Duodenoscope Reprocessing and Verification of Interdependencies in Clinical Settings

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23RD WORLD STERILIZATION CONGRESS

OVERVIEW

01 Background and Disclaimer

02 National Survey in France

03 Findings

04 Mitigation Actions

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01 Background and Disclaimer

DISCLAIMER

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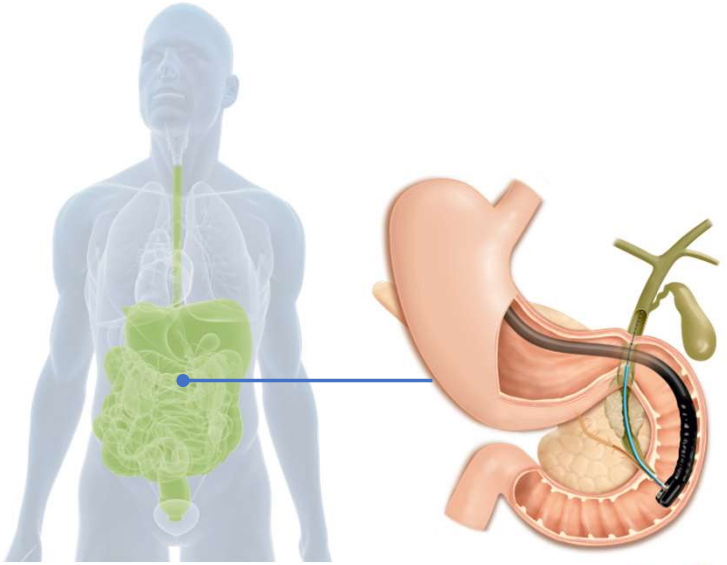
PATIENT INFECTIONS ASSOCIATED WITH ERCP

- More than 2 Million ERCP (**e**ndoscopic **r**etrograde **c**holangio-**p**ancreatography) procedures are performed on a global basis every year
- In 2012, increasing number of reports of infections with **antibiotic resistant germs** of patients undergoing **duodenoscopy** (endoscopic, non-invasive treatment of the bile duct).
- **Suspicion** of the **link** between **infection transmission** and **endoscopes** (i.e. Olympus TJF-Q180V)
- Hospitals claimed to meticulously follow the instructions for use
- **Design** of the duodenoscope is accused by some as a **root cause**
- **Investigation** rolled out to **all** endoscope **manufacturers**
- **Corrective actions** were taken by **all manufacturers**, adapting **design** and / or **reprocessing instruction** enhancements



INFECTIONS IN ERCP IN FOCUS OF SCIENTIFIC DISCOURSE

Publications on infections associated with duodenoscopes

2015


SHORT REPORT Open Access

An outbreak of carbapenem-resistant OXA-48 – producing *Klebsiella pneumonia* associated to duodenoscopy

Axel Kola[1*], Brar Piening[1], Ulrich-Frank Pape[2], Wilfried Veltzke-Schlieker[2], Martin Kaase[3], Christine Geffers[1], Bertram Wiedenmann[2] and Petra Gastmeier[1]

Source: Kola, A., Piening, B., Pape, UF. *et al.* An outbreak of carbapenem-resistant OXA-48 – producing *Klebsiella pneumonia* associated to duodenoscopy. *Antimicrob Resist Infect Control* **4,** 8 (2015). https://doi.org/10.1186/s13756-015-0049-4, (accessed on 12.09.2021)

2015


Endoscopy 2015; 47(06): 502
DOI: 10.1055/s-0034-1392080

Correction

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

Charlotte J. Verfaillie, Marco J. Bruno, Anne F. Voor in 't holt, Jolanda G. Buijs, Jan-Werner Poley, Arjo J. Loeve, Juliette A. Severin, Leo F. Abel, Bert J. Smit, Inge de Goeij, Margreet C. Vos

