Original article

Sabine Gleich[1], Bernarda Lindner[1], Peter Heeg[2]

1 Department of Health and the Environment, City of Munich
2 Hygiene in Healthcare, Ammerbuch

Endosonographic probe re-processing (ultrasonic probes coming into contact with the mucous membranes) – an un-derestimated problem?

Summary

Background: Inadequately reprocessed endosonographic probes can transmit pathogens. Outbreaks caused by these medical devices have been described in the literature: trans-esophageal probes were affected in the USA and Germany. Potentially carcinogenic viruses such as human papillomavirus (HPV) also can be transmitted by transvaginal and transrectal probes if they are not adequately reprocessed.
Aim: Reprocessing methods used for endosonographic probes with mucous membrane contact in Munich hospitals should be investigated. Existing user problems should be identified and need for consultation determined.
Material and Methods: In February 2017, the health authority of Munich sent a letter to 19 hospitals with the special fields of gynecology, urology, cardiology and cardiac surgery, and asked for the hygienic standards and working instructions (standard operating procedures) for endosonographic probes. The documents were registered in a standardized manner and analyzed descriptively.
Results: None of the hospitals fully adhered to the requirements of the KRINKO/BfArM recommendation for medical device reprocessing. General reprocessing practice is wipe disinfection of the probes, whereas immersion disinfection procedures and semi-automatic processes are restricted to few cases. Not all device components are reprocessed, most of the time there is no verification of the reprocessing results.
Conclusion: The reprocessing of ultrasound probes with contact to mucous membranes presents an unsolved problem – in terms of liability for the operator or user, and in terms of infection prevention for the examined patients. The development of guidelines and quality assurance standards for the hygienically correct treatment of these medical devices is absolutely necessary. The manufacturers must be legally obligated to develop and launch reprocessable medical devices for this sector.

Keywords: endosonographic probes · reprocessing · Human Papilloma virus · infection prevention · Public Health Service

*** Corresponding author**

Dr. med. Sabine Gleich
Referat für Gesundheit und Umwelt der Landeshauptstadt München
Bayerstr. 28a
80335 München, Germany

E-mail: sabine.gleich@muenchen.de

Conflict of interest

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Introduction

Infectious risks associated with endoscopic examinations

Diagnostic imaging of the gastrointestinal tract has witnessed revolutionary progress since the 1970s: with the advent of endoscopy, in particular esophagoduodenoscopy and colonoscopy, it is now possible for the first time to introduce instruments into the human body for direct visualization of the mucous membranes and for sampling. This examination modality has also benefited the patient since, unlike the barium swallow test and radiocontrast media, it is better tolerated and does not involve any radiation exposure.

Soon after the introduction of these novel diagnostic techniques there were reports of transmission of nosocomial pathogens (bloodborne viruses, salmonellae and parasites [1, 2, 3]. In recent years there have been increasing reports of transmission of multi-resistant pathogens (MRPs) during endoscopic examinations as well as of outbreaks [4, 5, 6, 7, 8]. The enduring perception that undergoing endoscopy is seen as an infectious risk is also underlined by the fact that, pursuant to the guidelines for obtaining blood and blood products and for the administration of blood products (haemotherapy), endoscopic examination constitutes an exclusion criterion for blood donation for four months afterwards [9].

Infectious risks associated with endosonographic examinations

The continuing technological progress has also meant that ultrasonic probes (transducers), which are introduced into the body, are now also routinely used for ultrasound diagnostic examinations. Ultrasonic (US) probes that come into contact with mucous membranes are used, inter alia, in gynaecology, urology, cardiology and cardiac surgery. Transvaginal ultrasound is carried out in most gynaecology examinations: in the National Health Service in the United Kingdom, more than 9 million such examinations are performed every year [10].

It has not been possible to obtain valid information on the number of examinations conducted in Germany because of the complex coding systems based on the diagnosis related groups and the classification procedure for the encoding of operations (DRG/OPS procedures) used for the inpatient setting and the uniform assessment standard (EBM) for physician fees in the outpatient sector. There have also been reports of outbreaks linked to these medical devices: transesophageal echocardiographic probes (TEEs) in the USA and Germany [11, 12, 13, and 14]. In particular, transvaginal probes (TVUS) and transrectal probes (TRUS) in principle present a risk of transmission of potentially carcinogenic viruses such as human papillomavirus (HPV) from one patient to the next patient.

