How safe are your medical devices?

Presentations on reprocessing at the annual conference of the Infection Prevention Society, Liverpool, 28–30 September 2015

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The annual conference of the Infection Prevention Society attracts about 800 visitors every year. This year was no exception. Participants could choose between different parallel sessions on various topics. CSSD manager Mark Campbell (Cardiff) spoke about the reprocessing of transoesophageal ultrasound probes (TOE). These are not necessarily designed with a view to easy reprocessing options. No fully automated process exists; rather, manual methods are generally used. On the other hand, cases of hepatitis B virus transmission by such probes have been described. Thus, a safe reprocessing result does not always seem to be obtained.

Campbell presented some systems currently on the market with their advantages and disadvantages. Although some of them were made specifically for TOE probes and there are validated cycles, none of the systems is optimally suited. It would be desirable to have a fully automated process such as that used for endoscopes used in invasive procedures.

Concluding, Campbell pointed out there was now a system for high-level disinfection with H_2O_2 for ultrasound probes for vaginal or rectal use for which the process can be validated and whose cycle times are short enough to render the system practical.

Information for newcomers

Some lectures appealed directly to newcomers to the profession, including the presentation by Pat Cattini (Royal Marsden NHS Foundation Trust), who presented her "infection prevention tool kit". She mentioned essential documents, such as the recently revised Health and Social Care Act, that all newcomers to the profession should know. She also offered some personal tips for everyday work. What is important, Cattini said, is close networking with other organizations and experienced professional colleagues. Valuable information can easily be found on the Web, for example in a blog on issues related to infection prevention (reflectionsipc.com). Notes and photos describing and showing important procedures can help create a personal manual over time.

Still, the most important factor for success, said Cattini, is sporting the right attitude. Patient safety must always take precedence; taking patients seriously and using common sense is the only way to make success possible.

Tina Bradley of the Queen Elizabeth Hospital (Birmingham) spoke about the decontamination of medical devices and related subjects. Medical devices include not only surgical instruments; the term "decontamination" covers the entire spectrum of cleaning, disinfection and sterilization. It is important to follow the manufacturer's instructions in all cases. Yet guidelines and procedures are easily confused. Whilst guidelines describe intentions, procedures and instructions directly instruct users how to handle a specific product.

Responsibilities need to be defined. In the hospital setting, this is best done within the context of a medical devices committee. Particularly important is staff education and training, which it is essential to document.

Bradley listed the key questions to answer ahead of any reprocessing task – for example whether the device is a single-use product. How it is used – invasively or not? Are enough instruments of the same type available? One thing to be avoided at all costs is reprocessing "in some dark corner of the surgical tract", said Bradley. Nevertheless, a desire to do just that will develop especially if too few instruments are available and turnaround times appear oppressively long. If reprocessing takes place externally, the stock of instruments must be even more comprehensive.

Bradley concluded her presentation with some observations on disinfectants. Their selection must be based on the intended use and on what pathogens are expected to be present in a specific environment.

Impregnated wipes are not the best solution, as their effectiveness depends greatly on the degree of moisture present. Often these wipes will be used for too long and start drying, so that effective concentration levels are no longer attained.

Exposure times, too, must be strictly observed; Bradley pointed out that some disinfectants have long exposure times that frequently are not respected in actual practice. Even 30 seconds can feel like a long time, and standardization is difficult.

Water – what are the risks?

The second day of the congress began with a number of sessions under the heading of "Meet the Expert". Microbiologist and water expert Jimmy Walker, Salisbury, addressed the potential risks to patients emanating from the hospital's water supply, specifically including Legionella and Pseudomonas. Walker pointed out that the source remains unclear in over 50% of cases of Legionnaires' disease, although some factors favouring it are now known. In water-conducting systems, Walker said, the rule should be that "hot water must be really hot and cold water must be really cold". Moreover, stagnation in the system's flow should be avoided. Nevertheless, even 39 years after the first description of Legionnaires' disease we still have not succeeded to adequately control the risk of this and similar diseases.

Regarding *Pseudomonas*, Walker described several installation problems that can lead to the formation of biofilm and the recurrence of pathogens. Even systems designed to prevent this, such as UV-light units at water outlet points, must themselves be carefully kept clean – otherwise there will just be an extra risk of biofilm formation. Walker recommended the establishment of interdepartmental water-safety groups to address the problem and to keep an eye on routine precautions, not just to react when there has been an actual outbreak.

