Original article

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HYGENDA 2013 hygiene in endoscope reprocessing: a study on the reprocessing of flexible endoscopes in hospitals and medical practices

Summary

Background: The difficulty and complexity of reprocessing of flexible endoscopes have been known for more than 20 years and have been already discussed after publication of the HYGEA study in 2002. More than ten years later, we now have re-evaluated this investigation using a comparable methodology.
Method: The quality of the reprocessing procedure of colonoscopes, gastroscopes and duodenoscopes was tested under routine conditions in 16 endoscopy hospital facilities as well as in seven practices. In our investigation we included different types of endoscopes from different manufacturers as well as the associated water bottle systems and the air/water and suction valves. In addition, data about the performance of the reprocessing procedure were collected using a questionnaire.
Results: Of 30 biopsy channels of the endoscopes tested, eight sampled by taking swabs and seven sampled by investigating the rinse fluid (in total 13 of 30 tested endoscopes) showed bacterial contamination at low levels (< 10 Colony Forming Units (CFU) per endoscope). In addition five of 30 water samples drawn from rinsing water of the optical rinsing systems and six of 30 samples of the rinsing bottles showed weak microbial contaminations (> 1 CFU per ml or per tube). The tube of one optical rinsing system had a bacterial load of 52 CFU per ml. Although unacceptable results were not observed for the endoscopes themselves, the air/water and suction valves were often found to be microbially contaminated. Samples taken from the valves showed contamination in case of 24 air/water valves and 24 suction valves, five of them having more than 100 CFU per valve.
Conclusion: The results presented here of the endoscope tests (reprocessing with washer-disinfectors (WD) and validated processes) and the flushing bottles of the optics tests show that lessons were learned from the HYGEA study and improvements in everyday endoscopy facilities have been achieved. However, the consistent annual average complaint rates of about 4 % as part of the quality review for colonoscopies conducted by the German Associations of Statutory Health Insurance Physicians should prompt further efforts in endoscope reprocessing.
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Introduction

Due to their complex design and the nature of their use on patients, endoscopes make exacting demands on the reprocessing processes and on the qualifications and con-

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scientiousness of the reprocessing personnel [1–4].

Apart from the risks and complications associated with endoscopy itself, endoscopic examinations and procedures, like all invasive procedures, also pose a potential risk of infection [1, 2]. However, despite the vast number of endoscopic examinations carried out there is a paucity of data on the actual infection risk emanating from such examinations [1, 2]. In 1993 Spach et al. calculated the statistical risk to be 1:1.8 million [5]. It is difficult to determine the absolute risk since many infections are of a subclinical nature or they manifest only after a long period of time, and are then rarely imputed to endoscopy [1, 2].

Since the 1970s there have been a series of sporadic reports on exogenous infections in relation to endoscopic procedures [5–9]. In these cases the endoscope or the endoscope accessories had served as a vehicle for pathogens or facultative pathogenic organisms originating from previously examined patients or from the environment. In the majority of cases reported serious reprocessing errors and failure to observe the guidelines were mainly responsible for infection transmission [1, 2, 5–7]. From that can be concluded that standardized and validated reprocessing processes [1, 2] as well as the increasing use of single-use materials [2] and strict observance of reprocessing guidelines largely assure the requisite patient safety.

The HYGEA Study [10] – during which in 1999/2000 endoscopes from hospitals and medical practices were tested and revealing bacterial contamination in up to 49 % of the endoscopes – led to significant improvements being made with regard to infection control for endoscopes in the German-speaking countries. The findings of that study were incorporated into the amended version of the KRINKO Recommendations* from 2002 [11]. The key statements from the HYGEA Study regarding endoscope reprocessing were:

- The call for standardized reprocessing, preferably in an endoscope washer-disinfector (EWD)
- Use of microbiologically safe (sterile) rinsing water
- Meticulous drying before storage

Furthermore, hygiene regulations were tightened in outpatient settings, in particular for colonoscopy as used for cancer screening [12]. Regular microbiology testing has been introduced since then, also for medical practices. It has been possible to gradually reduce the negative test rate encountered during quality control measures and, while including the necessary repeat tests, the average failure rate for Germany as a whole in 2011 was 4.0 % [13].

