ZENTRAL STERILISATION 3

Sustained Developments in Reprocessing

32nd French National Sterilisation Days in Lille, 28 and 29 April 2010

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The weather was not at all cool in the north of France, where the 32nd French National Sterilisation Days were held on 28 and 29 April in Lille. In brilliant sunshine more than 1500 sterilisation specialists assembled to debate the latest developments in the field of medical device reprocessing .

The topic on the first day's agenda was sustained developments in reprocessing. In the first lecture, Olivier TOMA presented relevant strategies. Areas of influence include water consumption, air pollution, energy consumption, structural aspects and waste disposal. He stated that each of these areas had to be analysed and optimised, while aiming at reduced consumption. For example, a 20% reduction in energy consumption was aimed at by 2020.

When constructing departments, certain areas can be optimised, e.g. energy supply. When selecting building materials, sustainability should also be borne in mind. Noise pollution should be reduced and natural light used for lighting purposes as far as possible – both contribute to a healthy climate in the workplace.

To reduce to a minimum the amount of waste, attention should be paid to the quantity and type of packaging already at the time of making purchases. An in-depth benefit-risk assessment should be made before opting for disposable products.

All measures should contribute to consolidating the present-day quality of care, while also bearing in mind the health of future generations.

Savings in sterilisation

Dominique GOULLET outlined where potential savings could be made in sterilisation. Sterilisers have very high energy consumption. Conversion of water into steam consumes 539 kcal/kg water. While it is not possible to change the laws of physics, there are still ways to make savings. Water consumption and energy consumption are closely related. A vacuum ring pump accounts for the highest water consumption. Goullet demonstrated novel, water-saving systems which have been developed in the meantime by various companies. Noteworthy here is a vacuum pump that can be operated with virtually no water. By directly comparing the cost factors for sterilisation with three different devices, Goullet showed that the annual costs could differ by more than 2000 euros. Thanks to water-saving systems all three systems allow further potential savings of between 700 and just over 1000 euros.

Detergents: environmental effects

Jaques CRIQULION, from the company Anios, explained in his talk how the environmental effects of detergents could be minimised. REACH, a new EU regulation for Registration, Evaluation, Authorisation and Restriction of Chemical Substances which came into force on 1 June 2007, calls for precise information on the entire supply chain, so that all parties involved, manufacturers, distributors, users, can discharge their risk management responsibilities in respect of such substances. Criquelion described development of detergents and their properties, stating that the new generation of detergents were more readily biodegradable than their predecessors. However, the widespread use of palm oil, which inter alia drives that trend, has a negative impact on the environment, in particular in Indonesia, where large areas of forest have been destroyed, and continue to be destroyed, for cultivation purposes.

Of paramount importance is astute use of substances. Based on the requirements, the concentration or exposure time of detergents could be changed to achieve optimal effects with minimal environmental impact.

Packaging: savings during production and by recycling

Annabelle FEGELE spoke from a manufacturer's perspective about energy consumption with regard to the production of packaging materials and potential recycling of packaging. In addition to the obvious factors such as energy consumption, water consumption and waste management, other measures played a role in the packaging-related environmental balance. For example, by switching to a lower paper weight of 60 g/m^2 more than 260 tons of paper and almost 150 tons of CO_2 could be saved annually in the balance. Of importance here was, of course, good reproducibility of sealing and peeling properties.

When using reusable packaging one should bear in mind that cleaning and reprocessing of such packaging entailed consumption of water, energy and chemical substances. In terms of transportation, the CO_2 balance was improved if supplies were ordered in large quantities and directly from the manufacturer so that additional journeys to intermediate dealers could be avoided. With proper segregation of waste considerable savings could also be made.

