Advancing knowledge – Signposting the future

WFHSS Congress in Antalya, Turkey, 6 – 9 November 2013

Gudrun Westermann

Several delegates at the 14th World Sterilization Congress of the World Forum for Hospital Sterile Supply (WFHSS) in Antalya, Turkey, had travelled long distances, e. g. from South America, Japan or Australia. But where else did one have a chance this year to exchange ideas on the topic of sterilization and instrument processing with over 1800 congress delegates from around the entire world?

The congress was opened by Wim Renders, WFHSS president, and Murat Günaydin, chairman of the Turkish Disinfection Antisepsis Sterilization Society (DAS). Both stressed the importance of a good standard of training and continuing education, while expressing the hope that this world congress would build bridges between North and South, East and West, thus paving the way for one worldwide sterilization practices' model. With Turkish music by the well-known Murat Salim Tokaç group and a Sema dance performance, the delegates were tuned into the local culture.

Surface disinfection – indispensable for infection prevention

The scientific programme was launched on 7 November with a talk by Martin Exner, Germany, on the role of surface disinfection in infection prevention. While the importance of this measure is generally well known, how to execute it is sometimes the subject of controversial debate. Exner cited the latest literature sources while emphasizing that surface disinfection had to be carried out in line with the respective risk profile. The choice of disinfectants to use was crucial. Failure to take account of the disinfectant efficacy profile could result in microbes being smeared onto the surface and spread even further. Standard test methods, as used to compile the Disinfectants List in Germany, gave users a good insight into the efficacy profile. In principle, standard protocols should be drawn up for cleaning and disinfection of surfaces to improve compliance and enable reliable testing, e. g. during audits.

Güven Çelebi, Turkey, spoke about methods that could be used to verify the effectiveness of cleaning and surface disinfection, e. g. microbiological methods, fluorescence methods or ATP-based methods.

Elif Doyuk Kartal, Turkey, advised against neglecting conventional cleaning methods. Detergent-based treatment was less expensive and infinitely less toxic than surface disinfection. Besides, the use of disinfectants created a false sense of security, while at the same time disregarding the fact that disinfectants would not be effective unless coarse soils were first removed from surfaces. Routine cleaning and disinfection measures should be tailored to the clinical risk.

OR and CSSD – constructional and spatial prerequisites

On the second day of the conference Dominique Goullet, France, reported on the establishment of a single sterile supply centre for hospitals in Lyon. This involved 14 hospitals, with in total more than 5,000 beds, whose medical device processing departments were now to be brought together at one central location. The initial centralization project was planned in 2002 but was cancelled before the intended inauguration date in 2006.

However, it was not possible to continue with the actual state prevailing at that time until a second centralization project could be designed. Therefore an interim solution was found for the existing three CSSDs until the new CSSD, measuring 2000 m², would be opened in 2011. Since this was set in the open countryside, information technology played a pivotal role: in addition to facilities for tracking processes and instruments, there was a transport module to identify the location of transport

Murat Günaydin and Wim Renders

Opening of the industrial exhibition

Sema dance performance

trolleys – vital information with distances of up to 30 km to the various hospitals. To optimize cooperation with the OR, there was also an interface with the OR management program where information on ORs could be remotely accessed.
Goullet described the new centre's equipment facilities and organizational practices, in addition to the challenges faced: maintaining effective communication with customers despite long distances as well as staff training.
Serpil Karatas and Murat Günaydin, Turkey, also spoke in a parallel session about constructional requirements. Karats described different ways of planning an OR wing, while Günaydin talked about constructing and converting a CSSD.

Quality and logistics

Tom Brophy, England, spoke about quality assurance of new surgical instruments. At Barts Health Trust a project was recently launched involving inspection of the new surgical instruments purchased. It emerged that in several cases the quality was so poor that the instruments could not at all be used. Many of the manufacturers did not have a proper quality management system in place. Armed with photos, Brophy showed the nature of the problems encountered, e. g. tungsten carbide inserts becoming loose, defective solder seams or failure to affix the manufacturer's name.
Poor quality containers were another problem. These could lead to instruments being damaged during transport.
An internal quality control facility, as introduced in the meantime by the Barts Health Trust, was a suitable mechanism for exerting pressure on the manufacturers, because they knew that defective instruments would be rejected. Indeed, some of the defects could be discerned with the naked eye; Brophy went on to say that on using a magnifying glass or microscope one could also detect hidden defects if one knew what to look for.
Jean-Marc Legentil, Canada, in his lecture focused on QM systems in the CSSD, in particular on ISO 13485. Citing a number of examples, he explained how the source of mistakes, which were not readily identifiable either, could be masked at any point in the processing circuit. But in principle the process control measures employed in a medical device processing department should be of industrial standard.
Staff are often left to their own devices. The sequence of events is not easy to understand and it is difficult to overcome customary habits.
Legentil stated that internal audits provided a good means of gradually checking all process steps. Appropriate personnel continuing education and supervision were indispensable to that effect.
Koen Vandormael, Belgium, spoke about a new logistic model for the OR. At Oost-

