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What standards should we use for the disinfection of large equipment?

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Summary: There are no universal guidelines for cleaning and disinfecting large items of medical equipment. Washer/disinfectors provide one method of making medical equipment safe for staff and patients. Methods of evaluating the performance of such machines are discussed in an attempt to stimulate a much needed review of existing advice and guidelines on cleaning and disinfection. A plea is made for interested parties to agree practical standards for the cleaning and disinfection of medical equipment using washer/disinfectors.

Keywords: Washer/disinfectors; endoscopes; medical equipment.

Introduction

The title of this paper poses several questions. So many factors influence the answers, even in relation to one specific piece of equipment under a given set of circumstances, that the aim must be to stimulate discussion rather than to presume to be definitive.

How should we define large equipment? Should we include a consideration of surgical instruments? If not, do we imply either that we already have satisfactory standardized methods for their disinfection, or that these items require different standards from other medical equipment?

Anaesthetic and respiratory equipment must be included in our definition. What about arthroscopes and endoscopes? Are we satisfied with existing guidelines for their decontamination? Is there a standard method acceptable to all? Should we include decontamination of bedpans and urinals? For all of these examples there are many publications offering advice and guidance and suggestions for standardization of disinfection. Some of these publications attempt to be definitive: for example, the Central Sterilising Club Working Party Report on sterilization and disinfection of heat labile equipment[1] and the British Society of Gastroenterology guidelines for the cleaning and disinfection of endoscopes.[2] Others are less ambitious and offer experience and discussion of alternative methodologies.

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What do we mean by disinfection? Do we all accept Reber's[3] definition: 'the selective elimination of certain undesirable organisms in order to prevent their transmission?' Is Kelsey's[4] suggestion more acceptable: 'the state of having been sufficiently freed from microorganisms to be deemed safe for some special purpose by some competent body?' In practice, we need to determine whether a given procedure provides the safety margin needed for the specific use of the article.[5] In this context a thorough cleaning process may well reduce the bioburden to such an extent that the level of disinfection required is more easily achievable and more readily defined.

Many years ago, Spaulding[6] suggested three categories of medical equipment according to their use. These were: (1) critical items that enter sterile tissues (for example surgical instruments); (2) semi-critical items that contact broken skin or mucous membranes (for example endoscopes and some anaesthetic equipment); and (3) non-critical items that contact intact skin (for example, bedpans). An alternative but similar classification was offered by the Central Sterilising Club in 1986[1] defining high, intermediate and low-risk categories of equipment. In 1989 Nyström[7] updated these proposals and suggested that Spaulding's categories were over-simplifications. This is particularly true for equipment in the semi-critical category which may be heat-labile and where there may be difficulty in exposing organisms to the disinfecting or sterilizing process—often because of the design of the equipment. Endoscopes and arthroscopes may be good representatives of this category. For example, is the endoscope used for upper gastrointestinal tract investigation still a semi-critical item when it is used for biopsy or when it is used in a patient who is bleeding heavily from oesophageal varices? Provided that high-level disinfection can be carried out, i.e. that vegetative bacteria and viruses have been removed from the endoscope, then the endoscope should remain in the semi-critical category. Ideally arthroscopes should be sterilized, but this is not always practicable.

Spaulding's and Nyström's comments lead us to logical guidelines under which critical items require sterilization. Semi-critical items require high-level disinfection by various methods including steam at low temperature, chemicals or washer/disinfectors, or by a combination of these methods. Non-critical items require low-level disinfection based, for example, on hot washing methods or exposure to chemical agents. In this last category there is again an over-simplification in dealing with bedpans; these fall into a non-critical category by Spaulding's definition but we recognize that they require, whenever possible, high-level disinfection in washer/disinfectors.

Most of us would agree that endoscopes, arthroscopes and anaesthetic equipment should receive high-level disinfection treatment. This seems to be ideal, although there is little evidence to support the case for such a requirement for respiratory equipment and many anaesthetists pay small attention to decontamination procedures—at least in relation to bacterial

infections. On the other hand, where anaesthetic equipment is contaminated with blood and we assume human immunodeficiency virus (HIV) or hepatitis B virus (HBV) contamination, it must be mandatory to use a method that achieves high-level disinfection.

