Ann Ig 2018; 30 (Suppl. 2): 45-63 doi:10.7416/ai.2018.2250

Procedures in endoscope reprocessing and monitoring: an Italian survey

M.L. Cristina[1], F. Valeriani[2], B. Casini[3], A. Agodi[4], M.M. D'Errico[5], G. Gianfranceschi[2], P. Laganà[6], G. Liguori[7], R. Liguori[7], N. Mucci[8], I. Mura[9], C. Pasquarella[10], A. Piana[9], G. Sotgiu[9], G. Privitera[3], C. Protano[11], A. Quattrocchi[4], G. Ripabelli[12], A. Rossini[13], E. Scaramucci[14], A.M. Spagnolo[1], M. Tamburro[12], S. Tardivo[15], L. Veronesi[10], M. Vitali[11], V. Romano Spica[2] and GISIO*

Key words: Endoscope reprocessing, Guidelines, Survey, Disinfection, New rapid methods
Parole chiave: Ricondizionamento degli endoscopi, Linee guida, Questionario, Disinfezione, Nuovi metodi rapidi

Abstract

Background. *The high diffusion of endoscopes worldwide and the need for effective reprocessing methods requested the development of guidelines and implementation of surveillance procedures at local level.*
Study design. *In order to collect data on everyday's practice and adherence to available guidelines, endoscopy units from different public institutions were surveyed using a dedicated questionnaire.*
Methods. *Between July and November 2015 a survey was carried in 12 main hospitals from 10 different Italian regions, involving 22 endoscopy units. The state of the art of national and international guidelines was investigated to compare the protocols adopted at local level.*
Results. *In all the surveyed hospitals, the reprocessing activity is based on pre-established protocols in adherence with principal guidelines. Enzymatic detergents, which are recommended by the international*

1 Department of Health Sciences, University of Genoa - UOS Igiene Ospedaliera E.O. Ospedali Galliera, Genoa, Italy
2 Unit of Public Health, Department of Movement, Human and Health Sciences, University of Rome "Foro Italico", Rome, Italy
3 Department of Translational Research and New Technologies in Medicine and Surgery, Pisa University, Pisa, Italy
4 Department of Medical and Surgical Sciences and Advanced Technologies "GF Ingrassia", University of Catania, Catania, Italy
5 Department of Biomedical Sciences and Public Health, Politechnic University of Marche, Ancona, Italy
6 Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina, Messina, Italy
7 Department of Movement and Health Sciences, University "Parthenope," Napoli, Italy
8 Department of Technological Innovations and Safety of Plants, Products and Anthropic Settlements, National Institute for Insurance against Accidents at Work, INAIL, Rome, Italy
9 Department of Biomedical Science-Hygiene Section, University of Sassari, Sassari, Italy
10 Department of Medicine and Surgery, University of Parma, Parma, Italy
11 Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy
12 Department of Medicine and Health Sciences "Vincenzo Tiberio," University of Molise, Campobasso, Italy
13 Fondazione Santa Lucia Institute for Research and Health Care, IRCCS, Rome, Italy
14 S. Andrea Hospital, Rome, Italy
15 Department of Diagnostics and Public Health, University of Verona, Verona, Italy
** GISIO - Italian Study Group of Hospital Hygiene - Italian Society of Hygiene, Preventive Medicine and Public Health*

guidelines, are used in 55.6% of units and peracetic acid is currently the most widely used chemical disinfectant. Discrepancies were observed in the application of periodic quality controls.
Conclusions. *Updated guidelines are generally applied in reprocessing practice. Quality controls may represent a critical issue to improve effectiveness and surveillance. The whole of acquired data can promote a positive trend towards the application of best practices.*

Introduction

It is estimated that 20 million gastrointestinal endoscopies are performed annually worldwide. In Italy, 1.7 million endoscopic procedures for diagnostic purposes and therapeutic interventions are performed each year, including approximately 500,000 colonoscopies (1, 2). The use of a contaminated endoscope may lead to infections through the contamination with potential pathogens from patient to patient (3). Following therapeutic gastrointestinal endoscopic procedures, several deadly outbreaks of multidrug resistant organisms (MDROs) were recently documented in the international scientific literature (4-6). Epstein and colleagues reported a cluster of New Delhi metallic-β-lactamase (NDM)–producing *Escherichia coli* infections associated with gastrointestinal endoscopy (6). These outbreaks were linked to contaminated duodenoscopes used to perform retrograde cholangio-pancreatography (ERCP). Several healthcare associated infections (HAIs) were described, but the exact incidence of endoscopy-related infections is unknown because of of inadequate epidemiological surveillance (7).

Gastrointestinal endoscopes are difficult to clean, sanitize and easy to damage, due to their complex design, the presence of narrow lumens, long and multiple internal channels and right-angle turns. Bacteria can form biofilms on the channels' internal surfaces, contributing to reprocessing failures (7). Moreover, since flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are the choice (8).

In general, endoscope reprocessing requires several steps, including pre-cleaning, leak testing, manual cleaning, high-level disinfection, rinsing, drying, and appropriate storage (9). Professional organizations and institutions such as the Centers for Disease Control and Prevention (CDC) have produced evidence-based endoscope reprocessing guidelines (1, 10). Although some data have demonstrated that rigorous adherence to these guidelines will result in a patient-safe endoscope, other reports highlighted that rarely all the steps associated with manual endoscope reprocessing are performed following the full sequence of operations. Essential steps such as brushing all endoscope channels and components are frequently skipped in the routine activity, increasing the possibility of cross-transmission of HAI (8). Microbiologic surveillance by culture-based methods represents an established and easy-to-use approach for assessing the effectiveness of reprocessing procedures, but several relevant limitations should be considered, such as the long response time, low specificity, and poor sensitivity in detecting microorganisms not cultivable on standard media, such as viruses, protozoa, prions, or viable but not cultivable bacteria (4-6, 11). Effective surveillance of flexible endoscope reprocessing ideally requires reliable testing methods that would allow for a rapid and simple assessment of the compliance with current reprocessing standards (12). Enforcement of guidelines by effective monitoring systems is a key issue, not only for confirming hygiene standards or for preventing cross infections by colonizing

bacteria including MDROs, but also for tracing contaminations to avoid infections by resistant agents or new pathogens (11, 13).

