

REPORT OF THE INTERNATIONAL SYMPOSIUM ABOUT THE REUSE OF SINGLE USE MEDICAL DEVICES IN THE HEALTH AREA

Date: May 25th and 26th 2006

Place: Brasilia

Organization: Julival Ribeiro (DF), Kazuko Uchikawa Graziano (EEUSP), Silma Pinheiro (PUC-MG), Heloisa Ribeiro da Silva (DF).

Promotion: Center of Hospital Infectious Disease Control of the Federal District, Group of Research (CNPq), Technology and Quality in Cleaning, Disinfection, Sterilization, and areas of anti-sepsis; Program of post-graduation in adult health of the nursery school of the University of Sao Paulo; Brazilian Infectology Society; Brazilian Association of professionals in Control of hospital infections and epidemiology and Alliance for Prudent Use of Antibiotics – Brazil.

Programme

05/25/2006 – Thursday

07:00 a.m. – 8:00 a.m. – Folders delivery

08:00 – 08:30 a.m. – Official Opening

08:30 a.m. – 12:00 p.m. – *Microbiology applied to the processing of hospital devices*

Coordination: Dr. Jorge M. Buchid Amarante – SP

Formation of biofilms and the reuse of single-use medical devices – Dr. Rodney M. Donlan (Biofilm Laboratory, Division of Healthcare Quality Promotion, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, USA)

Mechanisms of the formation of endotoxins / pyrogens – Dr. Rodney M. Donlan

Reprocessing and mechanism of bacterial growth and death – Professor Dr. Terezinha de Jesus Andreoli Pinto (Pharmaceutical Sciences College of the University of Sao Paulo)

02:00 – 3:30 p.m. – *Risks resulting from the utilization of reprocessed medical devices*

Coordination: Dr. Kazuko Uchikawa Graziano – SP

The efficacy in cardiac catheter's cleaning – Silma Maria Cunha Pinheiro (Nurse, Masters Degree in infectious and parasite diseases, Professor of the Pythagoras College of Belo Horizonte and PUC-Minas.

Adverse clinical events related to the single use – Dr. Cresio Romeu Pereira (Epidemiologist and Infectologist)

03:45 – 06:30 p.m. – *Bases of Reprocessing in hospital-medical devices*

Coordination: Dr. Maria Clara Padoveze – SP

Cleaning of hospital-medical devices (principles, methods, and validation) – Dr. Michelle Alfa (Ph.D., FCCM, Assistant Director, Microbiology Laboratory of Research Center of St. Boniface General Hospital, Winnipeg, MB – Canada)

Cleaning methods, disinfection, and sterilization in health institutions – Dr. Kazuko Uchikawa Graziano (Associated Professor of the Medical-surgical Nursery Department of the Nursery school of the University of Sao Paulo)

05/26/2006 – Friday

08:00 – 08:30 a.m. – *Is it possible to reuse under control? Principles, strategies, and risks*

Coordination: Silma Maria Cunha Pinheiro – MG

Dr. Michelle Alfa

08:45 – 10:15 a.m. – *The ethical and legal aspects of reprocessing? Reuse?*

Coordination: Dr. Jorge M. Buchid Amarante – SP and Professor Dr. Maria Lucia Pimentel de Assis Moura – SP

Lecturers

Professor Dr. Demercindo Brandao (Medical Doctor and lawyer – FCMMG)

Dr. Alvaro Luiz S. Pinto (Representative of the Federal Medicine Council)

Ivone Martins Oliveira (Representative of the Federal Nursery Council – COREN-SP)

Dr. Jose Luis Miranda Maldonado (Representative of the Federal Pharmacy Council – Technical assessor)

10:30 – 12:45 a.m. – *Brazilians Societies' stand in relation to the reuse of single-use medical devices*

Coordination: Dr. Anna Sara Levin – SP and Dr. Maria Clara Padoveze – SP

Dr. Jorge M. Buchid Amarante (Representative of the Infectious Diseases Society of Brasilia)

Dr. Teresa Sukiennik (Representative of the Brazilian Society for Hospital Infections and Epidemiology)

Joao Francisco Possari (Representative of the Brazilian Association of Nurses in Surgical Centers – Director)

