Second European Hygiene Experts Forum “Hygiene in Endoscopy” in Hamburg

Birgit Kampf, Olympus Europe SE & Co. KG, Hamburg, Germany

In the context of the 2nd European Hygiene Experts Forum (EHEF), current topics on questions of “hygiene in endoscopy” have been discussed by a group of experts from different professions – including doctors and endoscopy nurses, heads of reprocessing units for medical devices, microbiologists and hygienists.

Participants from Croatia, the Netherlands, France, Great Britain, Sweden and Germany – as well as from the USA due to current developments – accepted the invitation to Hamburg for this independent round table discussion under the moderation of PD Dr. Holger Biering. The intention of this forum in cross-regional approach was to better understand the motives and requirements with regard to the reprocessing methods of flexible endoscopes in the USA and Europe and thus contribute with this expert discussion to improve patient safety in endoscopy.

Following topics have been discussed in three sessions in the course of the 1.5 days:
- Sterilisation of flexible endoscopes: a globally harmonised approach/method?
- Compliance in endoscope reprocessing
- Routine testing and hygienic monitoring in endoscope reprocessing.

Each session was opened by a short presentation by the participants or a guest speaker. The topics were discussed in detail and very openly among the experts and briefly summarised at the end of each session. In the following, please find the results of the three discussion rounds.

- **Sterilisation of flexible endoscopes: a globally harmonised approach/method?**
  
  This session started with a contribution by Damien Berg (USA) and Prof. Dr. Michael Jung (Germany). Both speakers presented the current state of discussion on the reprocessing of flexible endoscopes, in particular with respect to the transmission of multi-resistant pathogens via duodenoscopes.

  Recently, increased attention is being paid to duodenoscopes and their reprocessing due to their complex design. This means that for endoscopes inserted through natural body orifices into the interior of the body, the focus in Europe is on thorough cleaning in accordance with the endoscope manufacturer's instructions for use and subsequent mechanical cleaning and disinfection.

  A modification of the Spaulding classification as well as the associated re-classification of thermo-sensitive endoscopes as critical medical devices, for which sterilisation would then be mandatory, is being discussed in this context in the USA.

  **Thorough cleaning according to manufacturer’s instructions is prerequisite for successful reprocessing.**

  It is undisputed among experts that the sterilization of flexible endoscopes used in sterile areas of the body and not inserted through natural body orifices (e.g. intraoperative endoscopy, cholangioscopy), is necessary.

  As described in the ESGE-ESGENA position paper [1], recommended practice in Europe is still thorough manual cleaning followed by machine cleaning & disinfection in washer-disinfectors for thermo-sensitive endoscopes (EWD)
with the requirement to strictly follow the manufacturer’s instructions for endoscope reprocessing. In addition, microbiological monitoring has been regarded as an important quality control in many European countries for decades. Studies have shown that microbiological testing allows to detect both deficiencies in the reprocessing process as well as defective endoscopes [5]. It was also discussed to which extent sterilisation would actually offer greater safety – which remains unclear on the basis of the current data. Additionally, recent publications show that after double disinfection [2] and ethylene oxide gas sterilisation, the removal of multi-resistant pathogens is not always possible [3].

It remains unclear to which extent sterilisation would actually offer greater patient safety.

Both the success of disinfection and sterilisation processes depends on:
- the design of the endoscope channels
- the previous thorough cleaning
- human factors, such as time pressure, staff qualification/training, equipment for reprocessing
- the handling of process fluids and accessories
- the restrictions on lumen length and diameter of the sterilising methods.

Whether sterilisation would bring an additional gain in patient safety if all the points described as key factors could be implemented sustainably remained open at the end of the discussion.

To sum up, the panel of experts agreed that only thoroughly cleaned endoscopes can be successfully disinfected or sterilised. In view of internationally differing test methods and test soils for determining sterilisation efficacy, its standardisation is necessary as is currently being discussed in the revision of Part 5 of the ISO 15883 standard series for the cleaning efficacy [6].