Optical rinsing systems

The water bottles used for optics systems showed particularly high levels of contamination in the HYGEA Study. In particular, optical rinsing systems that had been filled with tap water and for which there were no clear-cut reprocessing process revealed microbial loads of up to almost 80 % [10]. Henceforth reprocessing instructions would also be incorporated into KRINKO Recommendation 2002 for the optics rinsing bottles [11]. The amended version of the KRINKO/BfArM Recommendations** from 2012 confirmed as standard practice that optics rinsing bottles must at least be disinfected daily, ideally followed by sterilization, and filled with sterile water [1].

Valves

In the HYGEA Study the reprocessing outcome was not verified for valves. In some European countries, especially in the United Kingdom and in the Netherlands, special attention is paid to the valves, whereby the endoscope and the valves are considered to constitute one single unit that must not be handled as a separate entity even for reprocessing and storage [2, 14, 15]. The rational for that is the belief that inadequately reprocessed valves can also be a source of infection. Some European countries have increasingly switched to single-use valves and rinsing bottles [2, 14]. The KRINKO/BfArM Recommendations stipulate as standard practice for reusable valves manual pre-cleaning, followed by reprocessing together with the endoscope [1].

Aim of the HYGENDA Study

The study was aimed at collecting data on the quality of the processes routinely used in endoscopy centres to reprocess flexible endoscopes and their accessories, and this was based on microbiological testing of endoscopes, of rinsing bottles and of the air / water and suction valves.

Materials and Methods

Selecting the participating endoscopy centres

All members of the German Society of Endoscopy Nurses and Assistants (DEGEA) were invited by email in July 2013 to voluntarily participate in the HYGENDA Study (HYGiene in ENDoscopy Reprocessing). Overall, 49 endoscopy centres responded (seven medical practices and 42 hospitals) from throughout Germany. Following a brief preliminary survey, all seven medical practices and 16 hospitals were enrolled in the study. Selection was made in accordance with the normal market distribution, based on similar statements by all representatives of endoscope manufacturers in Germany – with as large a proportion as possible of medical practices.

Sampling

The selected endoscopy centres were given information in advance by telephone and in writing about the study procedures. In October and November 2013 sampling was then initiated at the various centres following a brief consultation with the responsible staff members at the different sites. Sampling was performed by trained personnel from the test laboratory HygCen Germany GmbH, Schwerin, which has been accredited pursuant to DIN EN ISO 17025. Only endoscopes intended for use on patients were sampled; these were randomly selected in situ. As far as possible, endoscopes from different manufacturers and of different types were sampled within the specific establishment. The samples taken from the endoscopes or valves were not neutralized.

Endoscopes

First of all, swabs were taken from the endoscope proximal (biopsy channel inlet) and distal ends. Next, the biopsy channel was rinsed from the biopsy channel inlet to the distal end with 20 ml 0.85 % sterile NaCl solution in order to obtain a liquid sample.

* KRINKO Recommendation: Recommendation for hygienic processing practices for medical devices, compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI)

** KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

Valves
Using an immersion procedure, the air/water and suction valves were sampled by repeatedly actuating the spring mechanism with a sterile clamp in aliquots of 50 ml TSB (trypticase soybean broth) for 15 seconds.

Optical rinsings system
The optical rinsing system was tested by taking samples from bottles that were already being used and mounted on the processor for further use on the next patient. Sampling was done by means of prograde injection of 20 ml 0.85 % sterile NaCl solution into the suction tube of the bottle lid and aseptic collection of the eluate from the connector device on the optical rinsing tube. In addition, a 20 ml water sample was taken directly from the rinsing bottle.

Sample transportation
Samples were transported under refrigerated conditions (within 12 h of sampling) and further processed in timely fashion at the accredited test laboratory HygCen Germany GmbH, Schwerin.

Laboratory analysis
Swabs were plated onto blood agar plates and incubated for 48 h at 36±1 °C. Aliquots of 1 ml of the elution liquid from all liquid samples were transferred to different selective media. Using a pour plate method, the total aerobic colony count was calculated on yeast extract agar (incubation 48 h at 22±1 °C and 36±1 °C, TN1290). Endo agar was used to identify enterobacteria (manufacturer: Merck, incubation 48 h at 36±1 °C); conversely, cetrimide agar was used to identify pseudomonads (manufacturer: SIFIN, incubation 48 h at 36±1 °C) The remaining sample volumes of the elution liquids were filtered through mixed cellulose ester membranes (pore size 0.45 µm; manufacturer: Merck Millipore) and the filter was incubated on blood agar plates (manufacturer: Oxoid) 48 h at 36±1 °C.

