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Position Paper

Multisocieties position paper: Microbiological surveillance on flexible endoscopes

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ABSTRACT

Transmission with endoscopes, particularly duodenoscope, of potential lethal infections prompted different scientific societies to deliver recommendations aimed reducing this risk. Some International societies extended recommendations on microbial surveillance to all the endoscopes and devices used in the reprocessing procedure. Considering the relevance of the topic, 8 Italian scientific societies of physicians, nurses and technical operators prepared a concerted document taking into account Institutional advisories and facilities in Italy. The rules for a correct microbial surveillance on endoscopes were detailed in term of what, how and when to perform the procedure, also suggesting behaviors in case of contamination.

1. Introduction

Although the possibility of infection transmission through contaminated endoscopes is well recognized, protocols for microbiological surveillance are not internationally standardized. Microbiological surveillance of flexible endoscopes after reprocessing, during storage, or before use is recommended in US standards merely for duodenoscopes [1,2]. The American Society for Microbiology underlined the importance of microbiological surveillance only for epidemiological investigations to verify the role of these devices in infection transmission or to evaluate the effectiveness of new or modified cleaning and disinfection procedures [3]. Even the recent multidisciplinary guidelines of the American Society for Gastrointestinal Endoscopy and the Society for Healthcare Epidemiology of America did not suggest to systematically carry out microbiological surveillance on endoscopes [4]. In 2015, following cases of KPC-producing *Klebsiella pneumoniae* infection related to the use of duodenoscopes, the Centers for Disease Control and Prevention (CDC), the American Society of Microbiology (ASM), and the Food and Drug Administration (FDA) produced a document highlighting the importance of performing microbiological surveillance to guarantee the safe use of duodenoscopes [5]. It was updated in 2018 providing specific protocol for surveillance sampling and culturing reprocessed duodenoscopes, also suggesting to apply modified procedures for other types of flexible endoscopes [6]. Conversely, guidelines from other scientific societies, such as the European So-

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ciety of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA), and those from Australia (GESA-AGEA-GENCA) reported an explicit recommendation to perform a microbiological investigation on all the endoscopes, not just on duodenoscopes [7,8].

There are only few Italian studies assessing endoscopes contamination following reprocessing, with conflicting results. Indeed, presence of indicator micro-organisms varied from 1.1% on 811 samples in a study [9] to as many as 35.7% on 180 samples, including multi-drug resistant bacteria, in another experience [10]. Moreover, only one study reported cases of *Klebsiella pneumoniae* carbapenemasi (KPC)-producing infections in patients undergoing ERCP, while in another study the role of duodenoscopes as a potential vehicle for patient-to-patient transmission of multidrug-resistant strains was confirmed by phylogenetic analysis [11,12].

Given the clinical importance of fighting against multidrug-resistant bacteria, the Associations SIMPIOS (Italian Multidisciplinary Society for the Prevention of Infections in Health Care Organizations), ANOTE-ANIGEA (National Association of Operators of Endoscopic Techniques-National Association of Gastroenterology Nurses and Associates), AIGO (Italian Association of Hospital Gastroenterologists and Endoscopists), AICO (Association of Nurses of Surgical Area and Operating Room), AIOS (Italian Association of sterilization operators) AIPO-ITS (Italian Association of hospital pneumologist- Italian Thoracic Society), ISSE (Italian Society of Surgical Endoscopy) and SIED (Italian Association of digestive endoscopy) produced a multi-society document on microbiological surveillance after reprocessing of flexible endoscopes, to support the quality of this process for patient safety. These associations include operators involved in the use of endoscopes, in the reprocessing process, and in the prevention of healthcare-associated infections.

2. Methods

Each participating scientific society indicated one delegate to constitute the panel of experts. A literature review was performed, with particular attention to International guidelines and Institutional documents (FDA, CDC, ISO, etc.). Two authors (BC and AZ) prepared the first version of the manuscript that was discussed and amended by the panel in specific face-to-face and online meetings. The updated version was therefore evaluated by other experts designed by each Society (for a maximum of 10 members for each Association), who have contributed to the final draft version.

