ZENTRAL STERILISATION 5

11th World Sterilization Conference

Sao Paulo, Brazil, 30 July – 1 August 2010

Walter Accoe, Wayne Spencer

2.850 delegates attended the 11th World Sterilization Conference that was organized by SOBECC (Sociedade Brasileira de Enfermeiros de Centro Cirúrgico) in close co-operation with the World Forum for Hospital Sterile Supply (WFHSS.) The congress was held in São Paulo, the biggest town of Brazil with more than 12 million inhabitants.

Over 70 companies had a booth at the technological exhibition. There was also a poster exhibition with over 150 posters.

On Thursday July 29 in the afternoon attendees had the opportunity to follow pre-congress courses about personnel management, current methodologies for sterilization, cleaning and packaging etc.

On July 30, the conference was opened by Janete Akamine, president of Sobecc Nacional, who stated that the preparations had not been easy but that the organisers were motivated by the goal to improve the quality of the event, offer participants up-to-date information so they can make the most of this time of learning and exchange of experience.

There then followed welcoming videos from the Governor of Sao Paulo and Jose Gomas Temporao, Minister of Health, and an opening speech by Wim Renders outlining the aim of the WFHSS to see harmonization of sterilization standards throughout the world. He stated that although all departments are unique and possess their own culture, all patients expect a good quality medical device, and evidence based practice is the way forward.

Today's sterilizer is not you father's water heater

Thomas K. "Chip" Moore, USA, was the first speaker after the opening ceremony and he gave some history of sterilizers and the standards now associated with them in the U.S. Today's sterilizers are sophisticated, automatic and computerized devices that execute programmed jobs accurately as well as create uniform conditions inside pressure vessels to achieve sterilization. Specialized knowledge is necessary to ensure that the right cycle is selected. This requires an educated and

Photo: Antonio Carlos Bertagnoli

competent operator. Users of sterilizers need to understand regulation guidelines and performance challenge requirements for the use of sterilizers, sterilizer designs, performance validation and sterilization cycles for everyday use. Moore explained the testing regimes for both gravity and dynamic air removal sterilizers and also talked about FDA 510K clearance; a sterilizer cannot be sold in the U.S. until it has this clearance.

He then went on to compare the difference between European and U.S. validation. Challenges to understand the differences of performance between European and U.S. sterilizers were discussed.

Queuing and chaos – how to handle them in the CSSD

The second lecture was given by Yaffa Raz from Israel who spoke about queuing and chaos theories and their application in CSSD. Yaffa discussed the basics of the queuing process and the concepts of arrivals and servers, with arrivals being the workload and the servers being the people and equipment that process the arrivals.

Queues are viewed as a symptom of inefficiency. They are unavoidable, but they can be reduced if disturbances and variability are handled well and/or by adding to the capacity of the system.

Chaos theory attempts to explain the fact that complex and unpredictable results can and will occur in systems that are sensitive to their initial conditions. Uncertainties, no matter how small, will eventually overwhelm any calculations and defeat the accuracy and the order that we wish to have in our systems.

Many of the variables that define the structure of work in CSSD are either queued or chaotic. This presentation demonstrated the importance and application of these two phenomena in CSSD management. The speaker emphasized that chaos is not necessarily a negative phenomenon, but a crisis with the opportunity to change. Constant change is the only constant phenomenon in healthcare. When managing chaos, you should:

- Focus on important issues
- Nurture your network
- Have the courage to tell the truth
- Look at your actions, revise, plan and then re-evaluate.

Steam – how does it affect stainless steel

Yahia L'Hocine from Canada began his talk with an overview of new sterilization technologies alternative to ethylene oxide, e. g. he discussed some history of ozone as a sterilant. He continued by describing described the effects of steam sterilization on stainless steel instruments. Stainless steels are the largest product group of the biomedical metals, accounting for more than half of the total biomedical metal market, followed by titanium/Ti-alloys and cobalt-based alloys. The largest and dominant application area of biomedical grade stainless steels is surgical instrument manufacturing, accounting for 55 % of total consumption.