Investigations carried out in hospitals and in one emergency department detected HPV contamination rates of sheathed probes after examination of 4.2 and 7.5%, respectively [15, 16]. These investigations demonstrated that even the use of sheaths did not protect the probe against contamination with potential pathogens. A systematic review with meta-analysis of 32 publications on infectious risks associated with transvaginal and transrectal ultrasound identified pooled prevalence rates of ultrasonic probe contamination after reprocessing (low-level disinfection) of 12.9% for pathogenic bacteria and of 1% for viruses (HPV, herpes simplex virus and cytomegalovirus) [17]. Unlike transmission of bacteria with evidence of a specific resistance pattern, but evidence of viral transmission cannot be found immediately since there are very long incubation times until onset of any cancer. To date, there have been no reports in the literature of outbreaks linked to TVUS or TRUS.

Specifications for risk assessment and medical device reprocessing

Endoscopes are classified as class B semi-critical medical devices due to their design with working channels, i.e. they make stringent demands on reprocessing, and thus preference should be given to automated reprocessing. Conversely, probes which have no working channels, are classified as class A semi-critical medical devices, and may in principle undergo manual reprocessing.

In Germany, class A semi-critical medical device reprocessing is regulated by the recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM), known as the KRINKO/BfArM Recommendation [18], setting out the following:

- Compliance with the manufacturer's reprocessing instructions
- Individual steps: precleaning, cleaning, intermediate rinsing, disinfection, rinsing, drying
- Documentation of reprocessing
- Use of validated processes
- Verification of the reprocessing results at defined intervals
- Expertise and experience of personnel entrusted with reprocessing
- Efficacy spectrum of the disinfectants used: bactericidal, incl. mycobactericidal, fungicidal and virucidal
- Stored medical devices must be protected against recontamination

Pursuant to Annexes 7 and 8 of the KRINKO/BfArM Recommendation [18], when using ultrasonic probes in gynaecology and ultrasonic probes that come into contact with mucous membranes, sheaths should continue to be used, and the use of sheaths alone without subsequent disinfection of probes is not admissible.

Reprocessing processes for probes that come into contact with mucous membranes

There are different reprocessing processes on the market for probes that come into contact with mucous membranes: the manual reprocessing processes essentially entail immersion and wipe disinfection methods. For TVUS partially automated reprocessing processes are also available based on hydrogen peroxide gas plasma and UVC rays.

For TEEs partially automated reprocessing process with automated rinse cycles in synthetic tubes are available. Automated processes are not routinely used to reprocess TEEs for various reasons: besides the heat sensitivity of the quartz transducer there is also the issue of permeability of the handheld attachment/flexion controller.

The use of disinfectants for probe reprocessing tailored to the pathogen spectrum

In principle, fungi, bacterial and viral pathogens can be transmitted from one patient to the next via ultrasonic probes [19]. Non-enveloped viruses present a particular risk since they are highly resistant to disinfectants.

The main pathogens implicated:

TVUS:

- Bloodborne viruses, such as hepatitis B and hepatitis C viruses as well as human immunodeficiency virus (HIV)
- Potentially carcinogenic viruses such as human papillomavirus (HPV)

TRUS:

- Bloodborne viruses, such as hepatitis B and hepatitis C viruses as well as human immunodeficiency virus (HIV)

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- Respiratory infection viruses, such as adenovirus and enterovirus
- Non-enveloped viruses, such as hepatitis A and hepatitis E viruses
- Potentially carcinogenic viruses, such as human papillomavirus (HPV)
- *Clostridium difficile*

TEEs:

- Respiratory infection viruses, such as influenza, metapneumonia, respiratory syncytial (RSV) viruses and varicella zoster virus (VZV)
- Bloodborne viruses, such as hepatitis B and hepatitis C viruses as well as human immunodeficiency virus (HIV).

In the interest of patient safety, it is therefore important to take the aforementioned spectrum of pathogens into account when choosing a disinfectant for each type of probe. For example, for TVUS a bactericidal, levoricidal, virucidal efficacy spectrum is needed, for TRUS bactericidal, levoricidal, sporicidal (*C. difficile*), virucidal, and for TEEs a bactericidal, levoricidal, tuberculocidal and virucidal efficacy spectrum [19]. The efficacy spectrum recommended in this present article differs from that of the KRINKO/BfArM Recommendation with regard to the fungicidal efficacy [18], and from the Guideline for Validation of Manual Chemical Disinfection of Medical devices, compiled by the DGKH, DGSV, AKI and VAH, with regard to the tuberculocidal efficacy [20].