In view of the large diffusion of endoscopies worldwide and of the still elevated complexity of the reprocessing protocols, the availability of effective surveillance strategies represents a priority issue where pre-cleaning phases and the high disinfection steps are critical points. A unique approach is lacking and comparison of recommendations from international and national guidelines shows several discordances in operative indications, levels of evidence and grading. This study aims to describe the state of the art regarding international recommendations and Italian guidelines and to collect data by a survey on the current practice of endoscope reprocessing in the hospitals of different Italian regions.

Guidelines on reprocessing of flexible endoscopes

Several countries have revised evidence-based guidelines on endoscope reprocessing in order to reduce the number of infections and improve safety in the routine practice. These guidelines guarantee that all clinicians and healthcare workers can be aware of the most updated evidence-based methods to ensure patients' and operators' protection. Multiple studies from different countries documented the lack of compliance with established guidelines for disinfection and sterilization (14-16). For this reason, in September 2015, the CDC and the Food and Drug Administration (FDA) issued a health advisory to alert healthcare facilities about the public health need to properly maintain, clean, disinfect, and sterilize the reusable medical devices, including gastrointestinal endoscopes and bronchoscopes (17). The FDA listed supplemental measures to consider when reprocessing duodenoscopes, including ethylene oxide sterilization, use of liquid chemical sterilant, repeated high-level disinfection and monitoring by microbiological culturing (18). The CDC published the "Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing", where it was stressed how surveillance cultures are not a replacement for appropriate training and oversight of endoscope reprocessing practices (19). Permanent education of personnel, careful supervision of activities and prepared management of procedures are essential for prevention, but appropriate monitoring is the necessary requirement for an effective surveillance. The frequency of collecting samples for microbial cultures was recommended as a periodic duty to be performed monthly or after every 60 procedures for each duodenoscope, according to the "Interim Duodenoscope Sampling Method and Interim Duodenoscope Culture Method" (19). The guideline recommends holding duodenoscope out of use while surveillance culture results are pending. The approach to surveillance of endoscope reprocessing, however, represents a more complex issue involving not only the effectiveness of monitoring technologies and the evaluation of their cost/benefit ratio but also the consideration of the specific device model and the facility context where it is used (11).

A multidisciplinary approach is necessary to manage appropriate reprocessing and different points of view can suggest different solutions and priorities. The American Society for Microbiology (ASM) recommended microbiological surveillance of flexible endoscopes only in response to epidemiologic investigations when instruments may be microbial sources of HAI transmission or in the case of testing new or modified reprocessing procedures (20). Still in 2015, the Healthcare Infection Control Practices Advisory Committee

(HICPAC), a federal advisory committee chartered to provide advice and guidance to CDC, established a guidance to assist healthcare facilities, including clinical and administrative staff, to achieve a reliable, high-quality reprocessing program. In this regard, a toolkit of sample documents was developed to help facilities create and maintain the infrastructure to support their flexible endoscope reprocessing program (10).

In 2018, FDA, CDC and ASM together with duodenoscope manufacturers and other experts, has released the new guideline "Duodenoscope Sampling and Culturing Protocols" (21). This document provided standardized protocols for duodenoscope surveillance sampling and culturing, as an update to the Interim Duodenoscope Surveillance Protocol released by CDC in March 2015. This document was developed to identify the types of resources and collaborative relationships required to standardize methods. Several institutions and scientific societies at the international, European and national level have updated their guidelines according to the CDC and FDA recommendations.

In 2003, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA) developed an initial set of guidelines for reprocessing gastrointestinal (GI) endoscopes. These guidelines used the Spaulding classification of medical devices to determine the effectiveness of disinfection or sterilization (22-24). In this regard, endoscopes are classified as "semi-critical" devices; they should undergo at least high-level disinfection. In 2011 ASGE and SHEA Multi-society Guidelines were updated with the recommendation that complete cleaning of endoscopes should be more thorough before high-level disinfection (25). ASGE and SHEA also updated specific information regarding those endoscope models with movable elevators at the distal tip, such as duodenoscopes. More recommendations were also provided about how long can endoscopes be stored between uses and how long can be used before their replacement. The question regarding the opportunity of environmental microbiological testing of endoscopes for quality assurance has not been established in the current American standards.

Conversely, many guidelines issued by international Societies are available: Gastroenterological Society of Australia, European Society of Gastrointestinal Endoscopy (ESGE), European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) committee. These documents provide recommendations for monitoring measures after reprocessing. In the 2016 update from the ASGE-SHEA Guidelines, several issues were further addressed, including: shelf-life and hang time periods for maintaining the endoscope during storage, as well as the role of microbiological surveillance by testing endoscopes after reprocessing. Moreover, additional questions regarding endoscope longevity and the implementation of different reprocessing approaches were considered (26).

In 2016, the Society of Gastroenterology Nurses and Associates (SGNA) updated the guideline "Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes" first published in 1996 and revised in the years 2000, 2005, 2007, 2008, 2011, 2012, 2015. The focus of this standard was to highlight the expectations of reprocessing staff and management responsibilities, the reprocessing environment, the steps in reprocessing and the rationale for their use, and the quality assurance. Understanding the reprocessing continuum from procedure room to storage was highly recommended as well as the diligence in the application of all reprocessing steps to obtain the safe delivery of endoscopic services (27).

In 2017, ESGE-ESGENA updated the Guideline 2007, addressed to validation and

routine testing of automated reprocessing procedures in washer-disinfectors for thermolabile endoscopes, complying with the final version of EN ISO 15883, parts 1, 4, and ISO/TS 15883-5 (28). This was a recent step of a longer revision process, starting in 1994, when the ESGE–ESGENA Guideline Committee had established guidelines for infection control of GI endoscopy and continued in 2007 with the guideline for process validation and routine testing in reprocessing endoscopes by the use of washer-disinfectors, according to the European Standard prEN ISO 15883 parts 1, 4 and 5. This guideline addressed the necessity for microbiological surveillance in endoscopy and provided practical information about testing the quality of the microbiological outcomes of manual and automated reprocessing procedures used in endoscopy (29). Routine testing should cover periodic microbiological surveillance of endoscopes, washer-disinfectors, accessories, and the water supply used in endoscopy. The ESGE–ESGENA guideline Committee recommends routine testing at intervals no longer than 3 months. In 2008, ESGE-ESGENA updated these guidelines for cleaning and disinfection of GI endoscopes (30). In addition to the seven steps of endoscope reprocessing, that are similar in different regulations, these guidelines provided detailed information for three different available reprocessing methods: automated washer-disinfectors, automated disinfection devices, and manual reprocessing followed by pre-cleaning and manual cleaning. The ESGE and ESGENA strongly recommend the use of washer-disinfectors including cleaning and disinfection, because automated reprocessing provides a standardized and validated reprocessing cycle, unlike manual reprocessing. In addition, automated reprocessing could ensure highly reliable reprocessing and minimal staff hazard and lower the risk of scope damage. Process validation and microbiological surveillance was recommended as well as the respect of manufacturer's instructions when performing process validation for washer disinfectors. However, routine microbiological testing for endoscopes still remains a controversial issue. The Gastroenterological Society of Australia guideline recommends microbiological monitoring of duodenoscopes, bronchoscopes, and automated endoscope reprocessors every four weeks and all other GI endoscopes every 4 months (31). Several alternative monitoring methods have been proposed and considered but still not included in novel guidelines (11, 32, 33).