The speaker stated that for steel sterility is not the only concern. Dirt and corrosion are also important. Corrosion is aggravated by moisture and high temperatures during sterilization processes and may result in serious damage to the instruments and even render them useless or dangerous for the patient. Nickel ion release (which would be poisonous) varies with the grade of stainless steel. L'Hocine explained that there had been only one publication on the effects of steam processing on stainless steel implants leading to them becoming corroded. However some studies on instruments have been done. He reported on comparative studies of ozone and steam

sterilization on stainless steel surgical instruments after 100 cycles. Few differences occurred here aside from cosmetic colour change. It was concluded that poor quality of water and incorrect dosing of cleaning agents had the most effect with respect to corrosion of the steel but further research is needed for any new processes for sterilisation to check that they do not corrode stainless steel.

Implants – reasons for failure

Michelle Alfa, Canada, dealt with problems related to the reprocessing of implants. The range of surgical procedures that use implants is rapidly expanding. Overall in North America about 10% of all implants fail and need revision. Aseptic loosening accounts for 51% of these primary implants failures and infection for about 8%. Published literature shows that friction due to movement of the joint or in areas where screws are inserted is known to produce friction particles. Studies have shown that if these particles contain foreign material such as endotoxin they will be more likely to stimulate an inflammatory response which ultimately leads to aseptic loosening. Endotoxins are not destroyed by steam sterilization and are still able to cause inflammatory response.

Implantable screws and brackets are cleaned and resterilized using steam every time the instrument set is processed; rarely used screws and brackets are reprocessed hundreds of times before they are implanted in a patient.

Alfa presented data from studies on surgical instruments before and after cleaning to show that accumulation of residual carbohydrates and endotoxin after cleaning can occur. Organic residuals and cleaning fluids may remain on instruments and implants by using poor quality rinse water.

Alfa concluded that users should ensure final rinse water of adequate quality. A move to individual pre-sterile packaging is problematic to surgeons but could be the answer in the long term.

Water quality

Robson Riberio Dias, Brazil, also talked about the quality of water – how should one choose the best water treatment. He began with a technical explication about the three systems for water treatment and the pro's and con's of every system. Further he reported on a project for the implementation of a water treatment system in a hospital of the city of Sao Paulo. He discussed the main factors that caused the project to be successful. Two of the fundamental tools that have been used were continuing monitoring and maintenance.

Evaluation of sterile barrier systems

Hartmut Dunkelberg from Germany talked about determination of the efficacy of sterile barrier systems against microbial challenges during transport and storage. The maintenance of sterility requires a particular process validation program that demonstrates the efficacy of the microbial barrier properties of the wrapped terminally sterilized products against the microbial challenge that the package encounters during storage and transportation. Different event-related factors limit the shelf life of sterilized medical devices e.g. impacts causing visible changes to the packaging (cuts or breaks on gaskets, punctures, tears, wetness, water stains, loosened locks and settled dust following storage on open shelves).

Besides that there are impacts by air flow into the packaging during transport and storage challenging the filtration efficiency (transport to different heights above sea level, weather-influenced atmospheric pressure changes and temperature variations).

Dunkelberg has devised an exposure chamber to check filtration ability of packaging. He presented a program using data on the effectiveness of the microbial barrier of the packaging. He stated that the higher the airborne microbial challenge the greater the required filtration efficiency and recommended that in practice the filtration efficiency should be printed on the packaging. He has provided an online checking tool at www.microbial-evaluation-of-sterile-barrier-systems.com

Outsourcing – the English experience

Wayne Spencer, U.K., gave an outline of the outsourcing work that had been undertaken in England from 2003 to the present day. He described the particular U.K. vCJD issues that had led to change and went on to discuss the public-private partnerships that had been created to provide new sterilization centres. The financial arrangements and procurement models were described. Spencer then went on to discuss the lessons learned form the experience including benefits of good specifications, the need for appropriate resources (which was often underestimated), the development of performance management and partnership approaches.