Marion NOUVEL reported on a study on reuse of paper/plastic packaging. The following principles apply: each sterile barrier system of this type should undergo only a single sterilisation cycle. If packaging is moist when withdrawn from the steriliser, the instruments have to be repacked before being resterilised once again. This means a waste of time and resources and the associated negative economic impact should not be underes-

Panel discussion with the second day's speakers

Free lectures: J.-M. Kaiser, J.-Y. Cabioc'h, C. Vaugelade, C. Faber

timated. In the study described, the sterilisation cycle was interrupted before the drying phase to obtain moist packaging. This same packaging was now subjected to a second sterilisation cycle. Before the first as well as after both sterilisation cycles various parameters were measured to ensure that the physical-chemical properties and the barrier function of the packaging were not adversely affected, e.g. porosity, pore diameter, water-repellent properties, sealing properties as well as peelability, in addition to the bacterial filtration efficacy and the barrier function as per DIN 58953/6.

While the study has not yet been concluded, the initial findings are very promising in terms of reusing packaging for a further cycle.

Single-use metal instruments

Jean-Marc DUBAELE and Francis DOURLENS spoke about disposal concepts when using single-use metal instruments. When switching over to such single-use instruments, which have been available on the market since around 2008, the reprocessing costs have to be compared with the costs incurred for supplying disposable instruments. However, the main problem relates to disposal after use. The regulations for dealing with infectious waste have to be observed as well as health and safety issues and environmental impact. Using a special box (VYBOX®) the instruments can safely disposed of and separately recycled. Of paramount importance here is proper segregation; for example, metal can be reused after melting down at a temperature of 1200 °C .

The morning proceedings were brought to a close with a panel discussion. In the afternoon delegates had an opportunity to participate in the various workshops.

How to reprocess osteosythesis materials

The second day of the congress focused on how to deal with osteosynthesis materials. In the opening lecture, Richard ASSAKER, neurosurgeon from Lille, spoke about the prospects opened up by modern spinal surgery. Implants are used in this field for both injuries as well as degenerative or tumour-mediated changes. By means of impressive photos, Assaker described trends in frequently used implants, e.g. the Caspar plate. The design of this plate has undergone a number of changes over the years to counter the problems often arising such as screw displacement or loosening as seen when the bone is healing or during scar formation. In the meantime, a number a minimally invasive techniques are also being used in this domain, accompanied by their attendant challenges.

Cathérine CUNAT from Lyon spoke about reprocessing implants in the CSSD: one screw tray can accommodate up to 400 screws, of which only a few are always used. One problem encountered relates to repeated cleaning and reprocessing of the other screws whose properties undergo possible change in the course of time. Often individual screws are lost or mixed up with screws from other trays. To retain an overview of matters, appropriate trays are of vital importance. Cunat stated that simplification of tray composition was also desirable to rule out as far as possible the aforementioned sources of mistakes.

Laurence MARTIN and Marie MEULE described how screw trays were managed in their institution in Dijon, after outsourcing of reprocessing to an external service provider in November 2009. Before making this change, the trays were first completely filled and sterilised. Thanks to the new organisational form, the trays were now sterilised without the already-used implants; the latter were packed individually and dispatched also so that when the tray was reused in the OR it would once again be complete. That procedure has proved successful in the meantime but gives rise to special problems, e.g. in terms of tracking. It also calls for good communication with regards to the parts to be added as well as for vigilance on the part of staff so that all the various items actually needed are then available.

Developing medical devices: requirements from a manufacturer's perspective

Claire JEGOU reported from a manufacturer's perspective on the problems arising when developing medical devices to meet current-day tracking requirements. A manufacturer's product range often comprises several thousand items. Today more so than ever in the past, new products have to be tailored to a specific patient, for example to the patient's age and the nature of his disease. Furthermore, they should permit tracking to individual patients. Jégou went on to say that finding practical, economical and sustainable solutions called for fundamental changes in the approaches used hitherto.

