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Quality control protocols, scope innovations, and training refinements

Results from the Endoscope Hygiene Experts Forum

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From February 11–12, 2020, the Endoscope Hygiene Experts Forum (EHEF) held a roundtable discussion on the latest topics in the area of infection prevention in endoscopy. Renowned European and American experts from different professions came together in Berlin to discuss regional variations in endoscope processing requirements to create a better understanding of related key aspects for the prevention of infections. The discussions were moderated by Holger Biering, with each session co-hosted by a subject matter expert.

Each session was opened by a short presentation by a selected participant or a guest speaker. The discussion of the topic was open to all of the experts. Even though the expert meeting took place some time ago, the results of the discussions are to be shared with a broad professional audience and are briefly summarized in the following report.

Session 1: Overview of current processing quality control measures

Michelle Alfa, an infection preventionist from Canada, started this session to provide a comprehensive overview of the current available quality control (QC) measurements in North America. Table 1 provides an overview of presented QC measurements.

In more detail, the following aspects of the listed QC measurements in processing flexible endoscopes were discussed:

- Prior to (high-level) disinfection, the efficacy of the preceding manual cleaning step could be monitored by **ATP systems or tests detecting organic residuals**. ATP tests demonstrate variability in the level of soiling of the endoscope channels, which can depend on the complexity of the procedure, the timing of the procedure, and other variables [1]. Advantages of these kind of in-process controls include rapid test results and ease of use, which results in immediate feedback to the member of staff and might serve as a training opportunity. A disadvantage is that neither ATP nor organic residue tests reliably predict a microbial contamination of the endoscope, and so they cannot be used to classify an endoscope as patient ready. Although ATP testing after every manual cleaning process of each endoscope would be optimal, it appears to not be economically sustainable, so the question of the frequency of these tests remained unanswered, e.g., how often each duodenoscope should be tested and is a weekly test suitable for all other endoscopes? In the case of test failures, re-cleaning and re-testing of the endoscope would be necessary in the event that a pre-defined threshold is exceeded. It was agreed that performing the tests themselves on a routine basis, as well as the necessary re-clean, represents an unreasonable additional workload. In Europe, at least, processing is mainly done using endoscope washer-disinfectors (EWD) and this is certified during the validation/performance qualification. Either this process reliably cleans and disinfects the flexible endoscopes, and can therefore be trusted, or it does not. Experts considered whether the endoscope manufacturers could weigh in, suggesting a reliable marker or method to certify that a scope is sufficiently clean for patient use.
- **Borescope inspection** of the instrument channel of certain diameters of flexible endoscopes has provided some important observations, e.g., when using simethicone, an oily mixture of silicone and oxygen or residual moisture [2, 3]. However, this method is limited by the endoscope channel diameter, and typically can only be used in the channel that is accessible for brushing, meaning that

inspections cannot be conducted in the additional vulnerable channels, such as the air and water channels. Despite the ability to see moisture, damage, and residuals such as from simethicone, guidance is lacking on when to conduct these inspections (e.g., after manual cleaning, or at some other point), how to interpret the findings, and what type of actions are needed. To make use of it, healthcare professionals need a fully developed grid and guidance.

- **Microbiological surveillance** of patient-ready endoscopes is another option. This quality tool would address the direct patient risk. However, sampling & culture protocols vary widely throughout the world, as do interpretation criteria. In some regions of the world, microbiological surveillance can include testing of the final EWD water. Most of the protocols do not list microorganisms that are present in our environment, and data suggest that environmental contaminants can survive the cleaning and HLD process. Thus, ignoring environmental microorganisms that could provide protection to critical microorganisms of human origin in endoscopy might be a problem. Given these complexities, all roundtable participants would welcome a globally harmonized, evidence-based sampling protocol and reliable interpretation criteria.