Source: Verfaillie CJ, Bruno MJ, Voor in 't Holt AF, Buijs JG, Poley JW, Loeve AJ, Severin JA, Abel LF, Smit BJ, de Goeij I, Vos MC. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing Pseudomonas aeruginosa. Endoscopy. 2015 Jun;47(6):493-502. doi: 10.1055/s-0034-1391886. Epub 2015 Mar 31. Erratum in: Endoscopy. 2015 Jun;47(6):502. PMID: 25826278., (accessed on 12.09.2021)

2018


Digestive Diseases and Sciences
pp 1–10 | Cite as

Duodenoscope-Associated Infections: Update on an Emerging Problem

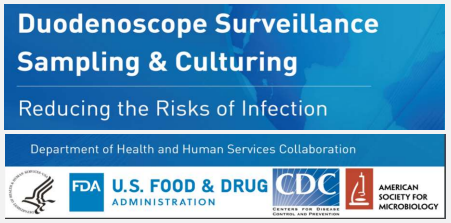
Authors Authors and affiliations

M. Rubayat Rahman, Abhilash Perisetti, Roxana Coman, Pardeep Bansal, Rajiv Chhabra, Hemant Goyal

Source: Rahman MR, Perisetti A, Coman R, Bansal P, Chhabra R, Goyal H. Duodenoscope-Associated Infections: Update on an Emerging Problem. Dig Dis Sci. 2019 Jun;64(6):1409-1418. doi: 10.1007/s10620-018-5431-7. Epub 2018 Dec 19. PMID: 30569333. (Accessed on 12.09.2021)

National recommendations on duodenoscope reprocessing and sampling

2015 / 2018


Duodenoscope Surveillance Sampling & Culturing

Reducing the Risks of Infection

Department of Health and Human Services Collaboration

FDA U.S. FOOD & DRUG ADMINISTRATION CDC AMERICAN SOCIETY FOR MICROBIOLOGY

Source: https://www.fda.gov/media/111081/download, (accessed 12.09.2021)

2018


Position Statement

Thieme

Prevention of multidrug-resistant infections from contaminated duodenoscopes: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA)

ESGE ESGENA

Source:https://www.esge.com/assets/downloads/pdfs/guidelines/2017_s_0043_120523.pdf, (accessed on 12.09.2021)

2018


Annexe Technique

TRAITEMENT DES DUODENOSCOPES

Source: https://endobiolab.com/wp-content/uploads/2019/09/2018_Annexe_technique_TraitementDuodenoscopes_08082018.pdf, (accessed on 12.09.2021)

INFECTIONS IN ERCP IN FOCUS OF SCIENTIFIC DISCOURSE

- National studies in the Netherlands (2018, 2020)
- Included duodenoscopes from Olympus, Pentax, and Fujifilm

Endoscopy

OPEN ACCESS

ORIGINAL ARTICLE

High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study

Arjan W Rauwers,[1] Anne F Voor in 't holt,[2] Jolanda G Buijs,[3] Woutrinus de Groot,[2] Bettina E Hansen,[1] Marco J Bruno,[1] Margreet C Vos[2]

What is already known on this subject?

- In the light of current outbreaks of multidrug-resistant organisms caused by contaminated duodenoscopes, understanding to what extent duodenoscopes are inadequately reprocessed is crucial. Despite current reprocessing procedures, contamination of duodenoscopes continues to occur on a large scale worldwide.
- Several studies assessed contamination of duodenoscopes with varying outcomes. However, it is unclear what the true burden on a national level is.

What are the new findings?

- This cross-sectional study showed high prevalence rates of duodenoscope contamination in Endoscopic Retrograde Cholangiopancreatography (ERCP) centres in the Netherlands.
- In a substantial proportion of the cultured duodenoscopes, organic material of previous patients was still present, as they were contaminated with microorganisms of gastrointestinal or oral origin. These results suggest that the current combination of reprocessing and process control does not suffice.
- In this study, contamination occurred with all types of duodenoscopes, independent of type specific design.

How might it impact on clinical practice in the foreseeable future?

- Patients undergoing ERCP procedures remain to be at risk of being treated with contaminated equipment.
- Efficient surveillance strategies and reprocessing control measures are required to reduce the number of contaminated duodenoscopes, minimising the chance of interpatient transmission of microorganisms.