Steve Mount discussed *Legionella* management in dental practices. The water utility provides water of the prescribed high quality, but the owner of the practice is responsible for the quality of the water once it has entered the building. It is advisable to perform a risk assessment for the various water-conducting systems and taps resulting in preventive measures to be implemented and documented. These measures can be very simple, such as rinsing the dental treatment unit in the morning and/or between patients, but they must be systematically carried out and docu-

mented, because inspectors will ask about them. Other measures include the installation of anti-reflux valves, the treatment and disinfection of water outlets or filter replacements if required.
If these tasks are delegated to a service provider, the competence of the provider must be assessed and the measures to be implemented must be clearly defined. This will require some preparatory work, such as the procurement of the building blueprints and contractual arrangements. Mount made it clear that any measures can only be carried out specifically for a given building or practice – no one-size-fits-all procedure is available. But the effort is worth it, especially given the fact that possible follow-up costs of more than 100,000 pounds may arise if infections can be traced to negligent water management, making a complete overhaul of the entire system necessary.

How safe is this medical device?

Wayne Spencer, authorising engineer, presented on the safety of medical devices. The term "decontamination" includes cleaning, disinfection and sterilization. The objective of decontamination is to provide a medical device that is safe for use on the patient. But is this always the case? Apparently not, as a number of reports of outbreaks or, e.g., the transmission of hepatitis B via medical devices have shown. A proper risk assessment is crucial to selecting the right decontamination steps. The same level of patient safety has to be guaranteed, regardless of where a device is processed. Spencer showed that even today reprocessing still takes place in many different places – in hospitals or in clinics, of course, but for some medical devices also within various hospital departments, such as the endoscopy department.
Decontamination is a special process whose outcome after sterilization cannot be checked directly. To evaluate the process, you have to understand it first. Processes must be validated, routine inspections and maintenance activities must be regulated and documented within the framework of a quality management system, including adequate documentation of each single step of the process.
This challenge is not to be underestimated; it is all the more important to ensure proper communication, the collaboration of all the departments concerned – for example as part of a working group on decontamination – and finally education and training using standardized and recurrent training units.

Risks in the dental environment

The special session for the dental field began with Peter Hoffman, Public Health England, reporting on contamination risks. He described the Spaulding classification as a first attempt to evaluate the risks.
Especially the handpieces are a problem in the dental practice. The use of lubricants gets in the way of sterilization with steam. Also, there are still very few washers-disinfectors deployed in dental clings, with cleaning being performed manually. With regard to endodontic instrument kits, for which there still is no satisfactory reprocessing standard, Hoffman advocated single-patient use, or the use of products that are disposable in the first place.
Hoffman praised the result of heat-based reprocessing while denouncing the highly variable results of chemical processes. Disinfectants work only in the presence of adequate moisture. The usual US designation of high-level disinfectants as "sterilants" is not accepted in Europe.
Of equal importance is the prevention of recontamination. To illustrate this point, Hoffman showed pictures of the spray that is formed when using dental handpieces. Depending on their mass, some of those particles can travel considerable distances and contaminate other instruments or surfaces.

Automated reprocessing is preferable

Jimmy Walker spoke about washers-disinfectors (WD) and the prion problem. One study attempted to simulate the transmission of prions in the dental field in a mouse model. Transmission occurred faster after duodenal than after gingival exposure. There has been no proof of any instance of prion transmission in a dental environment; the study, however, showed that this was theoretically possible.
Walker went on to speak about WD for the dental sector. A study had tested WD for dental use. There were problems with the plastic cuffs used for fitting the handpieces; these shed material or shielded parts of the handpiece so that it could not be effectively cleaned. However, the cleaning results of almost all WD met the requirements. Overall, therefore, automated reprocessing should be clearly preferred.
Water quality in dental treatment units can also be problematic. Walker pointed out that its quality often does not meet EU standards for drinking water. There are at least two case reports on aerosols from this area transferring *legionella*.

WD, sterilizers – which routine tests are necessary?