Dr. Ronaldo da Rocha Loures Bueno (Representative of the Brazilian Association of Homodynamic and Interventionist Cardiology)

Dr. Vera Helena Mello (Representative of the Brazilian Society for Gastrointestinal Endoscopy)

Dr. Guilherme Pinto Bravo Neto (Representative of the Brazilian College of Surgeons)

Dr. Valeria Cardoso de Souza and Dr. Alexandre Manzano (Representatives of the Brazilian College of Radiology and Images diagnosis)

Dr. Jorge Eduardo Amorim (Representative of the Brazilian Society for Vascular Surgery and Angiology)

01:45 – 03:45 p.m. – *Buyers and producer's stand in relation to the reuse of single-use medical devices*

Coordination: Dr. Marisa Santos – RJ and Eliane Molina Psaltikidis – SP

Afonso Medeiros (Brazilian Association of Industries and medical devices – ABIMO)
Eduardo Thompson (Brazilian Association of equipments, devices, and medical supplements importers – ABIMED)

Katia Simoes (Brazilian Association of Sterilization Companies in ethylene oxide)

Dr. Eduardo de Oliveira (Federation of Brazilian Hospitals)

Dr. Carlos Armando Lopes do Nascimento (High Complexity of the Ministry of Health – General Coordinator)

04:00 – 05:15 p.m. – *How to implement and to control the processing protocols*

Coordination: Dr. Jorge M. Buchid Amarante – SP

Maria Angela de Avelar Nogueira (Representative of the National Agency of Sanitary Control – ANVISA)

05:15 – 06:20 p.m. – *Synthesis of the event*

Dr. Anna Sara Levin Shafferman (HCFM-USP)

Professor Dr. Rubia Aparecida Lacerda (Nursery School of the University of Sao Paulo – Medical Surgical Nursery Department)

07:00 p.m. – *Closure – Organizational Commission*

INITIAL COMMENTS

We detach the merit of the event's organization in elaborating a programme with wide content, involving technical, ethical, and political aspects, which made possible the mobilization and debate among the participants, the representatives of the various sectors related to the health care, and the expression of favorable and unfavorable opinions related to the reuse of devices originally of single use and to the recent Resolution n° 30, of February 16, 2006 of the National Agency of Sanitary Control, about this same theme.

SYNTHESIS OF THE PRESENTED THEMES

Formation of biofilms

The content embraced the mechanisms of biofilm formation, its clinical impact, and the difficulties and possibilities of its removal. The main aspects presented were as follows:

- Biofilms form itself around inserted articles in the human body, being able to occur after a few hours of use.

- Biofilms include cells, microorganisms, and outer-cellular polysaccharides
- The variations associated to the formation of biofilms are: under layer (texture, hydrophobicity, conditioners of the plastic film), fluids (velocity of infusion, pH, temperature, cations presence, - Ca⁺⁺ e Mg⁺⁺ - (microbial agent's concentration), cellular surface (hydrophobicity, fimbriae, flagellum, EPS-extra cellular polymeric substances)
- Microorganisms that already were proved to produce biofilms: *S. negative coagulase*, *S. aureus*, *P. aeruginosa*, *P. mirabilis*, *E. coli*, *e. faecalis*, *S. viridans*, *C. albicans*, *C. parapsilosis*
- Strategies for the removal of biofilms:
 - Mechanical actions by the production of ultra sound through combs that carry out the mechanical treatment, as it is applied in odontology;
 - Active detergents over the surface (surfactants), which tend to change the surface tension of the biofilm, making its removal easier;
 - Enzymes;
 - Oxidants and chelators, where chelators can capture Ca e Mg, turning the element unstable and turning the removal easier;
 - Antimicrobial agents;
 - Bacteriophage;
 - Combinations of different agents. For example, a device named Prometron, combining enzymes, detergents, and surfactants not ionic and hypochlorite of sodium, was studied in dialysis machines.

