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Accreditation program for gastrointestinal endoscopes reprocessing in Italy: An on-site survey

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ABSTRACT

Background and study aims Endoscope reprocessing has been associated with a variable failure rate. Our aim was to present an overview on current practices for reprocessing in Italian facilities and discuss the principle critical points.

Methods In 2014 the Italian Society for Digestive Diseases implemented an accreditation program in collaboration with an independent organization for certification and with the Italian Association for Endoscopy Technical Operators. During a 1-day site visit of the endoscopy center, two endoscopists, one nurse, and the representative of the certification body evaluated the endoscope reprocessing.

Results As of July 1, 2020, 28 endoscopy centers had been accredited. Ten centers are completing the measures to correct deficiencies found at the visit. Three centers withdrew from the program. The accreditation program has found variations between the various centers, confirming the poor compliance with guidelines. Major deviations from the standards, established by the model before the site visit according to national and international guidelines, concerned instrument cleaning (44.7% of the centers), instrument storage (23.7%), and microbiological tests (31.6%).

Conclusions Our overview demonstrated the lack of many reprocessing phases, which are important to prevent endoscopy-associated infections. Accreditation can achieve a transformation in quality and safety of reprocessing with the Italian centrally-led approach.

Background

Gastrointestinal endoscopy is widely performed for diagnosis and treatment of patients with gastrointestinal diseases and it is also useful in healthy people who require clinical examinations or checkups. Endoscopy has changed significantly over the last 30 years as technological developments have established a great variety of diagnostic and therapeutic options.

Flexible endoscopes are reusable medical devices with multiple lumens and narrow channels. By definition, gastrointestinal endoscopes are semi-critical medical equipment requiring major quality assurance for disinfection [1].

Because endoscopic devices are temperature-sensitive, low-temperature chemical methods, such as liquid chemical germicide, must be used rather than steam sterilization. However, these instruments are difficult to clean and disinfect and easy to damage because of their complex design. Inadequate reprocessing of endoscopes or endoscopic accessories may result in infection outbreaks. In addition, the ability of bacteria to form a biofilm in the endoscopic channels, especially when the channels become damaged, can contribute to failure of the decontamination process.

Although the incidence of iatrogenic infection during gastrointestinal endoscopy was only about 1 in 1.8 million procedures in the United States from 1988 to 1992 [2], outbreaks of bacterial/viral infections, complicated by the contamination of endoscopes and washer-disinfector instruments, were also individually reported [3].

The US Food and Drug administration (FDA) has received notification of 142 cases of patient infections or exposure from reprocessed duodenoscopes since 2010 [4].

However, the true risk of transmission during endoscopy may go unrecognized because of technically inadequate surveillance, no surveillance at all, low frequency, or the absence of clinical symptoms.

In 2015, the FDA issued a safety alert and ascertained concerns about an association between multidrug-resistant bacterial infections and duodenoscopic investigations [5].

Colonoscopy-related infections and complications have been reported in multiple studies, although at lower rates compared with endoscopic retrograde cholangiopancreatography (ERCP) [6]. Colonoscopy infection rates are estimated at 3.7 and 1.6 per 1000 procedures with high costs per hospitalization [7].

These infections have occurred in American as well as European centers, and have also been widely reported by the media in view of their clinical impact [8].

Since 1994, the Guideline Committee of the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastrointestinal Nurses and Associates (ESGENA) have developed a number of guidelines and position statements focused on hygiene and infection control in endoscopy [9].

In 2019, a consensus document on the competencies required by healthcare staff to deliver adult endoscopy services throughout the UK was prepared by nursing representatives from the British Society of Gastroenterology Nurses Associates, the Royal College of Nursing and the Joint Advisory Group for Gastrointestinal Endoscopy [10]. This consensus document was created in partnership with the manufacturers of endoscopes and decontamination equipment, Direct Observation of Procedural Skill Forms, specifically on decontamination for technicians of the procedure. This document is available on the contamination page of the British Society of Gastroenterology website [11].

Many other international societies for gastrointestinal endoscopy have also issued guidelines for endoscopy reprocessing. These guidelines are constantly revised with the introduction of new disinfectants and devices.

In 2014, the Italian Society for Digestive Endoscopy (SIED) designed and implemented an accreditation program for endoscopy services, in collaboration with an independent international certification organization and the Italian Association for Endoscopy Technical Operators (ANOTE) [12].

In recent years, endoscopy units from a range of private and public institutions have been voluntarily surveyed by means of a dedicated questionnaire and a 1-day on-site visit.

In light of raised awareness about the need for reprocessing of all types of endoscopes to prevent transmission of infections, we present an overview of the current accreditation program for gastrointestinal endoscope reprocessing in Italian facilities. In addition, we will discuss critical issues found during endoscope reprocessing.