Microbial growth was evaluated qualitatively and semi-quantitatively, with microbial counts being expressed as follows:
– Very low load (< 10 cfu per filter)
– Low load (> 10 to 100 cfu per filter)
– High load (> 100 cfu per filter)

Differentiation into species was carried out for Gram-negative bacteria on the basis of API 20 E® or 20 NE® (manufacturer: bioMérieux Germany GmbH).

Further data collected using a questionnaire
In collaboration with the responsible endoscopy personnel, information on the following topics was noted in situ on a questionnaire after sampling:
– Type and number of endoscopes
– Number of endoscopic procedures performed each year
– Type of reprocessing (EWD, drying, storage)
– Optical rinsing method (system, reprocessing, optics rinse solution)
– Reprocessing the air/water and suction valves
– Division of reprocessing steps between endoscopy department and Central Sterile Supply Department (CSSD)
– Qualifications of reprocessing staff

On completion of the "field phase" (sampling and in situ interview of selected participants) the same questionnaire was then sent to the remaining 26 hospitals that were not enrolled in the field phase. These hospitals were asked to complete the questionnaire anonymously. Seven hospitals returned the completed questionnaire.

Results

Microbiology testing
Endoscope investigation
In total, 30 endoscopes from 23 centres were subjected to microbiological testing. In all departments/centres that had voluntarily participated in the study, endoscopes were reprocessed in a EWD using validated processes.

The endoscopes thus reprocessed consisted of 11 gastroscopes, five duodenoscopes and 14 colonoscopes. Olympus Germany GmbH was the manufacturer of 17 endoscopes, Fujinon (FUJIFILM Europe GmbH) of four, and Pentax (PENTAX Europe GmbH) of a further nine endoscopes. From the hospitals eight gastroscopes, five duodenoscopes and nine colonoscopes were investigated; from the seven participating medical practices three gastroscopes and five colonoscopes were tested.

None of the 30 endoscopes tested from the endoscopy departments that had voluntarily participated in the study revealed any microbiological shortcomings based on the recognized acceptance criteria.

Optical rinsing system
Likewise, 29 of the optical rinsing systems were free of contamination, but one rinsing tube from an rinsing bottle had a very high microbial load of a magnitude that could not be counted.

Air/water and suction valves
Only in four out of 30 samples were no microbes identified in the air/water and suction valves (otherwise there was contamination of the air/water and suction valves). Hence 26 samples were contaminated:
– From five samples taken, one of the two valves was contaminated.
– From 15 samples taken, both valves were contaminated (< 10 cfu per valve).
– From 10 samples taken, at least one of the two valves had a heavy contamination load (> 10 to 100 cfu per valve).
– Finally, for four participants, at least one valve had a comparatively very high microbial load of more than 100 cfu per valve (in total five valves).

Escherichia coli, *Oligella urethralis* and *Chryseomonas luteola*, *Pasteurella haemolytica*, aerobic spore-forming bacteria and moulds were isolated from the air/water and suction valves.

Identification of *O. urethralis* as wet bacteria in one suction valve can be interpreted as an indicator of contaminated rinse water and an inadequately dried valve.

The results of the contaminated samples are presented in Table 1.

Data acquisition on reprocessing practices
All 16 hospitals and seven medical practices visited participated in data acquisition by completing a questionnaire. Furthermore, seven hospitals for which sampling was not conducted provided data (Tables 2 and 3).

Endoscope reprocessing
In the 23 hospitals and seven medical practices surveyed the endoscopes were manually precleaned and then reprocessed in an EWD. Twenty hospitals (87 %) and five medical practices (71 %) used flexible disposable brushes, while three hospitals (13 %) and two medical practices (29 %) used reusable cleaning brushes.

