

Contaminated endoscopes; to worry about, to ignore or to combat?

The 20th World Sterilization Congress

The Hague, 2019

Prof Dr. Margreet C Vos

Clinical Microbiologist



Disclosures of Prof Dr Margreet C Vos, Erasmus MC Rotterdam, the Netherlands

- Unrestricted grant Pentax
- Unrestricted grant 3M
- Chair European Study group of Nosocomial Infections
- Chair of MRSA Working Group of International society of Antimicrobial Chemotherapy
- Projectleader of MACOTRA, MRSA clones
- Member of the Dutch guideline working group culture of endoscopes
- Member of the HIS/ESGNI/ESCMID infection prevention guideline
“Rituals and behaviour in the operating theatre”

Content

- Impact
 - Infections by contaminated endoscopes
- Prevalence
 - Contamination of endoscopes
- Solutions

Focus on duodenoscopes (ERCP/linear endo-echosopes)
not colonoscopes/gastrosopes/bronchoscopes/etc

Impact; infections

- Tip of a huge iceberg
- Thanks to resistance
 - Sensitive/normal gutflora not/never detected, unless unusual
- Infections post-ERCP are mostly assumed to be endogenous

Impact; Infections as a complication of ERCP

- *Source of bacteria;*
 - *Endogenous*
 - inherent to the ERCP procedure, translocation of a patient's own flora
 - *Exogenous*¹
 - contaminated ERCP duodenoscopes with
 - biomaterial of previous patients
 - Contamination by AER/drying/storage

Risks;

- breaches in reprocessing²
- complex design^{3,4}

¹ Kovaleva et al. 2013

² Muscarella 2014

³ FDA 2015

⁴ Verfaillie et al. 2015

Prevalence HAI post-ERCP; 4 years period, clinical samples, single center

Table 1 Prevalence of post-ERCP HAIs and biliary tract infections for different types of ERCP operations

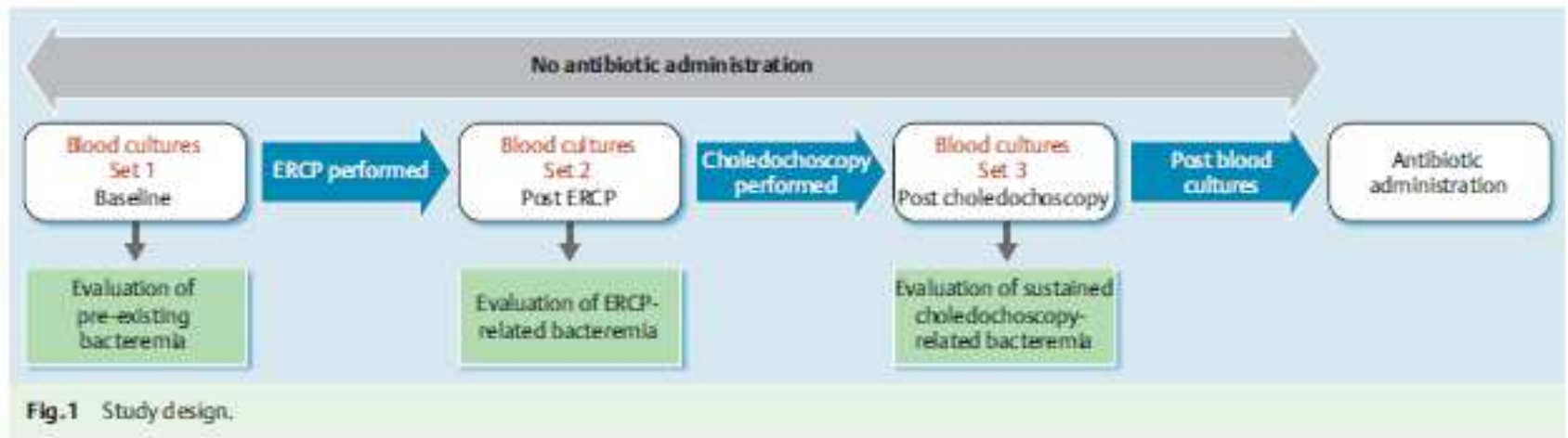
Operations	No. of operations	No. (%) of HAIs	No. (%) of biliary tract infections
Diagnostic ERCP	133	6 (4.51)	5 (3.76)
Diagnostic ERCP	133	6 (4.51)	5 (3.76)
Therapeutic ERCP	1610	126 (7.83)	65 (4.03)
Lithotomy of duodenal papilla	727	26 (3.58)	7 (0.96)
Biliary stent implantation	570	77 (13.51)	47 (8.25)
Pancreatic duct stent implantation	137	7 (5.11)	0 (0)
Bile duct lithotomy	69	7 (10.14)	4 (5.80)
Bile duct stent extraction and replacement	48	5 (10.42)	3 (6.25)
Other therapeutic ERCP	59	4 (6.78)	4 (6.78)
Total	1743	132 (7.57)	70 (4.02)

N=58 bacteremia

HAIs included biliary tract infections, transient primary bacteremia, and respiratory tract infections

ERCP endoscopic retrograde cholangiopancreatography, HAIs healthcare-associated infections

Bacteremia following ERCP



Positive blood culture rate; 27,8%

Bacteremia following ERCP; pre, per and post bloodculture; frequency of bacteremia

Table 3 Characteristics of patients with bacteremia following endoscopic retrograde cholangiopancreatography and single-operator choledochoscopy.

Age, years	Sex	Indication ¹	Pre-ERCP blood culture Set 1	Post-ERCP blood culture Set 2	Post SOC blood culture Set 3	Organism	Development of post-procedure chills/fever	Development of sepsis or cholangitis	Hospitalization	Antibiotic treatment (duration in days)
79	M	1	No	No	Yes	<i>Veillonella</i>	Yes	No	No	Yes (3)
85	F	1	No	No	Yes	<i>Klebsiella pneumoniae</i>	Yes	No	No	Yes (3)
52	M	1	No	No	Yes	<i>Escherichia coli</i>	Yes	No	Yes	Yes (7)
53	M	3	No	No	Yes	<i>Escherichia coli</i>	Yes	Yes	Yes	Yes (14)
81	M	1	No	No	Yes	<i>Klebsiella pneumoniae</i> Vancomycin-resistant <i>Enterococcus</i>	Yes	Yes	Yes	Yes (10)
70	M	1	No	No	Yes	<i>Escherichia coli</i>	No	No	No	Yes (7)
67	M	1	No	No	Yes	<i>Pseudomonas aeruginosa</i>	No	No	No	Yes (14)
32	M	3	No	Yes	No	<i>Escherichia coli</i>	No	No	No	No
53	F	2	No	Yes	No	<i>Enterococcus casseliflavus</i>	No	No	No	No
72	M	1	No	Yes	No	<i>Enterococcus faecium</i>	No	No	No	No
77	F	1	No	Yes	No	<i>Bacteroides Fragilis</i>	No	No	No	No
82	M	2	No	Yes	No	<i>Escherichia coli</i>	No	No	No	No
88	M	3	No	Yes	No	<i>Veillonella</i>	No	No	No	No
72	F	3	No	No	Yes	<i>Escherichia coli</i>	No	No	No	No
82	M	2	No	No	Yes	<i>Streptococcus Viridans</i>	No	No	No	No
85	M	1	No	No	Yes	<i>Klebsiella pneumoniae</i>	No	No	No	No
59	F	2	No	Yes	Yes	<i>Clostridium</i> spp. ² <i>Bacteroides thetaiotaomicron</i>	No	No	No	No
78	M	1	No	Yes	Yes	<i>Citrobacter freundii</i> <i>Enterococcus gallinarum</i> <i>Escherichia coli</i>	No	No	No	No
80	M	1	No	Yes	Yes	<i>Enterococcus faecium</i>	No	No	No	No
82	F	2	No	Yes	Yes	<i>Escherichia coli</i>	No	No	No	No

ERCP, endoscopic retrograde cholangiopancreatography; SOC, single-operator choledochoscopy; M, male; F, female.

¹ Indication: 1 = evaluation of filling defect; 2 = evaluation/electrohydraulic lithotripsy of stone; 3 = evaluation/biopsy of stricture.

² Not *Clostridium perfringens*.

Antibiotic continued in 7/20 pts

Impact of contaminated endoscopes; Unresolved issue yet

Up until now;

- No data on contamination of endoscope before procedure and measurement infection after procedure

Question remains;

- Is an infection related to a contaminated endoscope or is it endogenous?

→ risk on exogenous infection is not known.

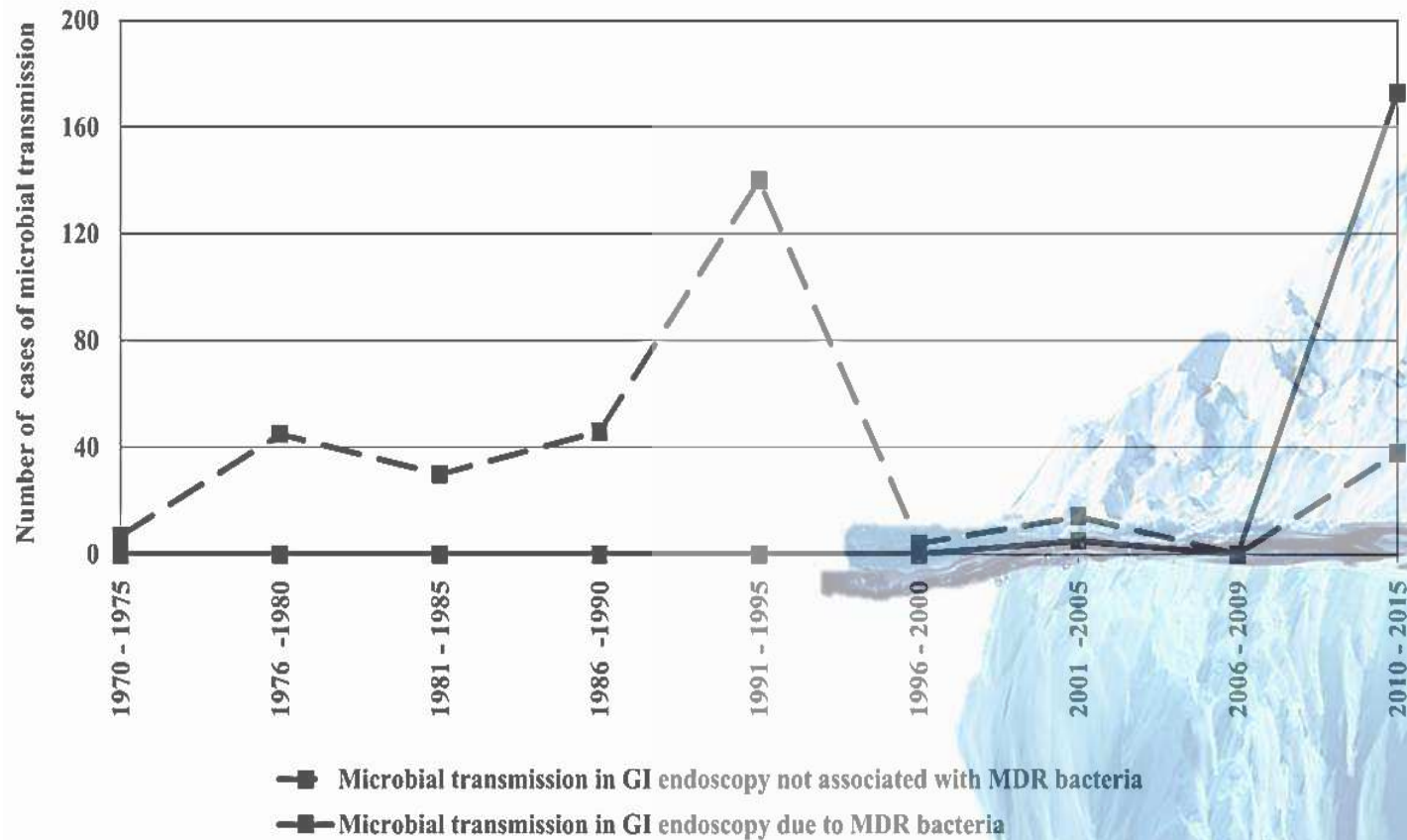
→ risk on exogenous infections should be derived from outbreaks

→ Thanks to MDRO we are now aware?

Outbreaks related to endoscopes: tip of the iceberg

Peak 1991-1995
Washer-disinfector related

Peak 2002 onwards
Outbreaks of MDRO



1. Kovaleva - Best Practice & Research Clinical Gastroenterology 2016
2. Rubin - Lancet Gastroenterology & Hepatology, 2018

ERCP outbreaks: a worldwide problem

- 2016 US Senate report:
 - Worldwide ≥ 25 outbreaks with ≥ 250 patient infections
 - 2012 – spring 2015
 - Multi-Drug Resistant Organisms
 - *Olympus, Pentax and Fujinon*

**Preventable Tragedies:
Superbugs and How Ineffective Monitoring of
Medical Device Safety Fails Patients**



- Failure of adequate Adverse Event reporting
- “Likely that outbreaks in smaller hospitals were never identified”