Risk management and quality

Janete Akamine from Brazil in her talk on risk management described the biological, physical, chemical and mechanical risks in a CSSD setting. As technology evolves, the demand for safety grows. Akamine gave particular emphasis to appropriate early identification and evaluation of risks, analyzing results and applying lessons. In general, healthcare workers seem to have a growing need these days; it's a very stressing environment. Burn-out used to be seen mostly in the nursing department but nowadays it is also quite common for CSSD personnel. It is imperative that we monitor risks at all times.

Silma Maria Cunha Pinheiro Ribeiro, Brazil, outlined quality indicators in the CSSD and described measurements of level of quality. She discussed a cause and effect of exercise with respect to CSSD activities and questioned whether stress levels of staff could affect quality performance. She then described a Plan, Do, Check, Act (PDCA) operational model for the CSSD. Finally, she gave some key indicators that could be used to judge CSSD quality performance such as:

- number of mislabelled packs
- percentage of compliance to protocols
- labour accident rates
- machine downtime.

Ergonomics – adapting to work conditions

The second lecture of the day was given by Jeane Aparecida Gonzalez Bronzatti, also from Brazil, who spoke about ergonomics in the CSSD. Ergonomics seeks to analyze human interaction with work environments regarding comfort, safety and efficacy and to intervene when adjustments need to be made regarding setup projects and equipment usage. Thus ergonomics is also useful to prevent diseases.

By means of a short video presentation the speaker gave some examples of

good ergonomics in the CSSD. She also focused on the risk classification relating to the work in the CSSD. Technical development has influenced ergonomics because machines took over the hard physical labor once done by men.

Evaluating personnel

Until very recently, the evaluation of CSSD personnel was not properly done since it was not very clear what the activities performed by nursing teams were and the amount of time the needed to do them. Janaina Anchieta Costa, Brazil, reported in her talk "Nursing Activities at the CSSD: Subsidies to Evaluate the Personnel" on current studies on the evaluation of nursing personnel in CSSD that have shown that the type and frequency of interventions they are involved with can provide the most accurate assessment of their work load.

The Lean Approach – how can it be applied to healthcare

Jean-Marc Legentil, Canada, opened the second day with a talk about the Toyota/ Lean Approach applied to healthcare. Several hospitals around the world have been adopting methods originally developed by Toyota using them to improve the efficiency and productivity of their operations. In a production system we find value-added activities (VAA) and non value-added activities (NVAA). Non value-added activities are considered as waste and increase costs. Under the "Lean Approach" non value-added activities are reduced or eliminated. By doing so, employees have more time to spend on activities that generate value for the patient and for the organization. In his presentation, Legentil explored the various tools like the Five-S, Process Mapping, SMED and the Poke-Yoke (means fool proof in Japanese , it's a system to prevent a person from making a mistake) required to put in practice.

Standardization is the first step of a continuous improvement program.

Sterilization processes – H_2O_2 plasma

Magda Diab Elschahawi from Austria was asked to investigate methods for decontamination of endoscopes that needed terminal sterilization. She obtained a Sterrad 100NX machine and planned to challenge the machine with different wraps and suboptimal cleaning to evaluate the process.

Carriers spiked with *B. stearothermophilus* were used in a 5-kg load of instruments without lumens. A half cycle approach from ISO 14937 was used and worst case conditions (wrong cycle, suboptimal cleaning etc.) were simulated.

The Sterrad performed as expected if the item was clean regardless of which of the recommended packaging and material was used. Results were erratic if there was an organic challenge left on the devices.

The triple wrap method was a benefit for some (TIT) materials but detrimental for others (PU or PE). The speaker highlighted some concerns regarding homogenous distribution of H_2O_2 in the chamber. She recommended that the manufacturer's wrap and cycle recommendation must be adhered to and a validated cleaning process must be followed prior to processing.

Alexander Blacky followed on from Magda Diab Elschahawi's work focusing on lumened devices. The Sterrad flex cycle was used with the same variants as in the previous trial but with the biological indicators placed in the midpoint of a lumened device. Experiments with heat shock processes were conducted at the same time.

Wires with inoculants were provided by ASP Ltd. The bioburden was less than desired so that extrapolation of results was required. Blacky also recommended that manufacturer's guidance regarding cycle and lumen length were essential.

