European Review for Medical and Pharmacological Sciences 2021; 25: 5029-5041

Development of a checklist as self-assessment tool to evaluate the reprocessing of endoscopic instruments in an Italian teaching hospital

S. VINCENTI[1], V. COLAMESTA[2,3], M.C. NURCHIS[1,2], G. DAMIANI[1,2], D. PASCUCCI[1,2], F. BONINTI[1], M. WACHOCKA[1], M. SAPIENZA[2], G. SGANGA[1,2], P. LAURENTI[1,2]

[1]Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy
[2]Università Cattolica del Sacro Cuore, Rome, Italy
[3]Complex Operation Unit Medical Directorate S. Spirito e Nuovo Regina Margherita, Local Health Unit ASL RM1, Rome, Italy

Abstract. – OBJECTIVE: The present study aims to develop a checklist, as a self-assessment tool, for evaluating all the items involved in the endoscope reprocessing that could be useful for the improvement and/or development of a safety endoscope reprocessing system.

MATERIALS AND METHODS: A three-step modified Delphi method, with an embedded qualitative component, was adopted to develop the checklist. According to it, corrective actions were performed before its further re-administration. Contextually, the microbiological surveillance of the endoscopes and of the wash disinfector machine was carried out.

RESULTS: Five areas were included in the checklist. After the 1st checklist application, only one of three wards reached the excellent scores in all the items. The other two wards showed an improvement in the Traceability and Endoscope Reprocessing areas after corrective actions. The McNemar's test reported significant difference in the proportion of satisfactory results before and after the 1st and 2nd checklist application. The microbiological surveillance, conducted after the 1st administration, showed unsatisfactory results for the 2 bronchoscopes available in the Intensive Care Unit and for 2 automated endoscope reprocessors. The analysis performed after the 2nd administration showed good results.

CONCLUSIONS: The periodic administration of the checklist is functional for a self-assessment of quality reprocessing procedures carried out in the large endoscopic services and in the wards occasionally providing those services, according to the good practice guidelines and for any corrective actions to increase the safety.

Key Words:
Self-assessment tool, Checklist, Endoscope reprocessing, Delphi method.

Introduction

Endoscopes are frequently used for the diagnosis and therapy of medical disorders. Over 1,300,000 gastrointestinal endoscopic procedures are performed each year in Italy. Despite improvements in knowledge and techniques, the endoscopic procedures can represent a risk factor for the onset of infections, although this risk is underestimated with an incidence of about 1 in 1,800,000 of procedures[1]. Recently, the Gastrointestinal (GI) endoscopes (e.g., colonoscopes, gastroscopes, and duodenoscopes) and bronchoscopes have been associated with more outbreaks of infections (>130 outbreaks) than any other reusable medical or surgical device in health care, causing death and illness[2-4]. The clinical spectrum ranged from asymptomatic colonization to death. More frequently, *Salmonella* spp. and *Pseudomonas aeruginosa* were identified as causative agents of infections transmitted by gastrointestinal endoscopy while *Mycobacterium tuberculosis* (TB), atypical mycobacteria, and *Pseudomonas aeruginosa* were the most common causes of infections transmitted by bronchoscopy.

According to Spaulding classification[5], which identifies how a medical device should be disinfected or sterilized, GI endoscopes and bronchoscopes have contact with intact mucous membranes, so they are classified as semi-critical device and require at least a high-level disinfection (HLD). Frequently GI endoscopes and bronchoscopes have contact with nonintact mucous membranes and sterile tissue through the endoscopic accessories that penetrate the mucosal barrier (e.g., biopsy forceps, guidewires,

Corresponding Author: Domenico Pascucci, MD; e-mail: domenico.pascucci@outlook.it

polypectomy snares, injection needles, etc.) *via* a biopsy or entrance into normally sterile areas (bile ducts, lung, etc.). This leads to a high risk of patient-to-patient transmission of potential pathogens with a subsequent risk of infection[2,3,6,7]. In these conditions, the accessories of reusable endoscopes could be considered as critical devices and must be sterile at the point of use[8].

GI endoscopes can have a normal bacterial load of 10^{8-10} (8–10 $\log_{10}$)[9]. Standardized automated reprocessing cycles lead to an 8–12 $\log_{10}$ reduction in microorganisms. Consequently, the safety margin is extremely low, at 0–2 $\log_{10}$. Accurate reprocessing of flexible endoscopes is a multistep procedure involving cleaning followed by high-level disinfection (HLD) with further rinsing and drying before storage. Major reasons for transmission were inadequate cleaning due to an improper selection of a disinfecting agent, the failure to follow recommended cleaning and disinfection procedures or automated endoscope reprocessors (AERs). Failure to follow established guidelines has continued to lead to infections associated with gastrointestinal endoscopes and bronchoscopes. Quality assurance in endoscope reprocessing could be assessed by microbiological surveillance of endoscope reprocessing that it has been recommended by several medical specialist organizations[10-13]. However, the literature provides no standards for the frequency of testing intervals of surveillance cultures. For example, the Gastroenterological Society of Australia guideline recommends microbiological monitoring of duodenoscopes, bronchoscopes, and AERs every 4 weeks and all other GI endoscopes every 4 months[14]. According to the European Society of Gastrointestinal Endoscopy guideline, routine microbiological testing of endoscopes is advised to be performed at intervals of no longer than 3 months[13]. Since the microbiological surveillance could not be performed daily, it is essential to adhere strictly to the reprocessing standardized procedures. The effectiveness of endoscope reprocessing depends on several factors: i) trained and dedicated staff, ii) standardized and updated reprocessing protocols, iii) cleaning and disinfection room dedicated with dirty and clean working area well separated by the one-way workflow from dirty to clean areas iv) a suitable storage area v) (if necessary) an adequate transport and vi) storage that prevent recontamination.

