

Ready for Reprocessing?!

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Already for the fourth time now, the firms Dr. Weigert and Sanaclean have organised the Basle Symposium, which this year used as its motto "Ready for reprocessing?!"

Prof. Heeg, Tübingen, gave the opening talk "Reprocessing of medical devices – Positioning and (attempted) prognosis". He described the legal framework comprising the German Medical Devices Act (MPG), Medical Devices Operator Ordinance (Switzerland), European Medical Device Directive 93/42/EEC, Recommendation by the Robert Koch institute (RKI) and the German Federal Association for Drugs and Medical Devices (BfArM) as well as national and international standards (EN ISO). The new European directive 2007/47/EC addresses, inter alia, the following topics:

- Importance of patient protection
- Ongoing investigations of medical device reprocessing in the European Union (EU), report covering period up to 05/09/2010
- Single-use devices are those designed for single use on one sole patient
- Manufacturer's obligation to provide information on the known, possible risks posed by reprocessing of single-use devices.

As regards positioning, the experience report published in 2008 by the German Federal Ministry of Health on medical device reprocessing in Germany could be consulted. The main purpose of this report was to grant an insight into whether the existing legal framework was sufficiently robust to assure reliable patient protection.

From the 79 comments, originating from, inter alia, professional and specialist societies, hospitals and reprocessing firms as well as government agencies (RKI, BfArM, ZLG – German Central State Body for Health Protection with Regard to Drugs and Medical Devices), it was concluded that overall there was little need for action.

It had been advocated on numerous occasions that the RKI-BfArM Recommendation be made legally binding. But this step is unlikely since in view of issues relating to the burden of proof, legally binding obligations are already in place. Conversely, a more realistic demand is for decontamination of "Critical C" devices to be subjected to accreditation as per EN ISO 13485. The manufacturers rejected the introduction of a ban on reprocessing of single-use devices: this was an unreasonable demand that was unlikely to have any chance of being implemented, espe-

cially in view of the activities currently underway at European level. According to the ZLG commentary, automated decontamination (in a washer-disinfector) should also be legally prescribed for "Critical B" devices.

From the users' viewpoint, the manufacturers' instructions were often inadequate.

Prof. Heeg then went on to describe the level of knowledge to be assured by the staff entrusted with reprocessing duties, while stressing that medical device decontamination called for qualified staff and validated processes.

In the future it was expected that reliable data would be gathered on the quality of reprocessed medical devices, in particular on the quality of cleaning, e.g. presence of protein residues, as well as on material and surface changes. A negative list of medical devices that did not lend themselves to reprocessing was also expected.

DRG – a chance for hospital hygiene?

Dr. Zastrow, Berlin, addressed the issue of whether the introduction of flat-rate case fees held out any chances for hospital hygiene. Diagnostic Related Groups (DRGs) were introduced in the Unites



P. Heeg



K. D. Zastrow



W. Schulz-Schaeffer



J. Staffeldt



V. Schmidt



H.-R. Widmer



H. Schenk

States of America (USA) in 1967 purely as a patient classification system to provide for measurement, evaluation and control of hospital treatment services. In 2000 the German healthcare service opted for an Australian system known as the Australian Refined Diagnosis Related Groups (AR-DRG). In December 2005 Switzerland decided to introduce a DRGs' system based on the German model but adapted to Swiss treatment practices. The plan was to legally enforce Swiss DRGs by 2012 in all parts of the country.

In Germany, however, the model has already fallen into disrepute: it has failed to put the intended stop to rising costs in the healthcare sector. Many doctors feel that their services to patients are being hampered due to economic pressures and bureaucratic demands.

According to Zastrow it was wrong to believe that flat-rate case fees alone would automatically lead to an improvement in healthcare processes. Anyone postponing reorganisational measures until the time of introduction of DRGs would have to face several disadvantages. Unlike remuneration practices based on the duration of the corresponding treatment periods – number of days spent in hospital – or remuneration for individual services, payment was calculated on the basis of the medical services rendered per treatment case when using flat-rate case fees. Hence prolonged hospital stays could lead to loss of revenue and jeopardise the hospital's survival.

Zastrow gave a number of drastic examples to highlight the effects of the DRG system, while citing Prof. Paul Robert Vogt from Zurich Cardiovascular

Centre (HerzGefässZentrum Zürich) who deemed this to be "profoundly unethical and immoral". For example, as per the DRG system, it was financially more rewarding to keep a patient on a ventilator for a longer period of time and thus risk ventilator-associated pneumonia with its 30% mortality rate so as to achieve a higher flat-rate case fee.

Hospitals that made no profit, or failed to, at least, cover their costs, had no future. In that respect Zastrow outlined possibilities for cutting costs – e.g. for laundry, catering, supply of drugs and medical devices, cleaning and last but not least staffing – and increasing profits. In particular, this meant providing treatment services to largely healthy patients whose rapid and complication-free recovery was assured and who could thus be discharged as early as possible, while generating attractive flat-rate case fees.