In Italy, the National Association of Endoscopic Techniques Operators and the National Association of Gastroenterology and Associated Nurses (ANOTE-ANIGEA) released in 2011 an update of the "Cleaning and Disinfection in Endoscopy" guidelines (34). A survey carried in 2009 in several Endoscopy Centers showed a lack of knowledge about the recommendations provided in the guidelines. In particular, critical issues include: the final stages of the process (drying and storage); the lack of a traceability system along the whole process; the need of standard protocols in carrying out microbiological surveillance of endoscope reprocessing. A working group was therefore set up for the revision and updating of the national guidelines, and for the implementation of the training program in order to increase knowledge and to develop and strengthen the contribute of nurses in endoscope reprocessing surveillance and management. This document is currently under review with the collaboration of other scientific societies. A significant contribute came also from the health agencies of some Italian Regions. In 2006, the Health Agency of the Emilia Romagna Region published the document "Reprocessing of endoscopes: operational indications", with the aim of directing the activity of professionals in the reprocessing of

endoscopes and of supporting programs of auditing of the care practices in the clinical facilities and endoscopy services (35). The document highlighted critical points in operational phases for reprocessing of endoscopes and their accessories, providing recommendations for microbiological surveillance and for occupational safety. Additional issues focused on the facility structure, process and outcome indicators, training goals for health professionals in Endoscopy Services. In 2013, also the Tuscan Health Agency published a regulation document entitled "The reprocessing in digestive endoscopy: critical issues and instruments for the process safety", in order to summarize scientific evidences and defining operative indications for good practice in the reprocessing of flexible endoscopes, including the use of effective check lists (36). Currently, several other working groups are involved in revising and updating local and national guidelines for improving endoscope reprocessing.

Figure 1. Map showing the regions involved in this study.

Materials and methods

Study design

A survey within a multicentric study proposed by the Italian Study Group of Hospital Hygiene - Italian Society of Hygiene, Preventive Medicine and Public Health (GISIO-SItI), was conducted between July and November 2015 in several hospitals of different Italian regions (Campania, Emilia-Romagna, Latium, Liguria, Marche, Molise, Tuscany, Veneto, Sardinia, and Sicily), involving 12 hospital facilities and 22 Endoscopy Units (Figure 1), including Digestive Endoscopy and Bronchoscopy Units (N = 18 and N = 4, respectively). A total of 176 questionnaires were collected. The Coordinating Unit (University of Rome "Foro Italico") collected all data and the results were analyzed within the collaborative networks.

Questionnaire development and survey administration

A questionnaire was developed to evaluate data concerning cleaning and disinfection methods for reprocessing of endoscopes and supplementary devices. The preliminary draft of the survey was developed and validated in a previous study carried on during year 2013, and improved according to literature reports (37). Validation was performed through a pilot study on 20 health operators from endoscopy facilities. The final questionnaire included 12 interviewer-based questions about reprocessing of flexible endoscopes and endoscopic accessories (Table 1 and supplementary material SM1a and SM1b) and was distributed to several employees, nurses and/or physicians, working in various endoscopy units. The survey was conducted directly by the researchers, who collected data by interviewing referents from different reprocessing facilities. The filled in questionnaires were sent to the coordinating unit that anonymously entered the data in a dedicated database. Up to three attempts

Table 1 - List of the topics included in the questionnaire.

Survey topics
1. Cleaning
2. Drying
3. Procedures of endoscope and accessories disinfection
4. Extraordinary procedures for device reprocessing
5. Treatment of internal channels
6. Separate treatments for composite device
7. Rinsing
9. Treatment registration (traceability)
10. The periodic quality control procedures
11. Protocol
12. Factors affecting the effectiveness of the treatment

were made to remind each participant to provide data, after which those endoscopy units that failed to provide the compiled questionnaire (just two), were considered as non-responders and excluded from this study. Conversely, some participant endoscopy units have collected and sent more than one questionnaire but filled by different operators. In this case, the data were compared and used to verify questionnaire effectiveness, acquiring information on the individual compliance to internal protocols, based on the different health operators independently involved in the study from the same facility (16, 35).

Statistical analyses

Descriptive statistics were used to summarize the principal results and characteristics. Categorical data were expressed as numbers (percentages), whereas continuous data were expressed as means ± standard deviations. The compliance to guidelines and internal protocols was calculated as a percentage: compliance % = (number of compliant answers/total of questionnaires collected) ×100. Statistical analysis was performed using the SPSS version 18.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

The survey allowed us to obtain data on critical issues in endoscope reprocessing and on the local application of recommendations and guidelines in everyday's practice. The general compliance to guidelines for flexible endoscope reprocessing was high (96-100%) for all queried items.

Table 2 shows informations regarding the cleaning procedures before disinfection and sterilization steps. Our data revealed that, in the surveyed centers, the reprocessing of flexible endoscopes and their accessories was regularly preceded by cleaning procedures (100%), and mostly using manual protocols (82%). The cleaning step was performed by: enzymatic products (55.6%) or a combination of water and detergent or disinfectant (16.7 and 5.6%), while some facilities reported the use of water only for the cleaning step (22.2%). In order to avoid disinfectant dilution, a drying step is usually included, as reported by 40.9% of endoscopy units, by using automatic systems (33.3%), simple sheets (22.2%), or a combination of sheets and forced air (22.2%). In the surveyed facilities, the responsibility for carrying out the cleaning step seems to be mainly up to nurses (62.1%), and in a lesser extent to physicians (13.8%) or both (24.1%). Adequate structures and dedicated equipment for manipulating chemical solutions with potential toxicity were assured in 72.2% of cases, but independent rooms for cleaning were available in only 28%, in agreement with other studies (38, 39).

