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Original Article

Both microbiological surveillance and audit of procedures improve reprocessing of flexible bronchoscopes and patient safety

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Abstract

Background: Microbiological surveillance of bronchoscopes and automatic endoscope reprocessors (AERs)/washer disinfectors as a quality control measure is controversial. Experts also are divided on the infection risks associated with bronchoscopic procedures.

Objective: We evaluated the impact of routine microbiological surveillance and audits of cleaning/disinfection practices on contamination rates of reprocessed bronchoscopes.

Design: Audits were conducted of reprocessing procedures and microbiological surveillance on all flexible bronchoscopes used from January 2007 to June 2020 at a teaching hospital in France. Contamination rates per year were calculated and analyzed using a Poisson regression model. The risk factors for microbiological contamination were analyzed using a multivariable logistical regression model.

Results: In total, 478 microbiological tests were conducted on 91 different bronchoscopes and 57 on AERs. The rate of bronchoscope contamination significantly decreased between 2007 and 2020, varying from 30.2 to 0% ($P < .0001$). Multivariate analysis confirmed that retesting after a previous contaminated test was significantly associated with higher risk of bronchoscope contamination (OR, 2.58; $P = .015$). This finding was explained by the persistence of microorganisms in bronchoscopes despite repeated disinfections. However, the risk of persistent contamination was not associated with the age of the bronchoscope.

Conclusions: Our results confirm that bronchoscopes can remain contaminated despite repeated reprocessing. Routine microbial testing of bronchoscopes for quality assurance and audit of decontamination and disinfection procedures can improve the reprocessing of bronchoscopes and minimize the rate of persistent contamination.

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Flexible bronchoscopes are semicritical devices that come in contact with mucous membranes and are essential for diagnostic and therapeutic procedures. Flexible bronchoscopes are used to visualize the nasal passages, vocal cords, tracheal bronchial tree and lungs. Between uses, these thermosensitive devices must be thoroughly cleaned followed by high-level disinfection.[1] The reprocessing can be done manually by scrupulously following specific steps. The use of automatic endoscope reprocessors (AERs) and/or washer-disinfectors can simplify the decontamination procedure. Several professional associations have developed guidelines on the correct reprocessing of bronchoscopes.[2–7] However, bronchoscopes are sophisticated tools that are difficult to disinfect on a routine basis. Thus, damaged and contaminated bronchoscopes are often used, even when high-level disinfection protocols are followed.[8] In the literature, rates of contamination following microbiological testing can vary from 6% to 26.3%.[9–11]

Recent published studies have shown that nosocomial infections have occurred from contaminated bronchoscopes. Also, several outbreaks or pseudo-outbreaks due to flexible bronchoscopes have been described, especially in intensive care units.[12] Many of these outbreaks were related to *Pseudomonas aeruginosa*. Transmissions of other pathogens have been identified, including *Stenotrophomonas maltophilia*, *Mycobacterium tuberculosis*, *Klebsiella pneumoniae* and *Serratia marcescens*.[13–17] More disturbing is that these outbreaks are sometimes linked to highly resistant bacteria such as carbapenem-resistant Enterobacteriaceae (CRE) or carbapenem-resistant *P. aeruginosa*.[18] However, recognition of endoscopy-associated transmission remains difficult in routine and needs genetic testing technology to identify particular strains implicated in outbreaks.

Surveillance cultures of endoscopes and using a automatic endoscope washer-disinfector are good ways to assess the effectiveness of disinfection despite the high cost.[19–23] Thus, many French, European and Australian guidelines recommend surveillance

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Table 1. Interpretation Criteria of Microbiological Testing for Bronchoscopes

Target Level	Alert Level	Action Level
Acceptable Result	Unacceptable Result	
Total flora <5 CFU/endoscope AND absence of indicator microorganisms[a]	Total flora 5–25 CFU/endoscope AND absence of indicator microorganisms[a]	Total flora >25 CFU/endoscope OR presence of indicator microorganisms[a]

Note. CFU, colony-forming units.
[a]Main indicator microorganisms: *Staphylococus aureus*, Enterobacteriaceae, *Pseudomonas aeruginosa* and other *Pseudomonas* spp, *Stenotrophomonas altophilia*, *Acinetobacter* spp and *Candida* spp.

cultures for quality assurance.[24,25] However, this method is not unanimously accepted, and guidelines from learned societies of the United Kingdom, the United States, and Canada do not recommend it.[4,7,26]

Hygiene teams can also practice regular audits of disinfection procedures to assess compliance with protocols. Regular audits allow continuous improvement of the quality of disinfection. The errors observed are reported to the teams, which makes it possible to correct the discrepancies. Audits and microbiological cultures are recommended by French authorities to improve reprocessing of endoscopes.