In some hospitals and medical practices disposable brushes had apparently been used repeatedly since only five hospitals and one medical practice stated in the questionnaire having used the cleaning brushes

Table 1: Overview of the number and type of endoscopes in the centres surveyed on the basis of a questionnaire (cfu = colony forming units, TOC = total aerobic count, ENDO = ENDO agar for identification of enterobacteria, CN = cetrimide agar for identification of pseudomonads, blood = blood agar, uc = uncountable).

Sample	Sampling	Test object	cfu	TOC/ml 22 °C	TOC/ml 36 °C	ENDO [cfu]	CN [cfu]	Blood [cfu] Filter/sample	Comment
1	Endoscope	Distal swab	0						
		Proximal swab	0						
		Rinse sample from biopsy channel		0	0	0	0	2	
	Valves	Suction valve		1	0	0	0	1	
		Air/water valve		0	0	0	0	1	
2	Endoscope	Distal swab	1						
	Valves	Suction valve		0	0	0	0	2	1 cfu moulds
		Air/water valve		0	0	0	0	6	
3	Valves	Suction valve		0	0	0	0	4	*Escherichia coli*
		Air/water valve		0	0	0	0	5	2 cfu moulds
	Optical rinsing system	Tube		0	52	0	0	uc	
4	Endoscope	Proximal swab	1						
	Valves	Suction valve		0	0	0	0	17	
5	Valves	Suction valve		0	0	0	0	33	Aerobic spore-forming bacteria
		Air/water valve		0	0	0	0	3	Aerobic spore-forming bacteria
	Optical rinsing system	Tube		0	0	0	0	5	
6	Valves	Suction valve		0	0	0	0	5	1 cfu moulds
		Air/water valve		0	0	0	0	4	
	Optical rinsing system	Tube		0	0	0	0	1	
7	Endoscope	Distal swab	1						
	Valves	Suction valve		0	0	0	0	4	
		Air/water valve		0	0	0	0	1	
	Optical rinsing system	Tube		0	0	0	0	1	
8	Endoscope	Distal swab	1						
	Valves	Suction valve		0	0	0	0	1	
		Air/water valve		0	0	0	0	10	
9	Valves	Suction valve		6	16	0	12	ca 150	2 cfu moulds, *Oligella urethralis*
	Optical rinsing system	Tube		0	0	0	0	3	
10	Valves	Suction valve		0	10	0	0	uc	15 cfu moulds, 2 cfu Aerobic spore-forming bacteria
11	Valves	Suction valve		7	4	0	0	> 300	
		Air/water valve		0	0	0	0	37	
12	Valves	Suction valve		0	0	0	0	1	
		Air/water valve		0	0	0	0	1	
13	Valves	Suction valve		0	0	0	0	28	
		Air/water valve		1	3	0	0	267	
14	Endoscope	Rinse sample from biopsy channel		0	0	0	0	3	
	Valves	Suction valve		0	0	1	0	35	
		Air/water valve		0	0	0	0	13	
	Optical rinsing system	Water		0	0	0	0	1	

Continuation of Table 1: Overview of the number and type of endoscopes in the centres surveyed on the basis of a questionnaire (cfu = colony forming units, TOC = total aerobic count, ENDO = ENDO agar for identification of enterobacteria, CN = cetrimide agar for identification of pseudomonads, blood = blood agar, uc = uncountable).

