„Only if we clean properly, can we disinfect correctly.“

Interview with Frau Professor Dr. Heike Martiny

We are happy to have won one of the most well-known hygienists in Germany for an interview with endoNEWS: Professor Dr. rer. nat. Heike Martiny (in the following abbreviated with HM).

Professor Dr. rer. nat. Heike Martiny
Technical Hygiene, Berlin

endoNEWS: Prof. Martiny, do we have to take additional steps during endoscopic reprocessing because of COVID-19?

HM: No, we must conduct the reprocessing as correctly as before. Additional measures are not necessary. The Commission for Hospital Hygiene and Infection Prevention (German: Kommission für Krankenhaushygiene und Infektionsprävention, KRINKO) recommends virucidal products for disinfection. Against SARS-CoV-2, already a limited virucidal activity would suffice. The efficacy against SARS-CoV-2 is also included in the surface disinfectants recommended by the KRINKO.

endoNEWS: The guideline by the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) recommends freshly preparing the cleaning solution for each endoscope if a cleaning agent (without disinfecting efficacy) is used.

HM: These requirements are not new. This was demanded by the Gastroenterological Societies in the USA even in 2003 [1]. There, everyone used enzymatic detergents and it was stipulated: Enzymatic detergents must be replaced after cleaning every endoscope. This has not been adopted in Germany. Apparently, also a majority in the ESGENA can see the increase in safety with this change. However, there are no references or studies on this, not even within the ESGENA-guideline [2]. It is indispensable, though, to validate the process with the “contaminated” cleaning solution.

endoNEWS: Is it justified that the ESGENA-guidelines are tightened? The KRINKO actually permits with cleaners – equally to the disinfectant cleaners – furthermore a work-daily replacement unless contamination is visible. The ESGENA, in contrast, recommends replacement of cleaners after every endoscope.

HM: With cleaning solutions the ESGENA obviously is not doubtful of the cleaning efficacy, but instead of the safety of the personnel. However, I do not consider the protection of the staff guaranteed with disinfectant cleaners either. At least I do not know of any meaningful data regarding this topic.
The disinfectant efficacy is typically substantiated by expert opinion under “dirty conditions”. However, “dirty conditions” are not comparable with a used gastro-, colo- or bronchoscope that has been placed in a formulation. In this case, the organic contamination is quite substantial, and I do not know of any data that show the efficacy of a cleaning disinfectant under these circumstances. On the contrary: The doctoral thesis of Patrick Haubrich shows, that disinfectants are not effective anymore, when they are confronted with larger organic contamination – larger than under “dirty conditions” [3]. He was also able to show that disinfectant solutions, that are listed with a potency of 5 log10, demonstrated in the experiments only an efficacy of 1 log10. I find this quite remarkable.

endoNEWS: With this in mind: Do you recommend to class cleaners and disinfectant cleaners similarly? In which interval should the user replace the solution?

HM: Definitely in the case of visible contaminations. And due to the high pathogen load, I recommend switching at least daily. But I know from teaching classes that in some areas, cleaners are actually replaced after every endoscope. We are in the process of developing a guideline for the validation of manual endoscope processing because nothing like this exists so far. The difficulty with this is that we do not have a testing specimen with which we can show the effectiveness of manual cleaning in endoscopy. If we take a test hose and brush it, we could check if it has been sufficiently brushed. But this has nothing to do with the actual conditions in the endoscope, because brushing there is much more difficult. If the endoscopes are pre-cleaned manually and are then reprocessed in the washer disinfector for endoscopes, we increase our safety by adding a second, automatic cleaning step. However, if we only reprocess manually, we cannot prove that we are cleaning properly. And only if we have cleaned properly can we properly disinfect.

endoNEWS: The other thing is the protection of personnel, which ESGENA is presumably trying to ensure with these recommendations.

HM: A possibility for infection exists already with the first endoscope as well as after the fifth. The ESGENA has defined the guideline in this way, but does not justify it, and there is no mentioning of references. By the way, ESGENA states “should not be reused”, not “shall”.

With regard to disinfecting cleaners, there are various questions to be clarified in advance with regard to personnel protection: Which active ingredient is contained in the disinfecting cleaner? Can it work despite organic contamination and how large can this organic contamination be for it to still be effective? Is the contact time adhered to?

endoNEWS: Does this mean, whether a cleaner or a cleaning disinfectant is used, that personal protective equipment must always and foremost ensure the safety of the personnel?

HM: Correct. Because when you put the first endoscope in the solution, you introduce between 10^9 and 10^{10} bacteria per channel. Let's say I have 10^9 on the first and second endoscope, respectively, that makes twice 10^9. With the third, I have 10^9 three times – that is not a large difference. The contamination does not get much greater because it was already high due to the first endoscope – which was highly contaminated. One always imagines that it will increase much more. Sure, there will be more, but when it comes to the power of ten, one or three billion are not relevant.

It is true that if the solution stands for longer periods and if it is warm in addition, another doubling is possible. Starting with twice 109 there will be possibly four times 109, if at all in the short time. So, that too can be ignored. By the way, this only applies to bacteria – viruses cannot multiply at all, they can only survive.

