Letters

Reprocessing bronchoscopes – is it time for a change?

Letter to the Editor from Prof. Dr. rer. nat. Heike Martiny, Technische Hygiene, Weygerweg 20, 12249 Berlin, Germany, and Prof. Dr. med. Ottmar Leiß, Bodelschwinghstr. 14, 65191 Wiesbaden, Germany, on the article by E. Bach: Reprocessing bronchoscopes – is it time for a change? Zentr Steril 2019; 27 (2): 114-117.

An explanatory commentary is needed on the publication "Reprocessing bronchoscopes – is it time for a change?" [1]. Since our article "Is sterilization of bronchoscopes and cystoscopes necessary? A discussion paper" [2] appeared in the same issue of the journal, we shall not put forward once again our arguments as they have also been repeated in various responses to Letters to the Editor on the aforementioned discussion paper as well as in relation to problems with drying endoscopes [3–5].

Whereas as stated expressis verbis our findings were based on German legislation, regulations and recommendations, Mrs Bach stated (in Table 1) "Devices intended for semi-critical use should also be sterilized if their constructional design permits that." (USA/FDA); "Semi-critical flexible endoscopes should preferably be sterilized." (Australia); "Semi-critical flexible endoscopes should preferably be sterilized but closely monitored HLD is currently permitted." (Japan); "Sterilization of semi-critical devices is deemed optimal." (Canada). Accordingly, in the sources cited by Mrs Bach, sterilization is not mandatory either. However, in that respect Mrs Bach omitted to point out that in the countries mentioned sterilization is not performed in addition to disinfection, as is the case in Germany, but rather instead of disinfection.

Mrs Bach then goes on to cite the KRINKO/BfArM Recommendation [6], stating "Bronchoscopes are advanced into normally sterile areas of the bronchial system. That implies more stringent requirements to assure a low microbial count (sterility)" (Germany). From the above enumeration she concludes: "A glance at the international guidelines confirms the trend reversal in the recommendations for reprocessing flexible endoscopes (Tab. 1)." We absolutely cannot endorse that conclusion.

The cornerstone of both publications [1, 2] is Annex 8, Appendix 6 "Reprocessing flexible cystoscopes and bronchoscopes" of the KRINKO/BfArM Recommendation [6], in particular Table 1 (page 1248), where the guidance to "Semi-critical B medical devices" draws attention to optional sterilization with the footnote "Possibly, for endoscopes used in sterile body regions" [6]. This leads Mrs Bach to address issues related to responsibility and decision-making on risk assessment and classification of medical devices by the user/operator on site, stressing that where there is doubt about classification, the medical device should be assigned to the higher (more critical) risk level. We would like to point out that in the years subsequent to publication of the KRINKO/BfArM Recommendation (2012) a specific microbiome has been identified for both the bronchial system and the urinary bladder and that, as such, the footnote cited above with regard to endoscopes used in sterile body regions can no longer be applied to bronchoscopic or cystoscopic examinations. That thus dispels any uncertainties about risk classification of bronchoscopes and cystoscopes, and the bronchial system and bladder can no longer today be regarded as sterile body regions.

However, that clarification puts to rest the attempt to newly interpret from one part of difficult risk classification the entire spectrum of bronchoscope reprocessing. There is no reason to overturn medical device reprocessing in general in Germany, as enshrined in the KRINKO/BfArM Recommendation from 2012, because of the previously upheld belief in the sterility of the bronchial system and bladder, which has now been unequivocally clarified.

We purposely refrain from commenting in detail on the arguments put forward by Mrs Bach (such as utilization of the available H_2O_2 gas plasma sterilizers, economic and logistic aspects). Critical readers of the two publications can themselves make a distinction between the medical/hygienic arguments and economic interests. But Mrs Bach's pivotal sentence "There are increasing reports about healthcare-associated infections (HAIs) linked to contaminated bronchoscopes" (Fig.1) [3, 4]." is incorrect. In the interest of good scientific practice, the following must be pointed out on the literature sources cited by Mrs Bach: The publication by Rutala and Weber dates back to 2013; that paper does not make any reference to an increase in infections linked to contaminated bronchoscopes, as claimed by Mrs Bach. The article by Kovaleva et al. is likewise from 2013. However, most of the literature sources cited by Kovaleva et al. in relation to bronchoscopy are more than 20 years old. That publication, too, makes no reference to an increase in the rate of infections, as described by Mrs Bach. The paper by McDonell and Burke was published in 2011. The outbreaks of disinfectant-resistant pathogens linked to endoscopic examinations or contaminated automated endoscope reprocessors can by no means be described as "recently" (reported outbreaks), as characterized by Mrs Bach, since virtually all date back much longer than eight years. Furthermore, while the publication by Culver et al. cited is from 2003 and thus does not qualify for description as "recent" reports, it also contains the following decisive statement: "To our knowledge, until 2003 [2, 3], nosocomial infections had not been reported in any case where all current guidelines were followed carefully" – and that in support of the argument that sterilization is additionally needed. That publication by Culver et al. also features Fig. 1 cited by Mrs Bach in her paper, without mentioning the source. However, in the original paper the bar graphs do not indicate the number of HAIs; rather, here is stated "Reports include pseudoinfections and true infections", but the statement "Most reports have described pseudoinfections" – i.e. false positive microbiology results – paints a totally different picture of that Fig. 1. The sentence "The most significant outbreak to date was reported in Brazil, and affected over 3000 patients following surgical or bronchoscopic procedures" is to be found in the publication by McDonell and Burke and not in that by Culver et al., as cited by Mrs Bach. Alas, authors McDonell and Burke also made a mistake because their cited source "Epidemic of Postsurgical Infections Caused by Mycobacterium massiliense" does not describe any link between those infections and bronchoscopic procedures [7].

Finally, a word about the statement made not just by Mrs Bach in her article but also appearing in the corresponding brochures of the firm ASP, suggesting that bronchoscopes used for therapeutic vs diagnostic purposes should be reprocessed differently. The source used to corroborate that statement is the KRINKO/BfArM Recommendation. However, the latter does not contain such a statement.

Medical devices, incl. bronchoscopes, used e.g. for surgical opening of the pleural space with the specific purpose of taking a biopsy (for histology or culture), for aspiration of a loculated effusion or detachment of fibrin deposits, must of course be sterile when put to use. But that is not the case for bronchoscopes advanced via the bronchial system.

References

1. Bach E. Reprocessing bronchoscopes – is it time for a change? Zentr Steril 2019; 27 (2): 114 – 117.
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3. Is sterilization of bronchoscopes and cystoscopes necessary? Letter from Dr. Thomas Fengler and Bruno Amann, Zentr Steril 2019; 27 (3): 190–192.
4. Martiny H., Leiß O. Sind Trockenschränke erforderlich? Ein Diskussionsbeitrag. Zentr Steril 2019; 27 (1): 25–27.
5. Sind Trockenschränke erforderlich? Leserbrief von Dr. Thomas W. Fengler, Cleanical GmbH, Augusta Hospital, Scharnhorststr. 3, 10115 Berlin, zu: H. Martiny, O. Leiß Sind Trockenschränke erforderlich? Ein Diskussionsbeitrag. Zentr Steril 2019; 27 (1): 25–27. Zentr Steril 2019; 27 (2): 93–96.
6. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstituts für Arzneimittel und Medizinprodukt (BfArM). Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsbl 2012; 55: 1244–1310.
7. Duarte R. S. et al. Epidemic of Postsurgical Infections Caused by *Mycobacterium massiliense*. J Clin Microbiol 2009; 47: 2149–2155.