Sample	Sampling	Test object	cfu	TOC/ml 22 °C	TOC/ml 36 °C	ENDO [cfu]	CN [cfu]	Blood [cfu] Filter/sample	Comment
15	Valves	Suction valve		0	0	0	0	6	
		Air/water valve		0	0	0	0	16	
16	Valves	Suction valve		0	0	0	0	2	*Chryseomonas luteola*
		Air/water valve		0	0	0	0	6	
17	Endoscope	Proximal swab	1						
18	Endoscope	Rinse sample from biopsy channel		0	0	0	0	1	
	Valves	Suction valve		0	0	0	0	3	
		Air/water valve		0	0	0	0	2	
	Optical rinsing system	Water		1	0	0	0	1	
19	Endoscope	Proximal swab	3						
		Rinse sample from biopsy channel		0	0	0	0	1	
	Valves	Suction valve		0	0	0	0	1	
		Air/water valve		0	0	0	0	7	
20	Endoscope	Rinse sample from biopsy channel		0	0	0	0	1	
	Valves	Air/water valve		0	0	0	0	2	
	Optical rinsing system	Water		0	0	0	0	7	
21	Endoscope	Distal swab	1						
		Proximal swab	0						
	Valves	Suction valve		0	0	0	0	1	
		Air/water valve		0	0	0	0	1	
22	Valves	Suction valve		1	0	0	0	0	
		Air/water valve		0	0	0	0	3	
23	Valves	Suction valve		0	0	0	0	2	
		Air/water valve		0	0	1	0	41	
24	Endoscope	Rinse sample from biopsy channel		0	0	0	0	4	
	Optical rinsing system	Water		0	0	0	0	0	
		Tube		0	0	0	0	2	
25	Valves	Suction valve		0	0	0	0	5	
		Air/water valve		0	0	0	0	4	
26	Valves	Suction valve		7	43	2	0	uc	
		Air/water valve		4	25	1	0	uc	
27	Endoscope	Proximal swab	10						
		Rinse sample from biopsy channel		0	0	0	0	1	
	Valves	Suction valve		0	0	0	0	4	
		Air/water valve		0	0	0	0	3	
	Optical rinsing system	Water		0	0	0	0	1	
		Tube		0	0	0	0	2	
28	Valves	Suction valve		0	0	0	0	3	
		Air/water valve		0	0	0	0	4	
29	Optical rinsing system	Water		0	0	0	0	1	

Table 2: Overview of the number and type of endoscopes in the centres surveyed on the basis of a questionnaire.

	Number of centres	Gastroscope per centre	Proportion [%]	Colonoscope per centre	Proportion [%]	Duodenoscope per centre	Proportion [%]	Average number of endoscopes
Total	30	8.9	47	7.3	40	2.8	13	19.0
Hospital	23	9.7	46.5	7.2	36.5	3.6	17	20.5
Medical practice	7	6.1	47	7.4	51	0.3	2	13.8

Table 3: Overview of the number of endoscopies performed per year in the centres surveyed on the basis of a questionnaire.

	Average number of endoscopies per year	Average number of endoscopies per endoscope
Total	5841	313
Hospital	5641	281
Medical practice	6680	446

only once per endoscope, while in eight hospitals and four medical practices the cleaning brushes were used throughout the day for different endoscopes. There were four abstentions as regards that question. The reusable brushes were replaced after between one and 10 endoscopes, once daily or only after infectious patients.

In all endoscopy centres the endoscopes were reprocessed in an EWD using a chemothermal process, including the following disinfectant products:

- Five medical practices (71 %) and 15 hospitals (65 %) used products based on glutaraldehyde (GA).
- Nine hospitals used products based on peracetic acid (PAA).
- One hospital used both GA- and PAA-based products.
- Two medical practices did not provide any information.
- Three hospitals stated also sterilizing the endoscopes.

Drying and storage

In all hospitals and medical practices the EWD drying step was used. In addition, 18 hospitals and six medical practices drying was carried out with a compressed air pistol. A commercially available drying cabinet was used for endoscope storage in all 23 hospitals and in the six medical practices. One medical practice used a special drying cabinet system.

Validation and performance requalification

All study participants stated that they reprocessed their endoscopes in an EWD using validated processes.

Twenty-one out of the 23 hospitals conducted annual performance requalification of the endoscope reprocessing processes, and one hospital did so only once every two years. The remaining hospital stated it had not set any interval for performance requalification. Of the medical practices, one indicated a six-monthly interval, two to a yearly and a further practice admitted to a three-year interval. However, two admitted to having set no interval, nor did they specify the date of the last performance requalification. One practice did not provide any information on this point.

Reprocessing the optical rinsing system

None of the endoscopy centres used single-use devices used for the optical rinsing system. All participants used reusable, heat-resistant rinsing bottles, which were reprocessed using steam sterilization as the final reprocessing step. All participants reprocessed and replaced the bottles at least once daily.

Eight hospitals and three medical practices indicated that they also replaced the optics rinsing system after infectious patients. Seventeen hospitals (74 %) and six medical practices (86 %) responded affirmatively with "yes" to the question regarding observance of a standard operating procedure (SOP) when reprocessing the optics rinsing system, while six hospitals and one medical practice responded with "no".