Current expert debate

TVUS reprocessing was investigated in gynaecology clinics in Munich over 10 years ago and identified the need for better hygiene practices to assure proper probe reprocessing [21]. These findings were also one of the reasons for inclusion of reprocessing recommendations in the revised Krinko/BfArM Recommendation.

Proper reprocessing of ultrasonic probes that come into contact with mucous membranes is back in the spotlight due to, inter alia, a paper published by the German Society of Hospital Hygiene (DGKH), which stated, among other things, that reprocessing consisting of a wipe disinfection method does not constitute an accepted form of instrument disinfection [22], as well as a position paper by the Central Association for the Electrical and Electronics Industries (ZVEI), stating that for TVUS and TRUS reprocessing consisting of disinfectant wipes alone does not meet the legal requirements [23]. Furthermore, a recommendation published by the Quality Task Group (101) of the German Society of Sterile Supply (DGSV) specifying that all ultrasonic probes which are inserted into natural body openings and come into contact with the mucous membranes or pathologically altered skin should be classified as class B semi-critical devices [24]. That classification would call for automated reprocessing.

Reason for conducting the present study

The reason for conducting the present study was a multispecies outbreak caused by 3-MRGN *Escherichia coli*, *Klebsiella oxytoca*, *K. pneumoniae* and *Proteus mirabilis* in a Munich hospital. Forty-three patients were affected and the identified outbreak source was identified as the damaged outer sheath of TEE probes. The invasive ultrasound examinations were carried out over several hours without a protective sheath [25].

Aim of the study

The aim of the study conducted by the Department of Health and the Environment (RGU) responsible for supervision of infection control/hygiene practices of Munich hospitals was to ascertain the following based on risk assessment:

- which methods were used in Munich hospitals to reprocess ultrasonic probes that come into contact with mucous membranes,
- whether the KRINKO/BfArM Recommendation was being implemented in its entirety.

Investigated also was

- who was entrusted with reprocessing
- what qualifications did the reprocessing personnel have
  and
- how the efficacy of the reprocessing process was verified and documented
  and
- whether the level of care category of the hospitals influenced the choice of reprocessing process used.

Other aims were to identify any user problems or need for consultation.

Materials and methods

In February 2017, the Department of Health and the Environment (RGU) of the City of Munich wrote to 19 Munich hospitals which operated departments for gynaecology, urology, cardiology and cardiac surgery and asked them to send it their in-house infection control policies/standard operating procedures (SOPs) for reprocessing transvaginal probes (TVUS), transrectal probes (TRUS) and transesophageal echocardiographic probes (TEEs). They also requested information on the types of equipment used, on the professional/occupational groups entrusted with reprocessing the probes and asked whether these staff members had a supplementary qualification (certificate of competence or DGSV Specialist Training Course I, respectively).

Staff of the Department of Health and the Environment (RGU) inspected the documentation submitted, and entered data in standardized, pseudo-anonymized form, using codes, into the table calculation program Excel® and then performed descriptive evaluation. After the submitted documents were reviewed, all hospitals were sent written recommendations by the healthcare authorities.

Results

All 19 (100%) hospitals contacted responded to the survey. Fourteen hospitals/specialist departments reprocessed transvaginal probes (TVUS), seven hospitals/specialist departments transrectal probes (TRUS), and 14 hospitals/specialist departments transesophageal echocardiographic probes (TEEs).

Despite the small sample size, to improve comparability of the subgroups the data was given not only as absolute numbers but also as percentages.

