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Help, endoscope reprocessing is not running smoothly!

DEGEA Online Seminar for endoscopy personnel together with the Endoscopy Campus, sponsored by Chemische Fabrik Dr. Weigert

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Under the title "Help, endoscope reprocessing is not running smoothly!", the German Society of Endoscopy Nurses and Associates (DEGEA) held its seminar once again online on 28 July 2021, sponsored by Chemische Fabrik Dr. Weigert. Ulrike Beilenhoff, DEGEA chairman, opened the topic, stating that the seminar would aim to identify typical sources of errors, present contingency and emergency concepts and develop solution approaches.

Gerlinde Weilguny, senior endoscopy nurse from Vienna, focused on research into the causes of contaminated automated endoscope reprocessors (AERs) and endoscopes. Infections in relation to endoscopy examination did occur, transmitted either by a previous colonized person undergoing endoscopy or spread from the patient themselves, e.g. transmitted during ERCP from the throat to the congested bile duct. Infection could also originate from members of staff, e.g. following poor hand hygiene or from aerosols generated when coughing, from the environment via an AER, the water supply or the endoscope itself. The incidence of such infections could only be estimated since often endoscopy was not identified as the source. Weilguny presented a literature review following a peak in infections linked to endoscopy procedures in the early 1990s – at that time systematic microbiology testing of endoscopes was initiated and increasingly more studies carried out on microbial colonization of endoscopes. The endoscope manufacturers made intensive efforts to design endoscopes such that they were easier to reprocess as well as to improve the hygiene performance of AERs. The majority of sources of endoscope contamination and ensuing infections reported in the literature were linked to gastroscopes and ERCP devices. The most resistant microorganisms recently identified, in particular, were pseudomonads and *Klebsiella*.

Based on the provisions of the Robert Koch Institute (RKI), no pathogenic microbes should be present on endoscopes following reprocessing. Such microbes included, for example, *Escherichia coli* or entrococci as indicators of inadequate cleaning or disinfection, pseudomonads as indicators of inadequate final rinsing or drying, streptococci, originating mainly from the throat region of personnel, or staphylococci as indicator of contamination following reprocessing because of poor hand hygiene.

Weilguny showed other ways to detect contamination also outside the scope of the officially prescribed annual microbiology tests, e.g. with Flexicheck tests. That entailed cleaning a small plate, contaminated with an artificial blood soil and polysaccharides, in a tube in the AER. If residual soils could be detected, the cleaning performance was not adequate. A poll of the audience revealed that over half of reprocessing departments did not conduct such tests. Weilguny stated that, however, they were a good way to detect any shortcomings with the AER early on. In addition, there were easily conducted tests with which protein residues could be detected in endoscopes (e.g. Pyromol tests), pointing to unsatisfactory endoscope reprocessing.

If contamination was detected, the problem could be contained by formulating and answering suitable questions. In which machine was the endoscope last reprocessed? Which microbes were implicated (as mentioned above, certain microbes served as indicators)? What was the cleaning outcome for other endoscopes reprocessed at the same time in the same AER, and how was it on changing to a different AER?

Weilguny went on to describe, step by step, how the problem could be contained, if microbiology or additional tests were positive. By reprocessing a contaminated endoscope in another AER, it was possible to identify whether e.g. the previously used machine had caused the problem. If that was the

case, the machine had to be appropriately disinfected and sampled again, and if necessary serviced by the manufacturer to eliminate the problem. It was important to note that all other endoscopes last reprocessed in a contaminated machine had to be reprocessed again in another AER.

If an endoscope that had yielded a positive test result was found to be microbially contaminated after being reprocessed once again, the possibility of microbially colonized endoscope microdefects should be considered – an investigation by the manufacturer should be able to clarify that. Furthermore, environmental testing should be instigated: had all steps been properly conducted? Had hand hygiene regulations been observed by all staff members? Other potential sources were the cleaning solution and cleaning canisters, storage times, detergents and disinfectants.

Between the various attempts described to identify the source, microbiology testing was continued. Weilguny stressed that the interval until the test result was available should be used to investigate all potential causes in the process.

If all efforts failed, replacement of the endoscopes and/or the AER should be considered.

Ulrike Beilenhoff spoke about contingency concepts. What about if equipment had to be replaced – how could that time be bridged? A contingency concept could be needed not just because of defective equipment, but also following disruptions in the infrastructure, structural damage or personnel absences. Construction or reconstructions work was an event that could be planned for, but in the case of other events one had to be able to react quickly. Various scenarios should be contemplated already as a prophylactic measure. Planning of such measures should also be preceded by risk analysis and assessment. Every disruption, every malfunction should be documented since it provided important insights for risk assessment and further planning.