Underreporting

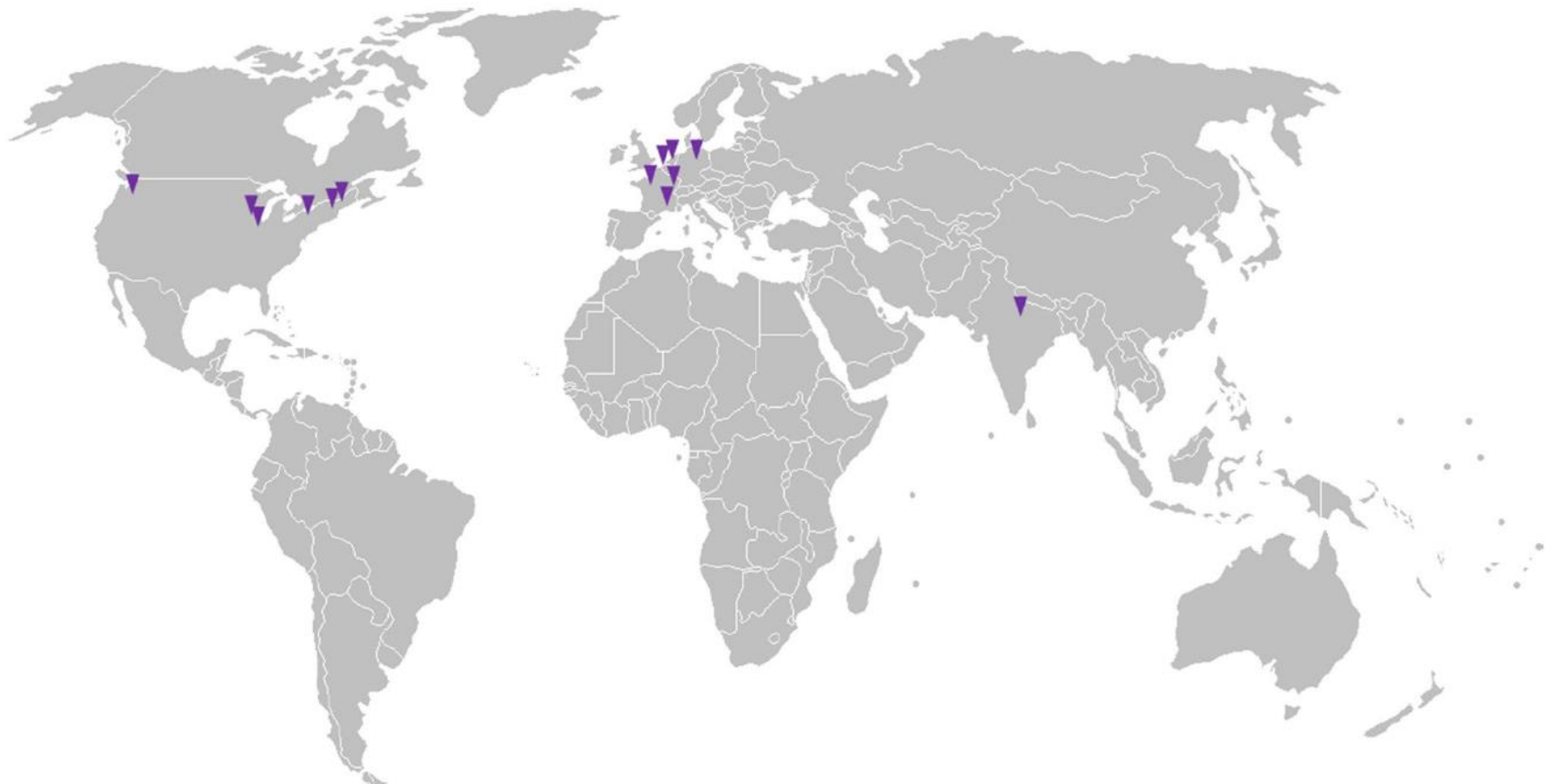


Fig. 1 Worldwide distribution of reported outbreaks of duodenoscopy-associated infections from 2000 to present

Breaking news; combination of MDRO and a procedure

A Killer on the Loose

Patients at UCLA were becoming deathly ill.

SUPERBUG SYMPTOMS?

YOU OR A LOVED ONE

SUFFERED FROM A SUPERBUG

DUODENOSCOPIC PROCEDURE

Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

How a medical device maker kept U.S. hospitals in the dark about deadly infections

By CHAD TERHUNE AND MELODY PETERSEN
DEC. 19, 2015



Home

Understanding CRE, the 'nightmare' superbug that contributed to deaths in

Los Angeles Times

FDA reveals 142 cases of tainted scopes



MDRO Outbreaks related to duodenoscopes

Year	Country	Microorganism	Duodenoscope	Infections / Transmissions
2009 - 2016 ¹	Spain	3 x KPC-producing <i>K. pneumoniae</i> 1 x ESBL- <i>E. coli</i> 9 outbreaks of non-MDRO	Unknown	Total # patients unknown 2 deaths
2015 ²	Colombia	KPC-producing <i>K. pneumoniae</i>	Unknown	3 (2 deaths)
2015 ⁵	Netherl.	VIM-2 <i>Pseudomonas aeruginosa</i>	Olympus TJF-180V	22
2016 ^{3,4}	France	OXA-48 producing <i>K. pneumoniae</i>	Olympus TJF-Q180V (Revised version)	5
2017 ⁴	France	<i>P. aeruginosa</i>	Olympus TJF-Q180V	5
2017 ⁴	Unknown	CTX-R <i>K. pneumoniae</i> (mobilized colistin resistance-1 gene)	Pentax ED-3490TK	2
2017 ⁴	France	OXA-48 producing <i>K. pneumoniae</i>	Olympus TJF-Q180V	4
2019 ⁶	Netherl.	ESBL <i>K. pneumoniae</i>	Olympus TJF-Q180V	26

¹ García-Cano et al. Abstract DDW 2016 ² Valderrama et al. ODIS 2016 ³ Pietersen. LA Times 2017 ⁴ FDA/MAUDE 2017 ⁵ Verfaillie 2015 ⁶ Rauwers 2019

Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*

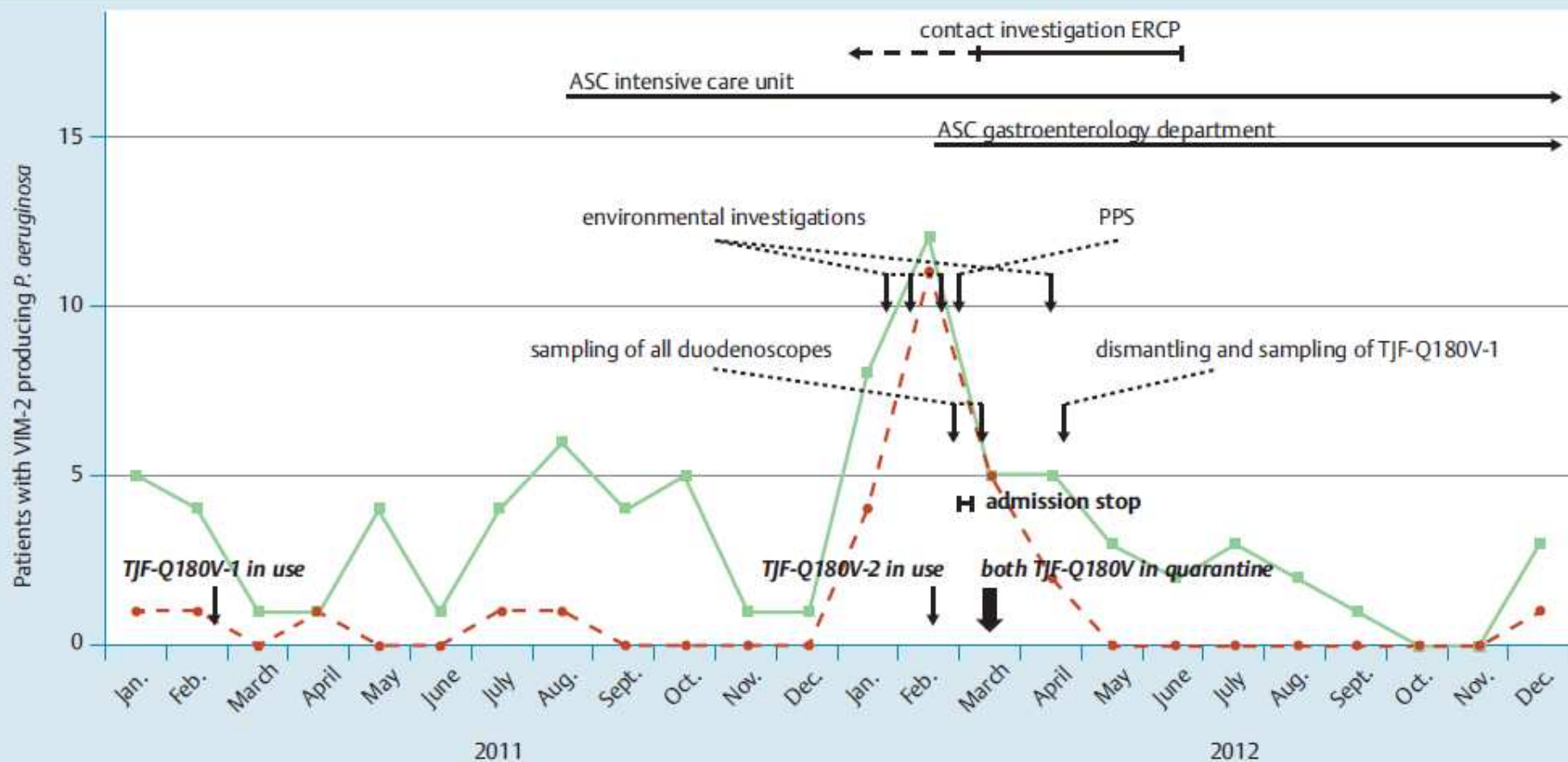


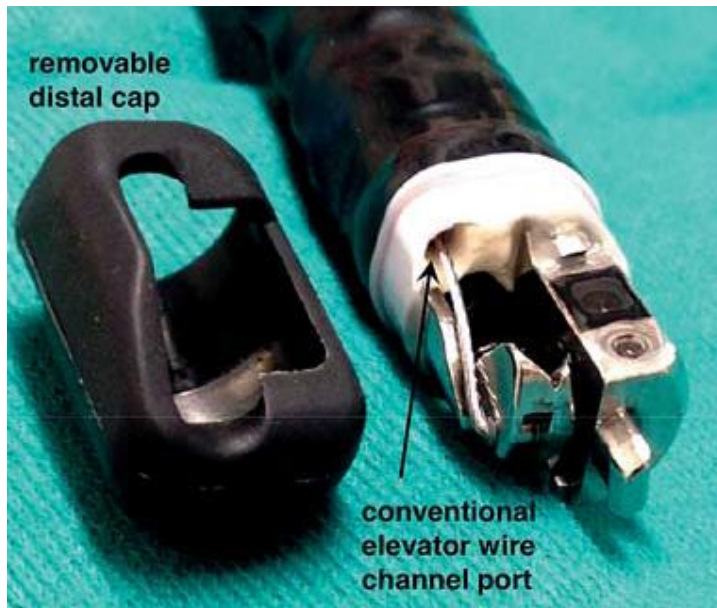
Fig. 2 Timeline of outbreak management. Solid green line, all patients with VIM-2-positive *Pseudomonas aeruginosa*; dashed red line, patients with VIM-2-positive *P. aeruginosa* who underwent an ERCP. ASC, active surveillance cultures; ERCP, endoscopic retrograde cholangiopancreatography; PPS, point prevalence screening.

Positive culture for the outbreak strain



Complex ScopeTip Design & Changes

- Initial design:
 - side-facing tip
 - elevator for guidewire or catheter
 - elevator wire channel
 - removable cap



- Novel design: TJF-Q180V
 - sealed protection cap
 - sealed elevator wire channel (O-ring)
- change from an open to a closed elevator channel



TJF-Q180V duodenoscope

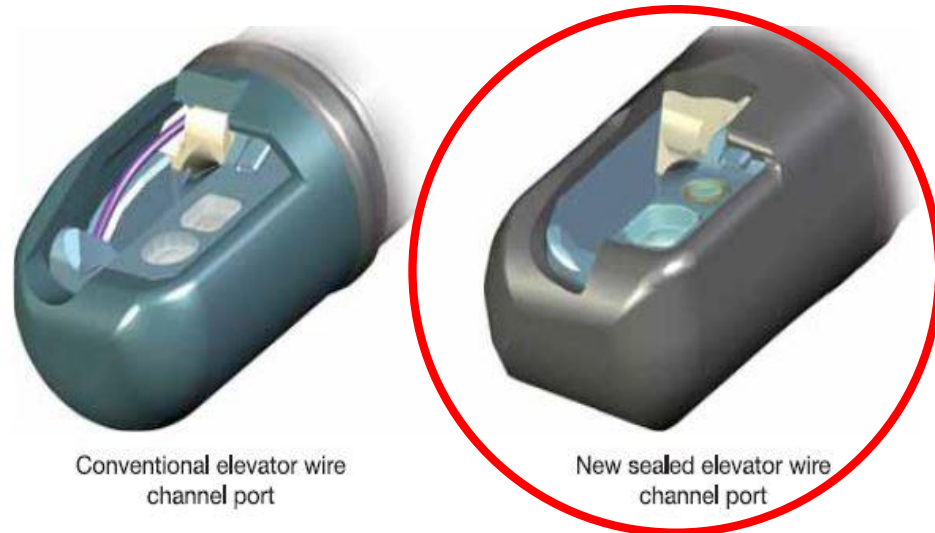
Design modified:



Easier Cleaning (Unique Fixed Distal End Design)

In addition to the clinical performance benefits of the TJF-Q180V's locking mechanism, the elevator wire channel port is now sealed so separate cleaning is no longer necessary. The result is faster, easier cleaning that makes scope reprocessing more efficient.

Bron: Product Brochure Olympus F1322SE-1109



Removal of the plastic cap and sampling



Figure 9: (First two photos on the left) Cutting open and prying loose of the hard plastic cap on the tip. (Two photos on the right)

Sampling interior under the removed hard plastic cap

Sampling behind the forceps elevator

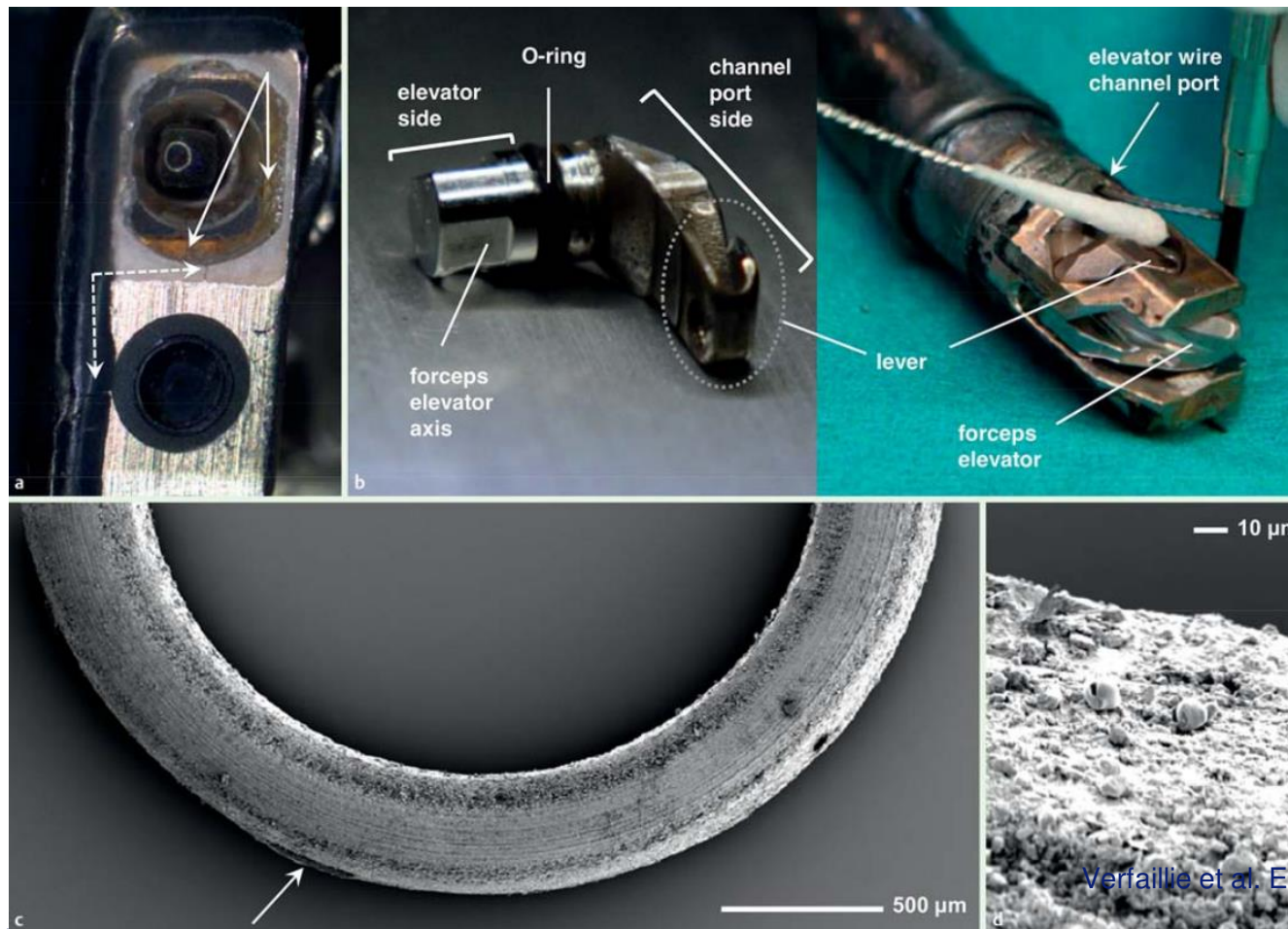


Figure 10: Sampling behind the forceps elevator (dismantled tip) with swabs and cytology brush.