Microorganisms in relation to equipment design

We should consider the problems posed by specific microorganisms and by the design of equipment in clinical use. Is the nature of the likely pathogens an important consideration with regard to the disinfection procedure proposed? Are the likely contaminating organisms spores or vegetative bacteria? Are they waxy coated bacteria or are they hydrophilic or lipophilic viruses? Do we possess enough information on the susceptibilities of different organisms to different processes to know the answers? Or, on the basis of past experience, can we assume that the exact nature of the likely organisms is not a critical factor? Numbers of microorganisms may be a much more important consideration. Numerous studies have provided information about the likely bioburden on certain items of medical equipment before decontamination.[8–10] Is this information applicable to other items under different conditions of use? It has been suggested that we require more studies of this kind before we can define standards for disinfection.[7]

The efficacy of any disinfection procedure is assessed on a balance of probabilities. We therefore need to know the likely level of contamination (as is required in industrial regulations)—unless we assume what might be called a Domesday scenario of the worst possible case. This has happened in clinical bacteriology laboratories where we attempt to make our discards absolutely safe. This situation is not accepted in the hospital wards and clinics where similar standards are not achievable or even thought necessary.[11] We do accept that physical cleaning reduces numbers of organisms. Should this cleaning be thought of as part of the disinfection process? This consideration raises major questions for us about methods of cleaning and about design of cleaning machines and the medical equipment to be processed in them.

The likely location of organisms on equipment and the presence of organic material must be considered. Joints, channels, crevices and blind ends all present difficult problems. Manufacturers of clinical equipment must be encouraged to consider the difficulties of the disinfection process. There is a continuing need for co-operation in designing both the equipment and the means by which it can be made satisfactory for its next clinical use. We have a responsibility to ensure that equipment is exposed to a level of decontamination sufficient for its clinical purpose and this requires consideration of individual items rather than blanket categorizations. We also have to make equipment safe for Sterile Services department staff to handle.

The discussion of a definition of disinfection is not part of this paper but there is a need to attempt to review methodologies and suggested controls for achieving disinfection, however this may be defined. It is intended to do this with particular regard to high-level disinfection achieved by washer/disinfectors. It is left to others to discuss, for example, low-temperature steam and chemical disinfection methods.

Washer/disinfectors

Autoclaving is not usually an option for large equipment with many heat-labile components. Repeated autoclaving tends to reduce the working life of equipment, and autoclaving before washing fixes proteinaceous material and poses serious subsequent problems. Can we afford to assume all possible risks at all possible times? The use of washer/disinfectors represents an attempt to provide reasonable safety margins for staff and patients. We are attempting to decrease the bioburden even though it may be relatively light in the first place.[8] In this context, the exercise is a compromise approach in an effort to avoid increasing costs and complicated procedures. Washer/disinfectors offer some advantages in that the process is controllable, often automated and avoids the use of potentially toxic chemicals and gases. Many sterile services departments have washer-disinfectors in daily use (Collins BJ, personal communication) but whether or not these are used optimally is difficult to say. Numerous documents and reports attempt to define standard guidelines for cleaning and disinfection of semi-critical equipment. Notable advice is given from such bodies as CDC Atlanta in the USA and the Swedish Planning and Rationalisation Institute of the Health and Social Services (SPRI). Within the UK a good example of sensible guidelines for the safe use of flexible intestinal endoscopes are those of the British Society of Gastroenterology. However, firm guidelines for all types of washer/disinfectors and their use with different items of medical equipment are not available in the UK. Others, notably our Swedish colleagues, have proceeded further along this road. The Central Sterilising Club has provided extremely useful Working Party Reports[1,12] but these are not exhaustive and many questions remain unanswered.

Assessing washer/disinfectors

Washing is an essential stage in the reprocessing of most clinical equipment; by washing early in the process cycle and then allowing adequate heat disinfection we should be able to render equipment safe. What then do we need to concentrate on when laying down specifications for washer/disinfectors? Estimates of the basic functions of cleaning and disinfection are but a part of any assessment.[13] We must also take account of energy and water consumption, safety and design features, and user and consumer satisfaction with processed equipment.

There are many variables that might affect cleaning and disinfection, for example, time of exposure of equipment to washing, disinfecting or even drying cycles. The temperature and pressure of water will be major considerations. Other factors of importance might be machine design, the equipment processed and the use or not of detergent. Finally, the size and configuration of the load might be relevant. Nystrom, however, has pointed out that it is important to assess and validate the basic functions of cleaning and disinfection and not the variable means by which they might be achieved.[14]