The U.S. approach to disinfection and sterilization

Lisa Huber, chairperson of the International Association of Healthcare Central Service Materiel Management (IAHCSMM), USA, stated that medical devices are often designed with little or no consideration of cleaning and/or sterilization. In the U.S. there is no requirement for a manufacturer to provide a validated process recommendation with proper reprocessing instructions. Loan sets coming in often cause chaos. IAHCSMM has established an orthopaedic interest group and wants to develop a collaboration between IAHCSSM, AAMI, and OSMA. (Orthopaedic Speciality Manufacture Association). There is also a need to provide education on reprocessing topics to OSMA.

Huber then went on to discuss flash sterilization and its misuse. She emphasized that flash sterilization should not be used as a routine alternative because of instrument shortage. The US Joint Commission surveys of CSSD are surveyor-dependent and therefore inconsistent, but have found inconsistent quality and procedures regarding flash sterilization. During a summit on flash sterilization with representatives from IAHCSSM, AAMI, FDA, and Nurses' Association, participants agreed on a set of points identifying good practice.

Huber then described the education challenges in CSSD education. New Jersey is the only state that requires certification for CSSD technicians. New York, Ohio, Arizona, and California are currently seeking certification legislation for SSD technicians.

She concluded by advocating the use of AAMI standards as the basis for establishing policies and procedures in CSSD in the U.S.

Endoscopes

Niels Buchrieser, Austria, studied the cleaning of endoscopes and the impact of different temperatures, detergents and performance of commercial cleaning indicators. He based this work on ISO/ TS IS883 Part 5. Indicators tested were:

- TOSI FlexiCheck
- Simicon
- Valisafe Wash-Check

He used a range of commercial enzymatic and alkaline detergents. Results shown were based on evaluation in a flow test rig; actual endoscope reprocessors were not used. The reference instrument was a Teflon tube soiled with blood/soil.

Results showed that 5 Minutes of enzymatic cleaning at 45 °C was not sufficient although FlexiCheck showed some cleaning and was the easiest to clean. 5 minutes alkaline cleaning at 45 °C was slightly better. 10 minutes alkaline cleaning showed best results. Wash-Check was harder to clean than control blood but the FlexiCheck was again easier to clean than the test soil. Higher temperatures did not necessarily improve performance.

Buchrieser concluded that indicators can indicate a cleaning phase but results are only comparable to a certain extent and some are less challenging than blood soil. He also pointed out that alkaline and enzymatic cleaners were not compara-

ble. Alkalines performed best. As a result Austrians propose longer wash times for machines than most other countries currently use.

Peter de Haas started his talk about central reprocessing of flexible endoscopes with some insights into the advantages of centralizing cleaning and disinfection of flexible endoscopes versus non-central reprocessing.

A central unit has a lot of advantages: one production site with standardized logistics, clear responsibilities, a better quality of process and quality assurance, lower investment costs, better process knowledge and last but not least an easier education of staff (training on the job, supervision and coaching, refresher courses,etc).

Endoscope reprocessing in South America

Suzana Muller described the reality of endoscope reprocessing in South America. An immersion apparatus using glutaraldehyde which is used for video endoscopes is still common in South America. There was largely no validation of this method until 2000.

Muller then described the pre-cleaning process used prior to inserting the endoscope into an automatic reprocessor. She stated that in Brazil, disinfection is largely still conducted manually using glutaraldehyde or peracetic acid baths with 30 minutes exposure times in 2 % glutaraldehyde. Scopes are dried with 70 % alcohol and air pistols. There are generally no drying cabinets in Brazil.

Accessories are not single-use. Hospitals generally autoclave accessories but clinics use glutaraldehyde. Clamps that should be single-use are often reprocessed. Muller demonstrated that the clamps cannot be cleaned properly.

She went on to describe the position in other South-American countries:

- In Chile glutaraldehyde is still used, but some automated processes have been introduced.
- In Columbia, ETO is used for accessories and scopes to achieve a high level of sterilization.
- In Peru, some automated processes are in use as well as glutaraldehyde.
- In Brazil and Uruguay, some peracetic acid was used, but now procedures have gone back to glutaraldehyde on a cost/convenience basis.