In such a situation, nosocomial (hospital-associated) infections put profits at risk and impeded cost-covering working practices.

While to date hygiene conferred an advantage exclusively on the patient, since every additional day spent in hospital due to a hospital-associated infection was paid for by the medical insurance companies, now as per the dictates of the DRG system a sharp rise in infections meant a significant decline in profits. An infection prevention policy with a high infection rate, which proved inadequate in the long term, would jeopardise the survival of the respective establishment. Hence successful hospital hygiene represented an important component of the successfully run hospital of the future.

Significance of prion infections

Priv.-Doz. Dr. Schulz-Schaeffer, Neuro-pathologist from Göttingen, reported on prion infections and their significance. Newly emerging aetiological agents that can potentially be transmitted to humans – in particular when they are able to reproduce in domestic animals – give rise to much concern since they pose an incalculable infection risk. Therefore such diseases have major implications where hygiene is concerned. In general the following applies: a decontamination process has to guarantee that the spread of unconventional aetiological agents is also reliably ruled out. If there is a perceptible risk, special reprocessing measures should be used.

Schulz-Schaeffer described the characteristics of Creutzfeldt-Jacob disease (CJD) and variant CJD (vCJD) as well as the spread of different forms of CJD. Already in 2004 his working group had furnished proof of the spread of prions in muscle tissue. Since 2007 it has also been known that prions can be spread via the nerves in skin tissue. Infectiousness varies according to the different types of tissue. For example, whereas a high degree of infectiousness has been detected for the brain, spinal cord and eyes, there is no evidence of infectiousness of body fluids – with the exception of cerebral spinal fluid (CSF). Although vCJD can be transmitted in blood products (three such cases have been detected in the United Kingdom to date), there have been no reports of bloodborne spread of sporadic or hereditary CJD. Nor have there been any reports of transmission following skin contact with patient blood or needle stick injuries.



G. Fecht



F. Cavin



H. Ney



E. Pflimlin

From this can be inferred that the standard hygiene measures in place are adequate when caring for CJD patients. For invasive procedures the precautions prescribed for dealing with hepatitis C patients are needed. Any suspicion of CJD at the time of a medical consultation or when dispatching a clinical specimen should always be reported.

Prions were also the focus of the talk given by Dr. Staffeldt, Hamburg, but on this occasion addressing material compatibility with respect to reprocessing. Increased wear could be expected for, inter alia, silicone elastomers, aluminium (e.g. the casings of motor systems, sterile supply con-

tainers), chromium-plated instruments, soldered and adhesive joints as well as plastic sheaths.

Staffeldt described an alkaline, enzymatic or surfactant-based detergent with optimised material protection that could be used as a standard practice for universal applications, while stressing that the alkaline detergents based on the methods proposed by the RKI had been found to be effective against prions. He elaborated on aspects of material development. Thanks to the use of innovative materials it was possible to improve material compatibility to withstand the demanding decontamination processes needed to deactivate prions.

Process safety for alkaline cleaning

Verona Schmidt, Hamburg, reported on development trends aimed at improving process safety for alkaline cleaning. Alkaline cleaning is characterised by its excellent ability to dissolve protein and fat residues as well as its antimicrobial activity. These advantages derive from its good degradation properties and rapid onset of action; concurrent cleaning and disinfection assure twofold safety.

Mrs. Schmidt compared the microbicidal activity of alkaline detergents with that of aldehyde-based disinfectants. The aldehyde-based disinfectants proved to

be endowed with the better microbicidal activity. Alkalinity on its own was not able to generate a comparable microbicidal action. Among the detergents, the best results seemed to be achieved with a combination of alkalinity and surfactants. In that respect, the surfactant composition appeared to be of decisive importance.

Apart from bactericidal activity, attention has also to be paid to the virucidal efficacy of the products used. The alkaline test detergent with a special surfactant combination generate an effect comparable with that of aldehyde-based disinfectants, while furthermore proving effective against prions.

Reprocessing in exceptional situations

Prof. Widmer, Basel, reported on reprocessing in exceptional situations. For example, how should one proceed if a patient's bone material had fallen on the floor during an operation? Widmer described the decision-making process needed in such cases. A search of the literature showed how the use of certain measures could be evaluated in various studies.

Based on such insights, the following hospital hygiene measures were agreed:

- Pulse lavage with sterile saline
- New, unopened povidone iodine solution, dilution 1 : 10
- Antibiotic prophylaxis with vancomycin 1g, 30 min before reimplantation
- Compile internal guideline

Widmer then spoke about how to deal with emerging pathogens and prions.