We evaluated the impact of routine microbiological surveillance testing and audit practice on bronchoscope contamination rates.

Methods

This prospective study was undertaken from January 2007 to June 2020 at the Brest hospital, a 2,800-bed teaching facility in France. We reviewed the evolution of contamination rates of flexible bronchoscopes, endobronchial ultrasound bronchoscopes, videobronchoscopes and AERs. We also evaluated the efficacy of audits of decontamination and disinfection procedures to improve contamination rates.

Bronchoscope reprocessing cycle

At Brest teaching hospital, bronchoscopes are cleaned manually immediately after an examination with a peracetic acid-based detergent disinfectant. Bronchoscopes undergo manual high-level disinfection or disinfection in an automatic endoscope reprocessor (Soluscope AER, Aubagne, France). If high-level disinfection is used, the bronchoscopes are rinsed with filtered water. They are then dried and stored in a sterile field. If time of storage is >12 hours, bronchoscopes must undergo a new disinfection before use. Bronchoscope reprocessing is done in unit where it is used, in the pneumology unit, in an operating room, or in an intensive care unit.

Bronchoscope and automatic endoscope reprocessor microbiological surveillance

Bronchoscope and AER microbiological surveillance testing were conducted once per week by well-trained technicians of the microbiology laboratory during the study period. The sampling and microbial culture protocols were based on the French national recommendations.[27] This included all routine microbiological testing performed: routine testing (once per year per bronchoscope), after maintenance, retesting controls after a previous contaminated test, and on all new bronchoscopes. The sampling was done using neutralizing pharmacopoeia diluent (NPD) buffer with sodium thiosulfate (AES Laboratoire, Combourg, France). Results were interpreted according to the National Technical Committee on Nosocomial Infection guideline (Table 1). When the action or alert level were reached, disinfection was considered as ineffective, and bronchoscope was subjected to a double manual reprocessing before being retested.

Microbiological surveillance of automatic endoscope reprocessor are also performed once each year for quality assurance. Total flora must be ≤1 colony-forming unit (CFU)/100 mL without *Pseudomonas* spp.

Audit of disinfection practices

The disinfection process was regularly evaluated by the hospital hygiene team, which is also responsible for training professionals. They used an audit grid that assesses all the stages in the treatment of bronchoscopes: pretreatment, transport, manual leak testing, brushing and swabbing, manual disinfection or in an automatic washer-disinfector, drying, storage, and step traceability. The expiration and proper use of detergent disinfectant products are also checked. A risk assessment inspection was done every 2 years to evaluate the respect of hygiene precautions.

Statistical analysis

We conducted statistical analyses using R software version 3.5.3 (R Core Team, R Foundation for Statistical Computing, Vienna, Austria). Rates of contamination were calculated per year, and we used a Poisson regression model to study their evolution.

We assessed the risk factors for microbiological contamination using a multivariable logistic regression model. We first included in a univariate model, variables described as risk factors for contamination in the literature[28,29]: the reason of testing (routine testing, after maintenance, routine retesting control, new bronchoscope), process of disinfection (manual or automatic endoscope washer-disinfector), the brand of bronchoscopes (Pentax vs others), the user service (pneumology unit vs others), and age of bronchoscopes. Variables with a P value < .20 were included in the multivariable logistic regression model. All tests were 2-sided, and $P < .05$ was considered significant. Adjusted odds ratios with their 95% confidence intervals (CIs) are presented.