Details regarding disinfection or sterilization procedures are reported in Table 3. The high disinfection protocols are usually performed in a dedicated environment (86.4%). The disinfection process is usually performed in closed systems (95.4%) by

Table 2 - Cleaning procedures before disinfection and sterilization steps and drying.

Item		Answers of Endoscopy Operation unit No. (%)	Compliance to recommendation and guidelines (%)*
Cleaning	Yes	22 (100)	98.9
	No	0 (0)	
Type of cleaning	Manual	18 (82)	100
	Automatic	2 (9)	
	Answer not available	2 (9)	
Product for cleaning	Enzymatic product	10 (55.6)	96
	Water	4 (22.2)	
	Water and detergent	3 (16.7)	
	Water, detergent, disinfectant	1 (5.6)	
Drying	Yes	9 (40.9)	100
	No	12 (54.5)	
	Answer not available	1 (4.5)	
Process of drying	Automatic	3 (33.3)	98
	Sheet	2 (22.2)	
	Sheet and forced air	2 (22.2)	
	Answer not available	2 (22.2)	

* Compliance % = (number of conforming answers / total of questionnaire collected) ×100.

endoscope washing machines (82%) or using the autoclave for some accessories and parts of endoscopes (13.6%). Among the available chemical disinfectants, products based on peracetic acid were currently the most used (91%), followed by those based on ethylene oxide (4.5%) and glutaraldehyde (4.5%). The contact time recommended by the manufacturers for high quality disinfection was carefully respected by all surveyed centers for endoscopies, but it seems very variable for non critical endoscope accessories: 30-39 minutes for 31.8%; 40-50 minutes for 18.2% and 10-20 minutes for 13.6% of cases; a large percentage of centers (36.4%) did not specify this detail. In addition, the questionnaire investigated motivations driving to the selection of a specific disinfection product and the results showed that in half of the cases (50%) the manufacturer's instructions were followed carefully. However, also the availability of protocols already in use in the facilities (9.1%) or economical cost (9.1%) played a role in the choice of a product compared to another. Only 4.5% of the decisions were determined after consideration of specific safety information or guidelines indications. The internal channels treatment was performed only when required (86.3%), and in particular: brushing all the accessible channels (31.8%) or combination of brushing with other mechanical procedures as aspiration (18.2%) or introduction of the disinfectant under pressure (18.2%). The final rinsing of the instruments was performed by 31.8% of endoscopy units, using sterile water (21%) or ethyl alcohol (18%). Endoscopes are usually stored in an area that is clean, well-ventilated and dust-free in order to keep them dry and free of microbial contaminations, such as in ventilated storage cabinets (63.6%); alternatively, the devices go back to use immediately (13.6%). The compliance to guidelines or recommendations for disinfection protocols was 100% for the items "product for disinfection" and "storage", but

Table 3 - Procedures for endoscope disinfection.

Item		Answers of Endoscopy Operation Unit No. (%)	Compliance to recommendation and guidelines (%)*
Setting	Dedicated disinfection room	19 (86.4)	98.2
	Operation room	2 (9)	
	External Operation Unit	1 (4.6)	
System	Closed	21 (95.4)	98.2
	Open	1 (4.5)	
Disinfection system	Endoscope washing machine	18 (82)	
	Autoclave	3 (13.6)	99
	Disinfection bath	1 (4.4)	
Product for disinfection	Peracetic Acid	14 (64)	100
	Endodis (4.25% Peracetic Acid, 7.3% Acetic Acid and stabililized and 27% H2O2)	4 (18)	
	Steril C (25-30% Peracetic Acid)	1 (4.5)	
	Rely+On Perasafe (Peracetic Acid)	1 (4.5)	
	Ethylene Oxide	1 (4.5)	
	Glutaraldehyde	1 (4.5)	
Time of exposure (minutes)	30 – 39	7 (31.8)	NA**
	40 – 50	4 (18.2)	
	10 – 20	3 (13.6)	
	Answer not available	8 (36.4)	
Motivation for selection of disinfection procedure	Supplied/indicated by manufactures	11 (50)	NA**
	Protocols already in use in the facilities	2 (9.1)	
	Financial resources of the healthcare provider	2 (9.1)	
	Internal evaluation of efficacy and safety	1 (4.5)	
	Guidelines	1 (4.5)	
	Not available the answer	5 (22.8)	
Treatment internal channels	Brushing or other mechanical technique	7 (31.8)	96
	Introduction of the disinfectant under pressure, brushing	4 (18.2)	
	Introduction of the disinfectant under pressure, brushing and aspiration	4 (18.2)	
	Introduction under pressure of the disinfectant	2 (9.1)	
	None internal channels	3 (13.7)	
Rinsing	Yes	7 (31.8)	99
	No	13 (59)	
	Not available the answer	2 (9.2)	
Storage	Cabinet ventilated dedicated	14 (63.6)	100
	Go back in use	3 (13.6)	
	Basket or envelop for autoclave	3 (13.6)	
	Other (such as endoscope case)	2 (9.2)	

* Compliance % = (number of conforming answers / total of questionnaire collected) ×100; **NA= Not applicable

Table 4 - Cases requiring alternative procedures of disinfection for the same medical device.

Item		Answers of Endoscopy Operation unit No. (%)
Different procedures	Yes	12 (54.5)
	No	10 (45.5)
Situations requiring different procedures	Infectious disease	6 (27.3)
	HIV and viral hepatitis	1 (4.5)
	Other (such as tuberculosis or candidiasis)	1 (4.5)
	Answer not available	14 (63.6)

slightly lower for the item "treatment of internal channels" (96%). As shown in Table 4, to avoid cross-contaminations, several alternative procedures of disinfection were considered (54.5%) for the same medical device in the occurrence of patients with specific infections at higher risk. In most of the cases (54.5%) the procedures for endoscope treatment have been modified based on HIV and viral hepatitis (4.5%) or other communicable diseases (27.3%), while the 63.6% of interviewed units did not provide a response to this question.