Outbreak investigation ERCP Scopes

VIM-2-positive *Pseudomonas*

- Brown scale near camera lens and on the tip
- Brown scale at the inside part of the forceps elevator



Persistent contamination: outbreak risk

- outbreak in Erasmus MC

Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*

- Genetically identical VIM-2 strain isolated from:
 - Forceps elevator recess
 - Protection cap
 - 22 patients infected
- No breaches in reprocessing procedures
- *This endoscope; the source of the outbreak*



How a medical device maker kept U.S. hospitals in the dark about deadly infections

By CHAD TERHUNE AND MELODY PETERSEN
DEC. 19, 2015

T

he hunt for a deadly superbug that sickened 22 patients at a Dutch hospital began just before noon on a spring day in 2012.

Inside a lab in the tiny hamlet of Zoeterwoude, a technician carefully peeled back the tip of a state-of-the-art medical scope.

Timeline

Recent events involving scope-related outbreaks of antibiotic-resistant superbug infections

Second Dutch outbreak

K. pneumoniae ESBL, Olympus TJF-180V

- Duodenoscope A;
 - First contaminated endoscope
 - Attack rate 35%; (17/49 pts)
 - Flush suction & biopsy channel positive culture

- Duodenoscope B
 - Second contaminated duodenoscope (6 mnths after A)
 - Attack rate 29% (7/24 pts)
 - Flush biopsy channel positive culture

- Patients; 15 by clinical samples, 11 by contact screening;
10 infections (9 sepsis, 1 cholangitis)

Dutch outbreak *K. pneumoniae* ESBL Olympus TJF-180V

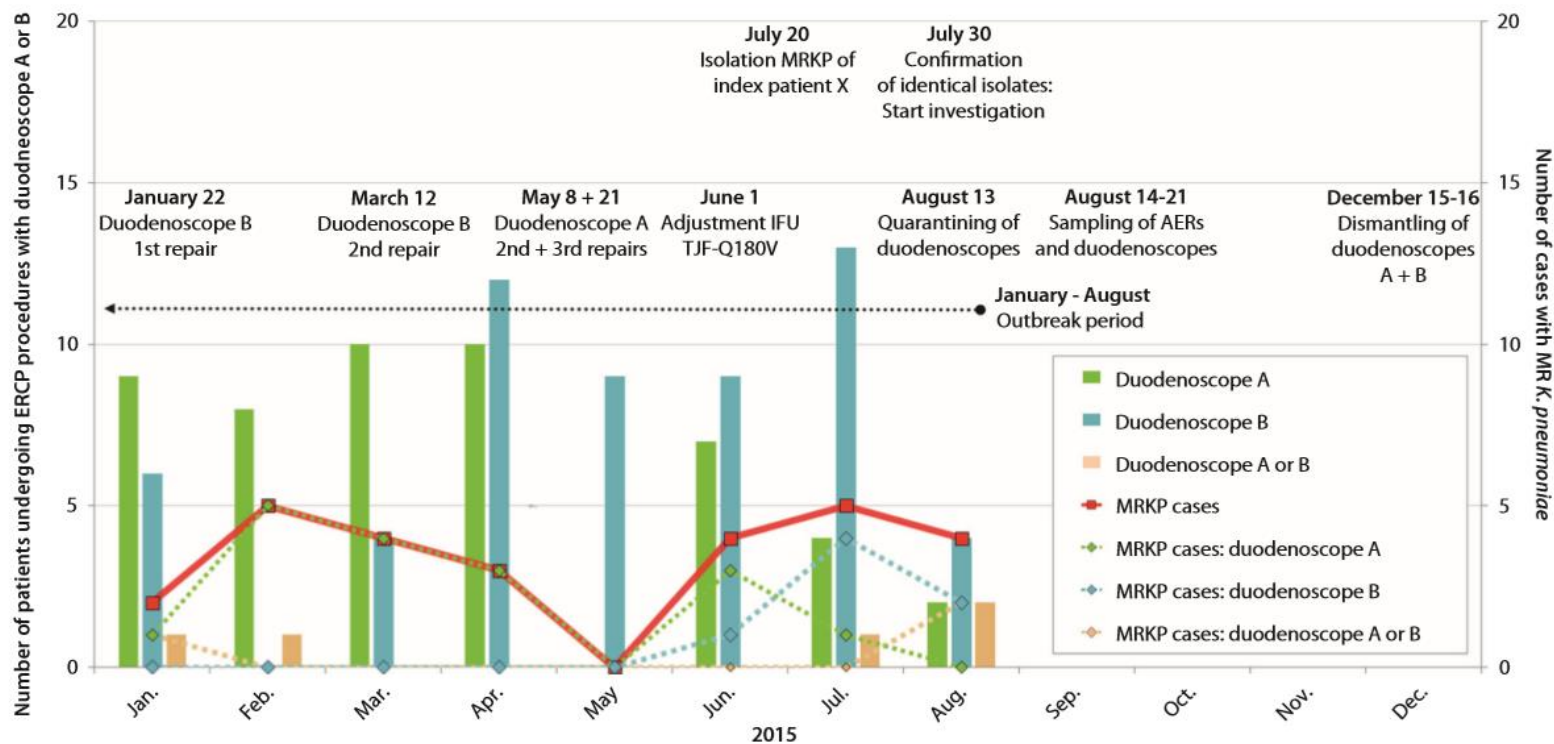
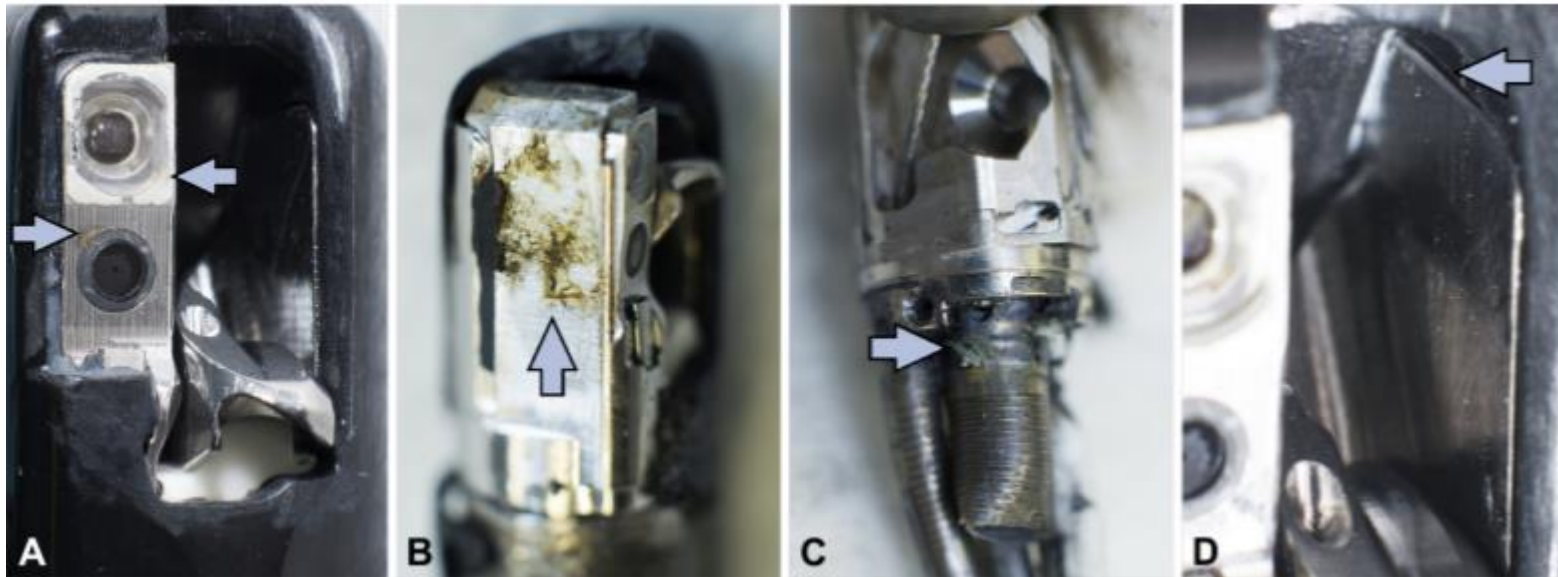


Figure 1. Timeline of the outbreak. *Green and blue bars*, number of patients who have undergone an ERCP procedure with duodenoscope A or B, respectively. Follow-up procedures with the same duodenoscope were excluded; *pink bar*, number of patients who have undergone a procedure with duodenoscope A or B; *solid red line*, all MRKP cases retrospectively detected by clinical or screening cultures; *dashed green line*, all cases with MRKP treated with duodenoscope A; *dashed blue line*, all cases with MRKP treated with duodenoscope B; *dashed pink line*, all cases with MRKP treated with a TJF-Q180V duodenoscope, either A or B. The outbreak period was set from January to August 2015. *MR*, Multidrug-resistant; *MRKP*, multidrug-resistant *K. pneumoniae*.

Reprocessing audit

- Deviations of IFU
 - Forceps elevator not moved in the upright position during cleaning
 - Not in the cleaning SOP
 - No switch to MAJ-1888 forceps elevator brush (Olympus; recommended June 2015, after start of the outbreak) yet, but use of BW-412T brush (formerly recommended)
 - Leakage test was not routinely performed, but on suspicion

Dismantling



- A: Distal tip showing sludge behind the glass that covers both lenses
- B: Dismantled distal tip: a brown layer on the frame and the cover plate incorrectly reused and reattached by soldering after repairs.
- C: Dismantled distal tip; incorrect fastening of the biopsy channel to the distal tip.
- D: Distal tip showing unwanted space between the tip frame and the protective cap

Why such large outbreaks?

- Breaches in cleaning disinfection
 - Only our center (and Utrecht..) ? = single/duo center problem
 - Complex design? = general problem
- 2 nation-wide studies on prevalence of contaminated endoscopes

Content

- Impact
 - Infections by contaminated endoscopes
- Prevalence
 - Contamination of endoscopes
- Solutions

PROCESS 1 and 2: Aims

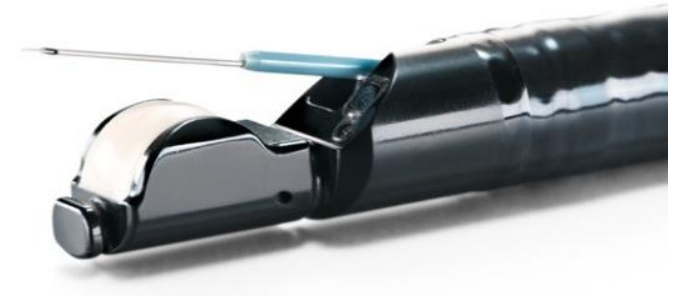
- 1; To determine the **bacterial contamination** of reprocessed **duodenoscopes** in the Netherlands
- 2; To determine the **risk factors** of **bacterial contamination** of reprocessed **duodenoscopes** and **linear echoendoscopes** in the Netherlands

Methods: sampling video instructions and sample kit



Methods: two studies, same design

- Prospective, cross-sectional studies including all Dutch ERCP centers
 - June 2015 - March 2016; Process 1
 - October 2016 - May 2017; Process 2
- Sampling by local staff
- Inclusion of Duodenoscopes (Process 1) and Echo-endoscopes (Process 2)



Methods: interpretation

- Two contamination definitions:^{1,2,3}
 1. Any microorganism with ≥ 20 colony forming units (**AM20**)
 2. Microorganisms with gastrointestinal or oral origin (**MGO**)