Methods

In 2014, SIED implemented an accreditation program in collaboration with KIWA CERMET ITALIA, an independent international organization for certification with a section specializing in healthcare, along with the Italian Association for Endoscopy Technical Operators. A team of eight endoscopists selected from different institutions and with at least 10 years' experience by the SIED council was given the task of drafting professional and service standards according to Italian [13] and international guidelines [9, 11] using a standardized system. For each center that voluntarily requests accreditation, a self-assessment checklist is provided as a tool for evaluating how closely they comply with the standards established by the model, before an on-site visit. The site visit applied by the centers lasts 1 day and is carried out by two expert endoscopists: the representative of the certification body -KIWA CERMET ITALIA – who ensures the fairness of procedures and a professional nurse nominated by ANOTE.

During the site visits to the endoscopy centers, the endoscopists and the nurse evaluate the endoscopic reports in a multidisciplinary approach, looking at the route taken as a patient is moved through the endoscopy unit, the nursing records, instrument reprocessing, and the technologies available (**Appendix A**).

As the efficacy of endoscope reprocessing depends on the staff's comprehensive knowledge of the construction and function of the endoscope, during the site visit, the nurse checks the availability of detailed protocols describing the different phases of reprocessing. The nurse specifically checks four different phases of reprocessing: bedside cleaning, manual cleaning at the reprocessing area (including leak testing and brushing of endoscope channels), cleaning and disinfection, drying, and storage. Irrespective of the size and design of the reprocessing area, the nurse also examines personal protective equipment, adequate equipment for manual cleaning steps (e.g. brushes, cleaning adapters, endoscopy leak test units), appro-

priate storage of process chemicals, compressed air for drying, documentation, and traceability equipment.

The nurse then verifies that the documentation for the reprocessing procedure includes the patient's name, the endoscope identification, the whole reprocessing cycle, and identification of the staff member involved in reprocessing. Microbial culture examination of the endoscope and its accessories is then certified.

At the end of the day's visit, the findings are presented and discussed during a meeting with the center's endoscopists, some of the nursing staff, and the representative of the medical and/or general management, the latter to approve relevant actions.

Service standards have been approved by SIED and ANOTE boards and are available to all SIED members and can be freely consulted on the site www.sied.it (in **Appendix A** only gastrointestinal reprocessing standards are reported).

Any non-compliance with SIED standards that comes to light during a site visit must be corrected by the endoscopy unit in the time assigned for the accreditation procedure. The team then checks whether the unit has implemented all the corrective measures required. The SIED accreditation program requires renewal every 2 years after the first site visit, in which all critical issues are resolved, in order to obtain accreditation.

Statistical analysis

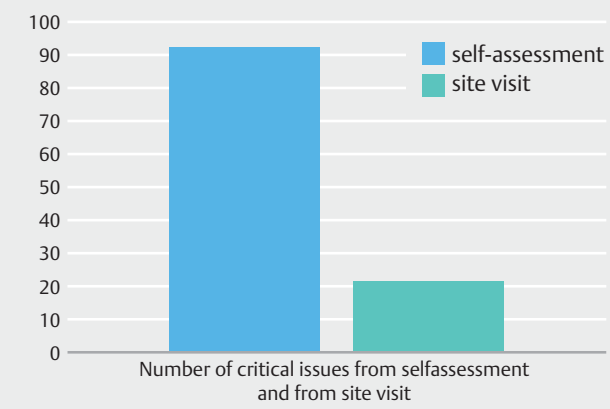
To analyze the differences between the criteria reported in the structure's self-assessment as being "not met" and those found on the on-site visit, we used a non-parametric test for paired samples. A two-sided $P \leq 0.05$ was considered statistically significant.

Results

From the beginning of the SIED accreditation scheme in 2014 until June 2020, 41 site visits occurred. All endoscopy services visited were centers of reference that carry out more than 8000 exams per year. As of July 1, 2020, 28 endoscopy centers had been accredited. Ten centers were not accredited because they had not completed the measures to correct points raised at the visit. Three centers withdrew from the SIED-ANOTE program after the first site visit.

In the pre-site visit self-assessment, 41 centers reported the presence of 21 critical issues with respect to SIED standards. In the same centers, the critical points detected by the members of the SIED and ANOTE team were 92 ($P = 0.008$) (▶ **Fig. 1**). In seven centers no deviations from the program standards were noted. In ▶ **Table 1** the critical points found in 31 centers for the reprocessing procedure are reported in detail.