In Table 5 the methodology for traceability of the endoscope reprocessing procedures are shown. Availability of accurate documentation and registries is essential for quality assurance of the procedures, monitoring on the long period and tracing of both medical device and its use on patients.

This step is performed in centers through the recording phases and control measures, following a standard format. In particular, the registration of the applied treatment was performed in 41% of considered endoscopy units, by traditional registration (66.7%) or by input into an analogical register (22.2%). The quality control of the cleaning and disinfection steps was regularly performed in 50% of units, using microbiological test (18.2%), Bowie-Dick test (18.2%), mechanic (9%) or sealing quality test (9%). Some factors that negatively affect the effectiveness of the endoscope reprocessing are reported in Figure 2: damaged or not working machines for disinfection, missed registration, emergency conditions, heterogeneity of the personnel, preferred disposable devices, complexity of the disinfection procedures, lack of standardized procedures, insufficient number of medical devices, lack of time, lack of protocols and of personnel. The whole of the information acquired from the survey allowed to observe a generally elevated professionalism and dedication in implementing updated procedures for endoscope reprocessing.

Discussion and conclusions

Flexible endoscopes acquire a high bioburden of microorganisms after their use, ranging from 10^5 to 10^{10} CFU/mL, with the highest levels found in the suction channels (3). The elevated contamination of these medical devices is a regular occurrence after contact with the mucosa epithelium, local microflora and biological fluids present in these human districts (11-13). Therefore, accurate reprocessing of endoscopes is an inescapable procedure, requiring different steps including cleaning and high-level disinfection as specified by different guidelines. In order to avoid

Table 5 - Availability of pre-established protocols and control procedures for reprocessing steps and their traceability.

Item		Answers of Endoscopy Operation unit No. (%)
Treatment registration	Yes	9 (41)
	No	7 (31.8)
	Answer not available	5 (22.7)
	Not known	1 (4.5)
Type of registration	Traditional	6 (66.7)
	Analogic register	2 (22.2)
	Label and analogic register	1 (11.1)
Control of treatment efficacy	Yes	11 (50)
	No	9 (41)
	Answer not available	2 (9)
Type of control	Microbiological	4 (18.2)
	Bowie-Dick test	4 (18.2)
	Vacuum leak test	4 (18.2)
	Seal examinations	2 (9)
	Mechanical	2 (9)

cross-infections, a rigorous application of updated protocols and a careful surveillance of the procedures are necessary. The published pathogen transmission episodes related to gastrointestinal endoscopy have been associated with non-compliance with established guidelines on cleaning and disinfection or use of defective equipment, although cases have also been reported in compliance with these recommendations (3-7). In order to prevent transmission of infection, endoscope reprocessing requires additional five steps after mechanical precleaning and leak testing: cleaning, high level disinfection (HLD), rinsing, drying and storage (8). Storage of the endoscope has

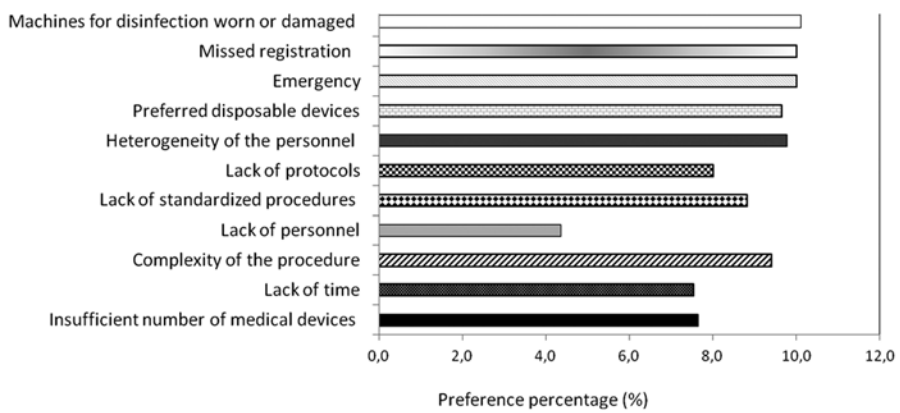

Figure 2. Factors that could interfere with reprocessing effectiveness.

to follow specific requirements in a way to prevent contamination and to promote drying under controlled conditions. Cleaning should be performed closely after each use of an endoscope to avoid drying of secretions and to allow easier removal of organic materials and microorganisms. Improper cleaning can overwhelm HLD, regardless of subsequent steps, representing a critical point most susceptible to error, as shown by several studies (11, 37-39). Even if guidelines are available, their application in everyday practice can be affected by several factors.

This survey aimed to provide information on compliance to endoscope reprocessing guidelines and recommendations in Italian hospitals from different regions. All endoscopy units showed to follow the pre-established protocols. Manual cleaning was largely applied to provide a potential basic step for protection against cross-infections and for a reliable maintenance of the medical devices. Among the products used for cleaning, the enzymatic detergents are mainly used in 55.6% of units. Although several guidelines consider this product effective in endoscope decontamination and they recommend it, several alternatives were reported (18). In the surveyed centers, HDL step was performed by peracetic acid - currently the mostly used among the liquid chemical sterilants, followed by ethylene oxide. The indications reported by the manufacturers of endoscopy washing machines are very relevant, representing a main source for the selection of disinfectants. Specific additional tests are not usually considered before selecting the disinfection product and other criteria such as safety parameters or the impact on health of workers and environment are rarely mentioned, in line with other studies (38, 39). Moreover, the choice of a disinfectant has to be compatible with the device model to be treated according to materials and specific needs, as in case of the high-risk contaminations. This issue does not seem to be considered as a priority and general protocols are chosen to satisfy the best protection level achievable in that facility, based on a cost-benefit evaluation. If keeping track of the application of protocols and daily activities is a crucial point, however, it is important to underline that the effective treatment registration does not occur if the procedure is not accomplished by means of an automated device, and this can constitute a weak point in the quality assurance of the process, even if well accomplished. In general, the use of an automated machine implies a higher availability of quality controls on the procedure; instead, in case of manual disinfection protocols, controls and quality tests tend to be less considered and performed. Management of reprocessing should be founded on adherence to updated guidelines, accurate surveillance of the process and respect of manufacturer's instructions for both instruments and chemical products, considering periodic quality controls as essential for prevention of infections as well as for effectiveness and sustainability in the long period.