The audience at the 14th World Congress

The baton is passed on to the professional societies of the Czech Republic and the Slovak Republic

Limburg Hospital the three ORs are situated at three different locations. The CSSD is housed in a separate department. Vandormael presented a project designed to improve the flow of materials and tracking. Implants were packed separately and, as such, could be traced back to the patient. The same held true for preconfigured OR sets. And of course the IT facilities were crucial. The software could be used to order and assemble sets as well as to track the materials used and for inventory purposes.

Occupational health and safety as well as error management – the human factor

Sharon Greene Golden, USA spoke about the human factor, without which processing would not be possible. After all, machines regardless of how modern they were had to be operated by people. She stressed that employees should develop a critical approach because a machine could only execute the working sequence prescribed, but was unable to react spontaneously or make decisions.

Deborah Spratt, USA, dealt with the issue of protective clothing. Using photos she demonstrated the correct clothing and personal protective equipment, and also showed how often these were not properly used. Regular training and continuous repetition were needed to assure proper handling of protective clothing. Movements, in particular in critical areas such as the OR, should be kept to a minimum.

For the dental setting Ismet Yildirim, Turkey, described the requirements to be met by protective clothing in dental treatment centres.

Christophe Lambert from Chambéry reported on error management and establishment of a committee for exchange of experiences. He went on to say that mistakes should always be a trigger for progress. In that spirit, since 2012 at regular interdisciplinary meetings in Chambéry information on mistakes/errors was systematically analysed and, if possible, translated into process-enhancing measures. That, stressed Lambert, was done without apportioning blame. Rather, the aim was to avoid similar mistakes in the future and also be able to identify precursor incidents that had repeatedly led to mistakes. The more the processes could be simplified by such an approach, the fewer the human errors will be occurring – the latter being the most common type of error.

Cleaning indicators – how reliable are they?

Mark Sutton, England, reported on an investigation with commercially available cleaning indicators.

Using a standardized test setup, it was possible to individually check factors of critical importance when cleaning instruments and endoscopes. Commercially available cleaning indicators were used in various cycles to investigate the effects of the cleaning time, detergent type, dosage and temperature. The results were compared with those achieved on using enzyme-based cleaning indicators, which permit quantitative insights. It emerged that often the test indicators had produced a pass result even before the required conditions had been met e. g. on using only 25% of the recommended detergent dose or at a temperature of only 22 °C (rather than the recommended 50 °C). Sutton therefore recommended exercising caution when interpreting the results of such indicators.

Sterile supply packaging and storage

Hartmut Dunkelberg, Germany, dealt with sterile supply storage. Compared with conventional, time-based storage, event-based storage attempted to incorporate scientific data on the factors that could adversely affect the sterile barrier function of packaging. Using a database approach, that method could be further developed. Dunkelberg described tests for investigating the capacity of various forms of packaging to filter out airborne microorganisms. As expected, that capacity could be greatly increased on using double-layer packaging. Since there were considerable differences in the filtration capacity between the packaging materials used by various manufacturers, and that at the same time was a highly relevant criterion of quality assessment, Dunkelberg advocated taking account of the filtration capacity during assessment.

What happened if the packaging was not endowed with adequate barrier function was demonstrated by Stephanie Dancer, Scotland, in her talk on infection transmission via contaminated surgical instruments. Following a significantly higher rate of wound infections after aseptic operations, e. g. knee endoprostheses, a study group was appointed to identify the source of the outbreak.

Sterile items of packaging, which were now stained and creased, were identified. These were found to harbour the coagula-

The poster exhibition at the Antalya conference

se-negative staphylococci and *Bacillus* spp which had also been isolated from the infected patients.

Dancer explained the reasons why this unfortunate set of circumstances had led to the outbreak: inadequate sterilization practices and handling mistakes in the CSSD as well as failure of OR personnel to properly inspect the sterile packaging before opening.

Once the outbreak had been brought under control, a number of procedures were implemented in the long term to prevent a similar occurrence in the future:

- Improved surveillance
- A ban on moist or stained items of sterile packaging – these should be inspected for any such manifestations already on entry into the department
- Continued regular meetings of the study group
- Appropriate antibiotic prophylaxis prior to surgery, e. g. with vancomycin.