Thorough manual cleaning with detergent was the most common deviation from guidelines, which was reported in 33 of 41 centers (80.5 %). Microbiological surveillance of a proportion of the department's endoscopes, with the requirements that all endoscopes used in the unit are tested at least once a year, was not correctly carried out in 13 of 41 centers (31.7 %). Storage in a controlled environment for the prevention of any secondary contamination was not considered adequate in 11 of 41 endoscopy units (26.8 %). Transport in closed containers, clearly marked as contaminated equipment in order to avoid contamination of the environment as well as third parties, was found insufficient in 10 of 41 centers (24.4 %). Reprocessing did not follow the officially required endoscopy reprocessing training program, nor was there regular practice and periodical updated training given to maintain competency in six of 41 centers (14.6 %). In six of 41 endoscopy services (14.6 %) nurses and allied healthcare professionals were not fully aware of their roles and responsibilities with regard to legislation concerning medicine management, professional accountability and responsibilities in the delegation of tasks. A complete reprocessing documentation was not considered adequate in five of 41 centers (12.2 %). Thorough drying of endoscope surfaces and channels to prevent any growth of waterborne microorganisms was wrongly performed in three of 41 endoscopy units (7.3 %).



▶ **Fig. 1** Number of critical issues from self-assessment and from site visit.

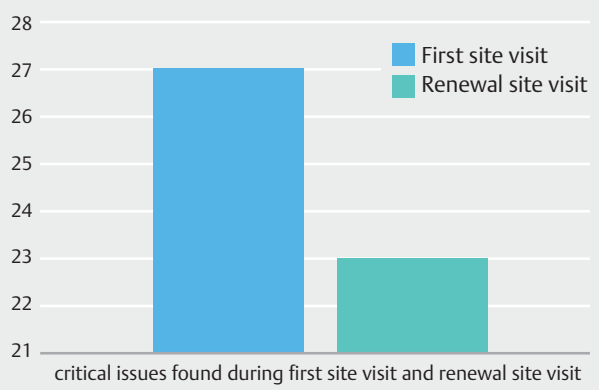
Thirteen centers renewed their accreditation after two years, as scheduled. No critical issues were found in three of 13 centers. During the first site visit, we found 27 critical issues; 23 were found during the renewal site visit ($P = 0.388$) (▶ **Fig. 2**). The results of the renewal accreditations are reported in ▶ **Table 2**.

Discussion

The SIED-ANOTE accreditation program has found variations in the methods of reprocessing endoscopes in the centers which confirm their poor compliance with the numerous guidelines issued by many scientific societies [9–15]. This variability and poor adherence to guidelines has already been reported in the literature and is based on various issues. In the work of Thaler AM et al. only 53 % of the 249 US hospitals considered performed surveillance microbiological culturing. Furthermore, forced air drying after reprocessing was used by 47.8 % of centers [16]. Moreover, an international survey on current endoscopic reprocessing identified a large variation in practices: 41 % of 165 services used adenosine triphosphate as an assessment method despite the fact that this technique has not yet

▶ **Table 1** Critical issues resulting from self-assessment and from the site visit.

Specific reprocessing area	No. of critical issues resulting from self-assessment	No. of critical issues resulting from the site visit
Standards of professional conduct	0	6
Operator skills	1	6
Compliance with reprocessing phases	1	5
Predetersion	0	0
Cleansing	1	33
Disinfection	0	0
Drying	0	3
Storage	6	11
Transport of contaminated equipment	3	10
Microbiological tests	6	13
Complete reprocessing documentation	3	5
Total	21	92



▶ **Fig. 2** Critical issues found during first site visit and renewal site visit.

been recommended in guidelines, 33 % of participating facilities reported their staff was still untrained, and only 57 % of the respondents carried out the drying process routinely [17].

In our study, using direct surveys carried out by experienced medical and nursing staff, the major deviations from the guidelines concern manual instrument cleaning (33 of 41 centers: 80.5 %), instrument storage (11 of 41 centers: 26.8 %), the lack or failure to carry out microbiological tests (13 of 41 centers: 31.7 %), incorrect transport in closed containers in 10 of 41 (24,4 %).

Moreover, we also found insufficient complete documentation in seven of 41 centers (17.1 %), insufficient operator skills and training in six of 41 centers (14.6 %), and incorrect drying of instruments in three of 41 centers (7.3 %).

In a recent review aimed at providing an update on endoscopy-associated infection, and the factors contributing to their occurrence, manual cleaning, which is crucial to prevent biofilm formation, was identified as inadequate in four of the revised articles [18]. Cleaning is the most important step in reprocessing. Bedside cleaning and the manual cleaning step with flushing and brushing of the entire channel systems are essential for the removal of debris, blood and body fluids. Biofilm formation is possible if any of the steps have not been carried out correctly. As some Gram-negative bacteria can undergo cell division every 20 to 30 minutes, it is essential to complete all reprocessing steps quickly, before bacterial growth and debris begin to dry on surfaces. Some national guidelines recommend performance of all manual reprocessing steps within 30 minutes after completion of the patient examination [9].