Results

Between 2007 and 2020, 91 different bronchoscopes were tested: 75 flexible bronchoscopes, 8 echo-bronchoscopes and 8 videobronchoscopes. In total, 478 microbiological surveillance tests were conducted. Of these, 74 tests (15.5%) showed that high-level disinfection of bronchoscopes was not reached. However, the rate of contamination significantly decreased over the testing period, varying from 30.2 to 0% ($P < .0001$). Characteristics of

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Table 2. Characteristics of Samples According to Levels of Contamination

Variable	Target Level (n = 404) No.	Target Level (n = 404) %	Unacceptable Result (n = 74) No.	Unacceptable Result (n = 74) %	Total No.
Testing					
Routine testing[a]	134	87.01	20	12.99	154
After maintenance[b]	176	86.27	28	13.73	204
Routine retesting[c]	35	60.34	23	39.66	58
New bronchoscope[d]	59	95.16	3	4.84	62
Process of disinfection					
AER	44	91.67	4	8.33	48
Manual	293	81.39	67	18.61	360
Age of bronchoscopes, y					
≤2	160	78.05	45	21.95	205
>2	244	89.38	29	10.62	273
Unit					
Pneumology unit	267	81.40	61	18.60	328
Other unit	137	91.33	13	8.67	150
Bronchoscope type[e]					
Echo-bronchoscope	35	94.59	2	5.41	37
Olympus UC160F	22	91.67	2	8.33	24
Olympus UC180F	13	100.00	0	0.00	13
Video-bronchoscope	37	94.87	2	5.13	39
Olympus BFQ190	40	95.24	2	4.76	42
Fujifilm series 530	3	100.00	0	0.00	3
Flexible bronchoscope	311	81.63	70	18.37	381
Pentax series V	105	76.64	32	23.36	137
Pentax series BS	28	96.55	1	3.45	29
Pentax series RBS	20	100.00	0	0.00	20
Pentax	102	79.07	27	20.93	129
Storz	55	84.62	10	15.38	65
Fujinon	1	100.00	0	0.00	1
Year of testing					
2007	44	69.84	19	30.16	63
2008	35	83.33	7	16.67	42
2009	30	81.08	7	18.92	37
2010	30	73.17	11	26.83	41
2011	33	73.33	12	26.67	45
2012	33	84.62	6	15.38	39
2013	33	86.84	5	13.16	38
2014	30	93.75	2	6.25	32
2015	24	100.00	0	0.00	24
2016	28	93.33	2	6.67	30
2017	27	93.10	2	6.90	29
2018	20	95.24	1	4.76	21
2019	22	100.00	0	0.00	22
2020	15	100.00	0	0.00	15

Note. AER, automatic endoscope reprocessor.
[a]Routine testing: microbiological testing of every bronchoscope is made at least once per year.
[b]After maintenance: bronchoscope returned from manufacturers after repair are systematically tested.
[c]Routine retesting: when microbiological routine testing failed to comply with the target level, a second test is done after double manual reprocessing of the bronchoscope.
[d]New bronchoscope: every new bronchoscope is systematically tested before use.
[e]Bronchoscopes packaged in a sterile field and stored horizontally in dedicated boxes.

bronchoscopes along with microbiological test results are presented in Table 2. When routine microbiological testing failed to reach the target level, a second microbiology sample was taken after the second manual reprocessing of the bronchoscope. Univariate analysis found that routine retesting of bronchoscopes was significantly associated with higher risk of contamination (OR, 4.16; 95% CI, 2.04–8.47; $P < .0001$). The results of logistic regression analyses are presented in Table 3.

We found no significant risk associated with the type of bronchoscope. However, bronchoscopes from the pneumology unit were at higher risk of contamination (OR, 2.38; $P = .007$). Paradoxically, the risk of contamination significantly decreased with age of the bronchoscope; the risk of contamination was reduced for those aged >2 years (OR, 0.45, 95% CI, 0.27–0.75; $P < .002$).

Multivariate analysis confirmed that when routine testing failed to comply with the target level, retesting of bronchoscopes was significantly associated with a higher risk of contamination (OR, 2.58; $P \leq .015$), but the risk of contamination was not associated with the age of bronchoscope.

Microorganisms identified from cultures of samples

The microorganisms isolated from samples are presented in Table 4. Many of the microorganisms recovered during the study were gram-positive bacteria (n = 65, 48.1%), mostly coagulase-negative staphylococci and *Bacillus* spp. *Pseudomonas* spp were mostly gram-negative isolates (44 of 61, 72.1%). *Candida* spp and other yeasts were isolated from 9 samples.