These requirements can be easily reached for large Endoscopy Service while for the wards in which endoscopies are not carry out routinely, some of these conditions may not be met. The present study aims to develop a checklist, as an assessment tool, for evaluating all the items involved in the endoscope reprocessing that could be useful for guaranteeing the safety both for the endoscopy service and for the staff of the wards in which endoscopic procedures take place.

Materials and Methods

Scoping Review and Guidelines Assessment

It was conducted a scoping review[15] of published literature and a guidelines assessment to identify evidence-based items used to analyze the reprocessing of endoscopes and endoscopic accessories used in several endoscopy hospital units. A modified Delphi method was used to incorporate expert opinion into item generation and refinement.

Identification of Participants and Recruitment of Expert Panel

To assemble the panel of experts and key stakeholders, it was recruited a purposive sample of most qualified individuals and experts[16].

The team of experts was recruited at the beginning of 2020 from the Fondazione Policlinico Universitario "A. Gemelli" IRCCS, a large teaching hospital in Rome. They were chosen based on their academic achievement, clinical knowledge, and status within their fields of expertise.

It allowed to obtain useful opinions from different professional experts, avoiding over-representation from one particular point of view of workers sharing the same characteristic (e.g., job type).

Once a potential panelist has been qualified as an expert in the field of interest, he or she should receive a personal invitation to be part of the study. This invitation (e.g., email or phone call) explains the topic to be examined, providing information about the Delphi method, the time required and the panelist adhesion request. During the entire process, the identity of the panelist giving individual comments and ratings was hidden to the central author group.

For each round of the Delphi process, a turnaround time of a minimum of 2–4 weeks was allowed including an email reminder. If no answer was received, the panelist was considered a non-responder.

The Delphi Process

The Delphi method is used in healthcare settings as an effective way of establishing consensus for specific clinical problems, especially those in which there is limited evidence and expert opinion is important[17]. The method is an iterative and systematic process of establishing expert group consensus through repeated rounds of voting[15]. Nowadays, the Delphi method has evolved to become a fundamental tool in the areas of forecasting, evaluation, and concept/framework development when there is a need to incorporate subjective information directly into evaluation models[18].

The First Delphi Round

Many studies using the Delphi process introduce small modifications to the methodology for reasons of expediency or scientific prudence[19]. In the traditional Delphi process, the initial step often involves a central author group or focus group creating a list of items to be assessed by the panel based on literature review and personal knowledge. This is a known weakness of the Delphi process as it allows for the authors to influence the panel[15]. To reduce this risk of bias, we adjusted the Delphi process to include an initial "brainstorming" round. Although "brainstorming" is not a typical part of a Delphi, it validates the topics that the researchers intend to study in the questionnaire session[20,21]. The panelists were asked to list in free text individual items they considered to be the key elements to perform a proper reprocessing of endoscopes. In conclusion, the items were aggregated and reviewed by the authors' group who by consensus merged similar items and eliminated duplicates and non-technical skills.

The Second Delphi Round

In the second-round, the researcher requests the panel of experts to consider, to rank and/or rate to define a preliminary prioritization, to edit and to comment upon the responses developed during round one. The experts were blinded to each other. They rated the items on relevance using a five-point Likert scale with the anchors: 1 = Irrelevant; 2 = Less relevant; 3 = Relevant; 4 = More relevant; 5 = Essential. For each item, relevant anchors were created based on standards for measurement scales[22]. Items for which 70% of participants did not rate within the scale of 4-5 were eliminated. These results were then feedback to participants for the third Delphi round.

The Third Delphi Round

In the third round, participants ranked the elements using the same five-point scale but this time with knowledge of the group scores maintaining anonymity to the group. Similar to round 2, items which 80% of participants did not rank within the 4-5 groups were eliminated.

When all the three round questionnaires are returned, the researcher tabulates results, then, it calculates means and standard deviations for each questionnaire item[15,20].

The list of items agreed at the end of the Delphi process were grouped according to phases of reprocessing and the list was named "Assessment tool for a safety reprocessing of the endoscopes".

This list was then further grouped into five major areas with each of the statements falling within one specific domain: 1) endoscope reprocessing (ER), 2) training (TR), 3) occupational safety (OS), 4) traceability (T), 5) adequate facility for the endoscope reprocessing (AF).