Definitions in Scope Contamination

- Microorganism categories



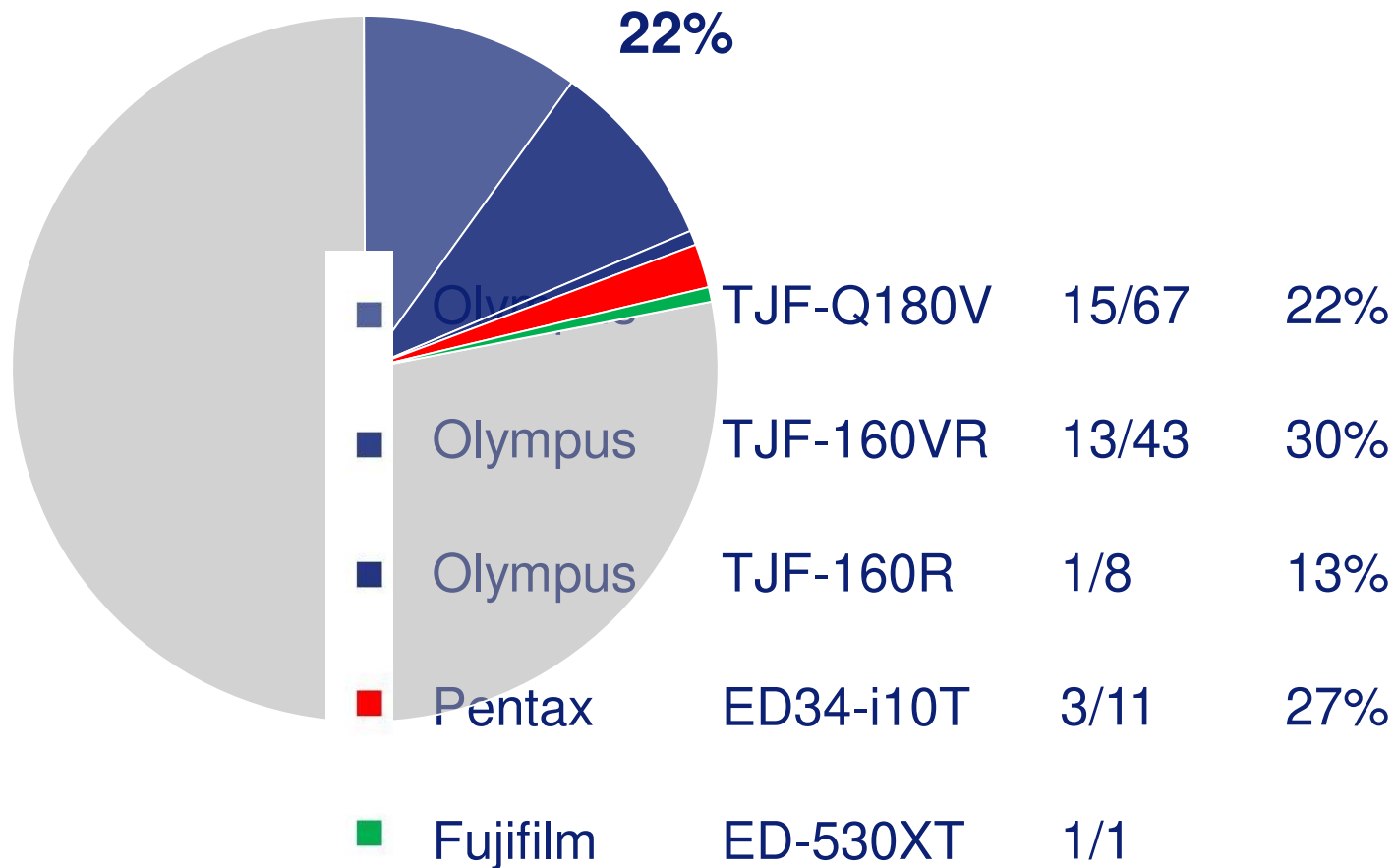
- Definition contaminated duodenoscope^{1,2}
 - AM20**: ≥ 1 microorganism with ≥ 20 colony forming units (CFU)
 - MGO**: microorganisms with gastrointestinal or oral origin, independent of CFU count

¹ Beilenhoff 2007

² SFERD 2013

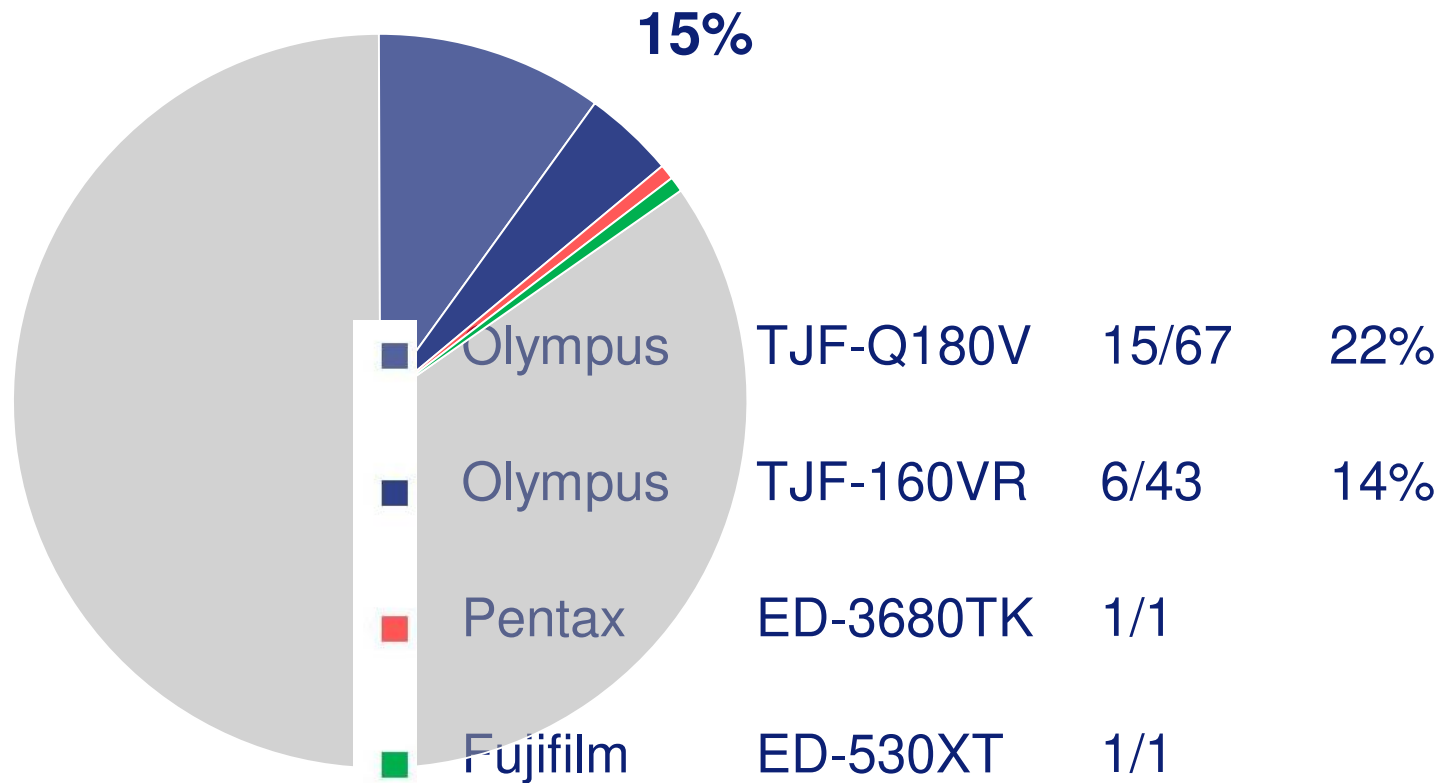
PROCESS 1 Duodenoscope Culture Study

Contamination according to AM20



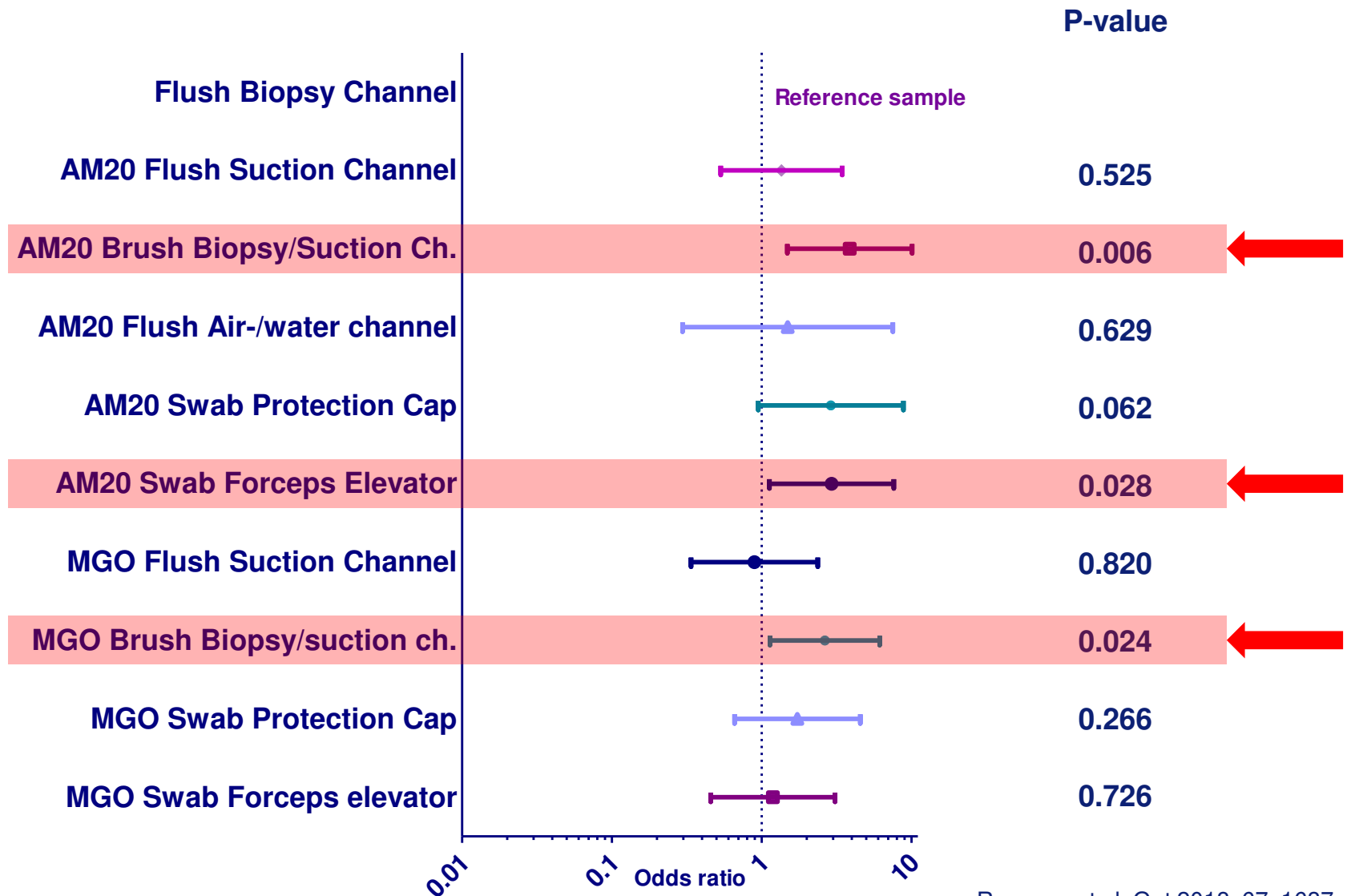
PROCESS 1 Duodenoscope Culture Study

Any presence of gut or oral flora



PROCESS 1 Duodenoscope Culture Study

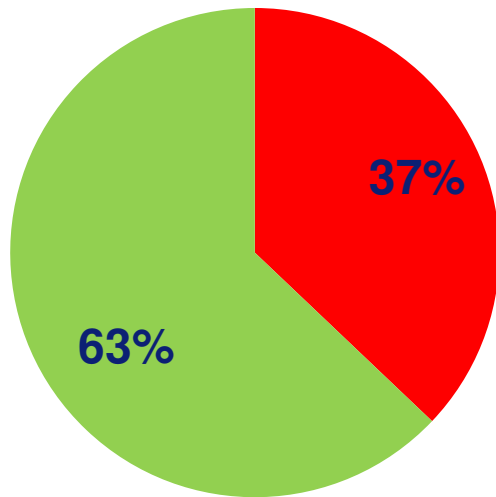
Predilection sites for contamination



ERCP/EUS centers ($n = 62$):