Source: Rauwers AW et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study, Gut 2018;67:1637–1645. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6109280/pdf/gutjnl-2017-315082.pdf (accessed on 12.09.2021)

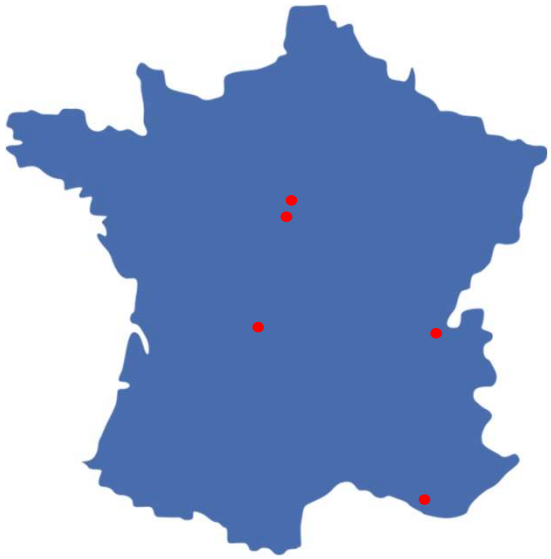
02 National survey in France

REOCCURENCE OF INFECTIONS

In 2017, singular infections were reported as associated with TJF-Q180V. In total, 5 isolated cases of patient infections were reported in **France**, from patients who underwent ERCP with a TJF-Q180V

Common factors:

- All **only** in **France**, but in different, not related institutions
- Patient infections **not** in strict **chronological** sequence
- Patient exams with **prolonged duration**
- Patients suffered from biliary stenosis / **limited drainage** of bile



IMMEDIATE ACTIONS INITIATED

In collaboration with French authorities, the manufacturer initiated enhanced root cause analysis to gain a **deeper understanding** of **contributing factors** that may add to a failure in reprocessing, in addition to the complexity of the device

On-Site diagnostics

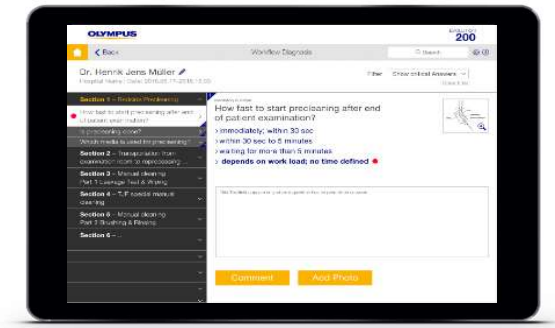
Review in real time

- **Device** status/integrity
- Reprocessing **Workflow**
- **Staff** qualification

Enhance know-how

- Implement a sustainable, long-term training approach
- Secure „front-line“ qualification despite staff turnover

- Collect data in a structured way (by app, based on IFU)
- Monitor critical areas and implement true solutions
- Verify actual influence on reprocessing success



03 Findings & Interdependencies

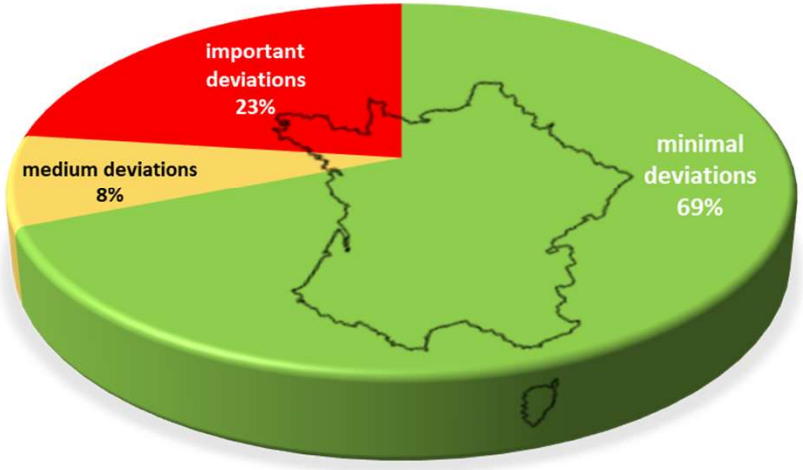
KEY FINDINGS

Basic data

- **182 hospitals** visited within 6 months after project initiations
- **358 endoscopes** identified and inspected on-site
- Status on actual reprocessing qualification recorded for **922 staffs** in reprocessing