Among the 74 microbiological tests that did not reach the target level, 64 (86.5%) found indicator microorganisms (*Staphylococus aureus*, Enterobacteriaceae, *P. aeruginosa*, and other *Pseudomonas* spp, *Stenotrophomonas maltophilia, Acinetobacter* spp, and *Candida* spp). Also, 10 microbiological tests (13.5%) did not find indicator microorganisms but had microorganism levels at ≥25 CFU.

Persistence of a strain of P. aeruginosa in a flexible bronchoscope

In 2007, a Pentax bronchoscope remained contaminated by a strain of *P. aeruginosa* P10 during nearly 1 year. From January

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Table 3. Results of Logistic Regression Analysis Testing the Association Between Bronchoscopes' Characteristics and Microbiological Contamination

	Univariate Analysis			Multivariable Analysis		
Variable	OR	95% CI	*P* Value	OR	95% CI	*P* Value
Testing						
Routine testing[a]	Ref			Ref		
Routine retesting[b]	4.16	(2.04–8.47)	<.0001	2.58	(1.20–5.55)	.015
After maintenance[c]	1.02	(0.55–1.89)	.953	0.73	(0.37–1.43)	.352
New bronchoscope[d]	0.33	(0.09–1.15)	.083	0.32	(0.09–1.14)	.079
Process of disinfection						
AER	Ref			Ref		
Manual	2.03	(0.70–5.90)	.196	1.38	(0.43–4.50)	.591
Age of bronchoscopes, y						
≤2	Ref			Ref		
>2	0.45	(0.27–0.75)	.002	0.63	(0.35–1.13)	.119
Unit						
Pneumology unit	Ref			Ref		
Other unit	0.42	(0.22–0.79)	.007	0.36	(0.18–0.72)	.004
Bronchoscope type[e]						
Bronchoscope	Ref			Ref		
Echo-bronchoscope	0.26	(0.06–1.11)	.070	0.38	(0.08–1.74)	.212
Video-bronchoscope	0.24	(0.06–1.02)	.053	0.23	(0.02–2.02)	.186

Note. OR, odds ratio; CI, confidence interval; AER, automatic endoscope reprocessor.
[a]Routine testing: microbiological testing of every bronchoscope is made at least once per year
[b]After maintenance: bronchoscopes returned back from manufacturers are systematically tested.
[c]Routine retesting: when microbiological routine testing failed to comply with the target level, a second test is done after double manual reprocessing of the bronchoscope.
[d]New bronchoscope: new bronchoscope is systematically tested before use.
[e]Bronchoscope packaged in a sterile field and stored horizontally in dedicated boxes.

Table 4. Main Identified Microorganisms Isolated From Bronchoscope Sampling

Microorganism	No.
Gram-positive bacteria	
Coagulase-negative staphylococci	34
Bacillus spp	17
Micrococcus spp	7
Enterococcus spp	2
Actinomyces spp	2
Brevibacterium spp	1
Staphylococcus aureus	1
Streptococcus spp	1
Gram-negative bacteria	
Pseudomonas spp	26
Pseudomonas aeruginosa	18
Stenotrophomonas spp	8
Klebsiella spp	5
Acinetobacter spp	1
Enterobacter spp	1
Moraxella spp	1
Pantoea spp	1
Fungi and yeasts	
Candida spp	2
Other fungi and yeasts	7

to November 2007, this bronchoscope was tested 14 times. The same strain of *P. aeruginosa* identified by pulsed-field gel electrophoresis was found 7 times from January to November (Fig. 1). During this period, 7 controls revealed no bacteria, whereas the P10 strain was still in the bronchoscope. Indeed, the bronchoscope has been sent several times to the manufacturer, who certified that the disinfection was effective after maintenance. During the period, 74 patients were identified in contact with this bronchoscope, but the strain of *P. aeruginosa* was not found in any of them.

Microbiological testing of automatic endoscope reprocessor

Over the study period, 57 microbiological tests of automatic endoscope washer-disinfectors were performed. No sample was determined to be contaminated. No microbiological test revealed *P. aeruginosa*.