3. Results

3.1. What to sample

Microbiological surveillance should be performed through an adequate sampling of matrices at potential risk for contamination, which may invalidate the endoscope reprocessing procedure [13,14]. These include: (a) the external and internal surfaces of the endoscope after reprocessing; (b) water of the irrigation bottle used to flush air/water channels during the examination; (c) water used during manual disinfection and by washer-disinfectors; and (d) surfaces of storage cabinets.

Failure to properly perform the various steps of the reprocessing procedure, in particular manual cleaning, can result in contamination of the endoscopes. The prolonged use of accessories (e.g., biopsy forceps, loops, brushes) into the channels may cause the formation of micro-lesions which can facilitate biofilms development triggering microbial contamination [5]. Microbiological surveillance involves the sampling of the external surfaces of endoscopes (distal end, elevator of duodenoscopes/echoendoscopes, inlet cylinder of the valve, etc.) and of the internal channels (air/water, auxiliary, biopsy, elevator channel of duodenoscopes, and echoendoscopes). The water from the air-water bottle used during the lens cleaning phases in endoscopic practice can be a source of contamination and therefore should be subjected to microbiological investigation [15]. The quality of the water used for the final rinse in washer-disinfectors should be investigated to exclude biological contamination of hydraulic circuits. Particular attention should also be paid to the evaluation of the hygienic quality of the inlet water of the washer-disinfector. Finally, storage environments, including cabinets compliant with EN ISO 16,442: 2015, should undergo to periodic cleaning and adequate disinfection, therefore microbiological monitoring is required to verify the effectiveness of these procedures [15,16].

3.2. What to search for

For microbiological surveillance is not necessary to test all the pathogens potentially contaminating endoscopes, but only those microorganisms representing a process indicator. Microbiological surveillance does not include virus detection, although cases of hepatitis B and C associated with endoscopic procedures have been reported in the literature [17-19]. The virological investigation was based on protocols that are not standardized, and not always able to detect viral infectivity and, therefore, to identify a real infectious risk. Unexpectedly, the risk of infection by severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) has been recognized as potentially low, both on bronchoscopes and digestive endoscopes [20,21], and the absence of the SARS-CoV-2 genome has recently been demonstrated after adequate endoscope reconditioning [22]. The process indicators used in endoscopy, their meaning and the corrective actions required are provided in Table 1.

3.3. How to sample

Sampling should be performed by two properly trained operators. One of them should carries out all the operations aseptically, while the other provides support for the management of containers and other materials. To avoid contamination of the sample, operators should wear appropriate Personal Protective Equipment (sterile gown, sterile gloves, surgical mask, covering nose and mouth, and bouffant caps for hair). A sterile work surface should also be set up.

Microbiological investigation on endoscopes should be performed after at least 6–12 h of storage to increase the likelihood of identifying bacteria from any biofilm formed into the channels [5,8]. Each channel should be analyzed by irrigation with an appropriate amount of eluent determined by the size of the channel. The US guidelines recommend that sampling procedure should be performed according to the 'Flush-Brush-Flush' method. Sterile disposable (or autoclaved in the rubber cycle) brushes should be used on each endoscope [6]. In the French guidelines, the 'Flush-Suction-Flush' procedure was suggested [23]. The results of one study showed that the addition of the suction phase during the procedure significantly increased the positivity of surveillance cultures compared with washing with saline solution alone, both on endoscopes and on model of channel in which a biofilm was artificially created [24]. To date, there are no specific comparative studies between the two methods. The microbiological sampling of the external surfaces includes valves, channel cylinders, and the outer surface through the use of sterile swabs soaked in the eluent. The step-by-step procedure is detailed in Box 1.

Box 1. Endoscope channel sampling tutorial.

- **Preparation of the setting:** Sampling should be carried out by at least two operators. The first operator (sampler) conducts the sampling phases aseptically, while the second operator (facilitator) supports, aseptically, the activity of the

Table 1
Process microbiological indicators.

