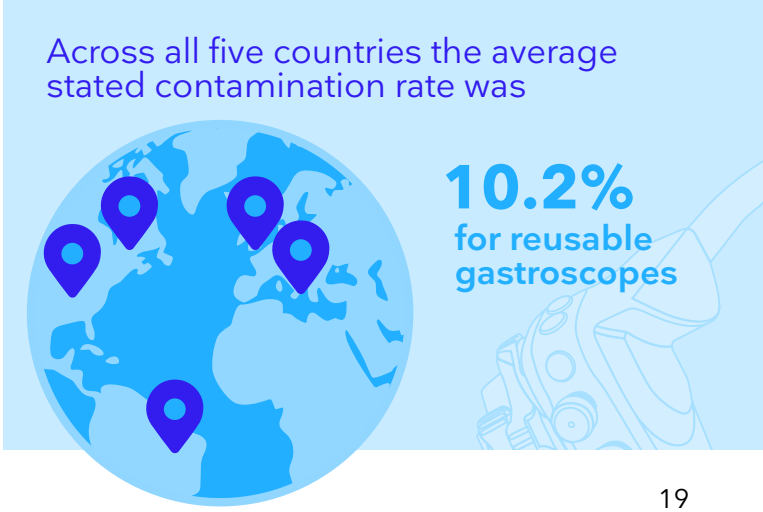
Larsen et al., 2021

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 24 September 2020 and 12 October 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.



★★☆ Contaminated gastroscopes Open access

TAKE AWAY

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 conclude: "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

- **Twenty-nine of 36 (81%) endoscopy centres 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[11]

Decristoforo et al., 2018

STUDY AIM

The aim of this multicentre 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 centres 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 centres 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 centres.
- In six 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*

★★☆ Contaminated gastroscopes | Open access

TAKE AWAY

Thirty-six 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

- **Thirty-six 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 fail 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[12]

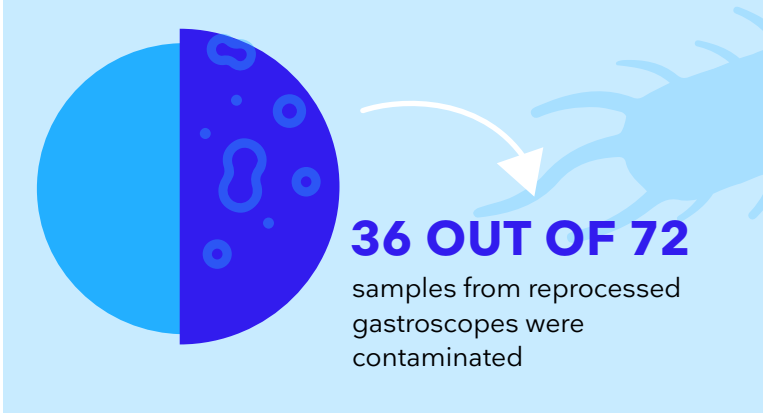
Ji et al., 2018

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, and 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.
- Two sampling techniques were used to sample flexible gastrointestinal endoscopes: (1) the conventional flushing sampling method, and (2) the pump-assisted sampling method.



★★☆ Contaminated gastroscopes | Not open access

TAKE AWAY

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 [CFU]). 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 two 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 the risk of conta-mination (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[13]

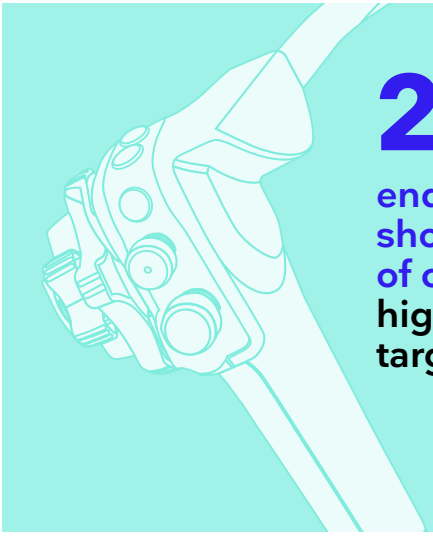
Saliou et al., 2015

STUDY AIM

Infectious outbreaks associated with the use of gastro-intestinal 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 gastro-intestinal endoscopes.

METHODS

- The authors reviewed the results of all microbio-logical surveillance testing of gastrointestinal endoscopes and automatic endoscope repro-cessors (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 following sampling, including microbiological tests of gastrointestinal endoscopes, was perfor-med: gastroscopes (n=271), colonoscopes (n=190), duodenoscopes (n=118), echoendoscopes (n=113), transnasal gastroscopes (n=48), enteroscopes (n=17) and choledoscopes (n=5).