Cleaning

The term must be defined. Evaluation by visual inspection is the obvious method but it cannot be standardized. Artificial soils have been devised in efforts to simulate natural soiling and these soils have been suggested as test methods for measuring cleaning efficiency in washer/disinfectors. A British Standard exists for an artificial soil for evaluating bedpan washers and this soil is a mixture of 10 ml serum, 6 g dried milk powder and 1 ml 1% nigrosin. In 1980, Cederberg & Osterberg described a method utilizing *Bacillus stearothermophilus* spores (which are not sensitive to the possible disinfecting effect of hot water) suspended in autoclaved faeces.[15] In any attempt to define acceptable standards, the use of faeces does not seem a reasonable proposition. More recently, colleagues in Sweden have produced suggestions for an artificial soil to evaluate the machine washing of surgical instruments, bedpans, urinals and anaesthetic equipment.[16] This consists of citrated bovine blood (between 5 and 14 days old) with calcium chloride 2·5 mmol l^{-1} in distilled water. For wash bowls, their suggested soil is a soap solution with calcium chloride in deionized water. These soils are used on predetermined machine loads together with pre-drying of the soil for a standard period. Other workers have attempted other ways to imitate natural soiling when evaluating cleanliness of bedpans. Koller[17] has suggested a mixture of eggs, wheat flour, commercial mashed potato, water and dye solution and claims that this is an acceptable imitation of faeces. German colleagues, in industry, have formulated a mixture of milk powder, sugar, butter and semolina as a test soil for washer/disinfectors of anaesthetic equipment (Romfeld, personal communication). In Birmingham a formula of 5 g plain flour, 5 g hog mucin, 20 ml horse serum, 20 ml distilled water, 1 ml 2% safranine solution with 0.1% benzalkonium solution as a preservative is used (Collins BJ, personal communication). This mixture was suggested as a suitable soil for evaluating the washing of anaesthetic equipment. The Edinburgh team formulated their own soil for this purpose consisting of 100 ml egg yolk, 10% sheep blood and 2% hog mucin.[13] In tests, the Birmingham soil was definitely stickier than the Edinburgh soil but the relative merits of these soils remains debatable.

This remains the problem in evaluating cleaning efficiency using artificial

soils. There is no internationally agreed standard for artificial soils and there is no agreement on how soils should be applied to test articles. There is an urgent need for these to be defined, in either British or International standards.

How well do these artificial tests imitate real conditions? Experience in Sweden with the SPRI tests[16] and experience in Edinburgh[13] suggest that machines that pass our artificial tests do actually clean most equipment well. However, this is not true for bedpan washers where test passes and real-life failures are the norm.[14] Further questions have been asked about cleaning tests. Should they be performed on new or old (and therefore scratched and dented) equipment? Should the detergent be standardized? What might be the effect of hard or soft water? Perhaps we should agree with Nystrom[14] and concentrate on the basic functions of cleaning and disinfection and not on possible variables.

Is it possible to replace these practical tests with specifications of machine function—for example, water temperature and volume and exposure times? This is unlikely to happen because of the enormous capital cost of incorporating new technology and monitoring devices. There might also be a significant revenue expenditure to be considered.

Disinfection

Is disinfection the destruction or removal of organisms, or a combination of these? The textbook concept is that the pathogenic challenge is significantly reduced. Nyström[14] and Groschel[18] have suggested that machines that achieve acceptable cleaning of surgical instruments and other equipment remove so many organisms that a disinfection cycle is unnecessary. This is not true for bedpan washers and this reflects the less efficient cleaning cycles of these machines. Effective cleaning, however, is a component of disinfection, though it is conceded that the term 'disinfection cycle' usually relates to an identifiable part of the process.

Before making any evaluation of the disinfecting cycle of a washer/disinfector, two factors should be considered. A preliminary assessment of the heat distribution characteristics of the machine is essential. Thermocouple testing is required to find any 'cold spots' that occur in many machines. Biological tests should be designed to take account of any such problems. Should the assessment of disinfecting ability take account of any drying cycle incorporated into the machine? If a machine has a pre-set drying temperature of 90°C might this not have an effect on thermal disinfection, for at least some items of the load? Recent studies in Edinburgh have suggested that variation of temperature on items of the load during the drying cycle could be very great, because air is the heat transfer medium.[13] This factor should probably be disregarded.

Swedish authorities do not accept that even excellent cleaning makes disinfection unnecessary and insist on a formal assessment of the

disinfecting ability of a machine. Nilehn[19] suggested a method that allowed testing of disinfecting function without interference from a cleaning procedure. This method uses suspensions of bacteriophage or *Streptococcus faecalis*, sealed in plastic capillary tubing taped to articles in the machine and to the machine surface. This methodology has been adopted and adapted by various authors, notably Ayliffe and colleagues.[20] At least three different strains of *S. faecalis* have been suggested for use and the Edinburgh team, disliking capillary tubing, used polypropylene microcentrifuge tubes to contain the suspensions of organisms.[13] These tubes were more easily handled and because of the greater thickness of the plastic walls they were likely to conduct heat more slowly and might therefore have been a more severe test. This has not, as yet, been confirmed in experimental procedures. Recent work on the Anda 9002 washer[13] with this test of heat disinfection showed that disinfection could be achieved over a wide range of temperatures (70–95°C) and times (3–15 min). Evaluations were not made over shorter times but it has been shown that in a bedpan washer, and using a *S. faecalis* test, thermal disinfection could be achieved at 65°C for 1 min.[12] The killing curve for *S. faecalis*, however, is flattening out at this temperature and the group's conclusion was to propose a minimum exposure of 2 min at 70°C. But can we accept the *S. faecalis* test as a satisfactory standard when we consider the possible threat posed by viruses and mycobacteria?