Initial observation

31% of all hospitals displayed **medium** to **important deviations** from the reprocessing protocol upon the initial visit



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WORKFLOW ANALYSIS

Key findings

- Reprocessing workflow deviations mainly concentrate on the cleaning of the distal end
- Major deviations were observed in **34** out of **135** steps
  - 10 steps with high deviation (>50%)
  - 15 steps with medium deviation (30-50%)
  - 9 steps with low deviation (20-30%)
- 18 out of 34 (**53%**) steps were **elevator-specific** steps
- 9 steps of 34 may not directly impact endoscope contamination
  - leakage test, removal of detergent

Exam Room	Reprocessing Room									
Bedside PreCleaning	Manual leak test	Brushing of elevator with MH-507	Brushing of the elevator with MAJ-1888	Aspiration instrument channel	Flushing air/water channel	Soaking & wiping	Flushing & air flush	Reprocessing of accessories	Automated endsocope reprocessing	Inspection & drying
34,9% No use of MH-948 cleaning adapter	**69,5%** No check of air coming from leak tester	**35,9%** No rotation of brush	**41,6%** No or inadequate operation of elevator	**60,5%** Nurse does not cover suction cyclinder	**50,3%** Only quick; too short flushing	**24,8%** No soaking and wiping of endoscope	**69,0%** No aspiration of channels	**59,1%** No wiping of outer surfaces after removal from basin	**24,0%** No check of LT connector before attachment to endoscope	**53,9%** No dedicated space for inspection
28,8% Elevator not lowered before suction	**37,6%** No moving of elevator	**20,0%** No brushing of recess on elevator	**40,0%** No flushing of the interior of elevator recess (raise postion)	**60,4%** No use of MH-856	**50,0%** No flushing of channels	**24,1%** No soaking and wiping of endoscope	**68,0%** No outside wiping	**47,5%** No sterilisation of reusables	**22,2%** No printed and visible instructions for connection of endoscopes	**36,4%** No special inspections done
27,9% Accessories were not detached	**34,5%** No check if leak test connector is dry		**38,8%** No flushing of the interior of elevator recess (low position)	**58,6%** No raising / lowering of elevator			**58,7%** No complete immersion	**31,0%** No flushing with cleaning solution	**21,6%** Elevator NOT at intermediate position	
	22,5% No waiting time before removal of LT connector at end of test		**35,8%** Syringe not close enough to distal end	**46,1%** Elevator not lowered			**50,9%** No flushing of channel	**29,7%** A/W adapter NOT depressed in cleaning solution		
			35,1% No rotation of brush	**44,3%** No immersion of distal end			**41,1%** No removal of detergent from channels and out surfaces	**29,5%** Brush NOTchecked for resduals		
			31,2% No or inade-quate brushing of grooves				**31,6%** No use of Olympus plugs (MH-944, MH-946)	**27,4%** No use of automated reprocessing		
			31,0% No flushing of elevator				**30,7%** No final inspection for residual debris	**26,6%** Accessories not immersed into detergent		
			26,7% Elevator not lowered to min. position				**25,3%** Flushing of endoscope NOT in separate basin	**20,2%** A/W valve not depressed while in cleaning solution		
			25,0% No or inadequate brushing of guidewire locking groove					**20,1%** Use of ETD for reprocessing		

Steps that concern the forceps elevator

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USER FEEDBACK ON WORKFLOW DEVIATIONS

Feedback was collected via individual user interviews from accounts customers with important deviations