264

endoscope tests showed a level of contamination higher than the target

INFECTIOUS OUTBREAKS

★★☆ Infectious outbreaks Open access

A systematic analysis of nosocomial outbreaks of nosocomial infections after gastrointestinal endoscopy[14]

Scholz PM et al., 2023

TAKE AWAY

The study analyzed 73 outbreaks and found that the attack rates for EGD, ERCP and CLN were 3.5%, 7.1% and 12.8%, respectively, with corresponding mortality rates of 6.3%, 12.7%, and 10.0%. Single-use devices may be an alternative option to lower pathogen transmission.

KEY FINDINGS

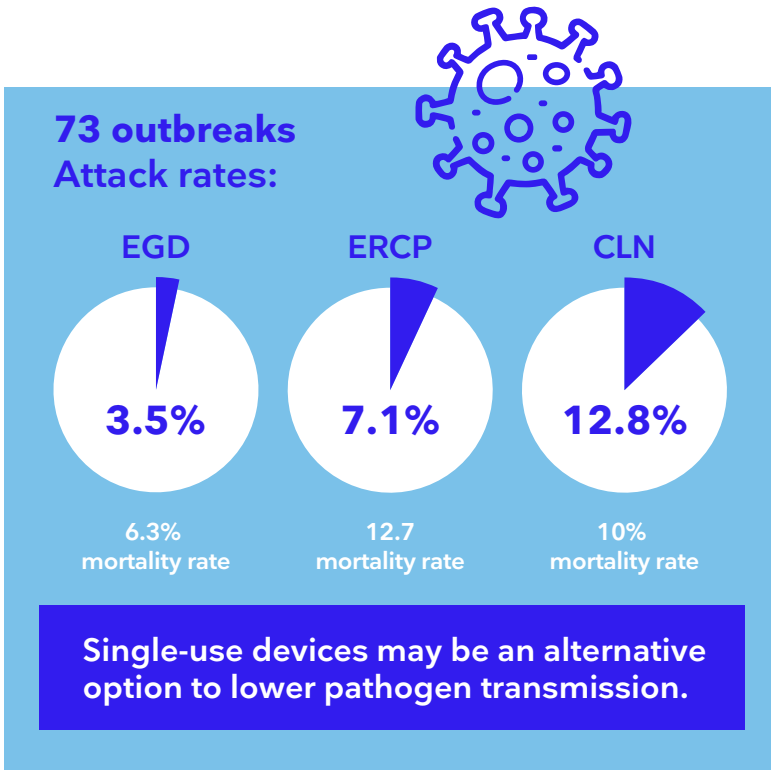
- **73 outbreaks (EGD:24, ERCP:42; CLN:7) were included. The corresponding attack rates were 3.5%, 7.1% and 12.8%, and mortality rates were 6.3%, 12.7% and 10.0%, respectively.**
- **EGD was highly associated with transmis-sion of enterobacteria, including a large proportion of multi-drug resistant strains.**
- **ERCP led primarily to transmission of non-fermenting Gram-negative rods.**
- **The most frequent cause was human failure during reprocessing, regardless of the type of endoscope.**
- **Staff working in the field of endoscopy should always be aware of the possibility of pathogen transmission, in order to detect and terminate those events at the earliest time.**

STUDY AIM

The study aimed to investigate further the causes and the distribution of pathogens within GI procedures.

METHODS

- A systematic review of the medical literature using the Worldwide Outbreak Database, PubMed and Embase was performed. Articles on potential sources of the outbreak, the spectrum of pathogens, the attack rates, mortality and infection control measures were reviewed.



★★☆ Infectious outbreaks Open access

TAKE AWAY

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 four of the six 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, two 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[15]

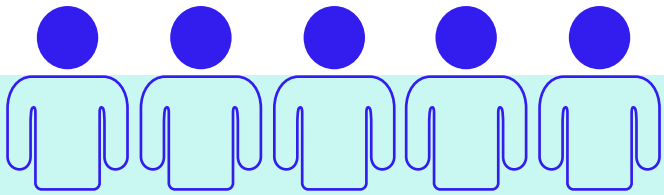
Sundermann et al., 2020

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 record 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