In summary, reprocessing in exceptional situations, as described above, called for common sense, a lot of expertise and interaction with specialist colleagues, to cite Widmer. New pathogens could necessitate new measures. While the infection risk posed by prions was lower, it was not negligible.

Requirements for decontamination staff

H. Schenk, Zürich, outlined the requirements to be fulfilled by decontamination staff. Proper instrument reprocessing meant coping with much more difficult, and often unforeseen, situations and use of correct procedures so as to successfully contend with even unusual demands.

That means working practices and processes have to function perfectly under difficult circumstances. But this is possible only if proper communication and information channels are assured in the hospital.

For the CSSD this means that defined competent partners or their representatives from the various departments should be known and present. Error management has to be implemented if services are interrupted or problems arise.

Using a practical example based on an instrument disposal concept, Schenk then described the requirements and how they could be met.

Reprocessing intricate medical devices

Gerda Fecht, Friedeburg, spoke about reprocessing intricate medical devices, while highlighting possibilities and limitations.

Apart from classification of medical devices, process validation as per the pertinent standards is important. Accordingly, Mrs Fecht described how in her institution, which was engaged in reprocessing of single-use devices, unknown medical devices were first of all compared with known devices. If it was not possible to identify a counterpart for the new device, risk assessment and remedial action were conducted by a competent team. This could mean that the sterile supplies would not be released. Changes could also be needed to the existing decontamination process, necessitating in turn investigation of materials and hygiene practices. Of paramount importance in all respects was functional testing: measures had to be taken to ensure that the reprocessed device was fully functional and did not pose a greater risk when reused.

Functional testing

F. Cavin, Lausanne, spoke about functional testing after medical device cleaning. Visual inspection of the cleaning results was needed after cleaning, as was a check to ensure that materials had not been altered/damaged and were fully functional.

All instruments that were used under microscopic control should also be subjected to microscopic inspection following decontamination. Using several photographs, Cavin described how this should

be done. He elaborated in particular on inspection of the insulation materials used for high frequency instruments, for which special facilities were available. If the insulation material was damaged, the currents could cause tissue damage, e.g. perforation of hollow organs with potentially fatal outcome. After a test phase, the insulation material was checked as a routine measure with a special instrument each time the device was reprocessed. Cavin continued by describing other functional tests and stressed that certain instances of malfunctioning should be foreseen by the CSSD and investigated before they occurred.

Quality management

H. Ney, Geneva, reported on the introduction of a quality management system in the Central Sterile Supply Department (CSSD) at Geneva University Hospital. First, he gave some general information on the CSSD, such as throughput, fittings and number of staff members. New perspectives were in sight for 2009 since around a twofold rise in the number of trays and soft packaging to be reprocessed for the surgical domain was expected; furthermore, an expansion of dental services with around a further 800 sets per day was planned.

A complete instrument tracking system was to be established, and the CSSD would bear entire responsibility in future for storage of sterile supplies. In line with these changes, staff numbers would increase from 38 to 60.

Ney then spoke about the principles of quality assurance. Analogous to the Sterility Assurance Level (SAL), he gave an overview of the Quality Assurance Level, which defined the degree of safety by which a medical device met the client's requirements and expectations. Quality had to be defined and mistakes had to be avoided. The aim should as far as possible be "to do everything right the first time", i.e. a zero-error quota should be assured. Errors that did occur and their consequences should be analysed and evaluated.

Ney described the preconditions to be met at the personnel level; for example, all staff members should be conversant with the targets. To that effect, the necessary information should be readily ac-

cessible to everyone. Moreover, a mistakes culture and a system for acknowledgement (of mistakes) and remedial measures were needed, and should be recognised by all staff members.

Endoscope decontamination

E. Pflimlin described the activities leading up to the new Swiss directives governing endoscope decontamination. Up till 2002, Switzerland still had no standard regulation for this. Decontamination was carried out to the best of the staff members' knowledge and belief; there was an enormous need for information. Following the foundation of the Swiss Association for

Endoscopy Personnel (SVEP/ASPE), the first workshop on reprocessing of flexible endoscopes was held in September 2004 at the congress in Montreux. The initial working group was composed of staff members from the field, who helped to formulate everyday-related approaches. But there was a lack of specialist knowledge of hygiene to clarify certain aspects, e.g. how to use sterile water. Hence the working group set up to revise the regulations also included infection control experts. The working group has in the meantime formulated recommendations for reprocessing of endoscopes and their accessories, for hand hygiene (with refer-

ence to hygienic hand disinfection as per EN 1500), ultrasound-based decontamination, microbiological testing as well as for personnel and patient hygiene. Pointing to the future, Pflimlin stated that the directives would be evaluated as from 2009. A broad input was assured thanks to the participation of institutions ranging from SVEP/ASPE, SwissNoso, Swiss-medica and SGSH, so that the directives could be made available free of charge to all interested parties. ♦