TVUS

TVUS reprocessing was similar across all hospital level of care categories, see Table 1. All hospitals had the legally prescribed minimum number of infection control staff members, with the proportion of in-house personnel being greater than that of external personnel; this information can be consulted in the table. For ten hospitals (71%) objective evidence that a protective sheath had been used for carrying out the examination was documented in the infection control policy. The majority of probes were reprocessed by the examining doctors and hospital nursing staff, but hospitals cited several professional groups. One hospital (7%) stated that the reprocessing personnel had completed DGSV Specialist Training Course I. In two hospitals (14%) the

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persons entrusted with reprocessing had been briefed by members of the hospital infection control team. TVUS were reprocessed (disinfected) using only a manual wipe disinfection method, while one hospital additionally performed immersion disinfection at the end of the working day. Based on the submitted documentation, there was no evidence that reprocessing had been validated in any hospital. All hospitals used disinfectants featured on the list of approved disinfectants drawn up by the German Association of Applied Hygiene (VAH). In 12 cases (86%) these were endowed with adequate efficacy spectrum (according to the manufacturer they were effective against SV40 virus). Thirteen hospitals (93%) had an in-house infection control policy for TVUS reprocessing. Evidence of the qualifications of the policy authors was provided in all cases. Release as required for legal validity was assured for three-quarters of policies. A review of the standard operating procedures showed that precleaning and disinfection had been conducted in 11 (79%) and 13 (93%) of hospitals, respectively. From the infection control policies submitted it was not possible to identify evidence that any hospital reprocessed the probe handheld attachment, connecting cable or power plug. Eight hospitals provided information on reprocessing the ultrasound machine (62%); that was done each working day in most cases, see Table 1. TVUS reprocessing was documented in one hospital (14%); the reprocessing outcome was not verified in any hospital.

Table 1: Reprocessing transvaginal (TVUS), transrectal (TRUS) and transesophageal echocardiographic (TEEs) ultrasonic probes

	TVUS	TRUS	TEES
Reprocessing hospitals/specialist departments	**n = 14 (100%)**	**n = 7 (100%)**	**n = 14 (100%)**
Structural data			
Level of care categories			
Private clinical not assigned to any level of care category	3 (21%)	1 (14%)	1 (7%)
Specialist clinics	3 (21%)	1 (14%)	4 (29%)
General care provider	–	1 (14%)	1 (7%)
Specialist care provider	3 (21%)	–	2 (14%)
Maximum level of care provider	3 (21%)	2 (28%)	4 (29%)
University hospitals	2 (14%)	2 (28%)	2 (14%)
Dedicated infection control personnel *of whom:*	14 (100%)	7 (100%)	14 (100%)
In-house[1] infection control physician	8 (57%)	4 (57%)	8 (57%)
In-house[1] infection control nurse	11 (79%)	7 (100%)	12 (86%)
Examination method			
Documented use of protective sheath	10 (71%)	6 (86%)	8 (57%)
Reprocessing			
Profession of reprocessing persons[2]			
Examining physician	12 (86%)	3 (43%)	5 (36%)
Hospital nursing staff	5 (36%)	4 (57%)	11 (79%)
Med. assistant	3 (21%)	2 (28%)	5 (36%)
Midwife	3 (21%)	–	–
OR personnel	1 (7%)	–	–
Emergency dept. assistant	–	1 (14%)	1 (7%)
Qualifications of reprocessing persons			
Certificate of competence	0 (0%)	2 (28%)	3 (21%)
DGSV Specialist Course I	1 (7%)	1 (14%)	5 (36%)
Briefing by infection control team	2 (14%)	–	–
Reprocessing processes used			#
Automated	0 (0%)	0 (0%)	5 (29%)
Manual, *of which:*	14 (100%)	7 (100%)	12 (71%)
– Wipe disinfection	14 (100%)	5 (71%)	10 (83%)
– Immersion disinfection	1 (7%)[3]	2 (28%)	2 (17%)
Documented validation			
Automated	–	–	0 (0%)
Manual	0 (0%)	0 (0%)	0 (0%)
Disinfectant use			
VAH List	14 (100%)	7 (100%)	14 (100%)
Appropriate specific efficacy spectrum	12 (86%)[4]	6 (86%)[4]	14 (100%)

TRUS

TRUS reprocessing was conducted primarily in specialist clinics and hospitals belonging to the high level of care category, see Table 1. All hospitals had the legally prescribed infection control personnel, with a greater proportion of in-house personnel; this can be consulted in the table.

For six hospitals (86%) there was objective evidence that examination had been carried out with a protective sheath. The majority of probes were reprocessed by the examining doctors and hospital nursing staff, but hospitals cited several professional groups. In two hospitals (28%) reprocessing personnel held a certificate of competence, in one hospital (14%) had completed Specialist Training Course 1. TRUS were all manually reprocessed, in five hospitals (71%) by means of wipe disinfection, in two hospitals (29%) using an immersion disinfection method. Based on the submitted documentation, there was no evidence that reprocessing had been validated in any hospital.