For each item there are three different answers with different scores: no = score 0, do not know = score 1, and yes = score 2. For each area, the sum of the scores, was used to calculate the final score. The percentage of the final score was used for the judgment according to the Table I.

Validation

The checklist was validated by administering it to three ward of a big teaching hospital in Rome: two Endoscopic Services (named as ES_1 and ES_2) and one Intensive Care Unit (ICU) in which the endoscopies were routinely performed. The check list was filled out by the nursing staff coordinator. According to checklist's results, specific corrective actions were performed, and the checklist was subsequently re-administered.

After the 1st administration of checklist, the microbiological surveillance of the endoscopes and of the wash disinfector machine was carried out. According to the checklist's results, specific corrective actions were conducted. Subsequently, the checklist was re-administered, and the microbiological analyses were carried out. Hazard/Hygiene indicators, useful to analyze expected results and to decipher results, were reported in

Table I. The score and the judgement relative to the checklist.

Unsatisfactory	Acceptable	Good	Excellent
0-25%	26-50%	51-75%	76-100%

Table II. Hazard/hygiene indicators and respective allowed limits relative to a) Liquid samples and swab from endoscope channels, b) Final rinse water of Automated Endoscope Reprocessors (AER).

a) Liquid samples from endoscope channels		
Hazard/Hygiene indicator	**Results**	**Interpretation**
Total microbiological count	< 20 CFU/channel ≥ 20 CFU/channel	satisfactory unsatisfactory
Pseudomonas aeruginosa	absent present	satisfactory unsatisfactory
Escherichia coli/ Coliforms and *Enterobacteriaceae*	absent present	satisfactory unsatisfactory
Staphylococcus epidermidis	absent present	satisfactory unsatisfactory
Staphylococcus aureus	absent present	satisfactory unsatisfactory
b) Final rinse water of Automated Endoscope Reprocessors (AER)		
Hazard/Hygiene indicator	**Results**	**Interpretation**
Total microbiological count	< 10 CFU/100 ml ≥ 10 CFU/100 ml	satisfactory unsatisfactory
Pseudomonas aeruginosa	absent present	satisfactory unsatisfactory
Legionella spp.	≤ 100 CFU/L > 100 CFU/L	satisfactory unsatisfactory

CFU = Colony Forming Unit.

Table II according to ESGE-ESGENA guidelines[12,13].

Endoscopes Microbiological Surveillance

In the present study only the endoscopes that were monitored after the 1st and the 2nd check-list administration were included. More specifically, seven colonoscopies named CO_1 up to CO_7, five gastroscopes named GA_1 up to GA_5 and two AER machine named AER_2 and AER_3 were analyzed from ES_1 ward after the 1st and the 2nd administration.

Two bronchoscopes (BR_1 and BR_2) and one AER (AER_1) were analyzed from ICU ward.

Three bronchoscopes (BR_6, BR_7 and BR_8), three colonoscopes (CO_10, CO_11 and CO_12), three duodenoscopes (DU_1, DU_2 and DU_3) three gastroscopes (GA_6, GA_7 and GA_9) and three AERs (AER_4, AER_5 and AER_6) were monitored from ES_2.

Sample Collection

Briefly, 20 mL of sterile 0.9% NaCl solution was flushed through the biopsy/suction and the water/air channels of the instruments from the proximal inlet to the distal end and collected in 50-ml sterile conical tube. Each channel was tested separately.

A swab moistened with sterile saline solution was used for sampling the distal opening of the biopsy/suction channel port and the distal end part of the endoscopes.

Each swab was broken off below the handling point into the 10 ml of sterile saline previously flushed through the instrument channel and vortexed for 2 min in 10-s bursts.

To check reprocessing quality of AERs after a completed cycle of cleaning and high-level disinfection, a sample of 250 mL and a sample of 1 liter of final rinsing water was collected.

Table III. List of selected panelists.

Name	Age	Profession
P1	68	Medical doctor, specialist in digestive endoscopy
P2	66	Medical doctor, specialist in emergency surgery
P3	63	Medical doctor, specialist in Anesthesiology, Resuscitation and Intensive Care
P4	46	Nursing coordinator
P5	61	Nursing coordinator
P6	55	Associate Professor of Hygiene and Public Health
P7	56	Associate Professor of Hygiene and Public Health
P8	44	Biologist
P9	44	Prevention technician
P10	60	Prevention technician
P 11	36	Prevention technician
P12	33	Medical doctor, specialist in Hygiene and Public Health
P13	27	Medical doctor resident in Hygiene and Public Health
P14	25	PhD student in Public Health
P15	29	Medical doctor resident in Hygiene and Public health

P = panelist.

Microbiological Analysis

Samples were transported in a cool box, protected from direct light and processed within 2 hours from collection. A microbiological analysis was performed on each sample in accordance with ESGE–ESGENA guideline[12]. All samples were processed under highly aseptic conditions. According to ESGE-ESGENA guideline[12], microbiological analysis, performed on endoscopes, were focused on these indicator microorganisms: *Enterobacteriaceae*, *Pseudomonas aeruginosa Staphylococcus aureus, Staphilococcus epidermidis*. Total bacteria count (TBC) was also tested; AERs were monitored for putative colonization of *Legionella* spp., *Pseudomonas aeruginosa* and TBC according to the specific standard reported by the International Organization for Standardization (ISO).

