Acceptance through competence

German Society of Sterile Supply (DGSV) Congress in Fulda, 2 – 4 October 2013

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Like every year in autumn, the German Society of Sterile Supply (DGSV) held its congress in Fulda, with an unprecedentedly high turnout that set a new record: 600 delegates and 60 exhibitors.

Cleaning

At the start of the conference, the coordinators of the Guideline Group Anke Carter, Dr. Holger Biering and Dr. Jürgen Gebel, presented the new Guideline for Validation of Manual Cleaning and Manual Chemical Disinfection of Medical Devices. In addition to a text section, the Guideline contains annexes, checklists and a text matrix. The checklists, in particular, are intended as guidance to help processing departments compile their own individual documents. The test matrix can be used to check the entire validation sequence of events.

What is important is the experiences to be gained in the future from using the new Guideline. Therefore feedback is actively sought and will be taken into account when revising the Guideline at a future date.

Dr. Patrick Haubrich, orthopaedist from Daun, reported on his doctoral thesis which involved tests aimed at standardization of manual cleaning and chemical disinfection of medical instruments. Haubrich pointed out that in practice in over 90 % of cases manual processes were being used, which often were neither standardized nor validated. He had conducted microbiological tests to assess the efficacy of manual cleaning and of chemical disinfection of clamps and forceps. While the forceps' tests had produced predominantly good and homogeneous results, those attained for the Crile clamps were mainly unsatisfactory (i. e. reductions of less than 5 $\log_{10}$ levels). Manual cleaning and brushing steps improved cleaning, but were not free of occupational health and safety risks. If ultrasound was used, one had to ensure that the disinfectant used was suitable for that purpose. From his investigations Haubrich concluded that manual cleaning and disinfection processes were acceptable under defined conditions. But the processes used in practice should be set out in detail and, at least standardized, and their efficacy verified with regard to the respective process chemicals and medical device to be processed.

Prof. Heike Martiny, Berlin, spoke about the pivotal role of appropriate cleaning, stressing the importance of removing all visible soils. Only then was it advisable to test, e. g. for residual proteins. The limit values specified in guidelines continued to be a contentious issue. Martiny stated that investigations had revealed that the limit values specified in the Guideline for Automated Validation of Automated Reprocessing were essentially set too high. Often, it was possible to achieve these limit values when using only water. Martiny continued by saying that the processes had improved over the years, hence the limit values should be brought into line with that trend.

The size of an instrument and the sampled surface area were also key aspects, and should definitely be taken into account when calculating such values.

Citing various studies, Martiny outlined how, contrary to earlier views, it was not possible to produce «sterile soils». The opposite was true: the residual soils were an impediment to disinfection and sterilization. If biofilm was present, it might even be impossible to eliminate this in preparation for disinfection, e. g. of an endoscope.

Karin Steinhauer reported on tests she had carried out on the cleaning efficacy of product formulations used to process medical instruments. She tested various detergents with and without enzymes in neutral and mildly alkaline environments. She also investigated the cleaning efficacy of disinfectants. The test soils used were defibrinated bovine blood, coagulated sheep blood as well as the TOSI PCD. While the detergents provided evidence of good cleaning efficacy for the soil types investigated, disinfectants yielded less good cleaning results. Cleaning efficacy was improved, in particular in the tests with the TOSI PCDs, when using a combination of disinfectant substances and enzymes as a two-component system. Better cleaning efficacy was achieved on using a combination of microbicidal agents and cleaning components as a single-component system.

Endoscopes – how and where to process them?

Ulrike Beilenhoff from the German Society of Endoscopy Nurses and Associates (DEGEA) spoke about the instructions set out for processing flexible endoscopes in the revised KRINKO Recommendation*. This now included, as Annex 8, endoscopy instructions that had previously been presented as a separate document. However, this annex was revised without consulting the relevant professional societies, giving rise to confusion. Following input by the specialist societies a commentary has been issued amending the most important points. Efforts continued to have endoscopes and/or ancillary equipment processed in the CSSD. Citing an example from Maastricht, Beilenhoff pinpointed how this form of cooperation could work. What was important was to have staff members pay guest visits to other departments to gain an insight into what was important and increase mutual esteem. Logistics was a key issue here; medical device transport and processing had to be perfectly coordinated such that it could unfold without facing any major hurdles (telephone calls, meetings, etc.). Beilenhoff finished off by saying that she greatly endorsed this form of cooperation because, after all, it was in the CSSD that the reprocessing experts were to be found.

Ekhard Ragotzki reported on his experiences of endoscope processing in the CSSD.