Indicator	Cause's analysis	Corrective actions
E. coli and other Enterobacteriaceae	**Hazard:** presence of organic residues and / or microorganisms. **Risk:** ineffectiveness of disinfection or sterilization. **Cause:** missing or delayed execution of the pre-cleaning phase. Errors in the cleaning phase (insufficient or inadequate contact with the proteolytic detergent, inadequate brushing, insufficient or inadequate disinfectant concentration). Insufficient drying of endoscopes before storage.	Review of the reprocessing procedure with a focus on manual cleaning. Check the disinfectant concentration as recommended by the manufacturer. Review of the endoscope drying procedure.
P. aeruginosa	**Hazard:** contamination of the water used for rinsing or of endoscopes storage cabinets. **Risk:** Endoscope contamination. **Cause:** contamination of filtration systems of endoscope washing machine (biofilm formation). Insufficient drying before storage. Inadequate sanitization procedure of endoscope storage cabinets.	Review of the quality of the water used by the endoscope washing machine. Arrange for machine maintenance and if necessary change the filters. Carry out a self-disinfection cycle in accordance with the manufacturer's instructions. Review of the endoscope drying procedure. Review of the sanitation procedure of storage cabinets.
S. aureus, S. epidermidis	**Hazard:** contamination of the hands of operators; contamination of endoscope storage cabinets. **Risk:** Endoscope contamination. **Cause:** inadequate hand hygiene of operators, inadequate transport and storage of endoscopes. Contamination during sampling.	Review of hand hygiene procedure. Review of sanitization procedure of endoscope storage cabinets. Repeat the sampling.
***Atypical mycobacteria, Legionella* spp.**	**Hazard:** contamination of the water used in final rinse of endoscopes; ineffectiveness of reprocessing. **Risk**: Endoscope contamination. **Cause**: contamination of the endoscope washing machine filtration systems ~~of~~ (biofilm formation). Ineffectiveness of disinfection (*M. chelonae* is resistant to glutaraldehyde and can contaminate washer-disinfectors). Insufficient drying of endoscopes before storage.	Review of the quality of the water used by the endoscope washing machine. Arrange for a complete maintenance of machine and filtration systems. Carry out a self-disinfection cycle in accordance with the manufacturer's instructions. Review of the endoscope drying procedure.

Modified by reference 7.

opens packages and handles the unsampled portions of the endoscope. Before starting the sampling, hand hygiene should be carried out and personal protective equipment must be worn (sterile disposable gown, sterile gloves, surgical mask and cap). You will have to disinfect the support surface, on which a sterile disposable cloth will be spread, where the instrument is to be placed.

- **Sampling the distal end of duodenoscopes with fixed distal or with removable cap and linear echo-ndoscopes:** Pass a sterile swab, moistened with the eluent, inside the elevator wire channel. The tip of the swab is cut with sterile scissors and collected in a sterile sample container. Using a sterile Pasteur pipette and / or sterile syringe, instill in the elevator channel 1 ml of eluent with the lever down and 1 ml with the lever up and repeat the operation in order to use 4 ml of eluent that is poured by gravity in the collection container (washing phase or "Flush"). In the next brushing phase (“Brush” phase), pass a sterile brush (or sterilized in a rubber cycle) in the recess of the elevator, once with the elevator lowered and once raised. Cut the end of the brush and add it to the rest of the sample in the collection container. If a metal brush is used, the cutting of the tip can be omitted and, in this case, the brush is shaken in the eluent accumulated in the collection container. Repeat the Flush step as described above, collecting another 4 ml in the collection container. In place of the eluent, the physiological solution can be used by instilling 5 ml in the recess of the elevator channel by raising and lowering the lever, repeating the same operation after the brush with another 5 ml (total volume: 10 ml).
- **Sampling the distal end of duodenoscopes with completely removable disposable distal cap and for all other endoscopes (gastroscopes, colonoscopes, enteroscopes, radial echoendoscopes, bronchoscopes):** Pass a sterile swab, moistened with the eluent, in the distal end. The tip of the swab is cut with sterile scissors and collected in a sterile sample container.
- **Sampling biopsy channel:** Hold the endoscope vertically and irrigate the biopsy channel with 20 ml of elution solution with a sterile syringe. The liquid is poured by gravity into the collection sample container. Subsequently, air is passed to remove any residue ("Flush" phase). Pass a sterile brush inside the biopsy channel until it comes out of the distal end. Make sure that the brush emerges from the opposite end of the instrument in a unidirectional way, that is, it must be extracted without retrograde movement. Cut the bristled portion of the brush and let it fall into the collection container (“Brush” phase). If a metal brush is used, the cutting of the tip can be omitted, and the brush is shaken in the eluent accumulated in the collection container. Pass another 20 ml of eluent inside the biopsy channel. The liquid is collected by gravity in the same collection container used previously. Air is then passed to remove any residue (“Flush” phase).
- **Sampling other channels:** The sampling of the additional channels, such as the suction or air / water one, involves the sampling method of the “Flush-Brush-Flush” for the suction channel, while for the air/water channel and for the auxiliary one, where it is not possible to use the brush, proceed with the washing phase only. The volume of the eluent solution varies according to the channel size. Connectors and sterile valves specific for the type of endoscope model should be used. Generally the volume used should be about three times the volume of the canal to ensure adequate sample collection.
- **Transport of endoscope sample and microbiological analysis:** In case the sample is not analyzed within 12 hours after sampling, add 45 ml of DE (Dey-Engley neutralizing broth, Sigma-Aldrich) or other neutralizing solution to the sample (20). Transport in a safety container at 2-8°C to the laboratory and analyze within 24 hours. For the determination of the indicator microorganisms, defined as “low, medium or high relevance” by the US guidelines (Table 2), it is necessary to analyze the entire volume of the sample.