Audits of practice

The first risk assessment inspection was done in 2007 in the department of bronchial endoscopy and had only 65% of conformities. The main deviation observed was the lack of control of the disinfectant baths and the absence of traceability of their renewal. In 2009, audit showed that procedures of reprocessing were known but the products used were not always good ones. Baths of disinfectant were not controlled. In 2012, the same risk assessment inspection showed 90% of conformity. In 2015, the French national audit revealed that professionals were not trained enough. The main mistake was the use of unsuitable swab to clean the bronchoscopes. In 2017, the risk assessment inspection reached 69% of conformities: the differences observed were not related to the

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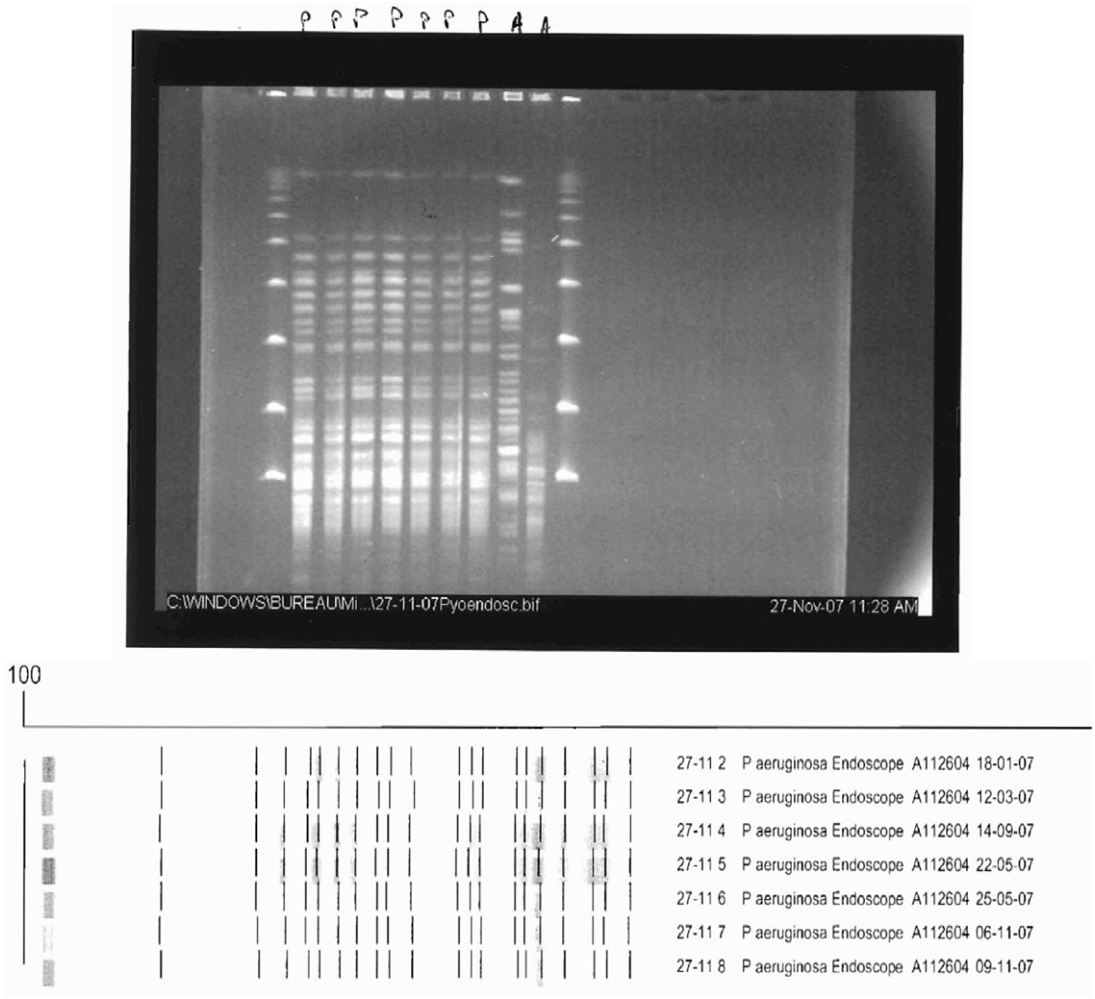

Fig. 1. Persistent strain of *Pseudomonas aeruginosa* P10 identified by pulsed-field gel electrophoresis on a Pentax bronchoscope (A112604).

treatment of bronchoscopes but to noncompliant professional clothing and lack of knowledge on standard hygiene precautions. Finally, the audit carried out in 2019 showed that the practices were well mastered by the teams and that only a few personal protective equipment did not comply.