Identification of Isolated Strains

Isolated strains were identified using specific card for the VITEK2 instrument (bioMérieux, Inc. Hazelwood, MO, USA).

Statistical Analysis

A non-parametric statistical test for paired nominal data, namely McNemar's test[23], was adopted to determine if there was a statistically significant difference in the proportion of satisfactory results, associated with the total microbiological count of the several endoscopes among the three wards, before and after the 1st and 2nd checklist administration. The alpha level was set at 0.05 (i.e., $p<0.05$).

Results

Out of the twenty panelists invited, fifteen (75%) completed the three rounds. (Table III)

The median age of the panelists was 49 years (range 25-68 years). Median experience was 31 years (range 15-40 years) in endoscopy and 21 (range 2-29 years) in hygiene and public health.

In the first round, 108 individual elements were identified. By eliminating duplicates and merging similar items, the elements were reduced to 65. In the second round, 56 elements received a rating of four or five on a five-point Likert scale by more than 70% of the panel. Two elements were removed by the central author group as they were related to i) the endoscopes manufacturing company and to ii) the environmental monitoring because they were not relevant compared to the topics considered. Fifty-four items were submitted for the third round.

In the third round, 4 items were excluded for scoring below the threshold of 80 and the remaining 50 items were approved by the panel.

The flow-chart of the Delphi process is shown in Figure 1.

The list of questions agreed at the end of the Delphi process, grouped into five areas, were reported in Table IV.

Results of the Checklist Administration

The results related to the 1st and the 2nd checklist administration were reported in Figure 2.

Table IV. The list of selected questions for each area.

AREA	Items		Round 3 mean score	Standard Deviation
Endoscope reprocessing	1	Are the endoscopes reprocessed by automated wash disinfector?	4.93	0.26
	2	Are the endoscopes transported in closed containers from clinical areas to reprocessing room, and vice versa?	4.47	0.64
	3	Is the reprocessing room provided with compressed air or medical grade air for drying the endoscopes?	4.13	0.74
	4	Is there an ultrasonic cleaner for the reprocessing of reusable endoscopic accessories?	4.13	0.64
	5	Is decontamination of the endoscope performed at bedside using enzymatic disinfectants?	4.87	0.35
	6	Does the AER submitted to self-disinfection cycle?	4.07	0.59
	7	Are the endoscopes stored in vertical position into the storage cabinet?	4.73	0.46
	8	Are the instruments stored in a storage cabinets with a drying function of the endoscope (compliant with EN 16442:2015 standard24)?	4.80	0.41
	9	Are the endoscopes stored in the storage cabinet equipment designed to provide a controlled environment?	4.87	0.35
	10	Are the endoscope reprocessed after the maximum storage time specified by the guideline (72 hours)?	4.07	0.70
	11	Is the use of enzymatic detergents rather than alkaline detergents preferred, in order to avoid the deterioration of the instruments?	4.13	0.74
	12	Do the reusable thermostable accessories sterilized at the Central Sterilization after manual cleaning?	4.13	0.64
	13	Is the precleaning performed immediately after that the endoscope has been withdrawn from the patient?	4.93	0.26
	14	Does the reprocessing of endoscopes follow these step: decontamination, cleaning and, disinfection, drying and storage?	4.67	0.62
Training	15	Has the hospital standard reprocessing procedures based on instructions for use manufacturers and guide lines?	4.00	0.65
	16	Is applied a regular microbiological surveillance of the endoscopes in order to verify the adherence to hospital standard procedures ?	4.00	0.38
	17	Are there a sufficient numbers of dedicated staff to the correct reprocessing of endoscopes and endoscopic accessories?	4.80	0.41
	18	Are endoscope reprocessing procedures performed exclusively by trained and dedicated staff?	4.93	0.26
	19	Does the dedicated staff meet competency standards for endoscope reprocessing including storage and transport?	4.80	0.41
	20	Is the staff appropriately informed about the risks (biological hazard, chemical hazard, injuries) to which it is exposed while reprocessing endoscopic equipment?	4.13	0.35
	21	Is the staff adequately trained to the all steps of reprocessing procedure?	4.87	0.35
	22	Is performed an update of the training with documented competency for new models of endoscopes, accessories, valves, and AER as they are introduced in the facility?	4.53	0.52
	23	Does the staff trained about the waste managment following the institutional policy according to the manufacturers' instructions and to the national legislative Decree (dlg.vo 152/200625)?	4.07	0.59
	24	Does the staff trained about the regular maintenance of all technical equipment, including endoscopes, AER, and storage cabinets according to the manufacturer's instructions for use?	4.27	0.46
Occupational safety	25	Does the staff wear the personal protective equipment (PPE) during the endoscopic procedure?	4.87	0.35
	26	Does the staff involved in the reprocessing procedure wear the appropriate PPE?	4.93	0.26

Table continued

Table IV. ***(Continued).*** The list of selected questions for each area.