Table 2
Relevance of microorganisms subject to microbiological surveillance.

HIGH	This definition includes pathogenic microorganisms whose isolation detects the ineffectiveness of reconditioning and therefore requires the removal of endoscope from clinical practice, as long as corrective actions have not allowed to reduce the risk and restore safety in the use of instrument. They are Gram-negative bacteria typical of the gastro-intestinal tract (eg *E. coli, K. pneumoniae* or other Enterobacteriaceae) or environmental, potentially pathogenic for humans (*P. aeruginosa*), Gram-positive bacteria *S. aureus, Enterococcus spp* . and yeasts).
MEDIUM	Microorganisms typically colonizing the oral cavity, not pathogenic, however detect the treatment ineffectiveness (eg: α-haemolytic or viridating streptococci, *Moraxella* spp., Neisseria with a saprophytic character).
LOW	Non-pathogenic microorganisms, the presence of which on endoscopes shows contamination that occurred during storage or sampling: coagulase negative staphylococci, excluding *S. lugdunensis*, micrococci, diphtheroids, *Bacillus* spp. and other Gram-positive bacilli.

Modified by reference 4.

1. For duodenoscopes and linear echo-endoscopes we suggest microbiological surveillance on a monthly basis, or after 60 procedures and whenever the device has been used on a patient with known infection with resistant multi-drug bacterial strains.

2. For the other endoscopes, microbiological surveillance is recommended every 3-6 months, rotating on the available instruments, so that all are tested at least once a year.

3. The instruments subjected to microbiological investigation should not be used until the outcome of the culture.

4. Microbiological tests should be performed on all the channels of the endoscope and on the external parts at risk of contamination.

5. We suggest the use of specific eluents for sampling, to increase the probability of isolation of microorganisms. Alternatively, saline can be used. Contrarily, the use of sterile deionized water is not recommended because the yield is lower.

6. The "flush-brush-flush" procedure is suggested for microbiological sampling.

7. The water from the air-water bottle, the manual rinse water and that for the final rinse in the washer-disinfector should be subjected to microbiological investigation.

8. The internal surfaces of the storage cabinets must be subjected to microbiological investigation.

Fig. 1. Take home messages.

The water used to fill the air-water bottle, either disposable or reusable, should be sterile. Reusable bottles and connectors should be sterilized at the end of the daily endoscopic activity. To verify the maintenance of the sterility of the water, it is sufficient to determine the Total Microbial Load (Table 2) at the end of the working day by taking two 10 ml samples of water from the bottle with a sterile syringe, putting them in a sterile container and storing the sample at ± 4 °C until arrival at the laboratory.

The sampling of water in the washer-disinfector (2-liter samples) should carried out in accordance with the National legislation relating to water intended for human consumption (Legislative Decree 31/2001 and subsequent amendments) [25]. The ISO EN 19,458:2006 standard defines the sampling method [26]. It is important to use sterile containers with the addition of a neutralizing solution, such as sodium thiosulfate 10%, to maintain the vitality of the microorganisms.