In 12 hospitals (52 %) and two medical practices (29 %), manual cleaning was performed in the endoscopy suite, followed by sterilization in the CSSD. Eleven hospitals carried out all reprocessing steps in the CSSD, while five medical practices implemented all reprocessing steps themselves, including sterilization.

Optical rinsing solution

Thirteen hospitals and three medical practices used Aquadest (non-sterile) as optical rinsing solution, nine hospitals and four medical practices stated that they used sterile water. One hospital admitted to using demineralized water.

Microbiology testing

Twenty out of the 23 hospitals and all seven medical practices performed annual microbiology testing of the optics rinsing system. Three hospitals admitted to not carrying out annual microbiology testing of the optics rinsing system.

Reprocessing the air/water and suction valves

All participants for whom data was collected used reusable air/water and suction valves. One medical practice stated it used single-use devices for endoscopic retrograde cholangiopancreatography (ERCP), placement of percutaneous endoscopic gastrostomy (PEG) and for infectious patients.

Staff qualifications

In 20 out of 23 hospitals and in five out of seven medical practices at least one staff member in the endoscopy department had completed a specialist endoscopy training course; besides, in 21 hospitals and four medical practices staff members had completed Specialist Training Course I organized by the German Society of Sterile Supply (DGSV). Among the participating hospitals, two employees had completed Specialist Training Course II, while this was the case for only one medical practice. Only one medical practice indicated having participated in the DGSV Specialist Training Course III.

Explanation of the term 'validation' of processes

The term 'validation' as used in the European standards comprises installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) which is carried out when the equipment is commissioned at the site of use.

The colloquial expression process 'revalidation' is not a standard term. This really denotes 'performance requalification' (PQ) whereby the performance data from the original validation are verified or a check is carried out to demonstrate that the process continually meets the given specifications.

Discussion

Within the framework of the HYGENDA Study microbiology testing of endoscopes, valves and rinsing bottles was carried out in hospitals and medical practices. Data were collected on the reprocessing processes used by means of a questionnaire.

Power of the study

In view of the voluntary nature of study participation and the widespread awareness of the issue of infection control – as will no doubt have also been the case among the participating centres – positive participant selection must be assumed to have taken place. Those endoscopy centres which do not implement reprocessing in accordance with the currently valid version of KRINKO/BfArM Recommendations [1] are unlikely to have voluntarily consented to participation in such a study. Furthermore, the power of the study is limited by the comparatively small number of samples taken. However, the study does give an insight into the current situation regarding endoscope reprocessing, in particular for valves and rinsing bottles as well as manual pre-cleaning of endoscopes.

Endoscope reprocessing

All endoscopes in the centres surveyed were reprocessed in an EWD – as stipulated as the method of choice in the KRINKO/BfArM Recommendations. Drying in the EWD, supplemented where needed with compressed air, was also well established.

Reprocessing the optical rinsing systems

The rinsing bottles were cleaned and sterilized at least once daily in the endoscopy centres surveyed. Only one department filled the rinsing bottle with demineralized water from its own supplies.

The current version of the KRINKO/BfArM Recommendations stipulates daily reprocessing of the rinsing bottles, but does not contain any unequivocal specifications regarding subsequent sterilization [1]. There is a risk of recontamination if reprocessing is limited to disinfection and the devices are then stored in an unprotected environment. Therefore national and European guidelines call for consistent use of sterilized rinsing bottles [2, 14, 15]. Encouragingly, all centres participating in the study routinely sterilized the rinsing bottles. But just fewer than half of participants filled the bottles with sterile water as advocated by the KRINKO/BfArM Recommendations. The centres surveyed did not use disposable systems for the rinsing bottles. These could serve as an alternative to reprocessing since they would dispense with personnel and reprocessing costs.

Reprocessing and storage of valves

Indicator microorganisms as well as maximum cfu counts are used as quality criteria for microbiology testing of flexible endoscopes [1]. These can also be applied analogously to endoscope valves. Microbial contamination of the valves was detected in 26 out of 30 tests, in particular skin microbes, spore-forming bacteria and moulds, wet bacteria as well as *Escherichia coli*. The high cfu count detected in isolated cases and detection of indicator microorganisms are suggestive of inadequate reprocessing (cleaning, disinfection, final rinse) and especially of inappropriate storage.