AREA	Items		Round 3 mean score	Standard Deviation
	27	Does the staff wear appropriate single use gloves compliant with UNI EN ISO 374-2:202026 and UNI EN ISO 21420:202027?	4.93	0.26
	28	Are the detergents used classified as class I medical device products recognized by the CE sign on the label?	4.60	0.63
	29	Are the disinfectants used classified ad class IIb medical device products recognized by the CE sign plus a four-digit number on the label?	4.67	0.62
	30	Are the updated Safety Data Sheets (Sds) for hazardous chemicals accessible?	4.13	0.52
	31	Are the Occupational Risk Cards available for consultation?	4.13	0.35
Traceability	32	Does each reprocessing step (including bedside cleaning, manual cleaning, and automated reprocessing in an AER) including the names of the persons undertaking each step, recorded?	4.80	0.41
	33	Is the traceability system regular used?	4.33	0.49
	34	Is the traceability system electronic?	4.27	0.70
	35	Are the endoscopes recorded by the endoscope's model and serial number or other identifier?	4.87	0.35
	36	Does the recording of the reprocessing procedure include the identification code of the staff member involved in each reprocessing 's step?	4.67	0.49
	37	Does each step of reprocessing procedure recorded in order to guarantee the traceability?	4.80	0.41
	38	Is the scheduled and the extraordinary maintenance carried out by the service in charge?	4.20	0.86
	39	Is the documentation relating to maintenance interventions archived by the Service charge and by the ward for a period of not less than 5 years?	4.20	0.94
Adequate facilities for the endoscope reprocessing	40	Is there a strictly separation between cleaning/disinfection room and the endoscopy room?	4.87	0.35
	41	Endoscope cleaning room: is there an operational separation of dirty and clean areas, to avoid recontamination of reprocessed endoscopes and endoscopic accessories?	4.80	0.41
	42	Is there a proper storage area for the reprocessed endoscopes and endoscopic accessories?	4.73	0.46
	43	Is there a ventilation system (supply and extraction) that guarantees 10 air changes per hour?	4.73	0.46
	44	Are there the cleaning sink and the rinsing sink?	4.13	0.52
	45	Are the sinks made of steel or non-porous material?	4.07	0.59
	46	Are the sinks supplied with hot and cold water?	4.00	0.65
	47	Are the sinks of appropriate size to allow the complete immersion of the instruments, without damaging them, and facilitating cleaning operations?	4.87	0.35
	48	Is there a separate dedicated hand-washing basin?	4.07	0.59
	49	Is there an appropriate lighting?	4.20	0.56
	50	Is there an appropriate fume extraction in order to minimize the risks from chemical vapors?	4.80	0.41

After the 1st checklist administration only the ES_2 reached the excellent scores (76-100%) in all five items analyzed while the ICU showed unsatisfactory results in the traceability and training areas. Unsatisfactory scores resulted also for the traceability item of ES_1.

According to the checklist's results, specific corrective actions were conducted, and a 2nd check list administration were carried out (Figure 2). Concerning the traceability area (T), the ES_1 and the ICU ward highlighted a very high improvement after the 2nd check list adminis-

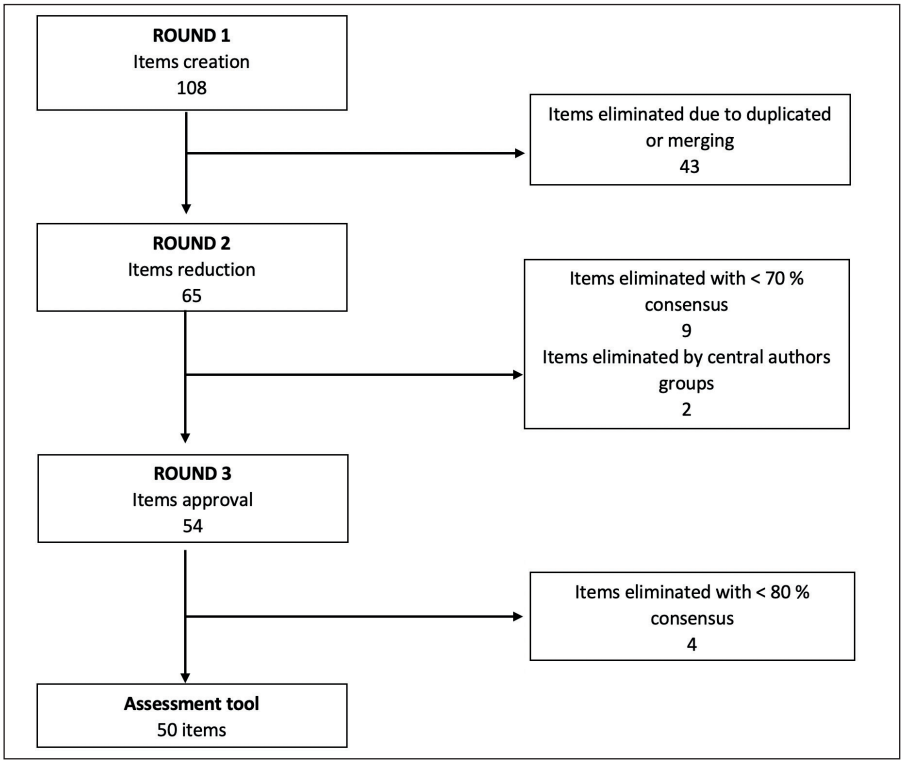

Figure 1. The flow-chart of Delphi process.