Endotoxins

In this presentation, conditions for the formation and the detection of endotoxins were related; being detached the possibility of its concentration to increase after the cleaning of these medical devices, where the quality of the rinse water represents an important role. The main aspects of this content were:

- Microorganisms, particularly the gram-negatives, can liberate endotoxins, basically the LPS (lipopolysaccharides), which are stable to heat, resistant to dissection, and highly adherent to non-organic material;
- Endotoxins trigger systemic inflammatory reaction;
- The potential source of endotoxins are: soil surface, gastrointestinal flora, and water system;
- The quality of water is not an indicator of water free from endotoxins. Therefore, the devices, mainly the critical ones, must suffer water rinsing free from endotoxins or pirogens, since it may occur re-contamination. Without this condition it is not possible to reprocess safely;
- Endotoxins' limits: 0,5 units/micrograms in medical devices in general and 0,06 units/micrograms in medical devices in contact with the cardiovascular system.

Reprocessing and mechanism of bacterial growth and death

The development of this technique allowed to recognize the different forms of behavior of the microorganisms, the aspects of the biocompatibility of devices, and the necessity of microbiological cleaning and sterilization tests to detect all of the known organisms and susceptible of transmission during the assistance procedures with

reprocessed devices, including all the virus and the prions. It was detached, as well, that the risks of reuse include the mal functionality of the device, cleaning failure – generating potential organic residuals – or failure in sterilization.

For secure reprocessing it must be assured that the device is sterile, without potentially damaging residuals and maintained functionality. For the evaluation of residuals in devices a few testes were suggested, such as the detection of proteins (Bradford test); detection of hemoglobin (TMB); detection of ATP (specific enzyme).

Physical, chemical, and functional changes

The results of a PhD thesis about the reuse of angiography catheters allowed the following and main conclusions:

- Automatic cleaning shows better results than manual cleaning;
- Cleaning in reverse osmosis results in less quantity of residuals than in tap water;
- The catheter can be sterile and functional, but can present other types of residuals, such as proteins and endotoxins that may interact with the host;
- The use of enzymatics increased the load of residual proteins, when compared with detergents formulated with the combination of hydrogen peroxide;
- There is a clear difference between qualification and validation of reprocessing, being necessary for validation the utilization of scientifically tested protocols.

Adverse effects related to reuse

The presentation of a systematic literature revisal about such effects revealed the existence of few studies and, nevertheless, with contradictory results and varied methodologies and problematic, which does not allow, still, conclusive evidence.

Principles, methods and validation in medical devices' cleaning

The lecturer considered that if the device cannot be cleaned, it cannot also be sterilized, and he showed himself favorable to the superiority of mechanical cleaning as opposed to the manual cleaning.

The definition for cleaning and sterilization must consider, as well, the type of device, according to the risk of contamination (critical, semi-critical, and non-critical), with special emphasis for the characteristics of devices that endanger the cleaning quality: narrow lumens (ex: esfínterotomos); edged instruments with hooks or sawed that do not have openings for internal cleaning (ex: video instruments); catheters with balloons (ex: cardiac catheters); non-disassembled devices. Therefore, devices with such characteristics must be discarded.

Methods for testing the cleaning efficiency were also mentioned: sonication, retro-flushing, high flow and forced entry of fluids. In some situations, the use of a retro-cleaning mechanism can improve the cleaning's final result, since it is associated with ultra-sound. Besides that, it was emphasized that the best sterilization method is still with the autoclave.

Cleaning, disinfecting, and sterilization methods in health care institutions

This presentation allowed to understand that the issue of reprocessing does not refer only to the fact of the device being originally defined as of single use or not, but in its possibility of being reprocessed with quality and control of risks. For so, one must initiate with an adequate infrastructure from the device and sterilization center, which includes physical plant, human resources, and process, where the availability of the best technology does not guarantee, for itself, effective result.

Other aspects discussed were:

- Cleaning represents the main aspect of reprocessing and we should question if we are doing everything that is possible;
- The enzymatic detergent, currently the most applied device for cleaning in our area, is limited and therefore other devices must be associated;
- Necessity to establish limits of tolerance to endotoxins;
- Generation of a validation “culture” from cleaning process;
- Consider the re-introduction of rinse with distilled water;
- Reinforced autoclave as the best method of sterilization for thermo resistant devices, since adequately validated;
- Preference for mechanical-chemical methods and not in solution for thermo sensitive devices, because of the difficulty in its abundant rinsing, of the risk of re-contamination, and of the impossibility to apply result tests, besides the occupational risks for its toxicity;
- The cost/benefit must never be primarily based in money;
- Assistance requirement and device’s manufacturer advisement in relation to its reprocessing.