Beilenhoff stressed that teamwork was essential when formulating contingency concepts. The operator, hygiene experts, in-house engineering department and also external departments had to work hand in hand with the endoscopy unit. She drew attention to the publication, Part 15, "Contingency concept for a RUMED to deal with expected and unexpected operational disruptions", drawn up by the Committee for Hygiene, Construction and Technology, of the German Society of Sterile Supply (DGSV e.V).

When assessing personnel shortages, one should first ask how many staff members were actually needed for routine operations. In that way it was possible to identify the "pain threshold". Contemplating various scenarios in advance was useful, e.g. staff absence due to illness or maternity leave. Temporary staff would perhaps have to be hired and appropriately trained.

Switching to loaned or disposable instruments, e.g. bronchoscopes, could help if equipment broke down. Likewise, plans should be made for the eventuality of having to manually reprocess all instruments. For example, four basins would be needed in such cases to prevent recontamination. Provision would also have to be made for a stock of suitable process chemicals to that effect. Beilenhoff pointed out that manual reprocessing resulted in high manpower demands and was very time consuming. New staff members, in particular, definitely needed careful induction in manual reprocessing.

If external AERs were used, one should check for which endoscopes validation had been carried out; appropriate adapters should be available. Contractual agreements would perhaps have to be put in place if the entire reprocessing operation was to be outsourced.

Prolonged storage periods prior to reprocessing should be avoided to counter biofilm formation. If necessary, the endoscopes should be brushed manually before transport.

Guido Merk, Dr. Weigert, spoke about process chemicals for an emergency concept. He described a routine reprocessing cycle with automated reprocessing. In the event of machine malfunction, the precleaning steps remained the same. The final disinfection should be performed as per the KRINKO/BfArM Recommendation* using bactericidal, virucidal, fungicidal and tuberculocidal/mycobactericidal disinfectants. Merk pointed out that with regard to the sporicidal action against *C. difficile* the microbial reduction could be achieved through a combination of cleaning and disinfection for manual as well as automated reprocessing.

The disinfectants were based on glutaraldehyde or peracetic acid. The chief determinant was the activity spectrum. Other factors to be clarified included the application parameters, material compatibility and compatibility with the precleaning agents. In addition, issues such as the work area ambient airborne contamination or the time intervals until the used devices were reprocessed had to be investigated.

Merk finished off by addressing potential errors. The active substances were liable to degradation. Test sticks could be used to check if the solution was still endowed with the required level of activity.

Frank Bieger from Zurich, a board member of the Swiss Association of Endoscopy Personnel (SVEP), described a difficult situation related to the planning and commissioning of a new department. Ninety days after commissioning, a *Pseudomonas* outbreak occurred and endoscopes were indeed found to be contaminated with both pseudomonads and other indicator microorganisms.

Therefore, shortly after commissioning the new department the old reprocessing equipment, which fortunately was still available, had to be placed in service once again. In parallel, efforts were continued to identify the source of the outbreak and find solutions for the new department. Other routine checks proved unfruitful, hence a task force was set up and other measures taken, e.g. the use of disposable valves and an increase in the peracetic acid concentration in the precleaning solution, to overcome the problem. The outbreak was notified to Swissmedic.

The (new) machines were recommissioned after extensive microbiology testing, but the source of the outbreak remained unknown, accordingly eroding confidence in these machines. By contrast, the test results for the old machines were always in order.

* KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

Further investigations showed that the new machines were contaminated in 60% of cases. With the assistance of an external consultant, who again investigated the machines, it became apparent that better results could be obtained by prolonging the cleaning time, but a decision was ultimately taken to replace the machines. With these new replacement machines there was no further sign of contamination.

Bieger stated that a lot of time and money was invested in operating the old machines which happened to be still available, because replacement of the AERs was not something that could be done overnight. This was also a major challenge for the staff since the department continued to operate during this entire time as if routine operations were still in place.

What could we learn from that scenario? Bieger emphasized that users needed to be more involved from the outset. The user requirements were the basis – but the entire system had to be considered. The duration of the reprocessing cycle should play a subordinate role. Additional testing of the machines with indicators was also useful. Already around one year before commissioning, the schedule of works should be analysed, for example validation should be carried out 10 days before commencement of work.

Bieger summarized difficulties in the planning meetings – often decisions were taken too quickly or too slowly. Good leadership in the meetings was important, possibly by a person not directly from the department. Earlier external advice would, no doubt, have been useful and could perhaps have expedited the decision-making process. Overall, the use of standard working procedures and documenting all activities were extremely important.