Sterilization and disinfection – old problems and new methods

Duygu Perçin, Turkey spoke about factors that could hamper attainment of a sterility assurance level (SAL) in a CSSD. Once a medical device had been sterilized, the probability of finding a single viable microorganism on it should be less than, or equal to, 10^{-6}. Microbial inactivation unfolded in accordance with a time-dependent process. Perçin explained how that process could be adversely affected by various interference factors that could not always be readily identified at first glance e. g. non-condensable gases or excessive condensate formation. In the latter case, in particular, the sterilization-control parameters used were often inadequate. Perçin continued by stating that in this respect the manufacturers were called upon to devise additional suitable parameters that would correlate with the physical measured values of a standard sterilization cycle.

Rodolphe Hervé, England, demonstrated a new cold plasma method for decontamination and sterilization of reusable surgical instruments. Unlike conventional cleaning methods, calling for the use of different chemical detergents, the plasma method involved the release of free radicals capable of eliminating organic soils from the most diverse surfaces. This technology has made tremendous advances over the past ten years and is now successfully used in various, including therapeutic, settings.

Saban Esen, Turkey, presented new sterilization and disinfection processes, including H_2O_2 gas plasma (Sterrad 100NX), vaporized H_2O_2 (V-Pro) and ozone with H_2O_2 (Sterizone). He also demonstrated new biological indicators that could be read much more easily than their conventional counterparts; besides, he described room disinfection methods using H_2O_2-steam and UV-C.

Endoscopes – processing and storage

Gülden Ersöz, Turkey, advocated processing of endoscopes and laparoscopes in an endoscope washer-disinfector (EWD), but pointed out that in the past contaminated or defective EWDs had led to infection outbreaks. Therefore endoscopes had to be processed in compliance with strict protocols and the results monitored. Ersöz stated that despite such measures, it was not possible to fully rule out the occurrence of biofilm within endoscopes. Hence cleaning was of paramount importance.

John Van Bergen Henegouw in his lecture on automated endoscope washer-disinfectors stated that only validation was able to guarantee process reproducibility.

Emine Alp, Turkey, likewise emphasized the need for thorough cleaning. Endoscope-related outbreaks were mainly imputable to inadequate decontamination. Final high-level disinfection sufficed in principle.

On the last morning of the conference, Caroline Conneely, Ireland, reported on her experiences of using an endoscope drying cabinet. If endoscopes were stored in such an approved cabinet, they had to be processed once again if the storage period exceeded 72 h. At the Children's University Hospital Dublin it was revealed that only one of three nasoendoscopes had at all been used in the meantime on a patient. The drying cabinets' manufacturer had indicated that new research had revealed that the storage duration could be increased up to 31 days. That should now be put to the test in the clinical setting. Citing nine criteria, Conneely explained how safety could be assessed after prolonged storage on the basis of qualitative and quantitative methods. Overall, the drying cabinet investigated produced good results in compliance with the provisions of standard EN 16442:2012. In practice, it might be possible to considerably reduce the number of endoscope processing cycles thanks to the prolonged storage period.

Prions – detection and removal

William Keevil, England, spoke about protein adsorption on the surface of surgical instruments. This was particularly interesting in the light of the potential transmission of prion proteins since it was easier to eliminate conventional test soils than tissue proteins or (abnormally altered) amyloid proteins. Keevil explained that amyloids could accumulate on surfaces over time. Therefore one should not rely on the total protein detected since most residual soils identified in this investigation were prions. Using a highly sensitive fluorescence microscopy method, it was also possible to demonstrate that protein adsorption continued to increase even after a 24-hour drying time, thus adversely affecting efficacy of the test detergent. Hence Keevil recommended timely processing and that instruments be kept moist after use until cleaned. It could be beneficial to group the instruments in accordance with how they were used on high-risk patients or tissues and assign them to low- and high-risk settings.

Michael Beekes, Germany, spoke about removal of prions from medical devices. As was well known, prions were particularly resistant to disinfectants and to steriliza-

tion processes and thus were interesting test organisms when investigating detergents, disinfectants and sterilization processes. Normally, it was animal prions that were used for test purposes. But there was evidence that human prions were even more resistant to chemical substances and to steam sterilization. Beekes finished by advising that therefore those processing methods that were able to inactivate animal prions should be retested using human prions.

Processing in the dentistry setting

Axel Kramer, Germany, reported on the specific problems encountered in the dentistry setting. Microbial colonization of the oral cavity was widespread, as was microbial persistence in biofilms. Hence microbial transmission to the patient's environment during treatment was common. The water-conveying systems in dental units had critical levels of contamination. Resistant microorganisms could persist on inanimate surfaces for a very long time in some cases. Nonetheless, it was difficult to provide proof of infection – but, to cite Kramer, that did not mean that infection did not take place.