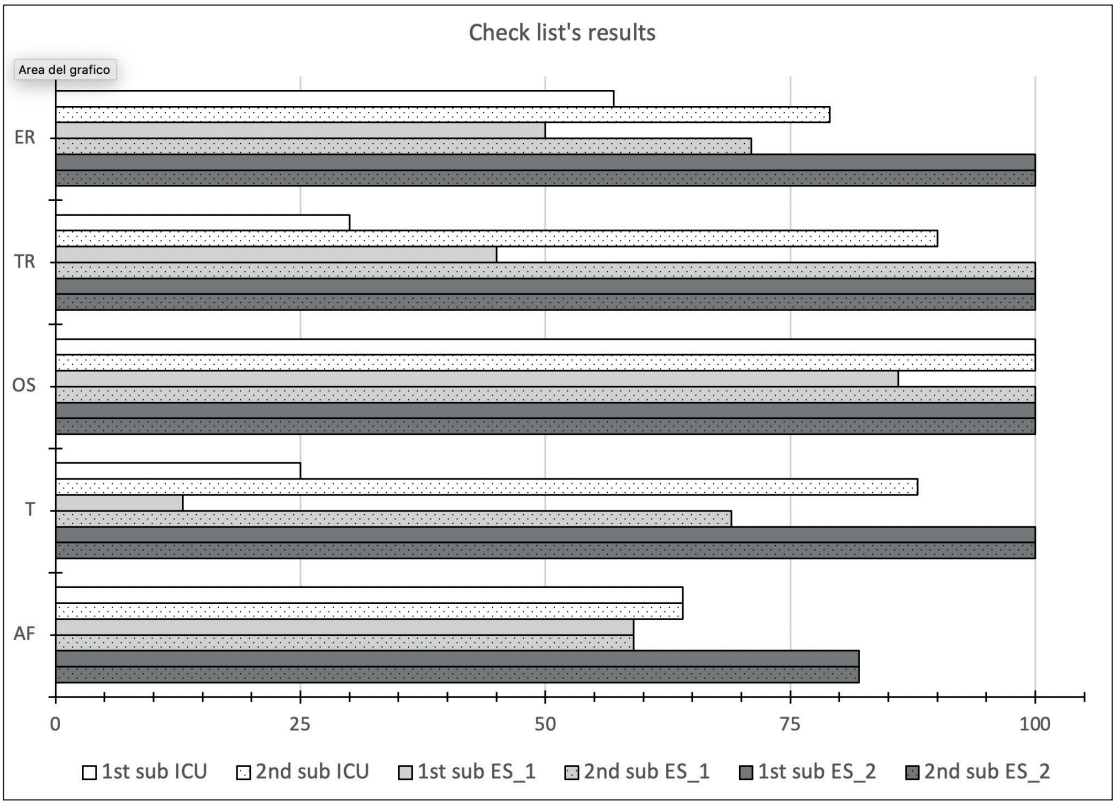

Figure 2. The results of 1st and the 2nd checklist administration. ER=Endoscope Reprocessing, TR=training, OS= occupational safety, T=traceability AF= adequate facilities for the endoscope reprocessing, ICU=Intensive Care Unit, ES= Endoscopic Service.

Table V. Results of the microbiological analysis of the endoscopes in Intensive Care Unit (ICU).

ICU	Total microbiological count		*Pseudomonas aeruginosa*		*Escherichia coli/ Coliforms* and *Enterobacteriaceae*		*Staphylococcus epidermidis*		*Staphylococcus aureus*	
endoscopes	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration
BR_1	**unsatisfactory**	satisfactory	**unsatisfactory**	satisfactory	**unsatisfactory**	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
BR_2	**unsatisfactory**	satisfactory	satisfactory	satisfactory	**unsatisfactory**	satisfactory	**unsatisfactory**	satisfactory	satisfactory	satisfactory

BR= bronchoscope

Table VI. Results of the microbiological analysis of the endoscopes in Endoscopy Service_1 (ES_1).

	Hazard/Hygiene indicator									
ES_1	Total microbiological count		*Pseudomonas aeruginosa*		*Escherichia coli/ Coliforms* and *Enterobacteriaceae*		*Staphylococcus epidermidis*		*Staphylococcus aureus*	
endoscopes	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration
CO_1	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_2	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_3	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_4	unsatisfactory	satisfactory	unsatisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_5	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_6	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_7	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_1	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_2	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_3	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_4	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_5	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory

CO= colonscope, GA= gastroscope.

Table VII. Results of the microbiological analysis of the endoscopes in Endoscopy Service_2 (ES_2).