Discussion

We investigated the evolution of contamination rates of flexible bronchoscopes after reprocessing. The overall rate of contamination we reported here (15.5%) is relatively high, but similar to those described in published studies where rates varied from 6% to 26%.[9–11] However, routine microbiologic surveillance allowed us to significantly lower the contamination rate from 30% to 0% over the 13-year period. This improvement is related to the practice audits of bronchoscope cleaning and disinfection, which made it possible to detect errors made during reprocessing and correct them. Manual reprocessing of bronchoscopes is a complex procedure, which can be the source of many errors. High-level disinfection should be performed by well-trained personnel. The preparation of the soaking baths, the handling of the disinfection products and the control of their effectiveness require in-depth training.

We also found that routine retesting of bronchoscopes was significantly associated with higher risk of contamination (OR, 2.58; $P \leq .015$). It is highly probable that the more the bronchoscope is used, the higher the risk of damage, making it difficult to decontaminate. The reuse and disinfection of this equipment also can lead to damage of channels and the formation of biofilms that are difficult to remove. The use of disinfectants based on oxidizing agents, such as peracetic acid, also may have deleterious effects on bronchoscopes.[30] In a previous study of the gastrointestinal endoscopy unit, we concluded that endoscopes that remained contaminated despite repeated reprocessing and maintenance should be withdrawn from further use. These endoscopes were usually old, and wear of channels made their disinfection inefficient.[31] Despite these risks, in a recent study, Ofstead et al[8] observed that damaged and contaminated endoscopes were used routinely in hospitals. Also, new technology of endoscopes may make it more difficult to disinfect them. Verfaillie et al[32] describe a large outbreak of VIM-2 *P. aeruginosa* that was linked to the use of a recently introduced duodenoscope with a specific modified design.

The microbiological investigation in our study found that the level of contamination may be high. Indeed, 34 microbiologic tests revealed >5 CFU even though these devices were cleaned and disinfected just before sampling. Most of indicator

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microorganisms were *P. aeruginosa*. This finding may reveal failure in bronchoscope drying. Indeed, endoscope drying has been described as one of the most important steps in limiting bacterial proliferation.[33] In wet conditions, *P. aeruginosa* is able to form biofilms that are difficult to remove by cleaning.[13] Moreover, biocides are less efficient on bacteria present in biofilms.[34] This conclusion was confirmed in our study by the persistence of a strain of *P. aeruginosa* in a flexible bronchoscope for nearly a year.

Our study has several limitations. We did not analyze the presence of multidrug-resistant microorganisms. Routinely, in accordance with French recommendations, the germs are simply identified to determine the level of disinfection but no antibiogram is performed. We did not sample for *Mycobacterium tuberculosis*. Also, we did not sample to detect viruses such as influenza, but no guidance recommends doing so. The study was conducted at a teaching hospital in France, and the findings may not be generalizable to other settings.

Carrying out audits makes it possible to detect the errors made during the reprocessing of the endoscopes and to correct them. Manual reprocessing of bronchoscopes is a complex procedure, which can be the source of many errors. High-level disinfection should be performed by well-trained personnel. The preparation of the soaking baths, the handling of the products and the control of their effectiveness by strips requires in-depth training. Audits are essential to identify errors and improve procedures. This study has enabled us to considerably improve the efficiency of disinfection and reduce the contamination rates.

In conclusion, our study showed that practice audits for quality assurance improve the reprocessing of bronchoscopes and routine microbial surveillance of bronchoscopes can reduce the rate of contamination. Surveillance cultures of these semicritical devices and automatic endoscope reprocessors is an effective way to assess the effectiveness of disinfection despite the cost and should be recommended by appropriate professional organizations.

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