Task	Failure	General deviation	+/- high deviation customers	Rationale
Bedsite / Pre-Cleaning	no use of A/W cleaning adapter	32%	+ 2-5%	Lack of Awareness
	no aspiration of detergent through suction channel	59%	0%	
Leakage test	no check of air flow	70%	- 3%	Lack of Understanding / done by EWD
	no moving of elevator	22%	- 5%	
Brushing with standard brush	no brushing with standard brush	36%	+ 11%	Lack of Awareness
Brushing with special brush	no brushing with special brush MAJ-1888	20-40%	+ 10-30%	Lack of Availability / Lack of Awareness
Flushing the elevator	no flushing of different areas of the elevator and recess	50-55%	+ 15%	Lack of Awareness
Aspiration of suction channel	no aspiration of detergent through suction channel	60%	+ 2%	Lack of Understanding
	no moving of elevator	59%	+ 5%	Lack of Awareness
Removal of detergent	no removal of detergent from outer surfaces or channels	50-68%	- 10%	Lack of Understanding / done by EWD
Adaptation inside EWD	no 45° position of elevator	22%	+ 6%	Lack of Awareness

INSPECTION OF ACTUAL DEVICES IN USE

Key findings: Irregularities observed during on-site **device inspection** were mainly related to the **distal end**

- Failure rate (>1%) observed on **12** out of **35** checkpoints.
- 67% (8 out of 12) of irregularities related to the **distal end**

Before-each-use inspection described in IFU

(Extract 12 high failure items out of 35)

Inspection item	NG rate
Visual inspection; control section and connector.	1.1%
Visual inspection; boot and insertion section near the boot.	2.3%
Visual inspection; entire insertion section, bending section, distal end.	6.3%
Pliability of insertion tube.	2.3%
Visual inspection; objective lens, light guide lens.	5.1%
Visual inspection; air/water nozzle.	1.7%
Bending mechanisms; smoothness, maximum angulation, return to neutral position.	1.1%
Bending mechanisms; lock function.	1.1%
Elevator mechanism; smooth operation.	2.8%
Suction function.	1.1%
Instrument channel and elevator; elevator operation with ET accessory inserted.	1.7%
Leakage test.	1.1%

Distal end close inspection

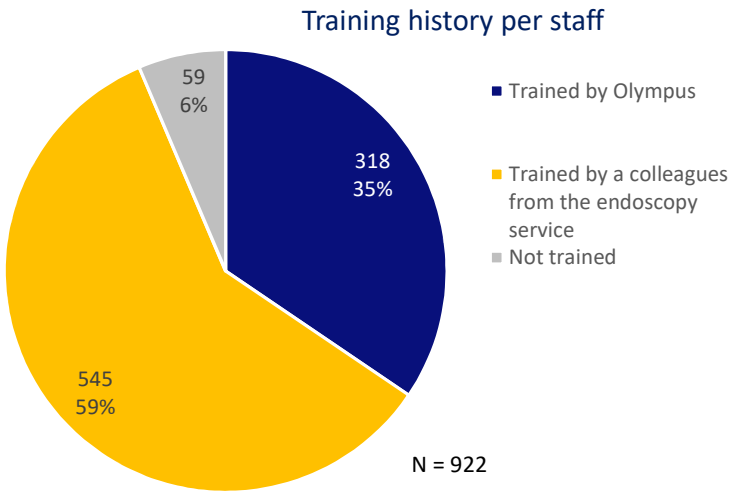
Part	Failure mode	NG rate
A-Rubber	Colour	10.8%
	Existing	11.4%
Around lens	Colour	7.4%
	Existing	6.3%
	Crack	4.0%
Plastic cover & nozzle	Colour	6.3%
	Existing	3.4%
	Nozzle	2.3%
	Hole	5.1%