	Hazard/Hygiene indicator									
ES_1	Total microbiological count		*Pseudomonas aeruginosa*		*Escherichia coli/ Coliforms* and *Enterobacteriaceae*		*Staphylococcus epidermidis*		*Staphylococcus aureus*	
endoscopes	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration
BR_6	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
BR_7	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
BR_8	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_10	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_11	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
CO_12	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
DU_1	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
DU_2	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
DU_3	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_6	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_7	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
GA_9	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory

BR= bronchoscope, CO= colonscope, DU= duodenoscope, GA= gastroscope.

Table VIII. Results of the microbiological analysis of the Automated Endoscope Reprocessors (AERs).

Hazard/Hygiene indicator						
	Total microbiological count		***Pseudomonas aeruginosa***		***Legionella* spp.**	
AERs	1st administration	2nd administration	1st administration	2nd administration	1st administration	2nd administration
ES_1_AER_2	**unsatisfactory**	satisfactory	unsatisfactory	satisfactory	satisfactory	satisfactory
ES_1_AER_3	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
ICU_AER_1	**unsatisfactory**	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
ES_2_AER_4	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
ES_2_AER_5	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory
ES_2_AER_6	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory	satisfactory

ES= Endoscopic service, ICU= Intensive Care Unit, AER= Automated Endoscope Reprocessors.

tration (ES_1: unsatisfactory vs good and ICU: unsatisfactory vs excellent). In addition, the ER area showed a good increase for both ES_1 and ICU. About adequate facilities' area (AT) and occupational safety area (OS), no differences were recorded between the 1st and 2nd checklist administration and no critical issues were highlighted.

After the 1st and 2nd administration of check list, the microbiological surveillance of the endoscopes and of the wash disinfector machine was carried out. Tables V-VIII showed the Hazard/Hygiene indicators and results. The 2 bronchoscopes (BR_1 and BR_2) and 1 AER (AER_1), available in the ICU, were analyzed. As observed, after reprocessing, both BR_1 and BR_2 showed microbial contamination and therefore were not compliant with the expected. The endoscopes (colonoscopies, gastroscopies duodenoscopies and bronchoscopes) of ES_2 showed a satisfactory result for all parameters analyzed. Also, the endoscopes of ES_1 were compliant to the expected. Two of three AERs analyzed after the 1st administration reported unsatisfactory results while the microbiological analysis performed after the 2nd administration found a good compliance with the expected.

Additionally, the McNemar's test revealed that there was a significant difference in the proportion of satisfactory results before and after the 1st and 2nd checklist administration ($p<0.05$).

Discussion

The present study developed a checklist as a tool for evaluating the items involved in the endoscope reprocessing process. The checklist was developed using the DELPHI method[16] that is based on a scoping review of published literature, a guideline assessment, and expert opinions.

At the end of the DELPHI process, five areas were identified and included in the checklist: endoscope reprocessing (ER), training (TR), occupational safety (OS), traceability (T) and adequate facilities for the endoscope reprocessing (AT).

The 1st administration of checklist in three different wards allowed to identify critical issues aim to perform specific corrective actions while the 2nd administration of the checklist allowed to evaluate the effect of the applied corrective actions such as the acquisition of the adequate storage cabinet, definition of the one-way workflow from dirty to clean areas, a training course for the staff, implementation of a traceability system etc. Except for the OS area in which the evaluated wards reached the highest score (i.e., excellent) after the 1st administration and the AF area where the structural limits determined a non-rapid resolution, we found that the score relative to the remaining analyzed areas (ER, TR and T) improved. In particular, we observed that for the traceability area (T) the ICU and ES_1 ward increased their score from the lower (i.e., unsatisfactory) to the highest (i.e., excellent). For the training area (TR), the ICU ward increased its score from the lower (i.e., unsatisfactory) to the highest (i.e., excellent). Again, the ES_1 ward improved its score from acceptable to excellent level. As shown in Figure 1, after the 2nd check list administration all wards reached the highest score in the ER domain.

The McNemar's test revealed that the highest score reached after the 2nd checklist administration was statistically significant. More probably, the improvements in the scores in two of the three areas (ER, TR) might be correlated with the im-

provement in the microbiological quality of the endoscopes and the AER observed following microbiological monitoring. These results showed that the application of this checklist could be a useful tool for the improvement and/or development of a safety endoscope reprocessing system which include the five main area evaluated in the check list.

Conclusions

In this study, we developed a checklist that can be used as a valid self-assessment tool to evaluate the endoscope processing in its entirety and to plan any corrective actions, if necessary, in a targeted way to increase the safety of the patients and the operators.

A checklist, using the DELPHI method, was developed to evaluate all the items involved in the endoscope reprocessing. This checklist can be considered a valid self-assessment tool to implement specific corrective actions in order to ameliorate the safety of the patients and the operators, regardless of the results of microbiological monitoring.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Author Contributions

Patrizia Laurenti, Sara Vincenti and Domenico Pascucci conceived the original idea, Gianfranco Damiani supervised the project, Gabriele Sganga conceived of the presented idea, Sara Vincenti took the lead in writing the manuscript. Mario Cesare Nurchis and Martina Sapienza derived the models and analysed the data, Vittoria Colamesta wrote the manuscript, Federica Boninti e Malgorzata Wachocka administered the check list, verified analytical data and contributed to the interpretation of the results.
All authors provided critical feedback and helped shape the research, analysis and manuscript.