All hospitals used disinfectants featured on the VAH List, in six cases (28%) these were endowed with an adequate efficacy spectrum. Three hospitals (43%) had an in-house infection control policy for TRUS reprocessing, three other hospitals (43%) made cross reference to their TVUS reprocessing policy, and one hospital (14%) had no infection control policy. All policies had been drawn up by the infection control staff, release as needed for legal validity was assured for one policy. A review of the standard operating procedures showed that in the two hospitals that used immersion disinfection details were given for all repro-

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Table 1 (cont.): Reprocessing transvaginal (TVUS), transrectal (TRUS) and transesophageal echocardiographic (TEEs) ultrasonic probes

	TVUS	TRUS	TEES
Reprocessing hospitals/specialist departments	**n = 14 (100%)**	**n = 7 (100%)**	**n = 14 (100%)**
Infection control policy for reprocessing, infection control management			
In-house infection control policy in place	13 (93%)	3 (43%)	14 clinics, 17 policies#
of which:			
Documented evidence of policy author's qualifications	12 (92%)	3 (100%)	16 (94%)
Formal release	9 (69%)	1 (33%)	14 (82%)
SOP[5] on reprocessing features details of			
– Precleaning	11 (79%)	3 (100%)	16 (94%)
– Cleaning	–	2 (66%)	15 (88%)
– Intermediate rinsing	–	2 (66%)	5 (29%)
– Disinfection	13 (93%)	3 (100%)	17 (100%)
– Rinsing	2 (14%)	3 (100%)	17 (100%)
– Drying	0 (0%)	2 (66%)	7 (41%)
– Storage	–	2 (66%)	13 (76%)
No cleaning on using protective sheaths	–	–	3 (18%)
The following also reprocessed:			
– Handheld attachment/flexion controller (TEEs)	0 (0%)	1 (33%)	5 (29%)
– Connecting cable	0 (0%)	1 (33%)	2 (14%)
– Power plug (TEES)	0 (0%)	0 (0%)	1 (7%)
Reprocessing of ultrasound machine Including keyboard, gripping surfaces	8 (62%)	0 (0%)	0 (0%)
Reprocessing interval			
– After each patient	2 (14%)	–	–
– As warranted	4 (31%)	–	–
– Each working day	7 (54%)	–	–
Other details			
Documented reprocessing	1 (7%)	2 (66%)	17 (100%)
Verification of reprocessing outcome	0 (0%)	0 (0%)	6 (35%)
Verification method	–	–	microbiol.
Use of critical B ancillary instrumentation (for biopsies and punctures)	–	1 (33%)	–
– Details		1 (33%)	
– Automated reprocessing		1 (33%)	
– Steam sterilization			
Details of reprocessing premises	–	–	6 (35%)
Separation of clean from unclean zone			6 (35%)

1 In-house = Permanent hospital/clinic employee
2 Multiple answers possible
3 In one hospital once every working day plus immersion disinfection
4 According to manufacturer, effective against SV40 (surrogate marker for HPV)
5 Standard operating procedure
In each of 4 clinics 2 processes used, in total 17 processes

cessing steps, see Table 1.

Two of the three standard operating procedures contained details of storage of reprocessed probes. Based on the policies submitted, there was evidence that two hospitals reprocessed the handheld attachment and connecting cable, there was no evidence the power plug was reprocessed in any of the hospitals. There was no evidence of reprocessing of the ultrasound machine in any hospital. Two hospitals documented probe reprocessing; the reprocessing outcome was not verified in any hospital.

Ancillary instrumentation for biopsies and punctures (critical B class) underwent automated reprocessing and steam sterilization in one hospital, in its RUMED (Reprocessing Unit for Medical Devices). One hospital reported using only single-use devices for punctures.

TEES

TEE reprocessing was carried out mainly in specialist clinics and in hospitals belonging to the high level of care category, see Table 1. All hospitals had the legally prescribed infection control staff members, of whom the majority were in-house personnel, as listed in the table.

For eight hospitals (57%) objective evidence was provided that a protective sheath had been used for carrying out the examination. The majority of probes were reprocessed by hospital nursing staff and medical assistants, but hospitals cited several professional groups. In three hospitals (21%) reprocessing personnel held a certificate of competence, in five hospitals (36%) reprocessing staff had completed Specialist Training Course 1.