In order to ensure the achievement and maintenance of optimal reconditioning, FDA provided supplemental measures, requiring periodic microbiological controls (18, 38, 39). In agreement with other reports, this survey shows that the control of process performance is often achieved (50%) but the microbiological surveillance is performed only rarely (18.2%) (38, 39). Probably, the support of simple and rapid tests could increase the percentage of endoscopy facilities undergoing quality controls. Nowadays, several novel monitoring strategies have been proposed based on molecular methods, that may provide additional promising resources to implement quality surveillance and update future guidelines (11, 39). Although the clear majority of endoscopy centers have reported procedures in line with official recommendation and guidelines (96-100%), however there is a slight variation in everyday practice.

In the light of the debate on updating guidelines and regulations for endoscope reprocessing, this survey provided some indications on the approach adopted in different Italian hospitals.

The acquired data are mainly in agreement with previously published reports and highlighted several critical

SM1: Questionnaire

SCHEDA N. |_|_|_|_|_|	UNITA' OPERATIVA	DIPARTIMENTO
DISPOSITIVO		CODICE MINISTERO

1. Le procedure di disinfezione/sterilizzazione sono precedute da un lavaggio?

□ Sì □ No □ Non so

Se sì, come? □ Manuale □ Automatico

Con quali prodotti?

□ acqua
□ acqua e detergente
□ acqua e disinfettante
□ prodotti enzimatici
□ altro……

2. Dopo il lavaggio, il dispositivo è asciugato?

□ Sì □ No □ Non so

Se sì, con quale metodo? ……

3. Come avviene la procedura di disinfezione/sterilizzazione? Indicare:

Ambiente di lavoro ……

Tipologia di sistema ……

Disinfettante e concentrazione ……

Tempo di esposizione (in minuti) ……

Sistema aperto o chiuso ……

Motivo della scelta del disinfettante ……

Ogni quanto tempo viene sostituito il prodotto chimico utilizzato per la procedura ……

4. Ci sono delle situazioni in cui per il medesimo dispositivo medico si effettua una procedura diversa?

□ Sì □ No □ Non so

Se Sì, quali?……

- Il disinfettante solitamente usato viene sostituito con un prodotto diverso?

□ Sì □ No □ Non so

Se Sì quale? ……

Se Sì, in quali situazioni? ……

- Viene aumentato il tempo di contatto con il disinfettante?

□ Sì □ No □ Non so

Se Sì, qual è il nuovo tempo di esposizione? ……

Se Sì, in quali situazioni? ……

- Viene cambiata la concentrazione del disinfettante?

□ Sì □ No □ Non so

Se Sì, in quali situazioni?……

Se Sì, indicare nuova concentrazione……

Altra procedura (non precedentemente indicata) ……

5. Nel caso in cui il dispositivo trattato presenti canali interni, che tipo di trattamento è previsto?

- ☐ non presenta canali interni
- ☐ aspirazione del disinfettante
- ☐ introduzione sotto pressione del disinfettante
- ☐ spazzolamento o altra tecnica meccanica
- ☐ nessun particolare trattamento

6. Nel caso in cui il dispositivo trattato sia composito, si prevedono trattamenti separati per le singole parti?

☐ Sì ☐ No ☐ Non so

Se sì, i trattamenti sono differenti? ……..

Se sì, quali? ……

7. Dopo il trattamento il dispositivo viene risciacquato per eliminare i residui di disinfettante?

☐ Sì ☐ No ☐ Non so

Se sì, come? ☐ Manuale ☐ Automatico

Con quali prodotti?

- ☐ acqua corrente
- ☐ acqua sterile
- ☐ acqua distillata
- ☐ altro……

8. Al termine del processo di disinfezione/sterilizzazione in che modo viene conservato il dispositivo medico?

……

9. Viene utilizzato un sistema di registrazione per l'avvenuto trattamento?

☐ Sì ☐ No ☐ Non so

Se si quale?…………

10. Sono effettuati controlli di qualità per valutare l'efficacia del trattamento?

☐ Sì ☐ No ☐ Non so

Se sì, quali?……..

Se sì, ogni quanto tempo vengono effettuati……

11. Sono seguiti dei protocolli scritti?

☐ Sì ☐ No ☐ Non so

Se sì, quali ……

Redatti da ……**Approvati da**……

12. Secondo lei, quali fattori potrebbero influenzare in maniera negativa l'efficacia del trattamento?

- ☐ numero insufficiente di dispositivi medici
- ☐ mancanza di tempo
- ☐ complessità della procedura
- ☐ carenza di personale
- ☐ carenza di procedure standardizzate
- ☐ altro……
- ☐ tutti i precedenti

Riscontra i fattori citati nella sua unità operativa?

☐ Sì ☐ No ☐ Non so

SM 1b. Questionnaire (translation in English language)

Form No. |_|_|_|_|_|	OPERATIVE UNIT	DEPARTMENT
MEDICAL DEVICE		MINISTRY CODE

1. Are the disinfection/sterilization procedures preceded by washing?

□ Yes □ No □ Unknown

If yes, with what procedure? □ Manual □ Automated

Which products are used for washing?

□ water □ water and detergent □ water and disinfectant

□ water and enzymatic products □ other (please state)……

2. After washing, is the device dried?

□ Yes □ No □ Not known or specified

If yes, which method is used for drying? ……

3. How the disinfection/sterilization procedure is performed? Specify:

Work environment

……

System type

……

Disinfectant and concentration

……

Exposure time (minutes)

……

Open or closed system

……

Motivations for choosing the disinfectant

……

How often is the chemical product used for the procedure replaced

……

4. Are there situations/conditions in which a different procedure is performed for the same medical device?

□ Yes □ No □ Unknown

If yes, which are the procedures? ……

If yes, is the regularly used disinfectant replaced with a different product?

□ Yes □ No □ Unknown

If yes, which is the product? ……

If yes, in which situations/conditions? ……

If yes, is the contact time with disinfectant increased?

□ Yes □ No □ Unknown

If yes, what is the new exposure time? ……

If yes, in which situations/conditions? ……

If yes, is the disinfectant concentration changed?

□ Yes □ No □ Not known

If yes, in which situations/conditions……

If yes, specify the new concentration ……

Different procedure (not previously specified) ……

5. If the device has internal channels, what treatment is performed?

- ◻ aspiration of the disinfectant
- ◻ introduction of the disinfectant under pressure
- ◻ brushing or other mechanical technique
- ◻ no specific treatment

6. If the disinfected device is composite, are disassembly procedures applied to the component parts?

◻ Yes ◻ No ◻ Not known

If yes, are the treatments different? .....