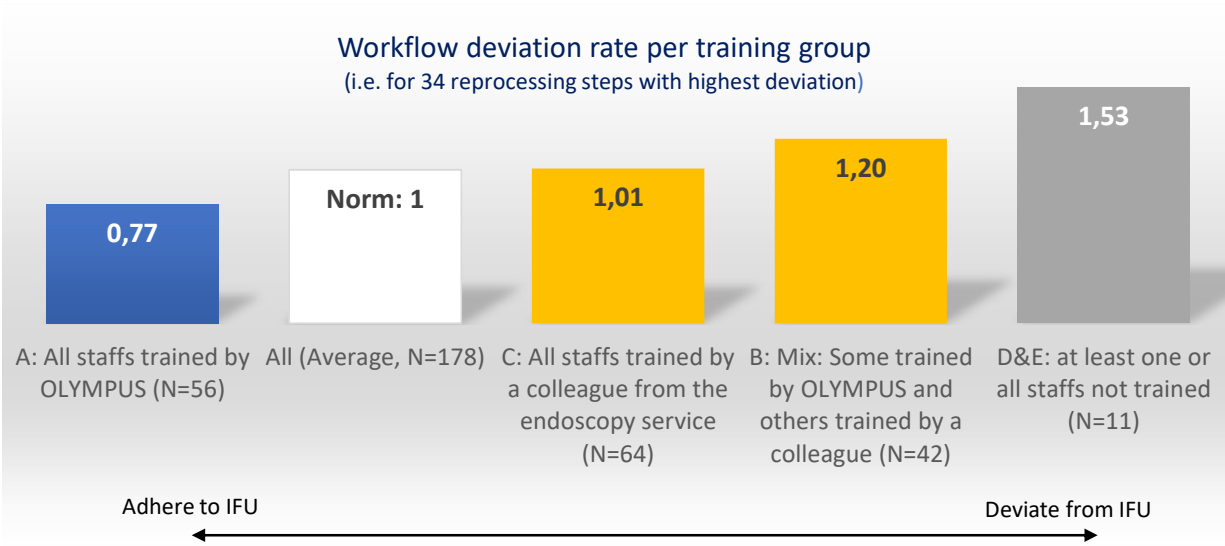
<1% : not shown
>1%
>5%
>10%

USER QUALIFICATION AND WORKFLOW DEVIATIONS

Key findings: **Staff qualification** by the manufacturer is **key** to ensure **adherence to IFU**

- Appr. 35% staffs were exclusively trained by Olympus (both per hospital and per staff)
- 44% hospitals (= 59% of staff) did not undergo direct training by Olympus
- Users **trained** by **manufacturer** showed **closer adherence** to IFU than others