■ ≥ 1 MGO DLE

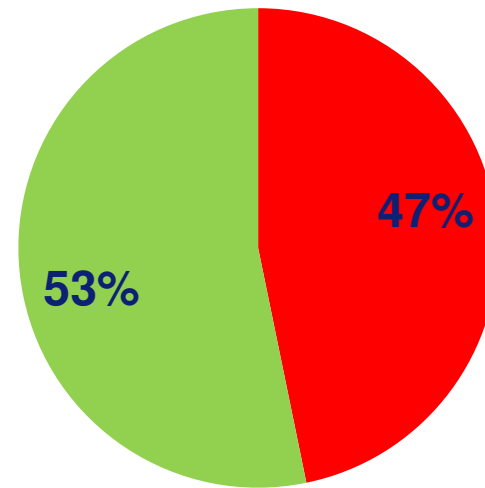
■ No contaminated DLE



37% (23/62 centers)
 ≥ 1 DLE with gut or oral flora

■ ≥ 1 MGO or AM20 DLE

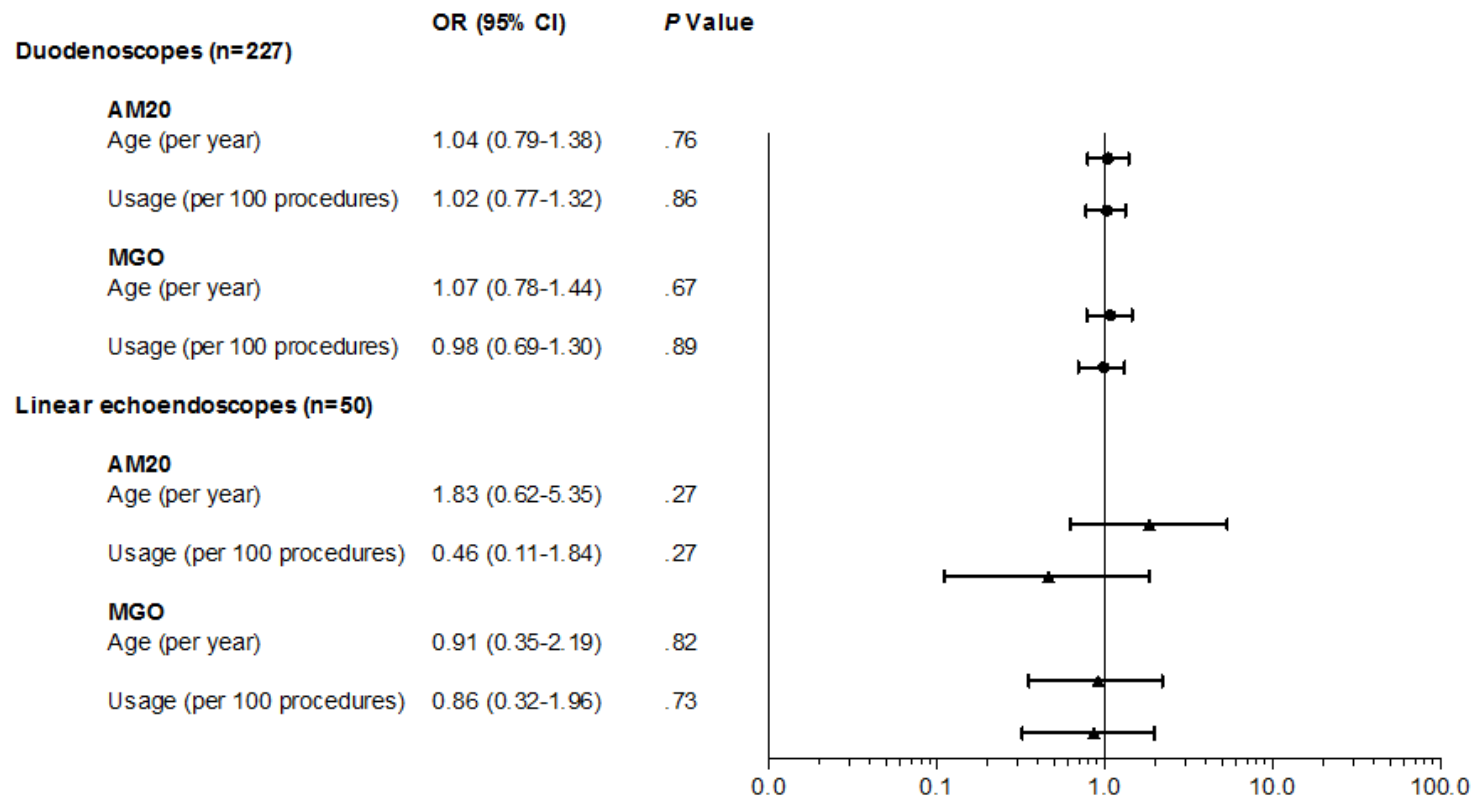
■ No contaminated DLE



47% (29/62 centers)
 ≥ 1 Contaminated DLE

Risk factors for contamination

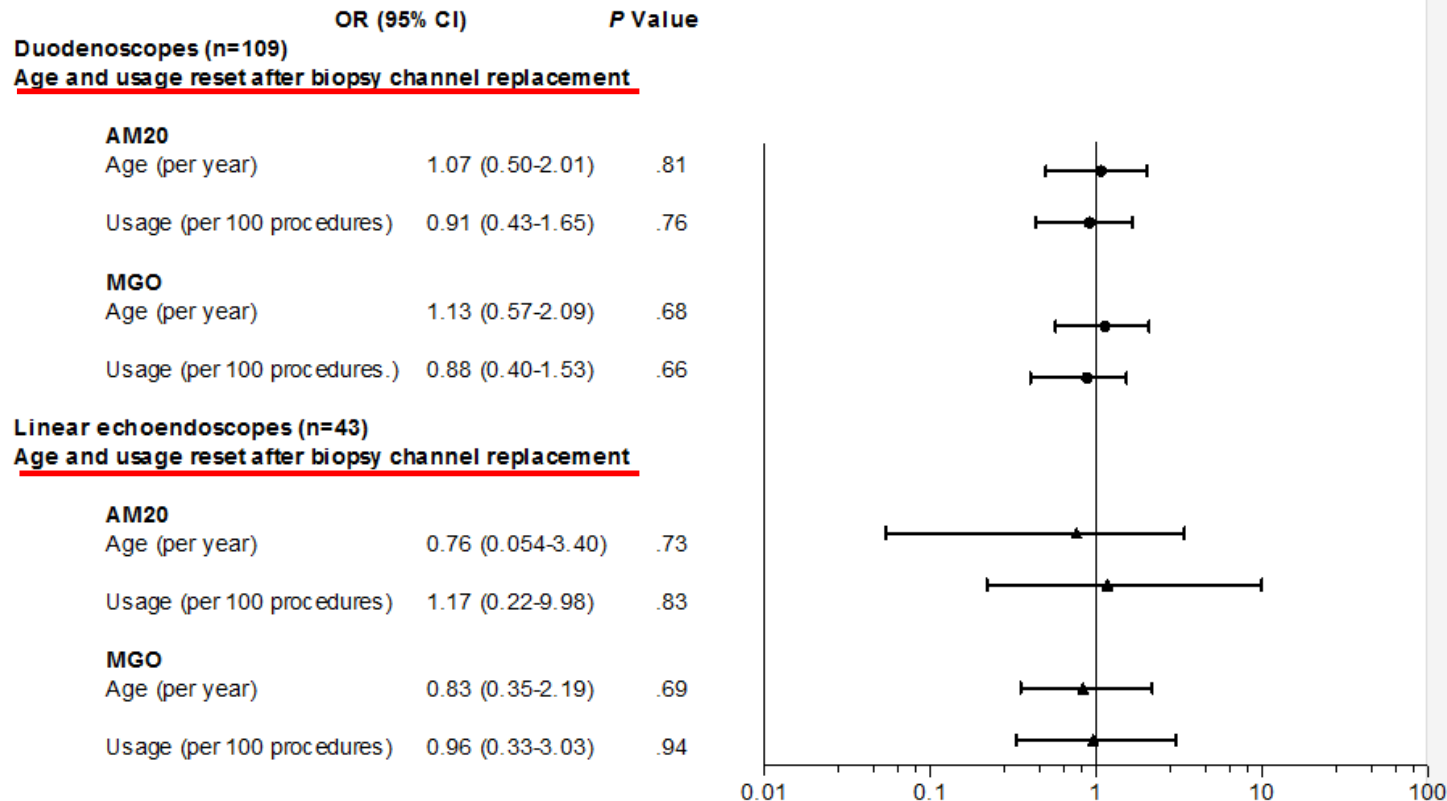
Figure 2. OR for age and usage on AM20 and MGO contamination in DLEs.



Abbreviations: DLE, duodenoscopes and linear echoendoscopes; AM20, microbial growth with ≥ 20 colony forming units/20 mL of any type of microorganism; MGO, presence of any microbial growth of gastrointestinal or oral microorganisms.

Risk factors for contamination

Figure 3. OR for reset age and usage on AM20 and MGO contamination in DLEs with information on biopsy channel replacement.



Abbreviations: DLE, duodenoscopes and linear echoendoscopes; AM20, microbial growth with ≥ 20 CFU/20 mL of any type of microorganism; CFU, colony forming units; MGO, presence of any microbial growth of gastrointestinal or oral microorganisms.

Results

Process 1 vs Process 2

- Contamination:
 - ✓ 22% vs 13% contaminated (AM20)
 - ✓ 15% versus 14% with any presence of gut or oral flora
 - ✓ 39% vs 47% centers with at least 1 MGO or AM20 contaminated DLE
 - **Comparable results: no lasting effect**
 - **Linear echoendoscopes have the same contamination risk**

- **In our study; Contamination is NOT related to wear and tear**

How often are DLE contaminated?

Single center incidence	Definition	Scope type	
Monthly cultures ¹	≥100CFU/ endoscope or Indicator MO	Duodenoscopes	35%
Yearly cultures ²	25CFU/ endoscope or indicator MO	Duodenoscopes	24%
Monthly cultures ³	10 CFU/ endoscope	Duodenoscopes	5%
Post procedure cultures ⁴	Any growth pathogenic MO	Duodenoscopes	2%
	Any growth all MO		13%
Monthly cultures ⁵	Any growth of CRE	Duodenoscopes	1,2%
Post procedure cultures ⁶	High-concern organisms	Duodenoscopes	0,7%
Post procedure ⁷	Any growth gram- bacteria	Linear echoendos.	4,2%

Multicenter incidence	Definition	Scope type	
Daily cultures, 21 centers ⁸	Any growth enteric bacterial flora	DLE	1%
	Any growth all MO		9%

Multicenter prevalence	Definition	Scope type	
Canada – 37 centers ⁹	≥10CFU/ml	Duodenoscopes	30%
USA - 3 centers ¹⁰	Any growth all MO	GI endoscopes	71%
Netherlands – 67 centers ¹¹	≥20CFU/20ml	Duodenoscopes	22%
	Any growth MGO		15%
Austria – 29 centers ¹²	≥20CFU/20ml / Any growth GI MO	GI endoscopes	3-4,6%

Prevalence; conclusions

- Depending on surveillance
 - Frequency
 - Definitions
 - Culture methods

- Gut/oral flora; about 15% of all endoscope are contaminated and used....
 - To worry about...
 - High attack rate, high number of serious infections

But why??

A few remarks on...

- Reprocessing
- Storage
- Biofilm

Reprocessing

Too complicated?
Not feasible to be compliant?

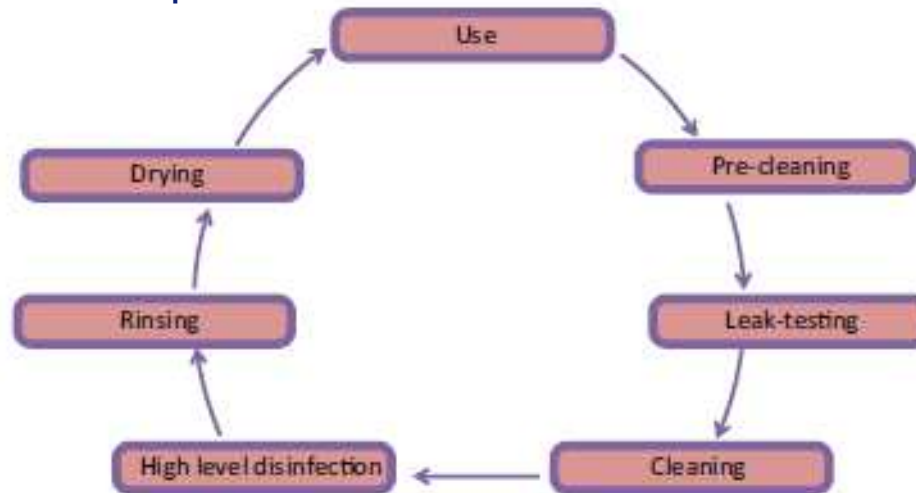


Fig. 3 Steps of a duodenoscope reprocessing

ESGE –ESGENA position paper

- Patients information; benefits and risks
- Trained and competent personnel
- Manufacturers; instructions on use and reprocessing
- Reprocessing protocols and equipment based on the manufacturer's instructions for each endoscope model.
- Type-specific, single use cleaning brushes
- Bed side cleaning, followed by leak testing, manual cleaning steps, and automated reprocessing

→ *Human error and inaccurate handling; pitfall*

Table II

Key points of the drying and storage procedures of flexible endoscopes according to several guidelines

Guideline	Use of alcohol flush	Manual drying	Use of drying/storage cabinet	Recommended storage time	Use of compressed air	Use of HEPA filters	Routine microbiological surveillance of endoscopes
AORN [34,35]	NR	NR	Yes	NR	Yes	Yes	Yes
ASGE [36,37]	Yes	Yes	NR	NR	NR	NR	No
BSG [38,39]	No	NR	Yes	72 h 3 h (if HEPA filters not used)	Yes	Yes	No
ESGE/ESGENA [6]	No	If necessary	Yes	NR	Yes	NR	Yes
CDC/FDA [4,40,41]	Yes	Yes	NR	NR	NR	NR	Yes
GESA [42]	Yes	NR	Yes	12 h (duodeno- and bronchoscopes) 72 h (other)	Yes	NR	Yes
HTM [43–45]	NR	NR	Yes	NR	Yes	Yes	Yes
PHAC [46]	Yes	Yes	Yes	7 days	NR	NR	No
SFED/H CSP [47–49]	NR	NR	Yes	72 h (≤ 7 days)	Yes	Yes	Yes
SFERD/WIP [50,51]	NR	NR	Yes	1 month	Yes	Yes	No
HGR/AZG [52,53]	Only if the AER out of service (HGR)	Only if the AER out of service (HGR)	Yes	1 month	Yes	Yes	Yes
SGNA [54]	Yes	Yes	Yes	7 days	NR	NR	NR
WEO/WGO [55]	Yes	Yes	Yes	NR	NR	NR	NR

AER, automated endoscope reprocessor; AORN, Association of periOperative Registered Nurses; ASGE, American Society for Gastrointestinal Endoscopy; AZG, Agentchap Zorg en Gezondheid; BSG, British Society of Gastroenterology; CDC, Centres for Disease Control and Prevention; ESGE/ESGENA, European Society of Gastrointestinal Endoscopy/European Society of Gastroenterology and Endoscopy Nurses and Associates; FDA, Food and Drug Administration; HCSP, High Council of Public Health; HGR, Hoge Gezondheidsraad; HEPA, high-efficiency particulate air; HTM, Health Technical Memorandum; GESA, Gastroenterological Society of Australia; NR, no recommendation; PHAC, Public Health Agency of Canada; SFED, French Society of Digestive Endoscopy; SFERD, Steering Group for Flexible Endoscope Cleaning and Disinfection; SGNA, Society of Gastroenterology Nurses and Associates; WEO, World Endoscopy Organisation; WIP, Infection Prevention Working Group; WGO, World Gastroenterology Organisation.

Storage; no consensus

Table III

Maximum safe storage time (shelf-life) for endoscopes suggested in the literature

Published studies	Types of endoscope tested	Storage time
Alfa et al. [3]	ERCP endoscopes	2 days
Brock et al. [71]	Gastro-, duodeno- and colonoscopes	21 days
Cooke et al. [63]	Not specified	3 days
Grandval et al. [64]	Gastro-, duodeno- and colonoscopes	3 days
Ingram et al. [72]	Colonoscopes	8 weeks
Osborne et al. [62]	Lower and upper GI endoscopes	1 day (5 days may be safe)
Pineau et al. [65]	Colono-, duodeno- and enteroscopes	2–3 days
Richard et al. [66]	Not specified	3 days
Rejchrt et al. [67]	Upper GI, duodeno- and colonoscopes	5 days
Riley et al. [68]	Colonoscopes	7 days
Riley et al. [69]	Colonoscopes	7 days
Vergis et al. [70]	Colono- and duodenoscopes	7 days (possibly up to 14 days)

ERCP, endoscopic retrograde cholangiopancreatography; GI, gastrointestinal.

Storage time;
1 day to 21 days

Biofilm...



Contents lists available at [ScienceDirect](#)

American Journal of Infection Control

journal homepage: www.ajicjournal.org



Major article

Correlation between the growth of bacterial biofilm in flexible endoscopes and endoscope reprocessing methods



Wu Ren-Pei MD^{a,1}, Xi Hui-Jun MD^{a,1}, Qi Ke MD^a, Wang Dong MD^a, Nie Xing PhD^b,
Li Zhao-Shen PhD, MD^{a,*}

^a Department of Gastroenterology, Changhai Hospital of Second Military Medical University, Shanghai, China

^b National Center for Nanoscience and Technology of Chinese Academy of Sciences, Beijing, China

Channels; provided by endoscope repair centers of Olympus, Pentax, Fujifilm in China.
66 suction and biopsy channels and 13 water and air channels (disassembled)
66 endoscopic centers

→ EM scanning; 36 / 66 (55%) and 10/13 (77%) obvious biofilm growth.

Hospitals without biofilm

Hospitals with biofilm

Table 1

Summary of answers to the follow-up questionnaire for endoscope reprocessing procedures in 66 hospitals

Characteristic and Recommendation	Group A (n = 30)	Group B (n = 36)	Total (N = 66)	P value
Daily surgical volume				.239
<5	70.0 (21/30)	83.3 (30/36)	78.8 (51/66)	
50-100	16.7 (5/30)	13.9 (5/36)	15.2 (10/66)	
>100	13.3 (4/30)	2.7 (1/36)	7.6 (5/66)	
Proportion of manual cleaning	50.0 (15/30)	91.7 (33/36)	72.7 (48/66)	.001
Suctioning all channel	90.0 (27/30)	83.3 (30/36)	86.4 (57/66)	.670
Use of biofilm removal detergent	26.7 (8/30)	0 (0/36)	12.1 (8/66)	.003
Repeated use of detergent	63.3 (19/30)	91.7 (33/36)	78.8 (52/66)	.005
Sterile water used to rinse	60.0 (18/30)	61.1 (22/36)	60.6 (40/66)	.927
Alcohol dry	76.7 (23/30)	38.9 (14/36)	56.0 (37/66)	.002

NOTE. Values are percentages (compliance with recommendations for reprocessing or characteristic).