The water used for the final rinsing of endoscopes should comply with EN ISO 15,883–1:2014 and EN ISO 15,883–4:2019 for the parameters Total Microbial Load at 22 °C and 36 °C, *P. aeruginosa, Legionella* spp. and non-tuberculous mycobacteria [27,28]. The sampling site should be properly sanitized before sampling, and the sample volume should be not less than 200 ml for each test. It is possible to sample directly from the tank of washer-disinfector, whatever possible. Use syringes if necessary and sterile tubes containing neutralizing solution. The sampling should be carried out every three months.

The internal surfaces of both unventilated vertical cabinets and medical storage cabinets should be sanitized weekly with detergent and disinfectant solutions. For medical cabinets, the choice of the sanitizing solution should be made according to the manufacturer's instructions (UNI TR 11,662) [29]. Medical storage cabinets compliant with EN 16,442:2015 should respect the microbiological limit for surface ($\leq$25 UFC/24 cm^2) and for the inside air quality [16]. Each surface in contact with the endoscopes should be sampled every six months, in agreement with the ISO 14,698 method, employing Rodac contact plates [30]. Use at least 4 plates for each tray (at the two diagonally opposite corners and in the center of two side walls) and 1 for the lid (at the center of the internal wall), for cabinets with horizontal shelves. The overall procedure is summarized in Table 3.

3.4. What to use

The eluent solution to be used for sampling the internal channel of endoscopes should be sterile, nontoxic for microorganisms, able to neutralize the activity of any residual disinfectant, and have a good recovery capacity. The CDC guidelines delivered on 2015 recommended an elution solution of 0.01 M Phosphate

Table 3
Matrix to be analyzed and parameters to be investigated.

Sampling site	Matrix to analyze	Parameters to investigate	Analytical method	Reference limits
Water from the air-water bottle	2 × 1 ml	Total Microbial Count at 36 °C and 22 °C	ISO 6222:1999	0 UFC/ml
Inlet water of washer-disinfector	2 × 500 ml	Total Microbial Count at 36 °C and 22 °C	ISO 6222:1999 ISO 9308–1: 2014	≤10 UFC/ml at 36 °C e ≤100 UFC/ml at 22 °C
		Coliforms, *E.coli*	ISO7899.2:2003	0 UFC/100 ml
		Enterococci	ISO 16,266:2008	0 UFC/100 ml
		P. aeruginosa		0 UFC/250ml
Water from the final rinse of the washer-disinfector (ISO 15,883–1, ISO 15,883–4)	2 × 800 ml	Total Microbial Count at 28°–32 °C/5days	ISO 6222:1999, ISO 16,266:2008	≤10 UFC/100 ml 0 UFC/250 ml
		P. aeruginosa	WHO, 2004	0 UFC/100 ml
		Non-tuberculous mycobacteria	(ISO 11,731–2:2017)	0 UFC/1000ml
		Legionella spp.		
Endoscopes: internal channels	45–90 ml	Total Microbial Count at 36 °C	ISO 6222:1999	≤10 UFC/eluate
		Coliforms, *E.coli*	ISO 9308–1: 2014	absent
		Enterococci	ISO 7899.2:2003	absent
		P. aeruginosa	ISO 16,266:2008	absent
		Staphylococcus spp.	Rapporti ISTISAN 07/05	absent
Endoscopes: external surfaces	Soaked swabs with eluent	Coliforms, *E.coli*	ISO 14,698–1	absent
		P. aeruginosa	ISO 14,698–1	absent
		Staphylococcus spp.	ISO 14,698–1	absent

Buffered Saline with 0.02% Tween 80 [5], whereas in the updated guidelines (2018), sterile deionized water is suggested, although its recovery capacity may vary from 65% to 100% [6]. Indeed, Tween 80 was shown to exerts disruptive role on microbial biofilm, and to neutralize the residual activity of disinfectants [31]. On the other hand, the French guidelines recommends the use of 0.067 M Phosphate Buffer, 0.43% [m/v] sodium chloride, 0.1% [m/v] peptone, 0.1% [v/v] Tween 80 solution added to 100 ml distilled water. In the same document, 0.9% saline solution was mentioned as an alternative, but underlining that the recovery capacity may be lower since this solution has neither neutralizing nor emulsifying properties [32,33]. The use of sterile water is discouraged because it is not considered suitable for the recovery and preservation of the viability of microorganisms [34].