If yes, what kind of treatments? .....

7. After treatment, is the device rinsed to remove residual disinfectant?

◻ Yes ◻ No ◻ Not known

If yes, is the procedure? ◻ Manual ◻ Automated

Which products are used for rinsing?

- ◻ running water
- ◻ sterile water
- ◻ distilled water
- ◻ other.....

8. At the end of disinfection/sterilization process, how the medical device is stored?

.....

9. Is a registration system used for the successful performed process?

◻ Yes ◻ No ◻ Not known

If yes, what kind of system? .....

10. Are quality controls carried out to evaluate the treatment effectiveness?

◻ Yes ◻ No ◻ Not known

If yes, which are the quality controls? .....

If yes, how often the quality controls are performed? .....

11. Are written protocols followed for quality controls?

◻ Yes ◻ No ◻ Not known

If yes, what are the protocols? .....

Written by .....

Approved by.....

12. In your opinion, which factors could negatively affect the treatment effectiveness?

- ◻ insufficient number of medical devices
- ◻ lack of time
- ◻ complexity of the procedure
- ◻ lack of personnel
- ◻ lack of standardized procedures
- ◻ other (please state) .....
- ◻ all previous answers

Do you consider these factors important in your operative unit for the disinfection of this device?

◻ Yes ◻ No ◻ Not known

issues. A weakness of this paper is that, even if our study refers to several regions evenly placed along the Italian peninsula, and even if data were mostly consistent, however the results are based on a limited number of major hospitals, suggesting the opportunity to further expand the sample including also decentralized and smaller facilities, where the situation could be more complex and less successful. In conclusion, the study of reprocessing practices in Italian endoscopy facilities provides information on the knowledge and compliance to guidelines and can contribute in identifying critical issues as well as supporting diffusion of best practices in everyday reprocessing activities and surveillance.

Acknowledgment

The authors thank Dr. Rachele Antonietta Mimmo (Presidio Ospedaliero "Antonio Cardarelli", Campobasso, Italy), Dr. Sandra Savini and Dr. Enrica Martini (Azienda Ospedaliero Universitaria "Ospedali Riuniti", Ancona, Italy), Dr. Anna Rita Mattaliano (Azienda Ospedaliera "Vittorio Emanuele", Catania, Italy), Prof. Armando Gabbrielli and Dr. Giorgia Zamboni (U.O. Endoscopia Digestiva - Azienda Ospedaliera Universitaria Integrata di Verona), Dr. Luigi Cugia (Operative Unit of Gastrenterology, A.O.U. Sassari, Italy) and Dr. Pietro Vitali (Azienda Ospedaliera Università di Parma) for supporting the survey. The authors also thank Dr. Lucrezia Petruccioli for English revision and editing of the manuscript.

Riassunto

Procedure per il ricondizionamento e la sorveglianza degli endoscopi: un'indagine italiana

Background. L'elevata diffusione delle prestazioni endoscopiche in tutto il mondo e la necessità di metodi efficaci per il ricondizionamento, hanno imposto lo sviluppo di linee guida e l'implementazione delle procedure di sorveglianza anche a livello locale.

Disegno dello studio. Al fine di raccogliere dati sulla pratica quotidiana e sulla aderenza alle linee guida disponibili, le unità di endoscopia di diverse istituzioni pubbliche sono state coinvolte in un survey svolto con l'ausilio di un questionario dedicato.

Metodi. Tra luglio e novembre 2015 è stata condotta un'indagine in 10 diverse regioni italiane, che includeva 12 ospedali e 22 unità di endoscopia. Lo stato dell'arte sulle linee guida nazionali e internazionali è stato eseguito per confrontare i protocolli adottati a livello locale.

Risultati. In tutti gli ospedali esaminati, l'attività di ricondizionamento degli endoscopi segue protocolli prestabiliti in aderenza alle linee guida principali. Detergenti enzimatici, raccomandati dalle linee guida internazionali, sono utilizzati nel 55,6% delle unità e l'acido peracetico è attualmente il disinfettante chimico più utilizzato. Alcune discrepanze sono state riscontrate nella applicazione periodica dei controlli di qualità.

Conclusioni. Le linee guida aggiornate sono note agli operatori e vengono generalmente applicate nella pratica quotidiana del ricondizionamento di endoscopi. I controlli di qualità possono rappresentare una questione critica su cui agire per migliorare l'efficacia dei trattamenti e la sorveglianza. L'insieme dei dati acquisiti da diverse regioni può consentire confronti e promuovere la diffusione di buone pratiche.

References

1. Visrodia K, Petersen BT. Gastrointestinal Endoscope Reprocessing. In: Sridhar S, Wu G, eds. Diagnostic and Therapeutic Procedures in Gastroenterology. Clinical Gastroenterology. Cham: Humana Press, 2018.
2. ANOTE. Linee guida pulizia e disinfezione in endoscopia. Update 2011. Available on: https://www.anoteanigea.it/linee-guida-public/linee-guida-pulizia-e-disinfezione-in-endoscopia-update-2011/ [Last accessed: 2018, June 14].
3. Weber DJ. Managing and preventing exposure events from appropriately reprocessed endoscopes. Infect Control Hosp Epidemiol 2012; **33**(7): 657-60.
4. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World J Gastrointest Endosc 2014; **6**(10): 457-74.
5. Wendorf KA, Kay M, Baliga C, et al. Endoscopic retrograde cholangiopancreatography-associated AmpC *Escherichia coli* outbreak. Infect Control Hosp Epidemiol 2015; 36(6): 634-42.
6. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-β-lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. JAMA 2014; **312**(14): 1447-55.