TEEs underwent partial automated reprocessing in five hospitals and manual reprocessing in 12 hospitals. Three hospitals used both partial automated and manual processes to reprocess their probes. In 10 cases (83%) manual reprocessing consisted of wipe disinfection, and in two cases (17%) of immersion disinfection. Based on the submitted documentation, there was no evidence that reprocessing had been validated in any hospital.

All hospitals used disinfectants featured on the VAH List, in all cases these were endowed with an adequate efficacy spectrum. All hospitals had an in-house infection control policy for reprocessing TEEs. Of the four hospitals using two reprocessing processes, one hospital did not have any policy (standard) for its partially automated reprocessing process. Three-quarters of policies assured release as needed for legal validity. A review of the standard operating procedures revealed that the majority gave details of all reprocessing steps needed apart from intermediate rinsing, which was addressed in only five standards, see Table 1.

Details of closed storage were given in 13 standards. Three hospitals (18%) reported omitting the cleaning step when sheaths were used. From the infection control policies submitted it was possible to infer that five hospitals (29%) reprocessed the handheld attachment /flexion controller, two hospitals (14%) the connecting cable and one hospital (7%) the power plug. All policies pointed to the need for documentation of reprocessing. The reprocess-

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ing outcome was verified in six hospitals (35%) through microbiology tests. The test intervals varied from quarterly to yearly. Six infection control policies (35%) gave details of the reprocessing premises: reprocessing was carried out in premises divided into clean and unclean zones.

Discussion

Compliance with the normative provisions for medical device reprocessing

In none of the hospitals surveyed were the provisions of the KRINKO/BfArM Recommendation for medical device reprocessing [18] fully implemented. The most commonly employed reprocessing method consisted only of wipe disinfection of the probes with wipe systems; no evidence of standardization of the wipe process could be found in most of the documentation reviewed.

TVUS are being reprocessed in the Munich hospitals only by means of manual wipe disinfection. The immersion disinfection method and partially automated process was reserved for, in individual cases, TRUS and TEE reprocessing. The choice of reprocessing process was not determined by the hospitals' level of care category.

Probe reprocessing in relation to the level of care, dedicated infection control personnel

Differences were discerned for probe reprocessing in relation to the hospital level of care category: TVUS were reprocessed in hospitals belonging to all level of care categories and university hospitals, TRUS and TEEs, in addition to specialist clinics, primarily in hospitals offering a maximum level of care and university hospitals (60%). All Munich hospitals have the legally prescribed infection control personnel, mainly permanent staff. Hospitals with permanent infection control personnel did not produce better reprocessing results than those hospitals with external personnel.

Personnel deployment for probe reprocessing

Probe reprocessing is entrusted to several professional groups: it is the examining physician who reprocesses TVUS in 86% of hospitals, TRUS in 43% and TEEs in 36% of hospitals. The hospital nursing staff and medical assistants are entrusted with reprocessing TVUS in 57% of gynaecology clinics, in 85% of urology and in all cardiology and cardiac surgery clinics. A major shortcoming was identified as regards the deployment of competent or well briefed personnel: of 14 gynaecology clinics, one had evidence of completion of Specialist Training Course 1, of seven urology clinics two had a certificate of competence and one evidence of completion Specialist Training Course 1, of 14 cardiology and cardiac surgery clinics three had a certificate of competence and one evidence of completion Specialist Training Course 1.Two gynaecology clinics reported reprocessing staff had received a briefing from the hospital infection control team but that did not apply to any of the urology or cardiology and cardiac surgery clinics.

That finding was deemed to be a shortcoming: medical device reprocessing calls essentially for qualified reprocessing staff members. The majority of reprocessing personnel such as the hospital nursing staff and midwives do not have such a qualification or experience of having exercised a relevant professional activity as required by the German Medical Devices Operator Ordinance (MPBetreibV) 2017, e.g. Article 5 (1) ("Up-to-date knowledge by virtue of appropriate training and exercise of a relevant professional activity") and Article 7(2) ("Maintenance shall only be entrusted to those persons who meet the prerequisites stipulated in Article 5"). A competent person is deemed to be someone with evidence of having successfully completed training in a relevant medical profession whose outline curriculum covered the requisite content. Article 4(2) MPBetreibV states: "Training or knowledge and experience" are in any case a criterion for operating and using the respective medical devices. Doctors, nurses and healthcare staff and other medical professionals may reprocess these specific devices if they have received a briefing from the manufacturer or the hospital infection control team.