My message is this: Staff must always protect themselves. From the very beginning. And personnel protection is achieved first of all by wearing protective equipment. This has improved a lot in recent years, but you have to wear it. It is useless, if the mouth/nose protection is hanging under the nose, the visor is missing, or brushing is done above the water surface.

endoNEWS: Which trends do you see in endoscope reprocessing in general?

HM: In certain areas, the trend goes to disposable endoscopes. Especially on night shifts and during weekends, single-use bronchoscopes are increasingly used. Hospitals have calculated that it is cheaper to take a disposable endoscope than to let someone come in for endoscope reprocessing. A sensible trend.
A second trend goes towards single-use duodenoscopes. As far as I know, two companies here have already developed disposable products. The problem: Both companies say they cannot produce at a sufficiently low price to allow performing all ERCP with a disposable endoscope. A bit unsettling to me in this regard is the statement that it is necessary to choose who will be examined with a single-use endoscope and who will be examined with a reprocessed endoscope. That means, it is implied that one is not at risk with the single-use endoscope, but is at risk with the multi-use endoscope because it allegedly cannot be properly reprocessed. Just now, in the context of the Corona pandemic we have all learned that it is not so easy to decide which patient is at risk. And I fundamentally reject this decision as to who "may" get a disposable endoscope because reprocessing cannot be done safely. Also with reprocessing of duodenoscopes, staff must be sufficiently qualified to reprocess them properly. If this is not the case, this examination must not be carried out. These are moral and ethical issues. Otherwise, I have to ask myself whether I've been doing something wrong from the start. Or, even worse: Whoever can afford it, gets a disposable, and those who can't afford it get a reusable duodenoscope.

Another trend, at least in Germany, is the following: The authorities are more closely monitoring, and due to the tighter controls there is a trend to automated reprocessing. Small practices that cannot afford this will either give up or have the reprocessing done by service providers.

Part 2: Interview with Prof. Martiny. In endoNEWS 2020-07 we printed the first part of the interview with Prof. Martiny. Here you can read the second part.

endoNEWS: There are more and more demands for sterile endoscopes, especially in the area of bronchoscopy. What do you think about this?

HM: Whoever demands this may not know that insufficient cleaning of an endoscope prevents sufficient disinfection and proper sterilization. This desire is understandable, bypassing insecurities about reprocessing, it just does not help. We cannot provide more safety with an additional sterilization step. First of all, endoscopes suffer due to the additional sterilization measures, meaning that they break sooner. Secondly, there is an elaborate discussion by Prof. Leiß and me in the central sterilization facility (Prof. Leiß significantly contributed to annex 8 to the reprocessing of flexible endoscopes by KRINKO that is still valid). We have described, why sterilization fails and why it is unnecessary for most endoscopes. In contrast to previous understanding, the lungs for example are not sterile. There is a microbiome in the lungs – as is in the bladder. Also, the bronchoscope does not stay sterile on the way into the lungs – exactly as it is the issue with a cystoscope on the way into the bladder. Although there are very few data regarding cystoscopes. We do have those data regarding bronchoscopes. We know that there are 10^9 to 10^{10} bacteria inside the canal of the bronchoscope after examination. These bacteria stem from the organs along the way to the target organ. It is superfluous to sterilize an endoscope, if it will be highly contaminated before reaching the lungs or the bladder.

endoNEWS: Sterilization of cystoscopes is still mentioned in the guidelines, if they are used in an intervention …

HM: This is still mentioned, because for a long time we thought that the bladder was sterile, which is wrong. The microbiome was always there, we simply did not look for it. It would not be logical, because how should a sphincter be so tight that nothing can enter from a highly colonized urethra?

That means that an endoscope does not need to be sterile because the way to and the target organ itself are not sterile. And if one follows the guidelines for reprocessing in a valid procedure, only

few bacteria can be present, which may not be (facultative) pathogens. In contrast the endoscope has to be sterile, of course, if it is used in a surgical opening as for example in a pleura biopsy and if there should be no contamination of the body or of the specimen via the endoscope. Thus, we need sterile instruments if we do not reach the target organ via natural orifices of the body, but instead from outside. This is what the KRINKO recommendation means with the term interventions.

endoNEWS: Obviously ...

HM: Yes, in principle it is obvious. With duodenoscopes there was a great outcry because when infections with multiresistant bacteria occurred, it became clear what had been done wrong. Partly, it was recommended to reprocess twice – a very strange recommendation: If I am not successful cleaning and disinfecting the first time, it probably will not be better the second time. There were also attempts at sterilization with ethylene oxide – those were unsuccessful as well. All procedures at low temperature are very prone to problems when there is organic contamination. If I have not cleaned properly, I cannot sterilize either.

endoNEWS: That means that we always return to proper cleaning.