Acknowledgments

We would like to thank Arianna Di Gemma, the Nurse staff Coordinator, for topical and intellectual discussions about the research which can lead to generation of new ideas.

References

1) Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy. Ann Intern Med 1993; 118: 117-128.
2) United States Senate. (2016). Preventable tragedies: superbugs and how ineffective monitoring of medical device safety fails patients. 13 January2016. Available at: https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf (Last access: 09 May 2021).
3) Kovaleva J, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013; 26:231-54.
4) Weber DJ, Rutala WA. Lessons from outbreaks associated with bronchoscopy. Infect Control Hosp Epidemiol. 2001; 22: 403-408.
5) Spaulding EH. Chemical disinfection of medical and surgical materials. In: Disinfection, sterilization, and preservation. Philadelphia (PA): Lea & Febiger, 1968.
6) Rutala WA, Kanamori H, Sickbert-Bennett EE, Weber DJ. What's new in reprocessing endoscopes: Are we going to ensure "the needs of the patient come first" by shifting from disinfection to sterilization? Am J Infect Control 2019; 47S: A62-A66.
7) Wang L, Mannalithara A, Singh G, Ladabaum U. Low rates of gastrointestinal and non-gastrointestinal complications for screening or surveillance colonoscopies in a population-based study. Gastroenterol 2018; 154: 540-555.
8) Department of Health and Social Care. (2016). Health Technical Memorandum (HTM01–06): Management and decontamination of flexible endoscopes. Part A: policy and management. 30 June 2016. Available at: https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes (Last access: 09 May 2021).
9) Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? JAMA 2014; 312: 1405-1406.
10) Centers for Disease Control and Prevention. (2019). Guideline for disinfection and sterilization in healthcare facilities. May 2019. Available at:https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf (Last Access: 13 March 2021).
11) Dutch Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD). (2017). Professional standard handbook - Cleaning and disinfection flexible endoscopes. Version 4.1. September 2017. Available at: https://www.infectiepreventieopleidingen.nl/downloads/SFERDHandbook4_1.pdf (Last access: 09 May 2021).
12) Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Schmidt V. ESGE Guidelines Committee. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. Endoscopy 2007; 39: 175-181.
13) Beilenhoff U, Biering H, Blum R, Brljak J, Cimbro M, Dumonceau JM, Hassan C, Jung M, Kampf B, Neumann C, Pietsch M, Pineau L, Ponchon T, Rejchrt S, Rey JF, Schmidt V, Tillett J, van Hooft JE. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates

(ESGENA) – Update 2018. Endoscopy 2018; 50: 1205-1234.
14) Suk PS, Won HK. Recent update on microbiological monitoring of gastrointestinal endoscopes after high-level disinfection. Clin Endosc 2015; 48: 369-373.
15) Murry Jr JW, Hammons JO. Delphi: a versatile methodology for conducting qualitative research. The Review of Higher Education 1995; 18: 423-436
16) Delbecq AL, Van de Ven AH, Gustafson DH. Group techniques for program planning: a guide to nominal group and Delphi processes. Scott Foresman Company Glenview, 1975.
17) Dalkey N, Helmer O. An experimental application of the Delphi method to the use of experts. Management science. 1962; 9: 458-467.
18) Zheng J, Lou L, Xie Y, Chen S, Li J, Wei J, Feng J. Model construction of medical endoscope service evaluation system-based on the analysis of Delphi method. BMC Health Serv Res 2020; 20: 1-3.
19) Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. J Adv Nurs. 2006; 53: 205-212.
20) Vasarhelyi MA, Lombardi D, Bloch R. The future of audit: a modified Delphi approach. In Canadian Academic Accounting Association, CAAA Annual Conference 2011.
21) Nayahangan LJ, Stefanidis D, Kern DE, Konge L. How to identify and prioritize procedures suitable for simulation-based training: experiences from general needs assessments using a modified Delphi method and a needs assessment formula. Med Teach 2018; 40: 676-683
22) Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. Oxford University Press, 2015.
23) McNemar Q. Note on the sampling error of the difference between correlated proportions or percentages. Psychometrika 1947; 12: 153-157.
24) EN 16442:2015_Controlled environment storage cabinet for processed thermolabile endoscopes. (Last access: 08 May 2021).
25) Gazzetta Ufficiale della Repubblica Italiana. (2006). Decreto Legislativo 3 aprile 2006, n. 152. “Norme in materia ambientale”. 14 April 2016. Available at: https://www.camera.it/parlam/leggi/deleghe/06152dl.htm (Last access: 09 May 2021).
26) UNI EN ISO 374-2:2020_Guanti di protezione contro i prodotti chimici pericolosi e i microorganismi – Parte 2: Determinazione della resistenza alla penetrazione. (Last access: 10 May 2021).
27) EN ISO 21420:2020_ Protective gloves — General requirements and test methods. (Last access: 10 May 2021).