The valves and distal caps are an inherent part of the endoscope and like the latter, after thorough manual cleaning, including with a brush, should preferably be reprocessed in an EWD using validated processes.

Certain valves can also be sterilized. That is recommended in some of the German and international guidelines. In the United Kingdom and the Netherlands the endoscope and the valves are considered to constitute one single unit that must not be handled as a separate entity even for reprocessing and storage [2, 14, 15]. But that topic has not been addressed in the amended version of the KRINKO/BfArM Recommendations [1]. It stipulates standardized reprocessing and – following thorough drying – contamination-proof storage. Since endoscope accessories are also medical devices within the meaning of the Medical Devices Act (MPG), protection against contamination must also be assured.

In the German-speaking countries, valves have not so far been assigned to a specific endoscope. In the endoscopy centres surveyed (as also observed in situ when visiting centres in the course of this study) open receptacles are used to accommodate several valves. The valves are then taken from that container whenever needed during the working day. If the valves are withdrawn with non-disinfected hands or with contaminated gloves, even appropriately reprocessed valves will also be recontaminated. The use of such receptacles is not the proper way to store a medical device.

The data collected by us underline the urgent need for discontinuing that practice. Instead, containers could be used for the reprocessed valves, which could assure assignment of the valves to the respective endoscope as well as contamination-proof storage. The impression we got when visiting the various centres suggests that, here too, there is need for information and action.

Biopsy channel valves are being increasingly used in gastroenterology as single-use devices, while the air/water and suction valves are reprocessed. Single-use valves are also being used increasingly in bronchoscopy .Whereas in countries, i.e. other than Germany, the guidelines increasingly recommend single-use valves as an alternative option, that trend has not yet taken hold in Germany [2, 14].

Cleaning brushes in the form of single-use devices

In the European and in other national guidelines cleaning brushes in the form of single-use devices are advocated [2, 14, 15]. The current KRINKO/BfArM Recommendations do not yet endorse that approach [1]. But a supplementary commentary draws attention to the requisite quality of cleaning brushes and to the difficulty of cleaning them [18], which in turn supports the argument for switching over to disposable (single-use) brushes.

Our study does discern a trend towards disposable brushes. In any case, the majority of centres surveyed had switched to disposable brushes. But, unfortunately, these were repeatedly used in eight hospitals and four medical practices. Replacement of the brushes only after reprocessing up to 10 endoscopes or only once daily was reported. Such practices are not in compliance

with the provisions of the Medical Devices Act (MPG). Single-use / disposable devices are intended only for single use. One can only speculate whether the brushes were repeatedly used because of financial pressure exerted by the respective hospital / medical practice management or whether the endoscopy centres concerned were experiencing reorganizational problems. Cleaning brushes are difficult to clean and therefore such a task calls for meticulous attention [2, 14, 15, 18]. Hence it would be advisable to switch to disposable brushes, but then these should only be used for one single endoscope to prevent cross-contamination of subsequent endoscopes.

Personnel qualifications

The current KRINKO/BfArM Recommendations require that each employee entrusted with medical device reprocessing must furnish proof of having the requisite expertise [1, 18]. The centres surveyed by us did have commensurately trained staff members. However, we were not able to ascertain on the basis of the survey whether each employee had received appropriate training (e.g. had completed the specialist training course run by the DEGEA).

Conclusion

Since the HYGEA Study from 2002, several improvements have been made in the domain of endoscopy hygiene [10].

That also applies to the reprocessing structures and processes. The currently valid version of the KRINKO/BfArM Recommendation from 2012 endorses the recommendations for reprocessing endoscopes and optics rinsing bottles, as inferred from the HYGEA Study [1].

The HYGENDA results presented in this paper and which were obtained after testing endoscopes (reprocessing in EWD and using validated processes) and optics rinsing bottles show that lessons have been learned from the HYGEA Study and routine improvements made in endoscopy centres. However, the Quality Check in Colonoscopy (carried out from 2005 to 2011) identified annual average objections / complaints rate of between 3.4 and 4.9 % for Germany on the whole [13], and this should underscore the need for further improvements in endoscope reprocessing. Special attention should be paid to the endoscope valves and the cleaning brushes.

Conflict of interest

The authors declare that they have no conflict of interests as understood by the guidelines of the International Committee of Medical Journal Editors.

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