Microbial culture examination of the endoscopes and its accessories is recommended to be performed periodically to control the quality of the reprocessing procedure, and in the event of suspected endoscope-mediated infection, a microbial culture study is mandatory [19]. However, specific conditions and principles concerning the examination interval and culture methods have not yet been established. To date, cost-effectiveness analysis of microbial culture studies is limited. Some queries about the interpretation of microbial culture results and the approach to take for culture-positive devices are still not sufficiently answered. In a recent international survey from 39 countries, a large disparity in the use of microbial cultures was observed [17]. Microbial cultures were used twice a year in 25 % of the centers. The final rinse water test was assessed monthly in only 22 % of the participating endoscopy units.

Transportation of a contaminated endoscope in a sealed container to the disinfection area had the lowest compliance rate (56.0 %) in a recent study from Korea [20]. The same study compared compliance rates for contaminated endoscope transport between hospitals with >100 vs <100 average daily endoscopic examinations, and found no significant difference in compliance. The compliance rates regarding the transport

▶ **Table 2** Critical issues

Specific reprocessing area	No. of critical issues after first site visit	No. of critical issues after renewal visit
Standards of professional conduct	2	1
Operator skills	2	0
Compliance with reprocessing phases	0	1
Predetersion	0	1
Cleansing	10	7
Disinfection	0	0
Drying	0	1
Storage	4	2
Transport of contaminated equipment	2	2
Microbiological tests	5	6
Complete reprocessing documentation	2	2
Total	27	23

of contaminated endoscopes in the United States and Portugal are 26 % and 44 %, respectively [21, 22].

The complete reprocessing cycle should be documented, including the names of the persons undertaking each step and the reprocessing record should be reported in the patient's files [9]. However, a lack of complete documentation was observed in 7 /41 centers (17.1 %) in our on-site study.

Guidelines recommend, after reprocessing, to flush each endoscope channel with compressed air and 70 % to 90 % ethyl or isopropyl alcohol to facilitate drying [9]. As moisture breeds and encourages microbial bacteria such as *Pseudomonas aeruginosa* to multiply, drying is a crucial procedure [9]. Moreover, alcohol helps residual water evaporate as air races through the channel. Issues with drying have been reported in many studies. Aumeran et al reported on a duodenoscope-associated outbreak with extended-spectrum beta lactamase-producing *Klebsiella pneumoniae* and a reprocessing audit revealed endoscopes were not fully dried before storage [23]. A recent systematic review highlights the importance of strict adherence to drying guidelines to make drying procedures more standardized and automated [24].

It is known that safe reprocessing is the key to patient safety and that non-compliance with guidelines and deviations from standardized protocols lead to reprocessing faults with the possibility of patient-to-patient transmission. Recent outbreaks of multidrug-resistant bacteria show how narrow the margin of safety is without compliance with protocols [25]. However, most endoscope reprocessing lapses are never reported or associated infections are not recognized, and if an outbreak has not been contained, it may not be reported. Moreover, it is very likely that outbreaks may not be acknowledged because they involve commensal bacteria of the gastrointestinal tract [26].

A statistically significant difference between the answers to the SIED-ANOTE checklist of indicators submitted to the inspection team before the site visit and the situation found on-site has also been noted in our study. This casts serious doubt on the utility of frequent surveys relying on participant self-reports. Participants may overestimate their own expertise or knowledge or may wish to limit embarrassment or answer in ways that make them "look better" [27].

It is relevant that the improvements obtained after accreditation are not maintained in subsequent years. In fact, in 13 centers that had positively complied with all SIED-ANOTE requirements in the first on-site visit, 2 years later, 23 unsatisfied standards were still detected. The findings especially concern cleansing and the incorrect or non-performance of microbiological tests. It should be noted that in our study, three centers did not have any findings in either the first or the second site visit for renewal of accreditation.

Similar problems of non-compliance with guidelines and standards have been found in other fields of medicine. One study reported that in cardiology, the maximum associated effectiveness of accreditation may be limited over time, supporting the rationale of reaccreditation, which may promote a long-lasting effect and help limit subsequent decline in associated benefits [28].

Another study demonstrated that subsequent accreditation surveys significantly reduce variation in quality performance, which correlates with higher reliability [29].

The results of this study need to be interpreted in the context of potential limitations. The generalizability of this study may be limited due to the self-selection of sites entering the SIED-ANOTE accreditation program. This may limit our action and only represent the tip of the iceberg. Moreover, we only visited centers of reference. However, the endoscopic reports, processes, and different reprocessing steps were directly assessed by an experienced multidisciplinary group.

Conclusions

In conclusion, our study demonstrates shortcomings in many reprocessing phases in endoscopy centers with a high volume of endoscopic exams subject to the SIED-ANOTE voluntary accreditation program. It also highlights the need for continuous surveillance, with periodic on-site visits, to maintain high safety standards.

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Competing interests

The authors declare that they have no conflict of interest.

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