*: Recommendation for hygienic reprocessing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

Essentially, there were three models for endoscope processing: this was done either directly in the endoscopy department, was done there but by the CSSD personnel, or the endoscopes were transported to the CSSD and processed there. Endoscopy personnel had manifold tasks to discharge, hence delegation of processing to the CSSD could relieve them of that burden. Conversely, the CSSD personnel's core competence lay in medical device processing. For the CSSD taking on endoscope processing would also offer a number of opportunities, e. g. ushering in a new and interesting line of work with more responsibilities. However, endoscope processing entailed manual working steps. The extra time investment needed here had to be taken into account when devising planning strategies in the CSSD. Transport of these delicate medical devices had to be well planned.
Ragotzki went on to stress that ultimately it was the logistics that was the key to success. Problems could occur if staff were assigned this new task without having undergone commensurate training. The involvement of the respective departments in planning should be enlisted and wishes and expectations clearly expressed.

DGSV specialist committees

October 3rd began with reports by the various DGSV specialist committees. Anke Westerberg reported on behalf of the Medical/Dental Practices Committee, describing the problems encountered in these settings. Often, the structural and spatial requirements were not met. The staff faced challenges because general and specialist knowledge of processing was not imparted as part of the training curriculum for medical assistants.
Anke Carter reported on behalf of the Education Committee. This committee had been restructured at the beginning of the year in order to facilitate, inter alia, decision-making. In the meantime there were 64 accredited educational institutions, offering general and specialist training courses at over 90 locations. One educational institution in Serbia had also in the meantime been given accreditation, and an application from Macedonia was pending. The health ministries of these countries had expressly requested setting up a continuing education programme based on the German model. The managers at these centres had completed Specialist Training Course III in Germany and, as such, were able to ensure that their institutions met the accreditation criteria.
Sigrid Krüger reported on behalf of the Quality Task Group. In addition to new topics that were being continually addressed (e. g. implants, dosing equipment, storage, etc.), the recommendations previously issued by this group had to be reviewed in terms of their topicality and revised as necessary. The committee had entrusted this task to a new, dedicated subcommittee. The recommendations for packaging

and quality management, for example, had been supplemented and updated.
Maik Roitsch spoke about the activities of the Public Relations Committee, outlining in particular the tasks involved in updating the homepage, presenting the Society to the public, e. g. at exhibitions and to the respective national and international associations.

Hygiene management in medical/dental practices

Maik Matschke, practice manager from Papenburg, reported on hygiene management in medical/dental practices. Just how much hygiene was needed? Matschke stressed that because this topic was the subject of continuous debate in the media, patients were much more demanding where hygiene was concerned than in the past. Also because of the inspections carried out by the supervisory authorities, irregularities were being uncovered and reported more frequently.
In all professional groups there was unwillingness to implement the knowledge underlying preventive measures. This was due, among other things, to the high workload as well as documentary obligations. Matschke stressed that, especially in medical/dental practices, transparent, patient-related computerized documentation was easy to compile.
He went on to say that advanced training and continuing education was expensive but that it also helped to cut costs, because well-trained staff could work more efficiently.

Professional job description

The second part of the day was devoted to the issue of a professional job description. Cordula Hoffmann presented a paper she had compiled as part of her Specialist Training Course III. The framework plans for state recognized medical assistant professions did not include medical device processing, or only parts thereof. As such, from a legal perspective there was an urgent need to formulate an independent professional job description.
Thanks to the curriculum on which the DGSV specialist training courses were based, there was now a solid basis for training. To make the content of these courses more comprehensive and detailed, dual training was needed so that legal and quality-related requirements could be met. Hoffmann said that state-recognized training would, of course, mean that the employers would have to pay higher salaries and ancillary costs, but there would also be many benefits to them. If there was a single state-recognized education model for the whole of Germany, refinancing would be assured pursuant to the Hospital Financing Act. Having employees trained to the highest standards would also mean a reduction in the number of occupational accidents and diseases. Healthcare establishments faced immense costs, e. g. longer hospital stays and, possibly, compensation demands, because of inadequately processed medical devices.
Esther Michaud reported on the situation in Switzerland. Like the DGSV, the Swiss Society of Sterile Supply (SGSV) was trying to gain nationwide recognition of sterilization assistants. The SGSV advocates devising a curriculum and an apprenticeship leading to a Swiss state-recognized diploma. In this respect, Switzerland has made more progress than Germany: of the three steps needed for creation of an independent job description, two have already been accomplished.
Klaus Wiese outlined the catalogue of criteria by the Federal Institute for Vocational Education and Training (BIBB) for Germany, while naming a number of professions that had been newly recognized in recent years, despite some of them training fewer than 50 persons per year.
Conversely, in Germany it was estimated that 20,000 persons were employed in the medical device processing sector. Other criteria, such as specific tasks, serving to distinguish this profession from others and perspectives for continuing professional development had been met.
The DGSV is still facing an uphill battle; this calls for a corresponding public relations' campaign and, possibly, lobbying.
Maik Roitsch presented the findings of the Sterilization Report. Prof. Busse from the Frankfurt Polytechnic College had evaluated a questionnaire with 19 questions, to which 120 CSSDs from throughout Germany had responded. A good 20 % of departments stated that they were understaffed. Likewise 20 % thought their employees were not adequately qualified. There is thus a tremendous need for better personnel qualifications.
Lack of recognition of their work by the OR (surgical department) and by other hospital departments was another problem: only 50% stated that they felt their work was appreciated.