★★☆ Infectious outbreaks Open access

TAKE AWAY

This is the first study to investigate infection rates after colonoscopy and EGD in freestanding and hospital-based ambulatory surgery centres (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 1/1000, and rates for esophagogastroduodenoscopy (EGDs) are 3/1000. This is two to five times higher than rates of post-procedure infection rates with mammography.**
- **Low volume of procedures at ambulatory 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 osophagogastroduoden-oscopy in ambulatory surgery centres in the USA[16]

Wang et al., 2018

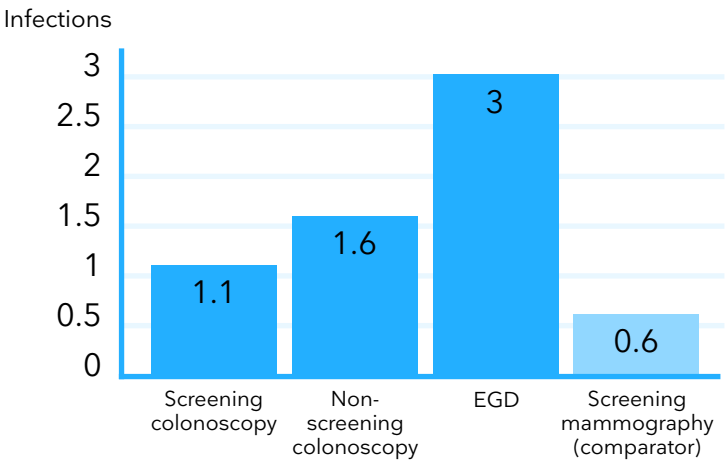
STUDY AIM

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 post endoscopy procedures in ASCs.

METHODS

- This study used Common Procedural Technology (CPT) claims associated with colonoscopy or EGD from six 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 post 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.
- Bronchoscopy and cystoscopy were used as controls as related procedures and as locations of the procedures.

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



ORGANISATIONAL IMPACT

★☆☆ Organisational impact Not open access

TAKE AWAY

The risks and resources associated with intra-hospital transport of critically ill patients with upper gastrointestinal bleeding (UGIB) could be reduced by 46% if therapeutic gastroscopes, necessary equipment and utilities were available in the intensive care unit (ICU). Single-use therapeutic gastroscopes could allow faster attention to patients in need. They could also free up time and reduce workload and stress of health care professionals (HCPs) and other staff who are currently involved in the transport and handling of patients with UGIB from ICU.

KEY FINDINGS

- **The study collected 341 responses from gastro-intestinal surgeons and gastro-enterologists.**
- **3% of ICU patients present with UGIB during admission.**
- **Currently, 45% of UGIB patients are treated in the ICU; 24% are transported to the operating room (OR); and 31% to the endoscopy unit (EU).**
- **Physicians estimate that 46% of currently transported ICU patients with UGIB could avoid transportation if single-use thera-peutic gastro-scopes were available in the ICU, and UGIB management was equally efficient as in the OR or the EU. This would mean that 75% of UGIB patients could be managed in the ICU compared to the current handling.**

Mitigating the need for patient transport by treating upper gastrointestinal bleedings in ICU-settings with a single-use therapeutic gastroscope[17]

This study is a conference abstract presented at UEG Week 2023.

Borja et al., 2023 (Search for PP0033)

STUDY AIM

The current study investigates the potential benefits of having single-use therapeutic gastroscopes, necessary equipment and utilities available in the ICU to treat ICU-admitted patients presenting with upper gastrointestinal bleeding (UGIB).

METHODS

- An anonymous survey was conducted between January 2021 and October 2022 in eight countries (Australia, France, Germany, Italy, Spain, the United Kingdom, the United States of America and Japan).
- The survey targeted gastroenterologists and gastro-intestinal surgeons working in various healthcare settings, including public hospitals, public university hospitals, private hospitals, private clinics, screening centres and ambulatory surgery centres (ASCs).
- The survey was distributed through M3 Global Research, and data was collected using Survey Exact and later analysed in Excel.

On average, it takes
22 MIN
and up to
6 HCP's
to transport a patient from ICU to the Endoscopy Unit or the OR

★☆☆ Organisational impact Not open access

TAKE AWAY

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

KEY FINDINGS

- **Amongst the five 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 respon-dents "always" had to wait for a reusable gastroscope to become available. Only 5% "never" experienced availability issues.**
- **High-volume centres were not significantly more likely to experience availability issues (p=0.2677).**
- **Sixteen percent of the respondents "often" experienced degradation of their reusable gastroscopes. Only 1% "never" experienced issues with degradation.**
- **There were no significant differences between high-volume centres and the experience of endoscope degradation (p=0.8682).**

Survey-Based Investigation Of Potential Organisational Issues Associated With Reusable Colonoscopes And Gastroscopes in Europe, Endoscopy Supplement [18]

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

Larsen et al., 2021

STUDY AIM

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

METHODS

- Between 24 September 2020 and 12 October 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 organisational issues they experienced at their endoscopy unit.
- Data was collected using QuestionPro and analysed using Microsoft Excel.