Other technical aspects presented and debated

- The evaluation of the device’s functionality is complex and no reference method was presented for its application in health institutions;
- User’s satisfaction was mentioned as a component to be evaluated;
- Validation of the procedures of reuse and its assurance was considered as being practically impossible for hospitals in their current conditions. Validation of protocols is not a routine procedure. These institutions can only do qualifications of their methods. A potentially viable alternative is an association of reprocessing institutions and universities for the elaboration of protocols scientifically validated;
- Necessity of research in order to identify the level of residual protein tolerance, when failure is not detected in sterility or high levels of endotoxins.
- Incorporation of new technologies should be based on evidence, mainly in relation to the device’s effectiveness.

This last aspect was frequently present during the various presentations and debates, including as follows:

- The definition and the quality of evidence must be considered before utilizing research as theoretical reference;
- While evaluating research with non simultaneous groups (historical control), it must be considered that the difference between two groups can be

conferred to the effects of learning, regression to average, and secular tendencies;

- In publications about the subject, one must evaluate: the design of the analyzed devices, because some devices are very different among themselves; if there was use of positive and negative controls for any physical/chemical/biological test done; if the test is destructive or if it is related to research *in situ*; if there was logarithmic reduction identification in the cleaning process;
- Sporulated forms are good sterilization evaluators, although they are not good cleaning evaluators. For cleaning evaluation vegetative forms must be utilized, especially from microorganism biofilm promoters.

Brazilian Societies' stand

In general, the Societies were not contrary to reuse, but they presented several considerations:

- Preference for permanent devices;
- Reprocessing validation;
- Creation of adverse events surveillance;
- Analysis of the availability of reprocessed devices, including necessary time spent and agility in accomplishing the procedure;
- Regularization of multiple-use devices;
- Better explanation by the National Agency of Sanitary Control – ANVISA as regards to the list of devices prohibited of being reprocessed;
- National Agency of Sanitary Control's decision on the reuse protocol;
- Development in the qualification of human resource involved in reprocessing.

Finally, in spite of the acceptance in relation to the necessity of regulation on this thematic, it was taken in consideration, as well, that the legislation, as it is, cannot be executed and that the government needs to be coherent with the legislation and financial subvention, since, for several times, the value paid by the health financiers is much inferior to the value of the necessary devices for the accomplishment of procedures. A re-evaluation of the device's tax burden can be one of the solutions to diminish the final costs of procedures.

Manufacturer and buyer's stand

Their stand was not consensual and it revealed the enormous conflicts of interests that are involved in this issue.

CONSIDERATIONS

From the themes discussed and the debates that occurred, the following considerations were as follows:

Ethical, political, and economical considerations

- Reuse is a reality in the country and in the world, and there are no predictions of changes in this situation in a short and medium term, at least in Brazil;
- The practice of reuse is very wide range, without standardized device and procedures and without control of final results;
- Increasing technology raises the prizes of developed devices;
- Devices are frequently more expensive than assistance payers – public and private – cover or, payers do not cover all the necessary devices to accomplish all procedures. This situation determines the following consequences: a) governmental contradiction between a recent legislation from the National Agency of Sanitary Control and the wage of the Unified Health System; b) veiled complicity between paying and accomplisher agents, establishing “closed parcels”.
- The patient, main interested, is excluded from the decisions taken, since he does not know either that reuse occurs or which devices are applied;
- Great controversy as regards to the patient’s necessity to sign an agreement term which informs about the reuse of medical devices;
- Difficulty to define reusable and non reusable devices, which currently depends only on the manufacturer’s decision;
- Research work statistics demonstrate that there are few registered adverse events, nevertheless the wide range practice. Research methodology of the few works that were done in this knowledge area is questionable; therefore, even though there are not evidence that reuse causes damage, there are not evidence as well that it does not cause damage. Besides that, several publications do not present the devices’ standardize utilized in cleaning;
- In the United States of America reprocessing of single use medical devices is done by outsourced companies regulated by the FDA;
- In Canada, studies that were done in 421 hospitals showed that only 20% had a Reuse Committee and, of these, only 30% with written protocols. In 1996, The Canadian Healthcare Association Guideline was published with recommendations about reuse practice. In this country, critical devices are not reused (except for some institutions that reuse homodynamic catheters), but semi-critical devices are reused with more frequency. Until now, health care systems are those who accomplish reprocessing, but due to the protocol’s validation complexity, the great majority of health services do not have conditions to maintain this practice;
- In Europe, since 2005, reuse is prohibited by law;
- In Asia, 95% of the health care services reprocess single use medical devices;
- The main causes of reutilization are: economical impact of new technologies; universal availability; outcome acquisition difficulties; ecological impact due to the accumulation of trash in the environment;
- Studies of the cost/benefit to compare new and reused devices are still very few and not conclusive.