Factors associated with biofilm;
 manual cleaning, repeated use of detergent,
 not using biofilm removal detergent and/or alcohol dry.

Conclusion; biofilm is quite common....

Content

- Impact
 - Infections by contaminated endoscopes
- Prevalence
 - Contamination of endoscopes
- Solutions

Content

Solutions;

- Improved Quality Assurance
- Alternative approaches to reprocessing
- New technologies

Content

Solutions;

- Improved Quality Assurance
 - Surveillance
 - Microbial
 - ATP
 - Inspection
- Alternative approaches to reprocessing
- New technologies

Surveillance

- Microbiological surveillance
 - Not a routine practice in The Netherlands (until 2018) and U.S.A.^{1,2}
 - Advised in ESGE, French and Australian guidelines^{3,4,5}
 - Differences in:
 - Sampling and culturing technique
 - Frequency: monthly to yearly

Indicator microorganisms

NVMM 2018 Gut/oral flora	CDC 2015 High-concern MO	ESGE 2007 Indicator MO	France 2016 Indicator MO
Enterobacteriaceae	Gram-negative	Enterobacteriaceae	Enterobacteriaceae
<i>Ps aeruginosa</i>	bacteria	<i>Enterococci</i>	<i>Enterococci</i>
<i>S. aureus</i>	<i>Enterococci</i>		<i>Pseudomonas spp</i>
Enterococci	<i>Staphylococcus</i>	<i>Pseudomonas</i>	<i>Stenotrophomonas</i>
<i>Stenotrophomonas</i>	<i>aureus</i>	<i>aeruginosa</i>	<i>maltophilia</i>
<i>maltophilia</i>		+ other gram-negative	<i>Acinetobacter spp</i>
<i>Acinetobacter spp</i>		nonfermenters	<i>Staphylococcus aureus</i>
<i>Candida spp</i>			<i>Candida spp</i>
		<i>Staphylococcus aureus</i>	
		<i>Staphylococcus</i>	
		<i>epidermidis</i>	
		Atypical mycobacteria	
		<i>Legionella</i> organisms	

Dutch culture guideline NVMM 2018

Starting point;

- Recommended frequency; depending on the results of the prevalence the frequency of next measurements is given
- Positive results → culture frequency increases

Dutch surveillance guideline 1

What's new?

- *Starts with a prevalence culture measurement of all endoscopes*
- *“how to” and “what to do in case of...”*

- **Depending on the micro-organisms; action**
 - Micro-organisms; gut-oral/water/skin
 - Gut–oral; scope in quarantaine
 - Water-skin; repeat cleaning disinfection

- **Depending on the number of scopes found positive;**
 - repeating frequency of prevalence measurement;
 - ≥ 2 scopes with gut-oral flora; repeat after 2 weeks
 - ≥ 2 scopes with skin or water flora; repeat after 2 mnths
 - No scope positive; repeat after 6 mnths

Dutch surveillance guideline 2

- *Other actions;*

- **Gut-oral flora** ≥ 3 positive findings ≥ 2 different scopes in 4 weeks;

- Audit department on cleaning and disinfection and flushing

- **Skin flora** ≥ 6 positive findings in ≥ 2 different scopes in 3mnths;

- Audit storage en culturing

- **Water flora** ≥ 6 positive findings in ≥ 2 different scopes in 3mnths;

- Control AER/culture water

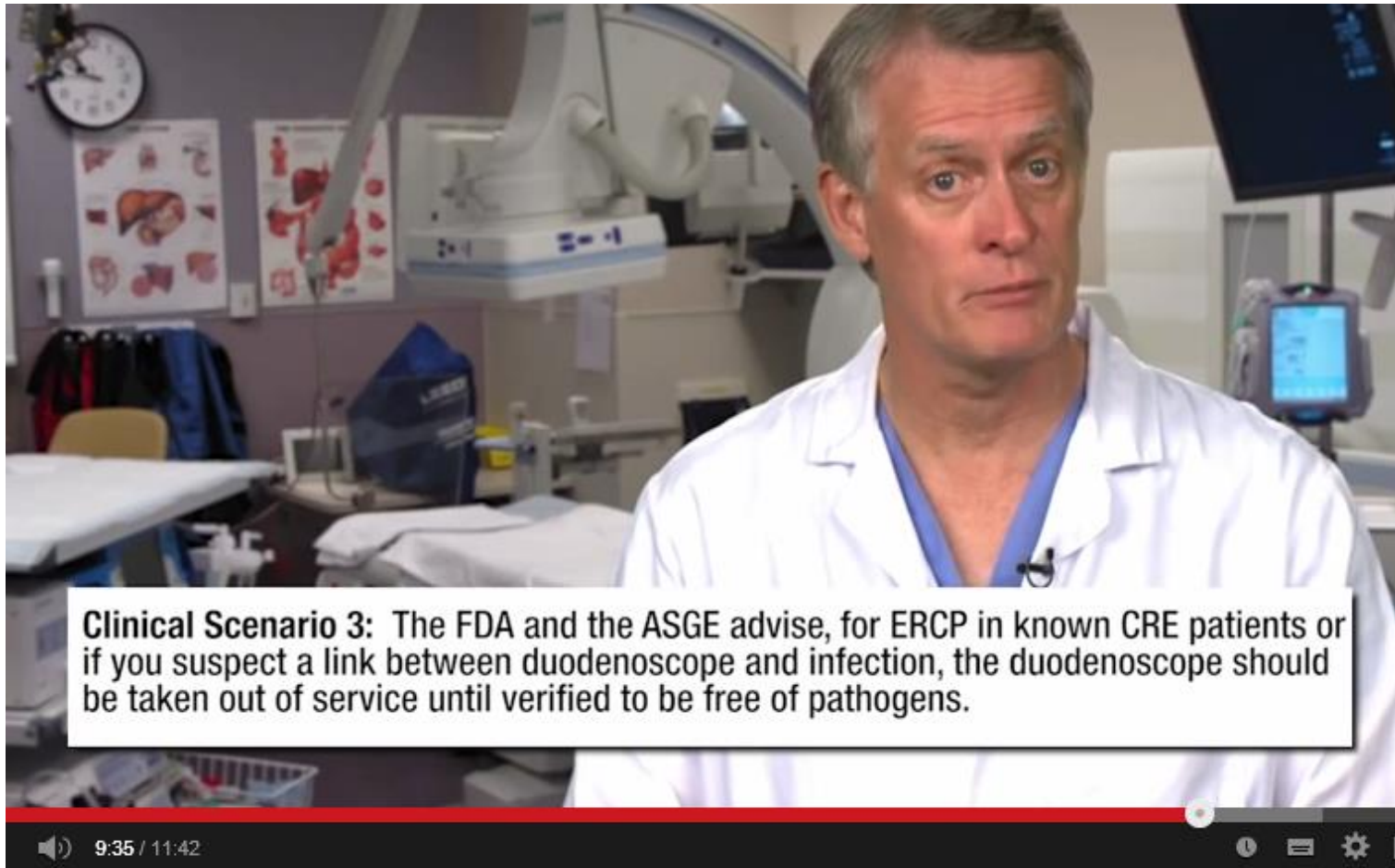
Dutch surveillance guideline 4; risk management; the hardest issue!

In case of gut flora;

- OMT, risk analysis

Consider;

- M.O and sensitivity pattern
- Decide on recall action by estimated risk on transmission of viruses
HBV HCV (HIV)
- Decide on contact-tracing in case of HRMO:
 - Consider risks (LTX and CRE), treatment options (hardly any in HRMO) and burden for patients

A middle-aged man with grey hair, wearing a white lab coat over blue scrubs, is speaking in a clinical setting. In the background, there is a large medical monitor, anatomical charts on the wall, and various medical equipment. A white text box is overlaid on the bottom left of the video frame.

Clinical Scenario 3: The FDA and the ASGE advise, for ERCP in known CRE patients or if you suspect a link between duodenoscope and infection, the duodenoscope should be taken out of service until verified to be free of pathogens.

9:35 / 11:42

Content

Solutions;

- Improved Quality Assurance
 - Surveillance
 - Microbial
 - ATP
 - Inspection
- Alternative approaches to reprocessing
- New technologies

Recent ATP studies

Encounters	ATP Outcomes after manual cleaning, culture outcomes after HLD
10 gastro / 10 colo / 10 duo 8 radial/ 10 linear ¹	48 Biopsy-suction channels ATP < 200RLU 19/20 elevator channels ATP >200RLU
304 coloscopes 143 gastroscopes ²	3/304 (1%) coloscopes ATP >200 RLU 74/143 (52%) gastroscopes ATP >200RLU
390 duodenoscopes ³	ATP testing and cultures after HLD No correlation was found.
60 gastroscopes ⁴	31 ATP >200 RLU of which 7 post HLD contaminated 26 ATP <200 RLU of which 2 post HLD contaminated
20 duodenoscopes ⁵	18/20 (90%) ATP > 200RLU 12/20 (60%) post HLD contaminated any growth ATP testing compared to cultures: Sensitivity 30% Specificity 53%
Systematic review 10 studies	ATP does not correlate with cultures during and after reprocessing

■ However.... No controlled studies!

1. Sethi et al. GIE, 2016
2. Ofstead et al. Am J Inf. Control, 2016
3. Olafsdottir et al. Infect control Hosp Epidemiol, 2016
4. Parohl et al. GMS Hyg Inf Control, 2017
5. Visrodia et al. GIE, 2017

Diversity in tests and frequency; an international survey in 39 countries

Table 2 Assessment methods and frequency for flexible endoscope reprocessing

Test	Every scope	Once a week	Once a month	Twice a year	Once a year	Never
Microbial culture	9%	6%	18%	25%	11%	31%
TOSI™	23%	10%	14%	6%	9%	38%
Final Rinse water test	15%	10%	22%	15%	10%	28%
Routine ATP	12%	5%	8%	12%	4%	59%
Routine protein test	11%	6%	7%	7%	7%	62%
Routine Other	12%	5%	10%	12%	7%	54%
AER Documentation	63%	5%	3%	6%	4%	19%

ATP Adenosine Triphosphate, AER Automated Endoscope Reprocessor

Thoughts on ATP.....

- Clean= <200 relative light units
 - equated to 10^{-4} CFU/cm²
 - = 10^{-6} CFU per endoscope

because the surface area of an endoscope channel is >100 cm².

→ An endoscope assessed as clean by ATP could still have a significant microbial load (eg, 10^{-6}).

→ Role of ATP in endoscopes not resolved yet

Content

Solutions;

- Improved Quality Assurance
 - Surveillance
 - Microbial
 - ATP
 - Inspection
- Alternative approaches to reprocessing
- New technologies

Let's have a look into the inner side...

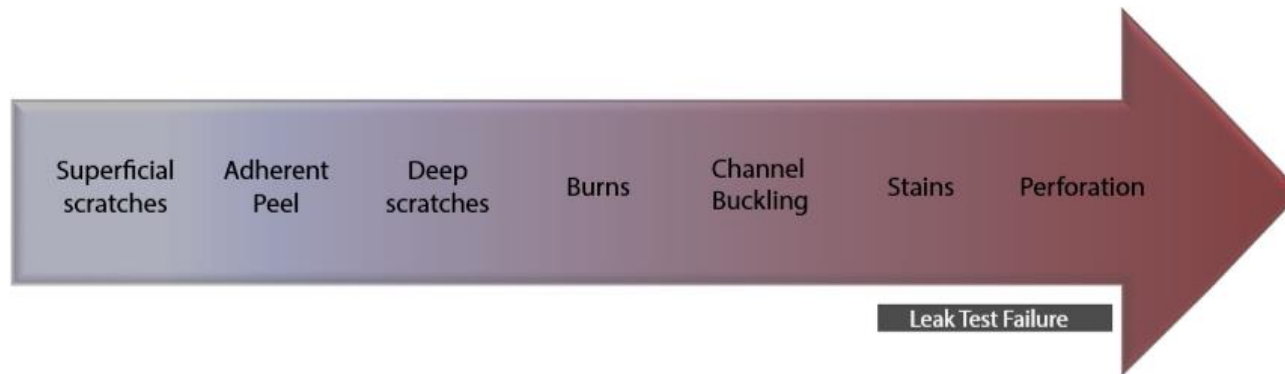


Figure 1. Schematic depicting the full spectrum of working channel damage from mild to severe: superficial scratches and scratches with adherent peel are almost ubiquitous and are consistent with normal wear and tear. The significance of deeper scratches and burns is uncertain, and these findings should trigger discussion with the manufacturer. Channel buckling may compromise the channel lumen, may impair the ability to advance accessory devices, and may impair manual cleaning. Channel repair is indicated. Perforations and related stains usually fail leak testing, and channel repair is indicated.

Scope the scope!

TABLE 1. Studies evaluating borescope examination in clinically used endoscopes

Study	Borescope device (manufacturer)	No. of endoscopes (endoscope type); no. of inspections	Borescope examination findings	Biomarker correlation	Interobserver variability
Ofstead et al, 2016-2017 ²⁻⁴	Flexible Inspection Scope; (HealthMark Industries, Fraser, Michigan)	20 endoscopes (7 AC, 7 PC, 6 gastro) at final assessment	Discoloration, scratches, debris (% NR) Fluid 95% after limited drying (including cloudy fluid in which simethicone was detected) 85% required repair	ATP and microbial cultures performed but not correlated with borescope examination findings	NR
Ofstead et al, 2018 ⁵	Ultra-Thin HQ Micro Borescope (Medit Inc, Winnipeg, Canada); Flexible Inspection Scope (Healthmark Industries, Fraser, Michigan)	45 endoscopes (13 colon, 12 gastro, 5 duo, 3 echo, 3 cysto, 3 uretero, 3 broncho, 2 intubation, 1 endobronchial EUS)	Discoloration, white/black residue, scratches, non-intact channel lining, debris, dented channels (% NR) Fluid 47% (21/45)	Residual fluid associated with higher ATP values after HLD ($P < .01$) and microbial growth ($P = .028$)	NR
Barakat et al, 2018 ⁶	SteriCam (Sanovas Inc, San Rafael, California)	68 endoscopes (16 AC, 17 PC, 23 gastro, 7 duo, 5 echo); 85 total inspections	Scratches 99% (67/68) Scratches with peeling 77% (52/68) Minor debris 96% (65/68) Fluid 43% (29/68) (predominantly clear, occasionally opaque) Channel buckling 3% (2/68)	Residual fluid associated with higher ATP values after HLD ($P < .0001$ independent; $P = .03$ clustered)	R mean values (3 endoscopists): Scratches 0.39 Fluid 0.89
Thaker et al, 2018 ¹	SteriCam (Sanovas Inc, San Rafael, California)	59 endoscopes (14 duo, 24 echo, 10 gastro, 11 colon); 97 total inspections	Discoloration 59% (35/59) Scratches 86% (51/59) Shredding 59% (35/59) Debris 22% (22/97) Fluid 8% (8/97)	NR	NR

What about the channel?