Single-use osteosynthesis implants

F.-A. GERME, Lille, spoke about switching over to single-use osteosynthesis implants. Since outsourcing of reprocessing was imminent, a study into optimisation of reprocessing cycles was conducted, focusing in particular on astute deployment of single-use devices. The study investigated, inter alia, hygienic safety, delivery and warehousing, costs and management of a procedure. Overall, it was possible to cut annual costs by around 12,000 euros through optimisation of the reprocessing cycle and storage.

A panel discussion on the topic of optimisation of the reprocessing cycle brought the morning's series of talks to a close.

Low tenperature sterilisation: what's new?

In the afternoon a number of independent lectures were given. J.-M. KAISER reported on the activities of the GEDESMAT group, dealing with low-temperature sterilisation. In 2009 the manufacturers of low-temperature sterilisers disposing of a CE mark were contacted. Two sterilisers, the V-PRO manufactured by Steris and

STERRAD NX and 100 NX from the firm ASP, were investigated in greater detail in respect of the microbicidal efficacy of the process, effects on the sterile supplies and environmental impact. This group had compiled a report on development of the STERRAD process and on its possible fields of application.

Sterilisation assistant: a job description

J.-Y. CABIOC'H from the continuing professional development institute CAFOC, Toulouse, addressed the issue of official recognition of the job description "Sterilisation Assistant". The institute conducts training courses on other topics, in particular for engineers. But the preconditions can, in principle, be applied to other professional groups. A reference system is needed for certification, and the acquired knowledge has to be validated. What is desirable towards that effect is European certification. The speaker went on to say that professionalism was particularly important so as to achieve a clearly defined job description.

Update on legal requirements

Dominique GOULLET summarised the amendments made to the regulation on validation of sterilisation processes and to the circular governing prions. The introduction of new validation standards (EN ISO 17665 und EN ISO 11135) has given rise to a situation whereby standards EN 554 and 550 2009 have forfeited their validity. However, since the period within which objections can still be submitted is still ongoing for EN ISO 17665, further last-minute amendments to the regulation can be expected. The new version was supposed to be published in May.

The new circular on prions contains some changes with regards to epidemiology, risk tissues and classification of patient risks as well as associated policies for dealing with instruments. The French Association of Sterilisation (AFS) has published a standard protocol on management of prion diseases, aimed at facilitating implementation of the new guidelines.

The standard protocol was presented in the next talk by C. VAUGELADE. Based on this protocol products such as detergents and disinfectants can be classified in terms of their prion-inactivating efficacy. To that effect, both *in vitro* and *in vivo* investigations are needed. The *in vitro* tests give more in-depth insights into the mechanism of action, while identifying the properties of products or processes underpinning inactivation or elimination of prions. The *in vivo* tests permit quantification of the reduction of infectiousness, which can then be compared with two known processes. This approach is also described in the revised version of Circular 138. A table with products and processes, based on the protocol, is available on the website of the French Health Products Safety Agency (AFSSAPS). For products already on the market conformity with the protocol also has to be demonstrated following a transition period; at present, AFSSAPS is conducting an inventory of such products.

The situation in Belgium

To bring the congress to a close, the focus was now on a neighbouring country, Belgium. Chantal FABER from Brussels described how reprocessing was organised there. In Belgium, too, the hospital pharmacist was responsible for sterilisation. Each hospital had to dispose of a reprocessing facility; since 2007 a Royal decree was in place, according to which outsourcing of reprocessing to another hospital or external service provider was permitted. A quality management system was needed. Two specialist societies, the French-speaking ASTER and the Flemish VSZ, were working for continuing quality improvement, for recognition of training and they themselves were contributing to training by organisation study days.

Faber described the training system in Belgium. The French-speaking society of hospital pharmacists had formed a sterilisation working group, which was involved in formulation of standard procedures for reprocessing. In addition, pharmacists were to be trained to carry out audits.

And with that prospect, a conference that once again highlighted the manifold aspect of a complex topic was brought to a close. Next year's CEFH Congress will be held on 6 and 7 April in Nantes. ✦