Compliance in endoscope reprocessing

The second session was introduced with a guest speech by Prof. Dr. Günter Kampf presenting examples of verifiably successful elements of patient safety campaigns. The question was treated to what extent successful elements from these campaigns can be implemented to attain better compliance in endoscope reprocessing:

It is known from the WHO campaign for the prevention of surgical site infections that the mortality rate could be reduced from 1.5 to 0.8% and the infection rate from 11 to 7% whenever a checklist “Surgical Safety Checklist” – before anaesthesia/before skin opening/after surgery is being used. The question was raised whether a similar checklist could be helpful in endoscope reprocessing. It is important for user acceptance that it refers to the essential aspects and does not lead to a larger additional effort.

The WHO Clean Hands campaign identified and presented the four aspects considered to be effective and contributing to increased awareness, namely

- the role model function of managers,
- the announcement and implementation of sanctions for non-compliance with hygiene measures,
- the great help when there is easy access or visibility to hand disinfectants, and
- the creation of a feedback culture with immediate as well as direct feedback.

These “soft” aspects were supported in the second introductory speech by Dr. Helen Griffiths on challenges in education on the example of Great Britain, where special courses for these “soft” aspects have already been introduced.

Training and qualification of reprocessing staff play a major role in compliance in endoscope reprocessing.

In the subsequent discussion on how to improve compliance in endoscope reprocessing, the training and qualifications of reprocessing staff play a major role. It became clear that there are big differences in Europe. In any case, the support of endoscope manufacturers – either via training, or user-friendly instructions for use – is regarded as an important component. ESGENA has developed an European Curriculum for reprocessing in GI endoscopy which will soon be available (in press) based on the European job profile for endoscopy nurses.

Routine testing and hygienic monitoring in endoscope reprocessing

In the introductory speech Ulrike Beilenhoff presented different possibilities of hygienic monitoring of thermosensitive endoscopes but also of EWD and/or water quality by means of the ESGE/ESGENA Guideline [7] compared to national guidelines. According to the ESGE/ESGENA guideline, hygienic microbiological monitoring is routinely recommended every 3 months, with each endoscope being examined at least once a year. In addition to the endoscopes themselves, monitoring of EWD and water quality is also described. Immediate action is required in case of incidents.

Microbiological sampling of flexible endoscopes has been regarded as an important quality control in many European countries for decades. This wasn’t the case in the USA so far; since February 2018 the final FDA/CDC/ASM guideline for sampling duodenoscopes is available [12]. During the discussion it became quite clear that national European approaches might differ. Routine sampling in endoscopy focuses in some European countries on EWD and/or water quality [8, 9]. In countries like France and Germany endoscope sampling plays a major role [4, 10]. However, the methods vary and therefore a comparison is hardly possible.
Microbiological sampling of flexible endoscopes has been regarded as an important quality control in many European countries.

According to ESGE-ESGENA recommendation 2007 [7], for thermo-sensitive endoscopes a sampling has to be carried out in external surfaces, all channels as well as, if necessary, other critical surfaces, like the albarran lever of duodenoscopes. On national level, only special endoscopes such as duodenoscopes [12] or all types of endoscopes [4, 10, 7] may be sampled. During sampling, different rinsing fluids (e.g. sterile distilled water or common saline, rinsing fluids with neutralisers), volumes, and methods of sampling (e.g. flush or flush-brush-flush or suction), time of sampling (immediately after EWD cleaning & disinfection or after a defined storage period?), etc. are being used. French studies show that recovery with sterile water and common saline is significantly reduced compared to rinsing fluids with neutralisers [11]. The type of sampling and the acceptance criteria may also differ at national level.

Another aspect discussed in this context was the handling of sampled endoscopes. In routine sampling, there was consensus that the endoscopes could be used further on the patient, if necessary after a further reprocessing. This is particularly important with bronchoscopes, for example, because otherwise the endoscopes would not be available for the detection of mycobacteria due to long incubation times. The situation is different in outbreak situations where the affected endoscope should be quarantined and, if necessary, the EWD blocked until final clarification.

The participants consider hygienic controls to be important. The participants agreed that further comparative studies on sampling and test methodology are desirable. All participants welcomed a uniform solution at European level, although it is worth mentioning that the ESGE/ESGENA recommendation from 2007 will be revised and should be available in a revised form by 2019.

On the whole, it was a successful event with lively participation in the discussion and our thanks go to all participating experts.

References
6. ISO DIS 15883-5: Washer-Disinfektors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy. 2018
12. FDA, CDC, ASM working group: Duodenoscope surveillance sampling and culturing protocols. 2018 https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCMS97949.pdf

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