Has the channel dried properly?

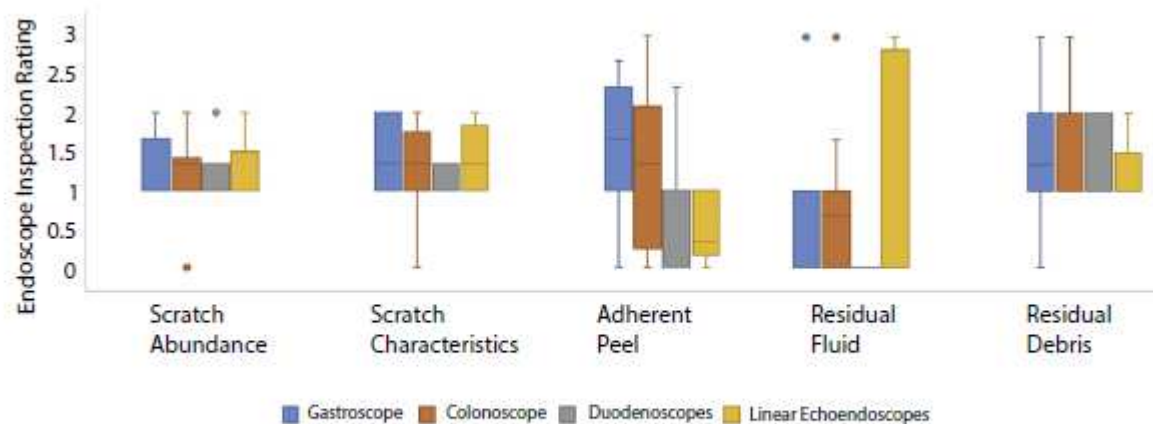


Figure 3. Graphic box plot representation of investigator ratings for scratch abundance and characteristics, scratches with adherent peel, and residual fluid and/or debris. Boxes represent the interquartile range. Horizontal lines within boxes represent the median rating. Whiskers represent the lowest or highest data point still within a 1.5-multiple of the interquartile range. Dots represent outliers.

Scratches; 98.5%

Scratches and peeling; 76.5%

Residual fluid; 42.6%

Small foci of minor debris; 95.6%

Endoscope length did not predict residual fluid

Biofilms were not evident in any endoscope working channel; visible?

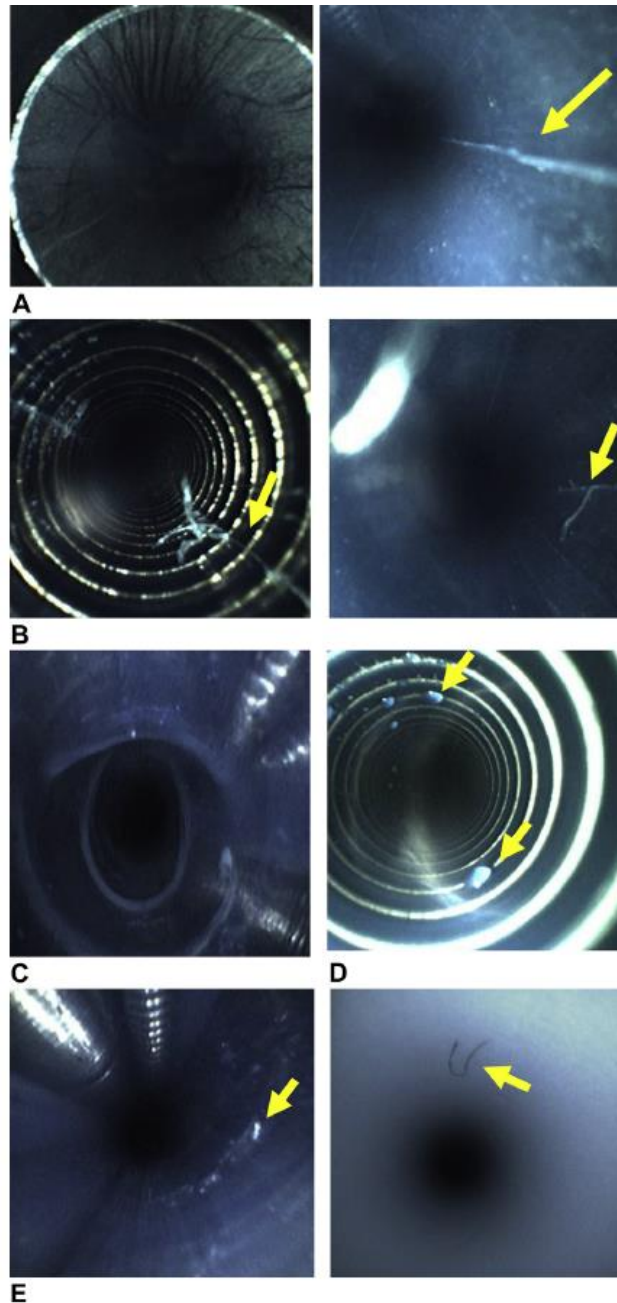


Figure 2. Images depicting working channel damage and residue visualized in endoscopes. **A**, Superficial scratches at the inlet region (*left*) and along the endoscope shaft (*right*). **B**, Scratches with adherent peel, perpendicular to circular rings of the endoscope bending segment (*left*) and along the endoscope shaft (*right*). **C**, Channel buckling of the endoscope shaft. **D**, Drops of residual fluid. **E**, White punctate (*left*) and black linear (*right*) residual debris.

ATP and scope the scope

- ATP values negative; range 3 to 87, median 10 (after HLD)
- Significant higher ATP values with;
 - residual fluid
 - latency from reprocessing
- Endoscope channel diameter/length;
 - Did not predict increased ATP
- Number of lifetime uses:
 - Did not predict ATP, working channel damage, residual fluid, or residual debris

Content

Solutions;

- Improved Quality Assurance
 - Surveillance
 - Microbial
 - ATP
 - Inspection
- Alternative approaches to reprocessing
- New technologies

Double HLD

Study question;

- Compare the effectiveness of single HLD versus double HLD in eliminating residual enteric pathogen growth in DLE
- 4 endoscopy facilities.
- daily cultures of stored DLEs

Randomized on single or double HLD

Double HLD

Outcome;

- N= 5850 surveillance culture specimens
- N= 2925 encounters, 45 DLEs in clinical use (including 7 on loan)
- Microbial contamination:
 - N= 235 specimens (4.0%) or 224 encounters (7.7%)
- High-concern pathogens:
 - N= 8 specimens (.1%) 8 encounters (.3%) from 5 different endoscopes.
- Median number of days between reprocessing and culturing was 1

Double HLD

TABLE 1. Details of 8 cultures positive for high-concern pathogens, cultured from 5 different duodenoscopes and linear echoendoscopes

Facility	Culture date	Duodenoscope and linear echoendoscope identification	High-level disinfection method	High-concern pathogen(s) detected
A	2/26/2016	1	Single	<i>Enterococcus</i> spp
A	4/8/2016	2	Double	<i>Enterococcus</i> spp
A	4/29/2016	2	Single	<i>Enterobacter cloacae</i>
A	5/6/2016	3	Double	<i>Aeromonas</i> spp
A	8/8/2016	4	Double	<i>Escherichia coli</i> (ESBL+), <i>Enterococcus</i> spp
B	7/15/2016	5	Single	<i>E coli</i> (ESBL-) and <i>Enterococcus faecalis</i>
B	7/29/2016	5	Single	<i>E coli</i> (ESBL+) and <i>Enterococcus faecalis</i>
B	8/1/2016	5	Single	<i>Enterococcus faecium</i>

ESBL + extended spectrum β -lactamase; + positive; - negative

High-concern pathogens positive cultures;
In 5 endoscopes from the elevator mechanism, 2 separate facilities

Persistent growth;
2 duodenoscopes: *E. faecalis* on 3 occasions, *E coli* on 2 of the 3 occasions, 1 ESBL

→ No significant differences between single HLD and double HLD

Double HLD

What a pity...

Missing...

“....High-concern pathogens were defined as potentially pathogenic enteric flora and included Escherichia coli, Enterococcus faecalis, Enterococcus faecium, Enterococcus spp, Enterobacter cloacae, Aeromonas spp....”

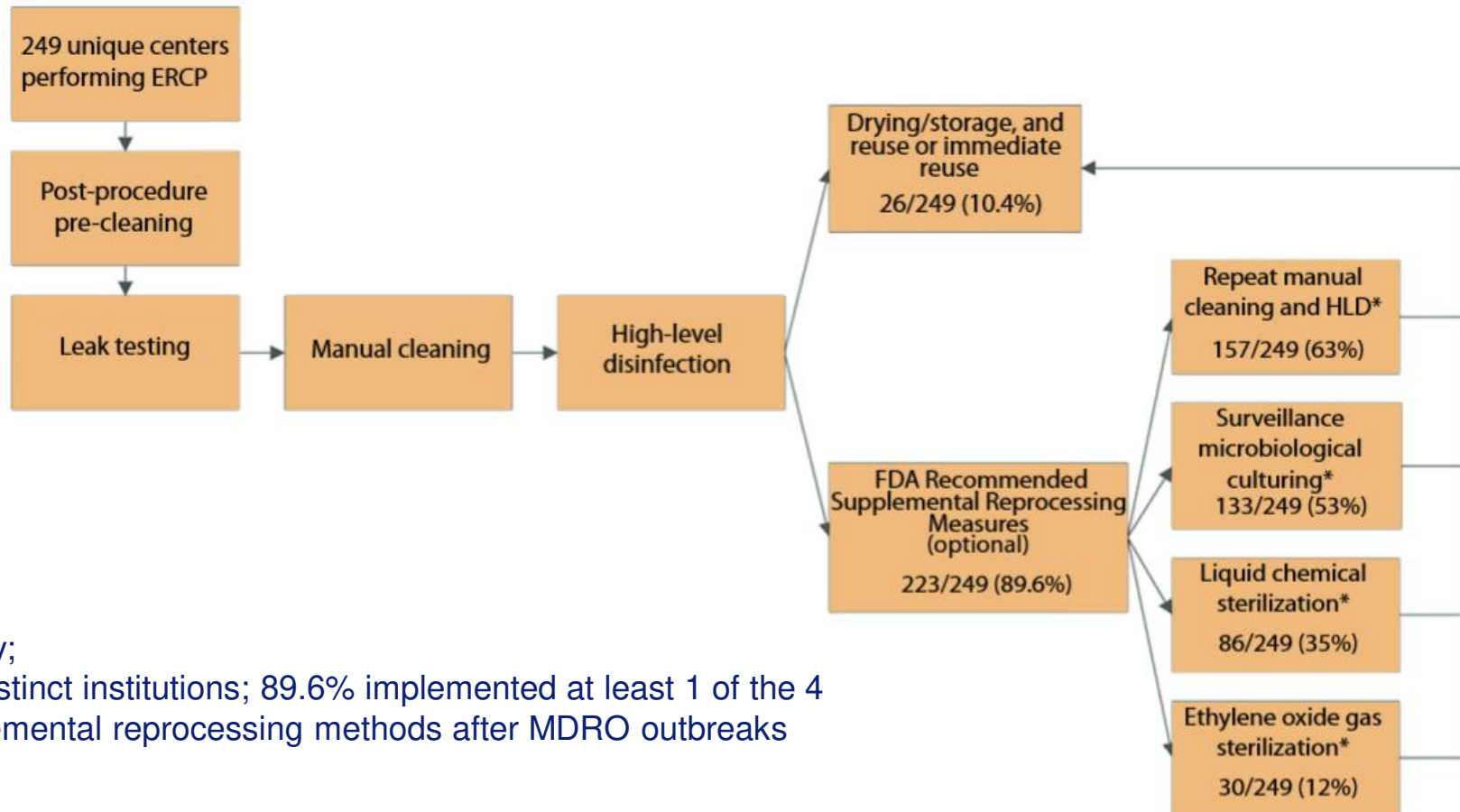
“...Coagulase-negative Staphylococci, Bacillus spp, coryneform gram-positive bacilli, and other gram-negative glucose nonfermenters were considered environmental colonizers....”

Misclassified...

○ Why?

→ Underpowered

Reprocessing practices in USA; the extra's



Survey;
249 distinct institutions; 89.6% implemented at least 1 of the 4
supplemental reprocessing methods after MDRO outbreaks

Figure 1. Flow diagram of duodenoscope reprocessing steps, including FDA recommended supplemental reprocessing methods and survey responses from unique centers. Results are non-exclusive. *FDA*, United States Food and Drug Administration; *HLD*, high-level disinfection. *Results are non-exclusive.

What do we do extra?

TABLE 3. Duodenoscope reprocessing practices on a per center basis

	Number of centers	% of total
Total number of centers	249	-
Supplemental reprocessing method*		
Repeat high-level disinfection	157	63.1
Surveillance microbiological culturing	133	53.4
Liquid chemical sterilization	86	34.5
Ethylene oxide (EtO) sterilization	30	12.0
None of the above	26	10.4
Additional measures*		
Patient MDRO screening	38	15.3
ATP testing	84	33.7
Drying technique*		
Ventilated cabinet	152	61.0
Hang overnight	134	53.8
Forced-air drying	119	47.8
None (used immediately)	22	8.8
Other	11	4.4
Unknown	8	3.2

MDRO, Multidrug-resistant organism; ATP, adenosine triphosphate.

*Results are non-exclusive.

Large variation...

Content

Solutions;

- Improved Quality Assurance
 - Surveillance
 - Microbial
- Alternative approaches to reprocessing
- New technologies

Re-Design of an ERCP Scope

ED34-i10T2 vs. ED34-i10T

ED34-i10T



Reprocessable Cap

ED34-i10T2



Disposable Elevator

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

[A to Z Index](#) |

Search FDA

[Home](#)

[Food](#)

[Drugs](#)

[Medical Devices](#)

[Radiation-Emitting Products](#)

[Vaccines, Blood & Biologics](#)

[Animal & Veterin](#)

News & Events

[Home](#)

[News & Events](#)

[Newsroom](#)

[Press Announcements](#)

FDA News Release

FDA clears Olympus TJF-Q180V duodenoscope with design modifications intended to reduce infection risk

[SHARE](#)

[TWEET](#)

[LINKEDIN](#)

[PIN IT](#)

[EMAIL](#)

[PRINT](#)

**For Immediate
Release**

January 15, 2016

Release

The U.S. Food and Drug Administration today cleared the Olympus TJF-Q180V

Not the (l)onelyone.....