Use of disinfectants

All hospitals used disinfectants on the VAH List for reprocessing the probes. The disinfectants used by both 14% of gynaecology and of urology clinics were not endowed with the specific efficacy spectrum needed to assure patient safety (here: human papillomavirus), thus putting patients at risk for infection because of the examination.

Use of protective sheaths

Another important aspect of patient protection relates to the use of sheaths as required and also mandated by the KRINKO/BfArM Recommendation [18]. From the infection control policies submitted in the context of our study, it can be seen that 90% of urology clinics, 75% of gynaecology and 60% of cardiology and cardiac surgery clinics used protective sheaths.

During routine inspections by the Department of Health and the Environment of the City of Munich (RGU) the reasons put forward by TEE users for not using sheaths were the lack of acceptance by wake patients of such examinations as well as the fear that the use of a sheath would degrade image quality. But there is no degradation of image quality if the gel is applied properly to the probe, without creating any bubbles, before fitting the sheath. Degradation of image quality is more an indication of a leak in the probe jacket (crack formation!). To date, the quality of these sheaths is not regulated by any particular standards.

Infection control policies, standard operating procedures and reprocessing documentation

Not all hospitals have in place the prescribed infection control policies: one out of 14 hospitals (14%) had no infection control policy for TVUS reprocessing, while four of seven urology clinics (57%) did not have such a policy for TRUS reprocessing One cardiology clinic, which used two reprocessing processes for TEEs, had a written policy only for one process.

In their responses, three urology clinics made reference to their TVUS policies. Only from one out of seven urology clinics could retrospective evidence be found regarding the use or reprocessing of critical B class ancillary instrumentation.

The quality of the content as presented in the inspected infection control policies was not correlated with the hospitals' level of care category. No infection control policy set out all requisite parameters for reprocessing of probes, handheld attachment, connecting cable, power plug, ultrasound machine as well as for the release for use and storage modalities. Some standard operating procedures contained the erroneous information that the cleaning step could be omitted if sheaths were used.

The present authors particularly applaud these aspects since all policies had been drawn up by infection control personnel. Very few gynaecology and urology clinics (one and two, respectively) had documented reprocessing, but all cardiology and cardiac surgery clinics did that. Incomplete reprocessing policy and failure to doc-

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ument proper and complete reprocessing can in principle have liability implications for reversal of the burden of proof in the event of damage.

Problems identified for users

From the survey, review of the manufacturer's instructions for the probes used and a review of the disinfection documentation can be seen that several problems were identified for the users. For example, when several types of probes are used at the same time within a hospital or department but which must be reprocessed in a different manner. That was true in particular for the TEE probes: 13 hospitals had 17 policies for manual and partially automated reprocessing.

Users also had problems in some cases when using disinfectants: manufacturers specify different products for reprocessing their probes. If the user then was using probes from different manufacturers, based on the specifications for essentially the same reprocessing process, they would have to not just maintain a supply of the various disinfectants and use them but would also have to validate each variant of the reprocess process.

Disinfectant manufacturers also prescribe different methods for a final rinse for the reprocessed probes. Some manufacturers state that for reasons related to cytotoxicity and allergy risk a final rinse is needed, other manufacturers take an opposite view and back that up by presenting expert opinions. There is no data to substantiate issues related to material compatibility when fitting the next protective sheath after using peracetic acid based products chosen for their toxicological safety.

A practical analysis of various TVUS wipe disinfection methods carried out during the study by the infection control nurse of the author group in one hospital revealed that on using wipes impregnated in disinfectant it was virtually impossible for one person to execute, with due regard to hygiene, the individual reprocessing steps prescribed: rinsing the probes used and reprocessed in the OR area was difficult since there were no water outlets in these examination areas.

Withdrawal of the wipes from the dispenser was possible only when using both hands; because of its design and low tare weight, the dispenser would fall over if one tried withdrawing a wipe with only one hand. The subsequent wipes needed to assure proper reprocessing would then inevitably have to be withdrawn with the contaminated hand/contaminated glove: it is not possible to replace the gloves since the probe cannot be put aside when reprocessing it. That observation has been supported by a study by Büscher et al. which investigated automated as well as manual reprocessing of 240 TVUS. They demonstrated that automated reprocessing compared with annual reprocessing had a significantly higher success rate (91.4% versus 78.8%, $p = 0.009$). For manual reprocessing the risk of contamination was 2.9-fold higher (odds ratio, 2.9, 95% CI, 1.3–6.3). Following manual reprocessing 36 different species of bacteria were detected on the probes, including pathogenic bacteria such as *Staphylococcus aureus*, *Enterobacteriaceae* and *Pseudomonas* spp. [26].