In Germany, the KRINKO (Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute) had issued special recommendations for the dentistry domain. An infection control policy with corresponding standard operating procedures had been prescribed. However, a survey conducted on hygiene standards in dental practises in 2003/2004 revealed that there was much amiss here: only in rare cases was a special appointment system in place for patients suffering from infection. No sterilization control measures were conducted in around 20 % of practices. Nonetheless, when the survey was repeated in 2009 significant improvements were noted. Kramer finished off by saying that there continued to be a need to verify that the legally prescribed requirements were being implemented

The dentistry setting was also the focus of the lecture by Alexander Franz, Austria. In that setting, instruments were often contaminated with dentistry substances such as cements. It was virtually impossible to remove these when cleaning the instruments. Franz therefore asked whether conventional test soils were at all fit for purpose in dentistry since most of these could be readily eliminated when cleaning instruments in washer-disinfector. Conversely, it was only through pretreatment measures and/or the use of ultra-

sonic cleaning that dentistry substances could be removed.
In a parallel session Nevin Acar, Turkey, gave an overview of the instruments typically used in dentistry. Zeynep Yigiter, Turkey, focused on sterilization and disinfection in dental treatment units, while Rahime Nohutçu, Turkey, spoke about the water quality in such units. Personnel and patients were regularly exposed to the water from these units. Among the microorganisms commonly isolated from that source were potential pathogens or opportunistic microbes. Standard infection control measures included the use of biocides, filtration and unidirectional valves.

Standardization – the difficulties

Ernst Dennhöfer, Germany, spoke about international standardization with regard to sterilization processes. He stressed that for an international standard – more so than for a national – the most diverse interests had to be reconciled with each other. As such, definitions often had to be changed, test procedures were only vaguely described and, in some cases, no acceptance criteria specified. Citing by way of example the harmonized standards for moist-heat sterilization, EN ISO 17665 and EN 285, Dennhöfer explained the nature of such difficulties.

Environmental pollution and waste disposal

Bénédicte Gourieux, France, spoke about sustainable developments in sterile supply processing. The main issues addressed were natural resources, waste segregation and energy savings. In recent years various catalogues had been drawn up for the healthcare setting, aimed at recording, evaluating and promoting sustainable measures. But these were of limited applicability to medical device processing. Gourieux described the formulation of guidance specially for sterile supply processing, listing all steps of the processing procedure. The guidance enabled self-assessment of the department's prevailing status in four stages (not available – fully implemented). It was possible to identify critical points and translate them into an action plan in which topics could be prioritised in accordance with their importance and the prevailing status.
Ronald Russell, Ireland, spoke about a related topic – treatment of potentially infectious waste. It was not just waste management that was a problem, proper classification from the outset could also be difficult. Russell described how for several years infectious waste had been placed in landfills. In some cases, such landfills had to be emptied again, something that proved expensive and onerous.
Russell presented different technical solutions that had in the meantime been implemented in Ireland, e. g. special facilities for waste sterilization. After that, the waste could be disposed of in normal landfills.

Advanced training and continuing education

In her talk, Maria Hansby, Sweden, spoke about advanced training and continuing education. She presented the VEDAS (Vocational Education for Disinfection and Sterilization) project aimed at drafting a completely new training policy. This would then serve as the basis and list of requirements for occupational activities involving sterile supply processing (see also p. 417).
Elinor Radke, Australia, reported on continuing professional development in her country. In 2012 efforts were made to review and standardize various aspects of advanced training and continuing education. Citing a government document template, Radke gave an overview of the new requirements, while explaining how, for example, the wording of the materials used had been adapted to the ISO standards. These innovations promoted cooperation in this area and helped to set uniform training and educational standards.

In a glance around the world, Maria Elena Jäckle, from Peru, gave an overview of the situation of sterile supply processing in Peru and South America. Soufiane Derraji, Morocco, described how sterile supply services were organized at a military hospital in that country.
Hiroyoshi Kobayashi reported on trends in sterile supply processing in Japan, ranging from the very first CSSD in in the 1960s up till the present day. Since 2000 there had been in place an advanced training programme for the Certified Sterile Supply Technician. This, stated Kobayashi, had greatly helped to promote recognition of sterile supply departments, in particular where hospital management was concerned.

The talks described here are but a snapshot of the myriad topics addressed in Antalya. Other experience reports and research results were presented in more than 150 posters.
As always, at the close of the congress the baton was passed on – going this time to the professional societies of the Czech Republic and the Slovak Republic who will organize the next WFHSS congress to be held in Prague from 15–18 October 2014. Make a note in your diary! ■