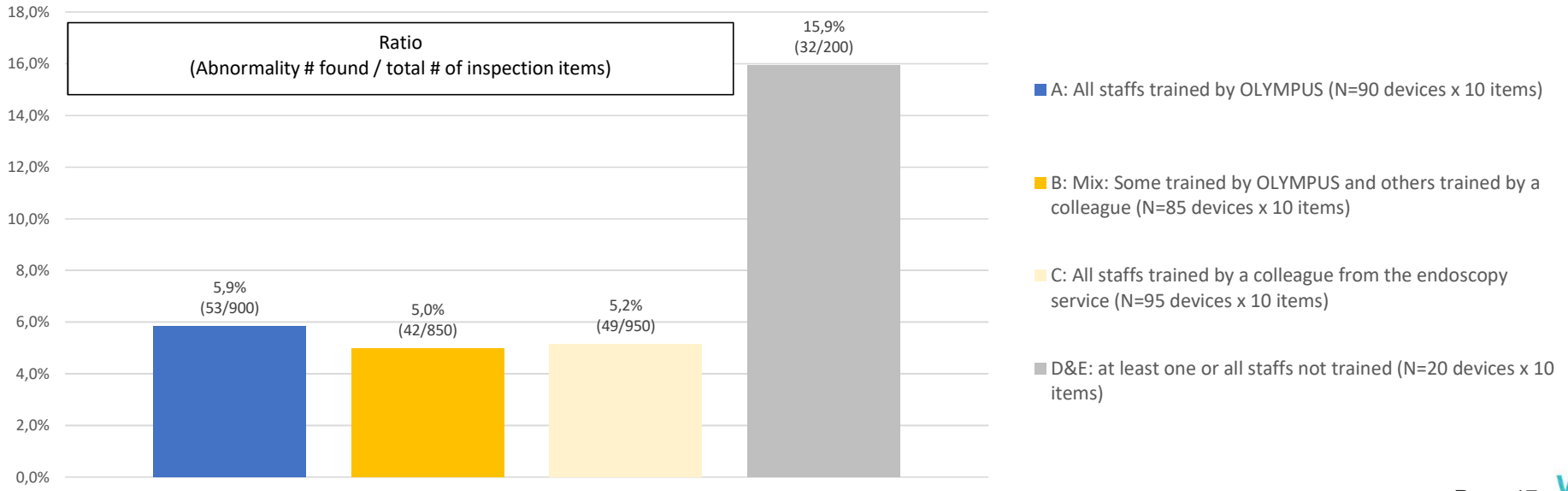




USER QUALIFICATION AND ENDOSCOPE DAMAGE

Key Findings: Lack of staff qualification seems to result in higher damage rates

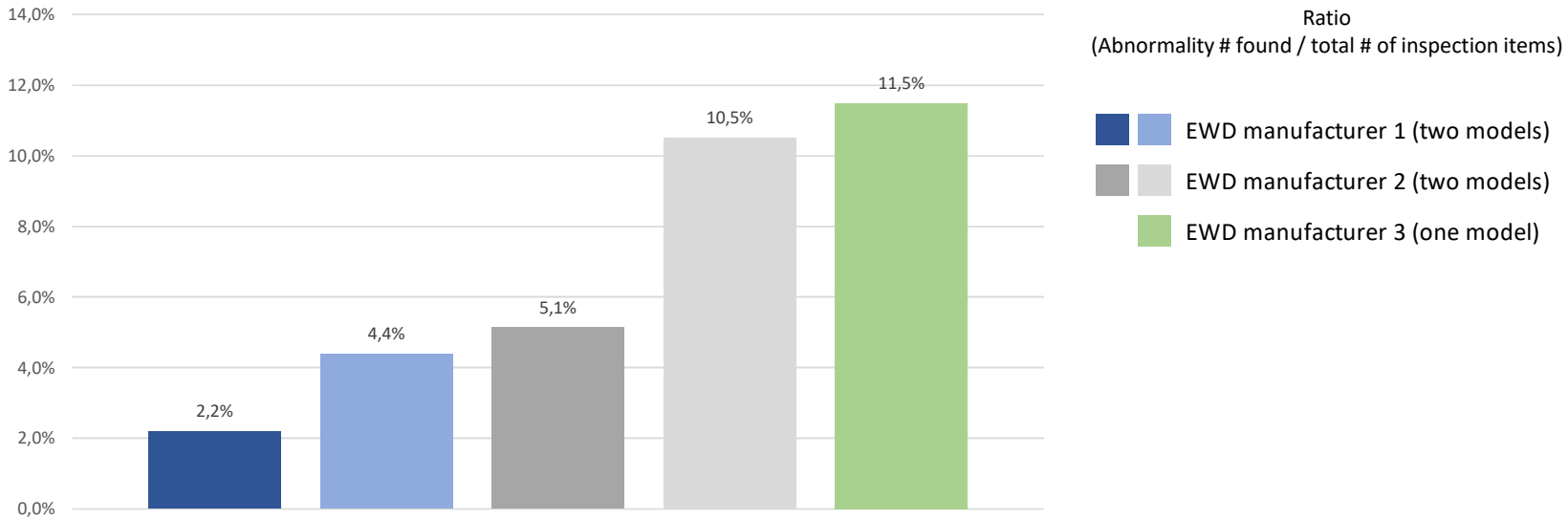
- No distinct difference among Group A, B, and C.
- Device handled by group D&E (not trained) indicate higher abnormality rate, although a small number of data (N=20)



ENDOSCOPE DAMAGE AND USE OF EWD

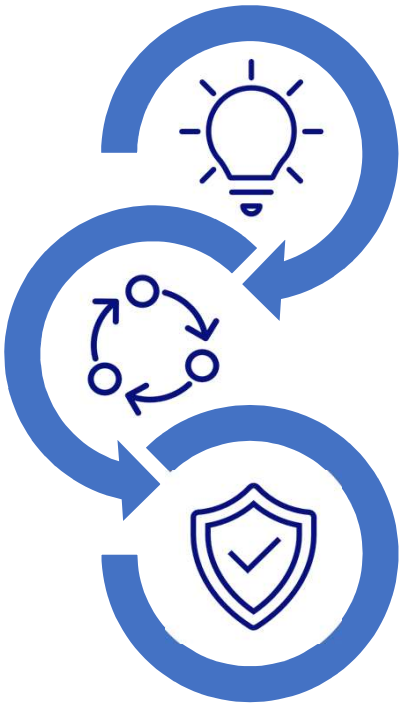
Key findings: Observed irregularities on endoscopes seem to correlate with use of **Endoscope Washer Disinfectors (EWD)**