During the discussion it became apparent that endoscope contamination is a persistent reality and that its causes need further research. A systematic review conducted by Larsen and colleagues suggests a duodenoscope contamination rate of up to 15.25%, within the context of a wide variability of sampling and testing protocols [4]. These data were supported by Lionel Pineau, who shared his observations of contamination rates of endoscopes in France, where it is required that all endoscopes are tested at least once a year. Data from 45,000 endoscopes sampled between 2004 and 2019 were presented, including their interpretation criteria (presence of microorganisms expressed as target level vs. alert and action level, see [5]). For the test period, these results showed that around 20% of endoscope models tested were in a non-controlled condition (i.e., the level of microorganisms is equal to the alert and action level). These findings show that, even in countries with QC required by regulations, duodenoscopes still have a contamination rate of around 10%. **Panelists agreed wholeheartedly that contamination rates should not be interpreted as infection rates.** Considering these French numbers and current post-market surveillance data (PMS 522-activity) in the USA for duodenoscopes from different manufacturers, which gave findings of around 5%, a number reproducible across all duodenoscope manufacturers, it appears very difficult to accomplish the very low contamination rate of 0.4% as defined by the Food and Drug Administration (FDA) [6,7]. Although the data are difficult to compare due to differences in the sampling and culturing protocols between the USA and France, the expert consensus is that the FDA targeting less than 1% is not realistic. There seems to be a core underlying issue that has not yet been understood and addressed.

Contamination rates should not be interpreted as infection rates.

In summary, apart from the endoscope design itself, the experts agreed that cleaning performance is key to successfully following steps employing either disinfection and/or sterilization. Easing the process through automation and/or developing new cleaning technologies combined with in-process monitoring, with the aim of entirely bypassing the manual cleaning process as much as possible, might be helpful to eliminate human factors. However, as long as the reprocessing efficacy relies on manual cleaning steps, a defined method/test to assess the successful outcome of the cleaning is needed. Verification of cleaning efficacy is important, and if that were part of the manufacturers' IFU, every processing site would do it. The roundtable reached the consensus that it is unrealistic to test each endoscope before disinfection,

Table 1: Tools for quality control monitoring in flexible endoscopy

Quality control measurement	When to perform?	Pros	Cons
ATP tests, other organic residue tests (e.g., protein)	After manual cleaning	▪ Fast and safe to perform ▪ Direct feedback to personnel	▪ No prediction of microbial contamination ▪ Additional workload ▪ Frequency of testing unclear ▪ Duodenoscopes only or all endoscope models to be tested?
Borescope inspection	After manual cleaning?	▪ Visual inspection of lumen	▪ Instrument inspections limited by inner channel diameters ▪ Interpretation and possible actions not yet defined
Microbial sampling and culturing of patient-ready endoscopes	After cleaning and disinfection? Or after drying / storage?	▪ Addresses direct patient risk ▪ Established method in some countries	▪ Takes time until results are available ▪ Questions over endoscope quarantine ▪ Variable culture protocol and interpretation criteria worldwide

given the burden on the reprocessing staff. However, periodic testing, e.g., in the context of validation or requalification of EWD based on a schedule, a number of processing cycles and/or as a function of test results might be reasonable. If in-process controls are introduced, standardization is needed so that healthcare personnel can reliably interpret rapid cleaning monitoring results (e.g. ATP), understanding what the results mean and how to respond to them. Such a cleaning monitoring test needs to be substantiated by validated clinical data. For the time being, it is suggested that routine microbiological sampling should be performed monthly or up to 4 times/year to identify endoscopes with a high contamination rate.

Session 2: Improvements and innovation in flexible endoscopy

The endoscopy landscape is changing with the addition of disposables: bronchoscopes, flexible intubation scopes, cystoscopes, and ureteroscopes. The more recent market entrant is the disposable duodenoscope, promoted by manufacturers as a solution for overcoming complex reprocessing issues. The FDA made an industry recommendation to consider the adoption of disposable duodenoscopes in August 2019 [8].

The introductory speeches from US gastroenterologists Bret Petersen and Michael Kochman started the first part of this session focusing on the endoscope design. The pros and cons of disposable and reusable endoscopes were discussed. The results of initial simulated uses and clinical studies with the disposable duodenoscopes were shared. A bench model comparison of the disposable duodenoscope and the reusable legacy duodenoscopes from various brands showed no significant difference in handling [9].

Table 2 below summarizes the advantages and disadvantages of disposable and reusable endoscopes.

In this session, the panel considered the "big question" – how to reliably provide endoscopes free of microbial contamination and reduce the risk of infection to patients. Studies show that contaminated endoscopes do not always lead to patient infections, even when multidrug-resistant bacteria are detected (10), which means that contamination rate and infection rate differ. The acceptable rate of contamination is unknown, as is the acceptable rate for culture positivity. Although contamination does not mean infection, the public expects zero contamination; therefore, it is a public relations issue, and the major benefit of disposable endoscopes is strengthening the hospital's reputation. By using sterile scopes, a simple, secure, and immediate solution is available. Within this framework, it was suggested that the guiding principle of radiation safety: ALARA, or As Low As Reasonably Achievable, is an appropriate lens through which to view endoscope contamination rates.