Emerging technologies: NOTES

In his lecture on disinfection of surgical procedures undertaken with the Natural Orifice Transluminal Endoscopic Surgery (NOTES) technique, Georg Spaun from Austria talked about the history of endoscopy and types of procedures that have moved from surgery to endoscopy. He went on to describe barriers to adaptation of NOTES that have been overcome, such as access to the peritoneal cavity and gastric closure such as tissue anchors.

Spaun stated that the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR®) group has published a white paper on NOTES. He described some of the infection control measures needed, such as a single shot of antibiotics and acid suppressants, and of course instruments must be sterile, although literature reveals controversy over this.

Spaun described various suturing and closure devices on the market and explained that small endoscopic cameras have been developed to go into the area and provide better special vision.

He then showed different types of experimental scopes that are being developed to accomplish procedures that require multi-tasking.

The second part of Spaun's talk dealt with decontamination and he went on to say that an additional sterilization stage was needed for NOTES scopes. At Portland, USA, the options available were evaluated and a protocol was created. Of the systems available to the investigators, ETO had the lowest risk but the highest cost. The Steris system 1E was ranked second for risk and second for cost, and this process was eventually adopted. The protocol states that standard reprocessing in an automated endoscope reprocessor be used, and that the endoscope be then stored in a hanging cabinet. The System 1E is then used two hours before the procedure to sterilize the scope.

Maintenance – what to check afterwards

Tillo Miorini reported on his work for the Austrian Society for Sterile Supply's (ÖGSV) testing committee looking at issues with machines after maintenance and repairs had taken place. Problems encountered included mixed up dose pumps, wrongly replaced spray arms and tubing fitted incorrectly.

ÖGSV has come up with a list of checks to be carried out and documented after any maintenance including thermometric tests, technical function tests and dosing checks. Miorini emphasized that checks and tests after maintenance saved time, money and reputation. The WFHSS will soon publish Guidance on this issue.

Prion disinfection processes for heat-sensitive equipment

Sylvain Lehmann, France, reported on new prion disinfection processes compatible with heat-sensitive medical equipment. Prions have a remarkable resistance to physicochemical inactivation procedures such as heat, ionization, radiation and conventional disinfectants such as detergents, alcohol, glutaraldehyde and formaldehyde. Prion decontamination therefore requires very harsh treatment in most cases and recommended methods in France include the use of sodium hydroxide, sodium hypochlorite or steam sterilization. However, these methods and solutions cannot be applied to sensitive medical equipment and instruments and represent serious handling risks.

The prion protein has a high affinity for divalent metal ions and in particular for copper. Copper is an essential redox transition element able to induce ion-mediated damage to proteins. Copper and hydrogen peroxide have a strong prion decontamination effect based on the cleavage of prions. Lehmann's group developed a new H_2O_2/Cu based disinfection procedure compatible with heat-sensitive medical equipment and efficient against both conventional and prion infectious agents.

Breaking the infection chain

In the last lecture of the conference, Jacqueline Delay, USA, discussed the role of the SSD in breaking the infection chain and reducing hospital acquired infections (HAI). She stated that HAI are one of the leading causes of death in the U.S. and occur in 2 – 5 % of patients in the U.S. It is up to healthcare professionals to break the chain. Incorrect SSD processing is a direct route to infection. Delay went on to discuss reservoirs of infection and the portal for exit (i.e. transmission routes).

She then described the Joint Commission's recommendations for competency of staff, standardization of processes and

Tillo Miorini, Niels Buchrieser, Magda Diab Elschahawi, Lisa Huber, Alexander Blacky, Birte Oskarsson, Wim Renders *Photo: Antonio Carlos Bertagnoli*

adherence to manufacturer's instructions. To the audience, she posed the question for everyone to consider: "Is your system designed for infection prevention?"

Importance of good hand washing was then reiterated and Delay detailed the AAMI standards that should be adopted to limit HAI.

At the conclusion of the conference, the president of the Portuguese Sterilization Association Associação Portuguesa de Esterilização (ANES), Luisa Nogueira, announced that in 2011 the 12th World Conference on Sterilization will take place in Estoril, Portugal, from October 12 to 15.✦