For immersion disinfection and the partially automated processes not all equipment components were reprocessed: the probes were disinfected only as far as the antikinking point, but manual wipe decontamination of the handheld attachment, cable and power plug is needed in all cases and these steps should be standardized. Likewise, when using hydrogen peroxide-based plasma processes precleaning/cleaning is needed but these processes have the advantage for the user that special components can also be reprocessed in the plasma step, thus obviating the need for subsequent rinsing. There are manufacturer's instructions for TEE reprocessing that fail to take account of the handheld attachment.

In the case of the TEEs there is the problem that to date, unlike endoscopes, it has not been possible to subject these to automated reprocessing in endoscope washer-disinfectors (EWDs): they contain heat-sensitive components (transducer) and permeable hand attachment/flexion controller. As regards the TRUS it must be borne in mind that while single-use biopsy needles can be employed, puncture adjuncts and guide tracks which are classified as critical B devices for reprocessing purposes are also used: that mandates automated cleaning/disinfection, followed by steam sterilization in the RUMED.

No quality assurance standards for reprocessing

For quality assurance reasons the trend for many years now has increasingly been towards medical device reprocessing in the RUMED, but where probes are concerned decentralized reprocessing at the point of use is common. From its routine inspection of hospitals, the Department of Health and the Environment of the City of Munich (RGU) is aware that this is done not just in the examination suites but also in areas used for disposal of materials.

Unlike the practices used to reprocess probes that come into contact with mucous membranes, standardized reprocessing specifications are applied to the endoscopy setting [18, 20] and have also been approved by the specialist societies [27]. Nevertheless, endoscopy examination is still viewed as a high-risk examination from an infectiology perspective [9] and the issue of the responsibility borne by the manufacturer for technical changes that have implications for patient safety and impede flawless hygienic reprocessing is currently the subject of critical debate [28].

At present, there are no official recommendations for probes that come into contact with mucous membranes; the design-related features that hamper hygienic reprocessing have been outlined above. Endoscopes are likewise addressed in the KRINKO/BfArM Recommendation [18], with Annex 8 containing specifications on the "Requirements for hygienic reprocessing of flexible endoscopes and endoscopic ancillary instrumentation: Subpara. 4 "Quality assurance of hygienic reprocessing recommendations on how and at what intervals the reprocessing results are to be verified." For the probes there are no such binding regulations or related recommendations. The British Society of Radiologists already drew attention to this problem in 2012, which is thought to be due to that the lack of awareness of the issues involved, and called for the formulation of national guidelines [29].

In our study the reprocessing outcome was not in principle verified for the TVUS and TRUS, and only in half of hospitals for the TEEs. In the latter case verification was based on microbiology tests, conducted at quarterly to yearly intervals. The test methods applied included swabbing techniques using wipes or sponges. This was a test of the outcome that does not necessarily give any insight into the efficacy of the reprocessing process. Such tests are of benefit only when conceived as an adjunctive measure.

Limitations of the study

The overall sample size was small and from the Munich setting it is not necessarily possible to conclude how matters are in other

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cities and healthcare institutions. Validation documentation was not expressly requested. Nor were office-based medical practices surveyed in this regard.

Conclusion

In summary, reprocessing of ultrasonic probes that come into contact with mucous membranes continues to be an unresolved problem – with liability implications for the premises operator as well as for the users, and with potential infection risks for the examined patient. There appears to be greater awareness of the risks associated with TEE reprocessing, probably since there have been reports of outbreaks in the literature. Users are faced with the conundrum of having to deal with, in some cases, unimplementable manufacturer's instructions, on the one hand, and the need for rapid, feasible and effective reprocessing of probes, on the other hand. Regulation of the current situation, which is unsatisfactory to all participants, is urgently required. Guidelines must be compiled and published for appropriate, hygienic reprocessing of these medical devices. The manufacturer must be required by law to develop and place on the market medical devices amenable to reprocessing for this sector.

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