Technical considerations

- Reprocessing validation is not a routine, protocol, or qualification, but a scientifically tested method;

- Reprocessing difficulties do not depend on whether it is single use device or not, being necessary a re-conceptualization of the single use device that does not depend only on the manufacturer's definition;
- The procedures to consider a single use device as of multiple use, with acceptable reprocessing and the establishment of discard moment, i.e. with the maximum number of reuses, are still not well established;
- Critical devices present greater risk for the patient when compared to semi-critical and non critical devices;
- Critical devices must have special attention on their evaluation, because these are the ones that show the highest costs and associated risks;
- Visibly deteriorated devices must be discarded;
- Preference to the similar reusable devices, when this option is available in the market;
- Establishment of validated protocol for any reuse;
- Use of water with controlled quality must be implemented;
- Use of enzymatic solution should not occur more than the established time and there should be abundant rinsing;
- Cleaning stage must be considered as fundamental, either in single use devices or in re-utilizable devices;
- The use of standardize methods of automatic cleaning evaluation, such as "TEST SOIL" (simulation with unclean blood) and TOSI Device (mechanism that is inoculated com uncleanness – pattern) for the validation of the cleaning's efficiency in cleaning machines;
- Necessity of validation not only of organic and sterile residual, but also of functionality. About this, there are doubts on how to proceed: user's satisfaction? Frequency on adverse events? Study on materials?
- Sterilization tests must consider long term incubation infections (HBV, HCV, HIV);
- Necessity to define who is responsible for the reprocessing validation, since it is not a synonym for qualification, demanding clinical research that the great majority of the health services do not have conditions to accomplish. Will this research exclusively depend on universities? Do manufacturers and reprocessing companies have interest?
- Wide spread penetration through the country of validation procedures by the government, by the ANVISA and by professional associations.

RECOMMENDATIONS

To the governmental organizations

- Clear definition of procedures considered as reuse validation;
- Control of manufactured devices' prices;
- Stimulate the low cost of single use material by reducing taxes and developing "generics";
- Institute guard, notification, and publishing system of adverse events related to reuse;
- Subsidy for research projects of general interest. If well divulged and financed, these projects will clear aspects which are not conclusive at the present moment;

- Stimuli to the production and use of permanent material, with good development;
- Exigency of supply by the validated protocols producers for reprocessing reusable device.

Professional associations

- Elaborate recommendation guidelines that will certainly be incomplete in the beginning, but being able to improve in the future;
- Formation of Reuse Committees, which should be multidisciplinary, with the inclusion of administration professionals, CVC, microbiology;
- Accomplish a critical analysis of the cost in reuse;
- Definition of stages in reprocessing: infra-structure, cleaning (how to do it and how to evaluate), packaging, sterilization, storing, tracking (product x patient), control on the number of reuse, personnel training routine, discard criteria, requests and suggestions to maintain the water quality, criteria for decision on which products are possible to reuse and which are certainly of single use.

Health care services

- Formation of a reuse commission;
- Adequacy on infra-structure of the material center;
- Evaluation of each of the products before considering their reprocessing;
- Establishing clear routines for each of the stages in the process;
- Control of the number of times each item is reprocessed;
- Valorization of human resources.

CONCLUSION

The recognition about the necessity of regulation on reprocessing of devices utilized in assistance seems to be consensual. The dissent happened due to the new Resolution passed by the ANVISA, which was very much criticized by the representative of the various sectors of society. In the contrary, this Resolution had its merit due to the wide discussion that resulted from it about a thematic which is not of easy solution. It is a fact that there is a need for this Resolution to consider all the interests and necessities of the health care assistance body and being able to be open so suffer modifications and improvements, in a constant and steady process of evolution.