While research shows that flexible duodenoscopes can be successfully reprocessed, challenges remain (10, 11).

Compliance with IFUs is difficult to manage with their overwhelming size and innumerable steps. This becomes even more complex in cases where multiple endoscopes from different manufacturers are used in one unit. As cleaning efficacy is key, potential improvements include:

- Reduction of human factors when/where possible.
- Simplification of steps and cleaning accessories when possible/compatible with WD processing.
- Optimization of IFUs with images and videos (with regard to user-friendliness).
- Use of virtual reality tools in the reprocessing area for training/instruction.

If the efficacy of the procedure is the same and the device is not going to transmit patient-to-patient infection it boils down to the cost and the storage issues. Generation 1 of disposable duodenoscope is currently available, and there will be incremental change. Issues will change as the ability to produce disposable devices increases, and the cost point will drop per unit.

As it stands, the experts speculated that replacing legacy duodenoscopes with disposables will not result in significant savings, because ERCP procedures represent about 10 %

Table 2: Pros and cons of disposable endoscopes in comparison with reusable endoscopes

	Disposable endoscopes	Reusable endoscopes
Pros	▪ Patient safety benefit: Eradicates risk of exogenous transmissions – major benefit: reputational risk versus insurance ▪ May simplify management of endoscope stock (e.g., purchase, surveillance, overhauls, cultures) ▪ Potential to change interfaces easier ▪ No processing required	▪ Reproducible specifications of legacy endoscopes ▪ Reproducible elevator force of duodenoscopes ▪ Integrated into the ecosystem: documentation, processing, etc. ▪ Insignificant relief to processing function of a typical unit as duodenoscopes reflect only a small percentage of volume that includes reprocessing balloon enteroscopes, endoscopic ultrasound endoscopes, specialty endoscopes, etc.
Cons	▪ Functionality has not been established in comparison to legacy endoscopes ▪ Environmental aspects, such as the amount of waste (incineration vs. parts recycling) ▪ More storage space needed ▪ Ethical aspect of availability, as all patients should receive the same standard of care ▪ Costs ▪ Lack of safeguards to prevent reuse	▪ Maintenance (i.e., downtime, costs) ▪ Variability in processing (technique, technology, chemistry, process verification) predominantly depending on human factors ▪ Complex design of duodenoscopes ▪ High bioburden after use ▪ Overwhelming IFU ▪ Loss of public trust

of endoscopic procedures. Capital equipment still has to be maintained for reprocessing the remaining inventory for more common endoscopic procedures, in addition to special procedures for neonates, the pediatric population, and procedures such as endoscopic ultrasound fine-needle aspiration, none which currently have disposable endoscope options. Another concern voiced by participants is preventing reuse of one-time devices and environmental sustainability concerns related to disposables. Societies seem to be taking a wait-and-see approach in this unstable and moving environment. Will the disposable duodenoscope reduce the infection rate? Will the disposable endcap yield the same legacy data or an improvement? Instead of switching to disposable scopes, it was suggested that the focus should first be on how to move forward with legacy duodenoscopes. Multiple data-driven solutions should be approached, such as evaluating endoscopes with a removable distal cap, a structured post-market surveillance approach addressing real-world efficacy, and improvements to IFUs.

How clean must a medical device be for its intended application?

In light of this, the question of how clean a medical device needs to be for its intended application is important. Within the framework of duodenoscope processing quality, in 2015 the FDA proposed sterilizing them, among other measures [12]. Due to their heat-sensitive nature, most flexible endoscopes are not allowed to exceed temperatures of 60 °C, which limits the methods used to low-temperature sterilization methods. At this moment, no hydrogen peroxide sterilization technology is compatible with duodenoscopes.