Wayne Spencer discussed the testing requirements for reprocessing equipment in the dental field. Ultrasonic baths are frequently available. They should at least have a cover and a drain to facilitate an easy water exchange.
Connectors for handpieces are often problematic in WD because they may cover parts and thereby prevent a complete cleaning. Automatic dosing of the detergent is preferable; filters must be changed regularly. Particular attention should be paid to water quality, because hard water – to say nothing of limescale deposits – increases energy consumption.
Sterilizers, which can be hard to distinguish from the outside, can be divided into different classes. Class N sterilizers are suitable for unwrapped, solid medical products, but only for non-critical medical devices, for which the sterilization is not mandatory. Most of these devices found in dental practices are older than 25 years, said Spencer.
Class S sterilizers are suitable for medical devices for which the manufacturer has approved them, including single and multiple layers of packaged medical devices (e.g. scissors, tweezers).
Class B sterilizers are suitable for all wrapped or unwrapped medical products including hollow lumens and therefore most highly recommended.
Spencer presented some case reports to demonstrate the importance of validation. Often incorrect wrong device settings – and therefore insufficient sterilization – went undiscovered. During validation, it is important to carry out the appropriate tests, but also to document these tests and their results, and any changes to the device or its settings must be clearly attested. Attempts are often made to save the cost of validation. Cutting corners in this respect will not pay off in the end, however.

Spencer concluded by presenting some routine inspection modes, such as methods for protein detection after cleaning and steam penetration tests for sterilizers. Good training or equivalent CPD is required to properly perform these tests, some of which must be carried out on a daily basis.

Specific infections and antibiotic resistance in the dental field

Andrew Smith, Glasgow, spoke about S. aureus and its role in oral infections. In addition to well-known diseases such as angular cheilitis, there are infections beyond the oral cavity, such as osteomyelitis, where the pathogen plays a role. Children and older patients – especially denture wearers – are more commonly carriers of *S. aureus* and *S. epidermidis*.

Smith pointed out that in periodontitis, the surface increases from less than 1 cm^2 to almost 40 cm^2 – a wound surface that should not be underestimated but often is. During dental treatments, substantial reflux occurs within the handpieces. Germs may then proliferate through the formation of an aerosol. Smith therefore advocated not to disregard the oral cavity during eradication efforts.

Smith later returned to the podium to talk about antibiotic resistance in the dental field. Resistance is said to be present when no further reaction occurs to the maximum doses to be administered. Studies on resistance in alveolar infection in the UK had shown that resistance to penicillin was already present in 38% of cases. In *Prevotella* species, which play a role in ENT infections, resistance to metronidazole is also on the rise. Why is that?

Smith explained that prescriptions for antibiotics in the dental field had doubled in the UK between 2008 and 2013 alone. Unfortunately, antibiotics are often prescribed simply due to uncertainty or time constraints, without a clear diagnosis – with promotes the development of antibiotic resistance. This prescribing behaviour needs to change urgently.

Smith advocated relying not on assumptions but on hard data in this area. However, this would call for systematic surveillance, which does not exist for dental outpatient treatment, even though dental procedures are increasingly invasive.

Frequent infection control failures

At the conclusion of the dental session, Elaine Ross talked about inspections in dental practices. In most cases, the focus is on reusable medical devices. Ross made clear, however, that there are other areas where infections may occur and that these are equally important.

Ross showed photographs demonstrating typical infection control failures, for example protective gear donned insufficiently or wrongly. Often jewellery is worn. Washbasins are often located in infelicitous locations, potentially resulting in the contamination of neighbouring areas and floors by splash water. Uncertainty often prevails as to when and how often to clean and disinfect. Unfortunately, it was also found that single-use devices are increasingly reprocessed, the legal consequences of which were emphasized.

Ross reported that inspections in her area carried out every three years. They now include practice observations to obtain positive information on specific processes. Cases of virus transmission (e.g. hepatitis B) have occurred more commonly in the dental environment, some of them leading to extensive patient recalls drives. So preventing the transmission of infectious material at the dentist's is a task that is as important as it is timely.

Sometimes connections are not that obvious, as Ross illustrated by a case report from Scotland. The occurrence of an unusual antibiotic-resistant germ in a patient suffering from an infection of the urinary tract attracted the attention of the health authorities, especially since the same pathogen had occurred in two other patients who, at first glance, were not in any way connected with the first one. Some detective work was necessary to identify the link – via a caregiver and a locum physician who both came from the Manchester region.

Many additional presentations on various topics within infection prevention were held at the IPS conference, attesting to the broad range of expertise assembled. Next year the event will take place from 26 to 28 September in Harrogate.