Human immunodeficiency virus (HIV) and hepatitis B virus (HBV)

McDougal and colleagues[21] proved, for HIV in a liquid matrix, that heating to 60°C reduced virus titre by one log in 24 s. By extrapolation, heating to 70°C would reduce the titre tenfold in 0·5 s. On the other hand, lyophilized virus requires 32 min at 60°C to reduce the titre by one log. Other workers[22] indicate that 60°C for 30 min will inactivate 10^5 units of infectious HIV. It seems reasonable to conclude that if a washer/disinfector achieves temperatures, on articles, of over 70°C (and most operate at temperatures significantly higher than this) then HIV inactivation is assured. None of this takes account of the cleaning action of the machine.

HBV is much less heat-sensitive. We know that exposure to 98°C for 2 min will inactivate at least 10^5 infectious units of HBV, as assayed by inoculation into chimpanzees.[23] Data for lower temperatures and other exposure times are not available, apart from probably impractical exposures such as 10 h at 60°C or 85°C for 1 h.[24] The major problem in researching this is in assaying titres of activity, in that chimpanzees are the only system available to us. In January 1990 an HIS Working Party concluded that, with regard to HBV, the disinfecting efficiency of an exposure to 80°C for 1 min or to 65°C for 10 min is uncertain. However if this exposure is associated with a washing process they concluded that equipment should be safe from the risk of transmission of HBV.[25]

Mycobacteria and other organisms

Those mycobacteria that might pose a threat on clinical equipment have a thermal death point of 60°C when exposed to dry heat for 15–20 min.[26] There is no suggestion that mycobacteria are more difficult to deal with than HIV or HBV. One other organism that may require further consideration is *Clostridium difficile*. Nystrom[7] has briefly questioned the adequacy of present washing and disinfecting procedures in bedpan washers, in respect of an organism that sporulates easily and which is recognized as a cause of infection transmissible in hospitals.

Finally, with regard to disinfection, can we substitute the suggested practical tests with specifications of machine function? Nystrom[14] has pointed out that specification of, for example, water temperature and rinsing time could not guarantee that satisfactory temperatures and exposure times would be achieved for all items within a machine load.

Safety, design and user satisfaction

There are other considerations to be made when evaluating either established or new washer/disinfectors. With regard to machine safety and design, and leaving aside the need for conformation to electrical safety standards, are energy and water consumption within acceptable limits? Is contaminated rinse water (especially in continuous process washers) safely removed with no possible recontamination of articles? Would it be possible to install control mechanisms to indicate when jets or nozzles become blocked or supporting metal work becomes misaligned? One essential control is to ensure that if pre-set exposure times and temperatures are not achieved then there should be some indication of machine failure. Under these conditions it should be impossible for any operator to remove the load under the assumption that it had been disinfected. It should also be possible to ensure that the machine cycle cannot be interfered with during operation. Any machine must also be evaluated from the point of view of the users of the processed product. Recent experience with an anaesthetic equipment washer resulted in the manufacturers making design modifications in order to prevent damage to equipment.[13] More details of evaluation techniques are available in Central Sterilizing Club publications.

Conclusion

It must be conceded that the questions posed within the title of this paper have not been answered. Emphasis has been placed on the real need for firm guidelines on standards for cleaning and disinfection that should be applied to washer/disinfectors. Is there a basis for such standards in the information we now possess? There is a requirement for us to pool this information and to extract from it, if we can, agreed principles, methods and standards for disinfection. Who should define those standards? Should individuals stand

alone or should we insist on international co-operation? We need to include manufacturers of both clinical and machine equipment in our debates. We must attempt to eliminate, so far as is possible, designs that are difficult to clean. We should encourage the use of new materials and technology, for example, distributed sensing using fibreoptic technology. There is a need for further development of machine design and of monitoring and control systems. We must decide what we require from such machines, bearing in mind the intended clinical use of items that might be processed in them. Surely it will not prove impossible for interested (or even nominated) parties to agree appropriate standards but we should exercise the greatest care to avoid excessive costs that might arise in installing additional control mechanisms or test procedures.[27]

Our approach to this task must be to ask ourselves: is any suggested procedure reasonable? Is it feasible? Is it practical, especially for those with either limited facilities or expertise? Is the result obtained a reliable indicator of whether or not cleaning and disinfection has been achieved? Finally, is the approach reasonably cost-effective?

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