Low-temperature sterilization of thermolabile endoscopes with vaporized hydrogen peroxide

- In the context of potential low-temperature sterilization methods, guest speaker Dr Ulrike Prüfert-Freese from the Municipal Department 39 – Testing Centre, Inspection and Certification Body in Vienna presented initial test results, which impressively showed that the effectiveness of this type of sterilization with vaporized hydrogen peroxide is limited in the presence of organic and inorganic residues. Results in the test setting were not always reproducible, and current limitations of this technology are justified (the "lumen claims" limiting the portfolio of sterilization to certain endoscope models based on the channel length and diameter) as lumen up to 500 mm (Teflon) length proved to be successfully sterilized by hydrogen peroxide sterilization. It became challenging when adding proteins or inorganic soiling (e.g., hard water) and/or stainless steel. Residual humidity also plays an important role as it prevents the sterilization process from getting started. Further tests are under preparation to verify these initial results.
- The results clearly showed that there is still a long way to go in order to have a validated and reproducible hydrogen peroxide sterilization process. Decisions on the reprocessing method used – either (high-level) disinfection or sterilization – should be taken with care: Hydrogen peroxide sterilization seems to be challenging in the presence of residual protein, whereas disinfection is tested under clean and dirty conditions, thus providing a higher safety margin. Therefore, if the endoscope is clean then disinfection seems to be sufficient and there is no need to sterilize the endoscope. Furthermore, hydrogen peroxide sterilization requires dry channels in order to be recommended, thus drying conditions must be further specified and a test for residual humidity would be helpful. ISO 15883-5 defines what is clean, and this level should serve as the basis for disinfection or sterilization and should be reflected in the test conditions.

To summarize this session, it is currently impossible to say whether all flexible endoscopes will be replaced by disposable scopes. The transition phase is from legacy endoscopes and the current chemistries and technological components to an environment of proven sterility and single use devices. It will vary by device, as some will not be replaced but, for others of equivalent function, it will boil down to access and cost. Disposable endoscopes have the potential to gain market share (10–15 %) in the future, especially duodenoscopes, but adoption rates will vary among practices/institutions. Moreover, innovations in sterilization technologies could temper the adoption of and interest in single-use endoscopes.

Session 3: Advancements in securing individual reprocessing steps

Continuing education and certification are key components for reprocessing staff competences, and a hybrid of digital platforms and in-person learning can address these needs. In this session, Ulrike Beilenhoff, endoscopy nurse, president of DEGEA (German Society: Deutsche Gesellschaft für Endoskopiefachberufe e.V.), and scientific secretary of ESGENA (European Society of Gastroenterology and Endoscopy Nurses and Associates), and Harry Oussoren, an expert in sterile medical device reprocessing and current Vice President of WFHSS (World Federation for Hospital Sterilization Sciences), said that in-person learning can be supplemented with social media platforms, e-learning, and webinars, with hands-on-training at the top of this list. The use of a multimedia platform allows for more individualized learning in terms of the type and pace of learning, and all processing staff need adequate time for continued learning.

The general training approach is supported by the recent ESGENA curriculum [13] consisting of 6 modules. A three-and-a-half day course is recommended for qualified staff, with 3 weeks of study for non-qualified staff. In addition to reprocessing, the training includes endoscopic design, logistics, managing loaner devices, the basics of microbiology, and surveillance of endoscope reprocessing, as well as occupational health, see figure 1.

In Europe, training courses consist of 75 % theory to provide an understanding of what to do, and why and when to do it, as well as 25 % hands-on training. One-day refresher courses are offered for continuing education. The discussion revealed a wide variation in training duration and qualification across the globe. European endoscope training ranges from 10 to 120 hours, while in the US, there is up to 480 hours hands-on-experience, depending on the state, and finally a national exam. In the Netherlands, healthcare facilities' websites show that there is value in marketing the

EHEF participants (from left to right, from back to front): PD Dr. Holger Biering (Germany), Dr. Lionel Pineau (France); Dr. Bret Petersen (USA), Ulrike Beilenhoff (Germany), Dr. Ulrike Prüfert-Freese (Austria), Ross Segan (USA), Lea-Anne Myers (USA); Dr. Michelle Alfa (Canada), Prof. Dr. Heike Martiny (Germany), Damien Berg (USA); Prof. Dr. Michael Jung (Germany), Dr. Florian Brill (Germany), Dr. Michael Kochman (USA), Harry Oussouren (The Netherlands). (Photo: EHEF)

qualifications of processing staff, and that these qualifications provide transparency due to open access to audit reports. In Germany, non-compliances during audits may lead to penalties, e.g., the closure of processing areas.

In the subsequent discussion, the experts discussed how endoscope manufacturers themselves can contribute to supporting sustainable knowledge building. They are convinced that IFUs for endoscopes need to be easily accessible and understandable, e.g., a short, mainly picture-based version for all processing staff, and an extended version for experts. In addition, short video sequences should support the IFU; if these are provided by manufacturers, the uncontrolled development of self-made user videos might be reduced. Manufacturers and societies should seek a combined approach to demonstrate correct handling and digital delivery of videos. Within this framework, it is important to keep healthcare workers up to date on medical advances. With continuing education, workers' personal development and careers can be advanced, and this is more likely to lead to informed and well-calculated decisions that can reduce dependency on others. Generating professional satisfaction and identity may help to prevent burnout and, last but not least, will improve patient outcomes.