7. Kovaleva J, Peters FT, Van der Mei HC, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013; **26**: 231-54.
8. Rutala WA, Weber DJ. Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Available on: http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf. [Last accessed: 2018, June 14].
9. Kenters N, Huijskens EG, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open 2015; **3**(4): 259-65.
10. Centers for Disease Control and Prevention (CDC). Essential Elements of a Reprocessing Program for Flexible Endoscopes – recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC). Available on: https://www.cdc.gov/hicpac/pdf/flexible-endoscope-reprocessing.pdf [Last accessed: 2018, June 14].
11. Valeriani F, Agodi A, Casini B, et al; GISIO Working Group of the Italian Society of Hygiene, Preventive Medicine, and Public Health. Potential testing of reprocessing procedures by real-time polymerase chain reaction: A multicenter study of colonoscopy devices. Am J Infect Control 2018; **46**(2): 159-64.
12. Gorse GJ, Messner RL. Infection control practices in gastrointestinal endoscopy in the United States: a national survey. Infect Control Hosp Epidemiol 1991; **12**: 289-96.
13. Valeriani F, Protano C, Gianfranceschi G, et al. Infection control in healthcare settings: perspectives for mfDNA analysis in monitoring sanitation procedures. BMC Infect Dis 2016; **16**: 394.
14. Nelson DB. Infectious disease complications of GI endoscopy: part II, exogenous infections. Gastrointest Endo*sc* 2003; **57**: 695-711.
15. Rutala WA, Weber DJ. Outbreaks of carbapenem-resistant Enterobacteriaceae infections associated with duodenoscopes: What can we do to prevent infections? Am J Infect Control 2016; **44**: 47-51.
16. Rutala WA, Weber DJ. Reprocessing semicritical items: Current issues and new technologies. Am J Infect Control 2016; **4**4: 53-62.
17. Centers for Disease Control and Prevention (CDC). Immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices, 2015. Available on: http://emergency.cdc.gov/han/han00382.asp [Last accessed: 2018, June 14].
18. U.S. Food and Drug Administration. Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication. Date Issued: August 4, 2015. Available on: https://www.fdanews.com/ext/resources/files/08-15/081015-duodenoscopes-fda.pdf?1517512726 [Last accessed: 2018, June 14].
19. Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing, vs03.11.15. Available on: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf [Last accessed: 2018, June 14].
20. Garcia L. Microbiological Assay of Environmental and Medical-Device Surfaces, p 485-496. In: Clinical Microbiology Procedures Handbook. 3rd Edition. Washington, DC: ASM Press, 2010.
21 Centers for Disease Control and Prevention (CDC). Duodenoscope Surveillance Sampling & Culturing Reducing the risks of Infection. Available on: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf [Last accessed: 2018, June 14].
22. Spaulding EH. Studies on chemical sterilization of surgical instruments. Surg Gyne Obstet 1939; **69**: 738-44.
23. ASGE Standards of Practice Committee, Banerjee S, Shen B, et al. Infection control during GI endoscopy. Gastrointest Endosc 2008; **67**: 781-90.
24. Daniel G, Homan W, McDonald B. OSHA compliance: issues ethylene oxide in a commercial sterilization operation. J Occup Environ Hyg 2004 **1**: D121-D125.
25. ASGE and SHEA Issue Updated Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes. 2011.
26. Reprocessing Guideline Task Force, Petersen BT, Cohen J, Hambrick RD 3rd, et al.Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. Gastrointest Endosc 2017; **85**: 282-94.
27. Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes, Society of Gastroenterology Nurses and Associates (SGNA). Guideline, 2016.

28. Beilenhoff U, Biering H, Blum R, et al, ESGE-ESGENA technical specification for process validation and routine testing of endoscope reprocessing in washer-disinfectors according to EN ISO 15883, parts 1, 4 and ISO/TS 15883-5. Endoscopy 2017; **49**: 1262-75.
29. Beilenhoff U, Neumann CS, Biering H, Blum R, Schmidt V, Rey JF and the ESGE Guidelines Committee. ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfectors, according to the European Standard prEN ISO 15883 parts 1, 4 and 5. Endoscopy 2007; **39**: 85-94.
30. Beilenhoff U, Neumann CS, Rey JF, et al. Biering H, and the ESGE Guidelines Committee. ESGE–ESGENA guideline: Cleaning and disinfectionin gastrointestinal endoscopy Update 2008. Endoscopy 2008; **40**: 939-57.
31. Gastroenterological Society of Australia, Gastroenterological Nurses College of Australia. 2010. Infection control in endoscopy. 3rd ed. Gastroenterological Society of Australia, Sydney, Australia. Available on: http://www.gesa.org.au/resources/clinical-guidelines-and-updates/endoscopy-infection-control [Last accessed: 2018, June 14].
32. British Columbia Ministry of Health. Best Practice Guidelines for Cleaning, Disinfection and Sterilization in Health Authorities - December 2011 Available on: http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.pdf [Last accessed: 2018, June 14].
33. Bordas JM, Marcos-Maeso MA, Perez MJ, Llach J, Gines A, Pique JM. GI flexible endoscope disinfection: "in use" test comparative study. Hepatogastroenterology 2005; **52**: 800-7.
34. ANOTE-ANIGEA. Linee Guida Pulizia e disinfezione in endoscopia. Update 2011. Available on: https://www.anoteanigea.it/linee-guida-public/linee-guida-pulizia-e-disinfezione-in-endoscopia-update-2011/ [Last accessed: 2018, June 13].
35. Agenzia Sanitaria Regionale, Regione Emilia Romagna. Reprocessing degli endoscopi: indicazioni operative. Dossier 133, 2006. ISSN 1591-223X. Available on: https://assr.regione.emilia-romagna.it/it/servizi/pubblicazioni/dossier/doss133 [Last accessed: 2018, June 14].
36. Agenzia Regionale di Sanità, Regione Toscana. Il reprocessing in endoscopia digestiva: criticità e strumenti per la sicurezza del percorso. ISSN 1970-3244.
37. Spinzi G, Fasoli R, Centenaro R, Minoli G; SIED Lombardia Working Group. Reprocessing in digestive endoscopy units in Lombardy: results of a regional survey. Dig Liver Dis 2008; **40**(11): 890-6.
38. Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. Dig Dis Sci 2004; **49**: 1791-97.
39. Thaker AM, Muthusamy VR, Sedarat A, et al. Duodenoscope reprocessing practice patterns in U.S. endoscopy centers: a survey study. Gastrointest Endosc 2018; pii: S0016-5107-(18)32615-4.

Corresponding author: Prof. Vincenzo Romano Spica, Unit of Public Health, Department of Movement, Human and Health Sciences, University of Rome "Foro Italico", Piazza Lauro de Bosis 6, 00135 Rome, Italy
e-mail: vincenzo.romanospica@uniroma4.it