Amongst the five European countries

13%

of the respondents "often" had to wait for a gastroscope to become available before a procedure

ENVIRONMENTAL IMPACT

RETHINKING MEDICAL SOLUTIONS, RESPECTING THE ENVIRONMENT

At Ambu, we are dedicated to advancing healthcare solutions while safeguarding the environment for future generations. We aim to create solutions that not only improve healthcare for professionals and their patients, but also have the lowest environmental impact possible.

We continuously invest in the research and development of technologies and materials that lower the environmental footprint of our products, and by extension, your hospital's environmental impact.

Along with our customers, we have embarked on a sustainability journey, which is dynamic and ongoing, and there is no turning back. We apply the principles of the circular economy to every aspect of the design, manufacturing and disposal of our medical device solutions. And together, we will lead the way, set an example for the single-use medical device industry and make a difference to the world.

The goal of the circular economy is to create a closed-loop system where waste is minimized and materials are continuously reused, leading to a more sustainable and efficient economy.

TARGETS 2025

CIRCULAR PRODUCTS

- Bio-attributed plastics in all endoscope handles by 2025
- 95% of new products released after 2025 to be PVC-free

CIRCULAR PACKAGING

- Primary packaging for high-vol. products made from bioplastics

RECYCLING

- Recycling at scale in all focus markets by 2025
- Long term goal is to design for recycling

IMPLEMENTED

CIRCULAR PRODUCTS

- aScope 5 Broncho and aScope Gastro PVC free
- 100% phthalate-free endoscopes
- Plastics used in endoscopes in EMEA & Latin America is offset in partnership with Plastic Bank

CIRCULAR PACKAGING

- 100% recyclable secondary packaging
- 65% of all packaging (primary and secondary) is recyclable

RECYCLING

End-of-use recycling:

- Take-back and energy recovering partnership with Sharps in the US
- Take-back and recycling pilot project in Germany

Production recycling:

- 41% recycling of production waste

Ambu® aScope™ Gastro Large

A WORLD OF DIFFERENCE WITH 4.2

The Ambu® aScope™ Gastro Large endoscopy solution gives you the power of a single-use large-channel therapeutic gastroscope combined with the manoeuvrability and precision of a standard one.

aScope Gastro Large is a single-use therapeutic gastroscopes that addresses the needs of the Endoscopy unit, ICU and OR. It works with the Ambu® aBox™ 2 endoscopy system.

THE WORLD'S FIRST GASTROSCOPE WITH A 4.2 MM WORKING CHANNEL

The 4.2 mm working channel of aScope Gastro Large delivers approximately 90% higher suction flow compared to the newest therapeutic 3.7 mm channel gastroscope. In addition, the large working channel provides a platform for new and innovative instruments and treatment options.

ALWAYS AVAILABLE, ALWAYS NEW, NO SIGNIFICANT UPFRONT INVESTMENTS

When an unscheduled, out-of-hours or other time-sensitive situation arises, you should not have to wait for a gastroscope to become available. With aScope Gastro Large, there is no more waiting or delays when reusable endoscopes are being used, reprocessed, in quarantine or out for repair. Furthermore, when you consider the relatively low initial capital costs for a single-use setup, as well as the recurring costs associated with reprocessing of reusable endoscopes, aScope Gastro Large may be a cost-effective alternative.

SETTING NEW STANDARDS FOR SINGLE-USE SUSTAINABILITY

aScope Gastro Large is the first single-use gastroscope manufactured from bioplastics. From the user's point of view, there will be no difference in the look, feel and performance of the endoscope handle. In terms of carbon emission, however, it is a significant step forward, and one which aligns with Ambu's commitment to environmental responsibility.

KEY FEATURES

- Superior suction vs. 3.7*
- Large 4.2 mm working channel for a broader range of tools
- Consistent quality, feel and performance
- Single-use efficiency and convenience
- World's first gastroscope with bioplastic in the handle

*3.7 refers to the gastroscope channel size in mm

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.

THE WORLD'S FIRST GASTROSCOPE WITH A 4.2 MM WORKING CHANNEL

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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