To summarize this session, training is increasingly important for onboarding new staff as well as reinforcing knowledge and updating existing staff. The ESGENA curriculum in Europe has proved to be an excellent tool for providing a comprehensive continuing education program, including theory and practice, and helps to adapt the requirements for endoscopy staff. The experts also encourage a multimedia approach to optimize competencies.

Expert consensus on all EHEF sessions

Overall, it was a successful event with lively participation in fruitful discussions. Key takeaways and experts' recommendations are highlighted below:

- Quality control measurements should be performed in endoscopy units. For the time being, it is suggested that routine microbiological sampling should be performed at predefined intervals.
- Depending on the sampling & culturing protocol, the results show variability and are hardly comparable. The FDA targeting a contamination rate of less than 1% for duodenoscopes is not realistic, and there seems to be a core underlying issue that has not yet been understood and addressed.
- Single-use endoscopes will gain market share and become virtually equivalent to reusables, while their disposal will be an ongoing concern.
- Decisions on the reprocessing method used – either (high-level) disinfection or sterilization – should be carefully weighed up. Research presented on hydrogen peroxide sterilization suggests that this sterilization method is highly dependent on materials and lumen parameters. Moreover, the presence of residual protein presents a challenge in achieving reproducible efficacy results.
- Continuing education at all levels plays an important role in building knowledge and making sustainable use of it, while at the same time the variety of (new) media should be used to serve individual learning paths.

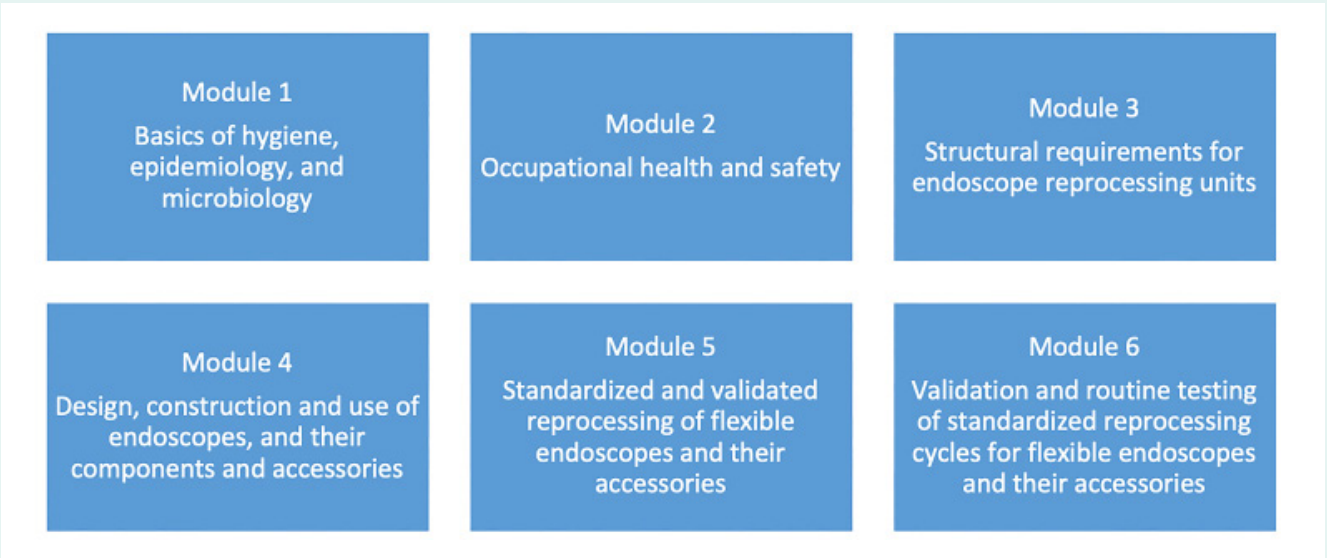

Figure 1: Learning modules according to the ESGENA curriculum [13]

We are grateful to all participants for their presentations, expertise, and opinions, and hope to see the EHEF reconvening soon to revisit the many opportunities to improve as the field evolves.

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