3.5. Frequency of sampling

Microbiological surveillance should be performed as a regular quality control of the reprocessing. The US guidelines recommend the sampling of duodenoscopes after 60 ERCP procedures or at least once a month, as well as every time that the device has been used on a patient for whom the status of colonization/infection by resistant multi-drug (MDR) microorganisms is known. The monthly frequency of microbiological tests on duodenoscopes, as well as on linear echoendoscopes and bronchoscopes, is also recommended by the Australian guidelines [8]. Sampled endoscopes should not be used until a negative microbiological report is issued. On the contrary, a specific ESGE document on the prevention of infections transmitted with duodenoscopes suggest to carry out microbiological tests every 3 months [35]. Regarding other types of endoscopes (gastroscopes, colonoscopes, enteroscopes, radial scanning echoendoscopes, bronchoscopes), microbiological surveillance is recommended with different periodicity by different guidelines. A quarterly frequency for analyses of endoscopes and washer-disinfectors is proposed by Dutch [36] and German [37] guidelines, while in Austrian [8] guidelines the proposed frequency is once a year, and in Italian guidelines every six months [38]. Moreover, there is no uniformity among the guidelines regarding the quarantine of endoscope until the availability of microbiological negative results. When microbiological sampling shows a positive result, it is necessary to review the entire reprocessing procedure to identify the cause of the failure of process. If the cause (water, washer-disinfector, storage) is not identified, the presence of microlesions in the internal channels should be considered and searched for [32,39-44].

3.6. How to interpret results

The levels of load of microorganisms with low and medium concern discovered on different types of endoscopes may vary according to the type of reprocessing, manipulation and sampling procedure performed. Therefore, during the first month of surveillance, the levels of these microorganisms should be monitored to define an appropriate basal target value of the center. Typically, a value <10 CFU/endoscope does not require intervention, a value between ≥10 and <100 CFU/endoscope requires revision of the reprocessing procedure and a new staff training program. For a value ≥100 CFU/endoscope of low/medium concern microorganisms or in case of detection of high concern microorganisms (≥1 CFU/endoscope), it is necessary to revise the reprocessing procedure, repeat the sampling, and quarantine the endoscope until the culture is negative or with acceptable levels for low/medium concern microorganisms. The follow-up of patients who underwent an endoscopic procedure with an endoscope testing positive need to be performed (Fig. 1). Microbiologic surveillance reports should be interpreted by Prevention and Control Infection Team in close collaboration with physicians and nurses, and other personnel involved in the endoscope reprocessing procedure, clinical engineering, and the companies that supply the endoscopes and the devices used to reprocess them.

3.7. Requirements and responsibilities

The process manager (UNI TR 11,662) is the person formally in charge of planning, organizing, and managing the whole process and responsible for the verification of the sampling procedure applied in microbiological surveillance [29]. To carry out all functions, the process manager can delegate some steps to other professionals, defining their roles, qualifications, competencies, and responsibilities. Any delegation should be accepted in writing by the delegate and documented. The process manager should verify that the personnel performing the procedure and the laboratory performing the microbiological analysis meet the requirements of their roles. Staff should demonstrate, through periodic audits, knowledge of the structure of each type of endoscope in use, ability to perform sampling under aseptic conditions, and knowledge of the protocol for sampling and storing samples before sending them to the laboratory [45].

4. Conclusions

The potential transmission of infections through flexible endoscopes and the recent evidence of transmission of multidrug-resistant bacterial strains through contaminated endoscopes motivated some Scientific Societies to work together for producing this document. Although the incidence of these issues is low, their clinical relevance cannot be ignored when considering that the reported events are severe. The reprocessing of instruments and the adequate cleaning of workplace and storage areas represent a complex process that involves different professional profiles. The correct execution of these procedures requires every phase of the process to be performed in a standard way by an adequately trained staff, and every step should be traceable. The quality check can be done by searching the process-indicator microorganisms at every step of the process through sampling and testing. The increasing structural complexity of endoscopes makes an adequate control of the contamination risk more difficult, especially because of the formation of biofilm, which happens frequently in particular areas of the endoscope, such as microlesions in channels, valves, distal lenses, etc., and is hardly removable with standard procedures. The execution of microbiological surveillance to prevent and reduce the infectious risk and the implementation, where possible, of disposable parts of the instrument, are desirable. The summary of the suggestions by the Panel is provided in Fig. 1.

Declaration of Competing Interest

none declared.

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Appendix

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