- Occurrence of **damages** seems to be related to **EWD models** and / or **process chemistry** used
- Findings increase with increased PAA concentration of process chemistry / pH value during reprocessing



04 Mitigation Actions

KEY SUCCESS FACTORS FOR SAFE REPROCESSING



Knowledge & Expertise

Safe Reprocessing

Device Condition

All 3 key factors are equally essential to minimize infection risks and improve patient safety!

MITIGATION ACTIONS – NOT ONLY FOR FRANCE

Based on these findings, primary focus was given is on the **prevention** of **workflow deviations** through **staff qualification** and process improvements

- **Securing** know-how and **competencies** of reprocessing **staff** to ensure adherence to instructions for use, i.e. through 24/7 access to **customer trainings** and **support materials** such as wall charts, videos, etc.
- **Ensuring** access to the **latest device generations** (i.e. those that **improve pain points** of TJF-Q180V via simplification and omission of specific brush/ distal end flushing)
- Confirm that manufacturer's **maintenance specifications are observed** (i.e. user driven and via professional service providers)

OFFICIAL RECOMMENDATIONS FROM LITERATURE

Recommendation for mitigation in **guidelines** and **publication confirm** this approach:

- Increasing the level of reprocessing
- Educational programs for reprocessing staff
- More stringent surveillance strategies

Reducing the risk of ERCP-associated infections

Reducing the risk of ERCP-associated infection will require a multifaceted approach including:

1. Prioritizing the improvement of reprocessing effectiveness by:
   a) Establishing educational programs that support real-world competencies (e.g., hands-on and train-the-trainer programs; simulators)
   b) Providing rigorous training and oversight to ensure adherence to optimal practices
   c) Advocating for automation of manual cleaning and drying to reduce human error
   d) Implementing the full range of quality assurance steps to ensure reprocessing effectiveness (e.g., leak tests, visual inspection, cleaning verification tests, HLD and sterilization monitoring, and drying verification)
2. Implementing mandatory duodenoscope servicing by:
   a) Establishing an evidence-based schedule for routine inspections by biomedical department personnel or qualified repair technicians
   b) Addressing defects that could injure patients or predispose endoscopes to harbor soil and microbial contamination

Review — Thieme

Duodenoscope-associated infection prevention: A call for evidence-based decision making

OPEN ACCESS

Authors
Cori L. Ofstead[1], Brandy L. Buro[1], Krystina M. Hopkins[1], John E. Eiland[1], Harry P. Wetzler[1], David R. Lichtenstein[2]

3. Enhancing the evidence base for assessing risks associated with ERCP by:
   a) Conducting studies to evaluate real-world outcomes
   b) Publishing findings from research and investigations that identify risk factors
   c) Including sufficient information when reporting outbreaks, infections, or breaches (e.g., types of endoscopes; number of patients exposed, tested, and infected or colonized; reprocessing methods and breaches; and maintenance issues or damage)
   d) Evaluating antibiotic usage and its impact on transmission and resistance
   e) Sharing innovations that may improve reprocessing effectiveness and patient safety
4. Partnering with manufacturers and biomedical engineers to address risks by:
   a) Considering alternatives to conventional reusable devices (e.g., duodenoscopes that are sterilizable, single-use, or have disposable components that facilitate reprocessing)
   b) Evaluating the impact of these innovations on outcomes

Source: Endoscopy International Open 2020; 08: E1769–E1781, DOI 10.1055/a-1264-7173, ISSN 2364-3722, © 2020. The Author(s). (Accessed on 21 April 2022)

Thank you!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