Validation of software

Sadmir Osmancevic from the Charité Hospital in Berlin presented a paper he wrote as part of his Specialist Training Course III, dealing with software validation. Validation was conducted for cleaning/disinfection processes, for the sterilization process as well as for the entire procedure used for tray processing in a CSSD. Osmancevic explained that the essential requirements 3.9 E 18 «Validation of production and service provision processes (including software)» compiled by the German Central State Body for Health Protection with Regard to Drugs and Medical Devices (ZLG) was a good guide for planning, organization, conduct and assessment of validation of process documentation software. Osmancevic stated that validation itself was a necessary, but laborious, activity and recommended compiling a precisely defined validation plan at the preparatory stage.

VDI Guideline on risk management

Prof. Marc Kraft, Berlin, reported on the current stage of VDI Guideline 5700 (compiled by the German Association of Engineers), now available as a «Green Print». This draft version would be published next year after expiry of a specified objection period. The guideline was intended as additional guidance to applying risk management to medical device processing. Kraft stressed that the guideline was intended as a practical guide, which could serve as a standard for a correct procedure.

Corrosion – the facts

On the last day of the congress, Gerhard Kirmse, from the firm Aesculap, focused on corrosion. In a talk entitled «Myths and Facts», he enumerated widespread opinions and analyzed them in terms of their veracity. It soon became clear that there was no such thing as absolute corrosion resistance of steel. But corrosion resistance had somewhat improved thanks to passivation and refinement of surfaces. But at the same time more stringent demands were made because of e. g. alkaline cleaning without neutralization. The ability to detect corrosion called for properly trained and motivated staff. Kirmse stated that the action needed if corrosion was detected had to be clearly defined.

Since there were no documented cases, it was difficult to show that there was a direct link between impaired wound healing and corroded instruments. But there was no denying that corrosion hampered cleaning. Corroded instruments therefore had to be withdrawn from circulation.
Corrosion was always a sign of process changes (e. g. in the water quality) that had gone unnoticed and could often only be identified through systematic observation. Corrosion was essentially transmissible, in particular from one instrument to another in the same tray. Kirmse finished by saying that it was not easy to eliminate corrosion, therefore swift action was vital whenever needed.

Cost allocation

Stephan Knoefel focused on the costs incurred for processing. The accounts department recorded the costs and services related to the hospital's various cost centres and allocated these progressively to the treatment cases. Doing so for CSSD-related costs was not easy, because numerous resources were needed for the task of instrument processing. Cost allocation errors were made, distorting economic efficiency analysis and could, e. g. portray the CSSD services in an unfavourable light compared with those of external contractors.
Knoefel highlighted the difficulties in calculating services. For example, the investment needed to process one sterilization unit (StU), a commonly employed reference variable, could vary greatly depending on its content. The more suitable processes took account of the number of instruments, but were generally based on one input per instrument.
Knoefel recommended having a look at how costs were allocated by the accounts department and conducting spot checks to verify this subsequently. By aiming for maximum transparency, the CSSD management could help the hospital achieve as far as possible an error-free system of cost allocation.

Ralph Schäpers dealt with the topic of motivation. It is precisely with regard to hygiene that the issue of how to convince employees permanently of the proper course of action is crucial. He demonstrated an excellent example from Geneva University Hospital of how compliance with hand hygiene regulations could be considerably improved.

This year's conference was brought to a close with a panel discussion on the revised KRINKO/BfArM Recommendation. One thing that was certain at the end: the discussion has just begun. It has already been proposed that this discussion be continued at the next DGSV congress. ■