→ much focus on Olympus new design, but all brands and types are at risk.....
(case reports, Process 1 and 2)

PENTAX
MEDICAL

Contact Us



Search

Home » News & Events » News » Press Releases

Events

News



Press Releases

Urgent Field Correction: Updated Instructions for Use for PENTAX Medical ED-3490TK Video Duodenoscope

February 19, 2016

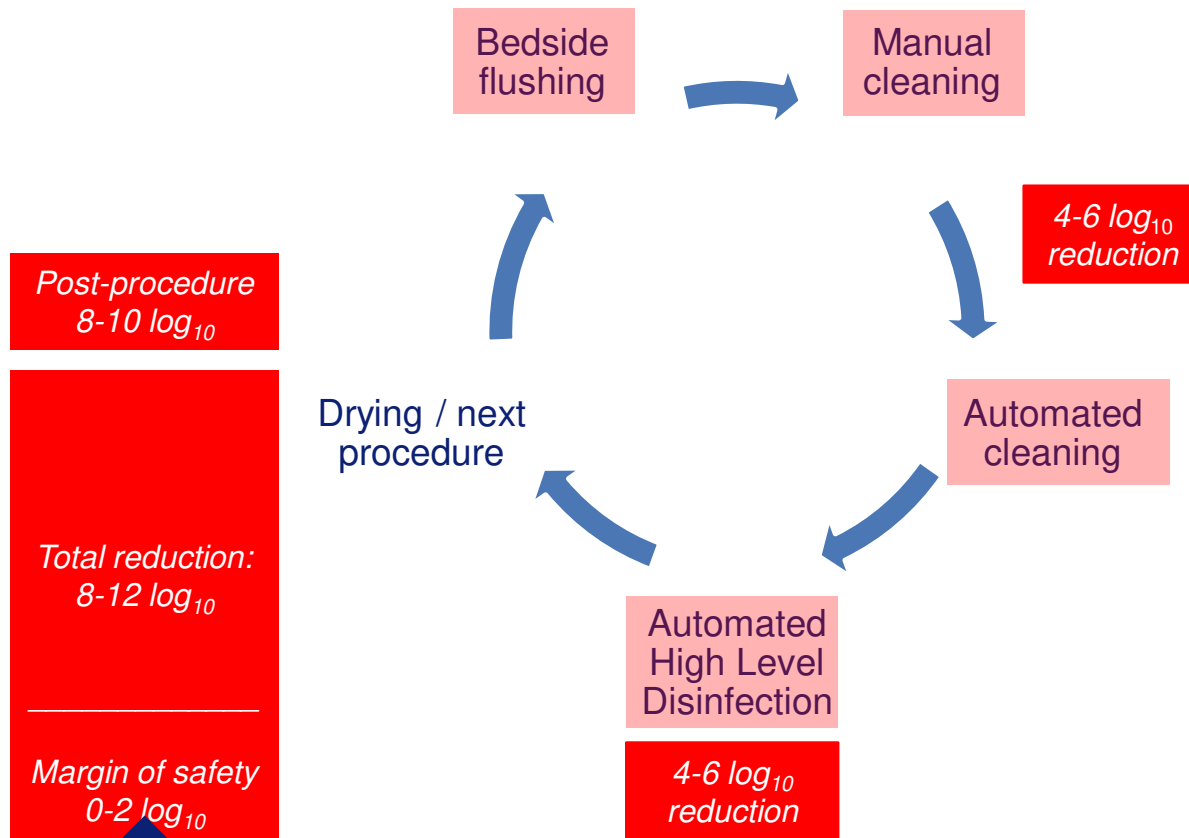
Dear Valued Customer,

The purpose of this communication is to inform you that PENTAX Medical is issuing an updated Reprocessing Instructions for Use (IFU) [S041_R00] and Operation IFU [Z933_R06] for the PENTAX Medical ED-3490TK Video Duodenoscope. The Reprocessing IFU includes updated validated procedures for cleaning, high level disinfection, and sterilization. The Operation IFU provides instruction to the user for the detection and resolution of a clogged channel and ensures consistent reference to the Reprocessing IFU for direction regarding the cleaning, high level disinfection and sterilization of the ED-3490TK. Both sets of instructions should be implemented as soon as possible. For your convenience paper copies of the Reprocessing and Operation IFUs are enclosed with this letter.

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on endoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures. Given these reports, and in an abundance of caution, PENTAX Medical has been working with the U.S. Food and Drug Administration ("FDA") to validate the reprocessing procedures that are provided in the updated Reprocessing IFU.

Revised Instructions

Scope Reprocessing



= **17** \log_{10} margin of safety associated with cleaning and sterilization of surgical instruments

Solution; sterilization (not new, but new for endoscopes)

- Most flexible endoscopes belong to category semi critical; HLD

But;

- Endoscopes often enter non-sterile cavities; ideally be sterilized?

→ sterilization;

→ more time

→ more resource intensive

→ more damaging to endoscope components

Alternatives...

Table 1
Summary of advantages and disadvantages of HLD and sterilization enhancements for reprocessing duodenoscopes

Method	Advantages	Disadvantages
Steam, sterilization	<ul style="list-style-type: none"> • Rapidly microbicidal • Least affected by organic or inorganic soils among sterilization processes listed • Rapid cycle time 	<ul style="list-style-type: none"> • Deleterious for heat-sensitive instruments • At present they cannot be used because current GI scopes are not heat resistant
Hydrogen peroxide gas plasma, sterilization	<ul style="list-style-type: none"> • Cycle time is ≥ 28 min, and no aeration necessary • Used for heat- and moisture-sensitive items because process temperature $< 50^{\circ}\text{C}$ • Compatible with most medical devices 	<ul style="list-style-type: none"> • Endoscope or medical device restrictions based on lumen internal diameter and length • GI scopes cannot be processed • No microbicidal efficacy data proving SAL 10^{-6} achieved • Studies question microbicidal activity in presence of organic matter and salt • May damage endoscope
100% ETO, sterilization after HLD, microbiologic surveillance	<ul style="list-style-type: none"> • Single-dose cartridge and negative- pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor • Compatible with most medical materials • Major endoscope manufacturer offers ETO as sterilization option • Ideally, ETO should be used after standard HLD • Some data demonstrate reduced infection risk with HLD followed by ETO 	<ul style="list-style-type: none"> • Requires aeration time to remove ETO residue • Only 20% of U.S. hospitals have ETO on-site • Lengthy cycle and aeration time • No microbicidal efficacy data proving SAL 10^{-6} achieved • Studies question microbicidal activity in presence of organic matter and salt • ETO is toxic, a carcinogen, flammable • May damage endoscope
Vaporized hydrogen peroxide, sterilization	<ul style="list-style-type: none"> • Fast cycle time (55 min) • Used for heat- and moisture-sensitive items (metal and nonmetal devices) 	<ul style="list-style-type: none"> • Endoscope or medical device restrictions based on lumen internal diameter and length • GI scopes cannot be processed • No microbicidal efficacy data proving SAL 10^{-6} achieved • No data demonstrating microbicidal activity in presence of organic matter and salt • May damage endoscope

...we still need HLD...

Who is in the lead?

Where do 39 countries listening to?

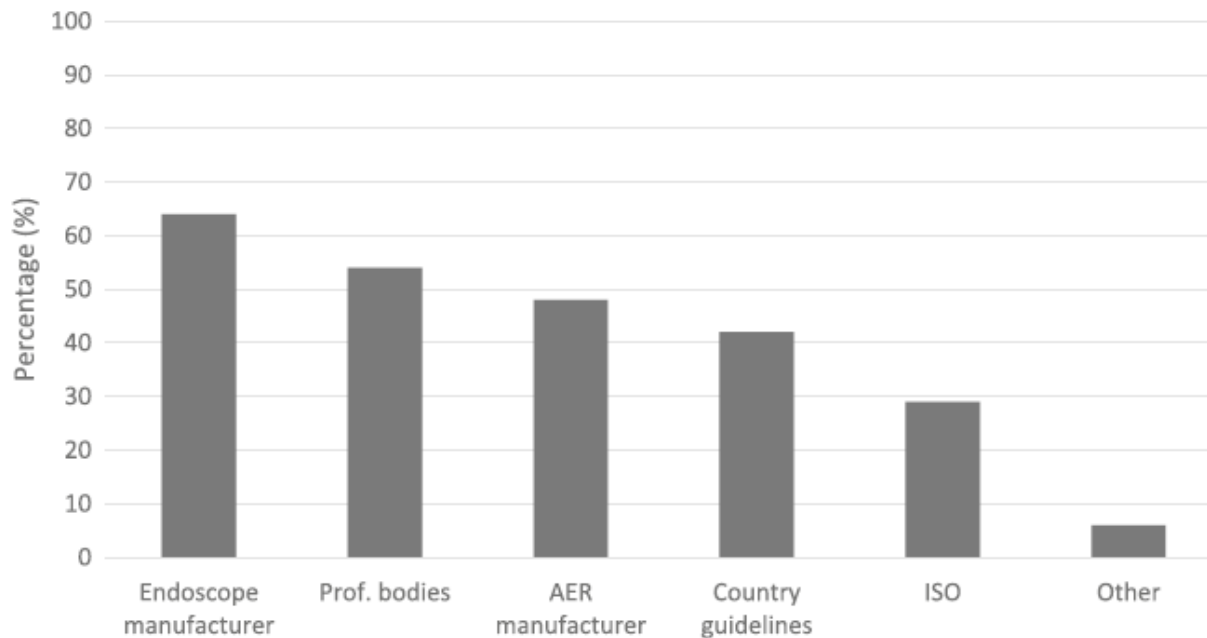


Fig. 5 Influence on developed standard operating procedures by the hospital

Disposable at what costs?

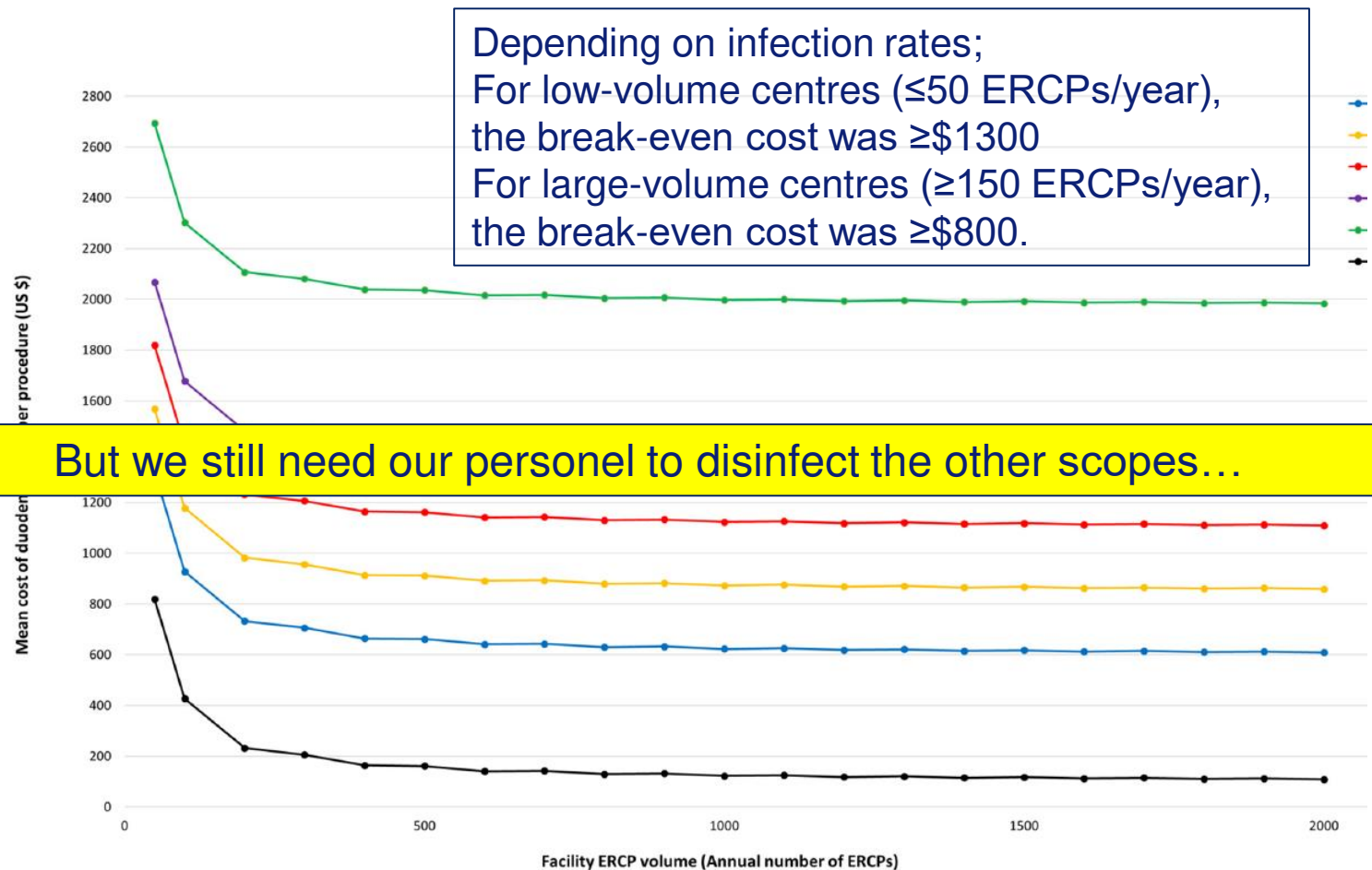


Figure 1 Line graph of the mean cost of duodenoscopes per procedure (US \$) according to infection rate and annual ERCP volume. ERCP, endoscopic retrograde cholangiopancreatography.

Summary

- Gastrointestinal endoscopy has been associated with more health care-associated outbreaks than any other medical device.

→ *Burden of disease has to be determined*

- Recent outbreaks related to duodenoscopes have occurred despite following guidelines

→ *Tip of the iceberg; MDRO noticed*

- Prevention requires

- strict adherence to current guidelines.

→ *Too many rules to adhere to? In other words; too complex to be succesful?*

→ *Too contaminated and complex to rely on HLD?*

Conclusions

- The burden of disease by contaminated endoscopes is not known
- The rate of contaminated endoscopes is high
- There is no agreement on anything (reprocessing method, storage, drying, surveillance, burden)
- The solution is far away;
 - Brand new endoscopes for every procedure?
 - Sterilization?
 - New design?

Awaiting solutions.....

- Microbiological surveillance
- Teach to clean; improve/adherence
- Monitor outcomes



Contaminated endoscopes....

To worry.....YES

To ignore;NO

To combatYES

ACKNOWLEDGEMENT

- Thanks to my researchers / colleagues

Prof Dr Marco Bruno

Arjen Rauwers PhD

Judith Kwakman PhD

And many others at ErasmusMC...

- Department of Medical Microbiology and Infectious Diseases
 - Unit Infection Prevention
 - Unit Clinical Microbiology laboratory
- Department of Gastroenterology and Hepatology
 - Reprocessing staff
- Office Medical Devices
 - DSRD / DSMH