HM: Without thorough cleaning I can forget everything else. In that case it is not effective to do something in addition in the following steps of the procedure. It may ease my conscience, but it does not help the patient. Cleaning correctly has to be guaranteed! This requires a validated and, in my opinion, machine-based process. Because in manual reprocessing, especially with endoscopes, it is very difficult to guarantee a validated procedure in everyday life.

But I would also like to make it clear that I don't want to prevent anyone from sterilizing endoscopes. Anyone having enough capacity and money can do that. However, this should not make you believe to have improved something that had not been okay before. Everyone may sterilize their endoscopes – it simply should not be required.

endoNEWS: In your opinion, what is the proportion of endoscopes in Germany which are currently still completely reprocessed manually?

HM: I don't know an exact number. I just know that there are fewer and fewer. This is confirmed in classes and at events. But we have not only gastroenterologists who complete many training courses. For example, urologists still have some catching up to do. They have just suspended the examinations in practices because the hygiene costs have become too high for them. ENT doctors also work with endoscopes. There are these containers with an ominous liquid into which the endoscope is immersed. Here, too, there is still much to be done. The good thing about the guideline for the validation of manual reprocessing, which we are currently working on, is that all professional societies that reprocess endoscopes are involved, including the ear, nose and throat specialists. There is room for improvement. I assume that this guideline will roughly describe what the KRINKO says: If automated reprocessing is available, manual or partially automated reprocessing must be raised to the same safety level. It will certainly be difficult to achieve this, so manual reprocessing will be done less and less.

endoNEWS: When can we expect the guideline?

HM: That goal is a long way off because it is very difficult to establish a test specimen for proving that cleaning has been done correctly. We don't want to replicate the disinfectant testing but show that we can clean the endoscope. We do not have a simple test specimen for that.

We would have to address the different endoscopes – the entire endoscope families – that are covered in the annexes of 15883-part 4. In principle, manufacturers know that their endoscopes can be cleaned properly. But we don't know how to manually prove this in a practice. I would not dare to give a date. It definitely will take years.

There is still a big question mark regarding inspections. We have the KRINKO, the medical devices act and the operator ordinance. We must apply validated procedures for the reprocessing of all medical devices. This must be checked, and the authority does not check whether the manual reprocessing is validated. Actually, the authorities cannot control this, because there are no methods to do so.

endoNEWS: Right now, the authorities can only check whether the steps are being followed according to the rules.

HM: Yes, that's right. But no one knows for sure whether these steps are successful. And if we follow up with a hygienic-microbiological examination, then we know that in the end we can only rinse out a very small part of the microorganisms that are possibly remaining. And if in addition the endoscope has not been cleaned properly, the organic residues will stick on the wall of the channel, and these residues cannot be rinsed out with water or saline solution. Simply flushing something out gives poor reprocessing results. But if nothing comes out – because everything is fixed to the channel wall – then we simply don't know whether the reprocessing was okay. This troubles us all.

endoNEWS: The practices often say: Nothing has ever been noticed during the regular inspections. So, everything should be good ....

HM: That is exactly the problem. We have the residues firmly inside the channel and they will be simply pushed out by the endoscopic instruments, into the patient. To simply flush during regular examinations is not sufficient. As part of a group of methods in the afore-mentioned guideline-committee, we develop a sampling method: there we rinse, brush and rinse to increase what we get out of the channel.

endoNEWS: What would you hope for from the manufacturers of washer disinfectors of endoscopes? And what from manufacturers of chemicals for reprocessing?

HM: For the washer disinfectors I hope that the manufacturers can, through appropriate management of the reprocessing, ensure that we do not need manual precleaning anymore. Actually, I know that this is possible if the mechanics and the cleaner work well together. There will probably be two developments: On the one hand, simpler, more cost-effective machines, where I have to pre-clean manually, and on the other hand technically more advanced, probably also more expensive machines, which also do the pre-cleaning. Then I can transfer the endoscope directly from the patient to the machine and no longer have to endanger the staff.

As for the manufacturers of the chemicals, I hope that they will continue to collaborate on a test method to prove the effectiveness of the cleaners. In the "cleaning, disinfection and sterilization section" of the DGKH (Deutsche Gesellschaft für Krankenhaushygiene) there is a working group that has already taken this problem a good step forward towards a solution. Because we all know that there are great differences in how well the cleaners work – from hardly effective to very effective. So that we will soon have only effective cleaners available.

endoNEWS: You mean an objective way to test and compare cleaners.

HM: Yes, to have a listing regarding cleaning effects – just as it is available for the effectivity of disinfectants. First of all, we have the effectiveness against blood. The typical contamination with heparinized blood in Germany is now also included in the new draft of DIN EN ISO 15883, part 5. But depending on where the endoscope has been, we have many other contaminations which need to be removed. For those, other test contaminations are necessary. I don't think you can test that with blood. These are, for example, fats, X-ray contrast agents or drugs. This probably has already been checked by one or the other manufacturer who have appropriately positioned their products. But we don't know what each cleaner can do. I hope that they will take this forward with seven-league boots. Cleaning is the most important thing for me. We already know how to disinfect.

endoNEWS: Thank you very much for this discussion!

The questions were asked by:
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