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PRACTICE FORUM

Safer use of disinfectants for instrument reprocessing: A call to action

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Health care-associated infections are a major cause of death and disability worldwide *"At any time, over 1.4 million people worldwide suffer from infectious complications associated with health care… in Mexico, health care-associated infections are the third most common cause of death for the entire population…Added to the considerable human misery caused by health care-associated infections is their economic impact...In Mexico, these costs represent 70% of the entire budget of the ministry of health"*.[1] In overcrowded and understaffed health services, the incorrect use of medical technology is commonplace - inadequate instrument reprocessing and contaminated disinfectants are important risk factors for the transmission of infectious diseases to patients while they receive care for other medical conditions.[2-4]

Heat sterilization of critical and semicritical instruments continues to be the safest and preferred means for instrument processing between patients.[5] Exceptionally heat-sensitive instruments may be cold sterilized or, at a minimum immersed in sporicidal solutions, capable of sterilization or high-level disinfection (S/HLD).[6,7]

In addition to the potential for misuse and abuse of efficient sporicidals, wherever manufacturers, regulators and end users don't apply the appropriate taxonomy and science-based recommendations, there is a risk for antiseptics and low to intermediate-level disinfectants to be improperly labeled, cleared for trade, sold, and used, under label claims for S/HLD of medical and dental instruments.

In many countries, this complex problem has its roots in those governmental agencies responsible for establishing standards and enforcing regulations. In the absence of scientific criteria and standardized evaluation protocols, regulation of disinfectants intended for S/HLD in health care facilities is based solely on good faith.

Without availability of well equipped testing facilities of their own, regulatory authorities accept reports on "presumptive" S/HLD-efficacy, resulting from arbitrary testing sometimes designed, performed and presented by manufacturers or their distributors.

In Latin America, a wide variety of chemical products are sold with label claims for "sporicidal activity", "sterilant", "high level disinfectant": In Mexico, a benzalkonium chloride (BKC) formulation manufactured in California and distributed from

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Atlanta, was registered by the Secretaría de Salud under a label claim for "instrument sterilization in one minute immersion". This product failed sporicidal activity tests.[8] Many quaternary ammonium compounds with similar claims remain in the market. In Mexico, the outdated national official standard NMX-BB-040-from the Secretary for Trade and Industry is the reference document for antimicrobial activity in germicides.

In an evaluation commissioned by Mexico City's public health authorities,[9] a super oxidation solution, made in Mexico under license from a US-based company, and registered as a sterilant effective in 15 minutes did not kill 106 spores in 10 hours. Three glutaraldehyde solutions registered as "sporicidals for S/HLD", one French, one Swiss, and one made in Mexico, all failed to destroy Bacillus atrophaeus spores in 10 hours.

In Venezuela, two companies produce and distribute the quaternary ammonium compound dodecyl dimethyl benzyl ammonium bromide (BAB) with label claims to sterilize medical and dental instruments. Both BAB solutions failed tuberculocidal activity tests.[10] BAB is a low level disinfectant that may have contributed to surgical-site infections.[11] A leading biomedical researcher independently evaluating these products and reporting his findings has been the target of legal action by the manufacturers. One of these BAB formulations made in Venezuela is distributed in Panama and other Latin American countries.

The international infection control community must be aware that many nations need help to develop and enforce scientifically sound standards for the registration, sale, and use of disinfectants. In particular, more stringent, evidence-based validation for sterilants/high level disinfectants used on medical and dental instruments. Introduction of a simplified and reproducible protocol for testing sporicidal activity will help in the identification of reliable products and the exclusion of unsafe formulations even in resource-limited settings.

In the absence of scientific criteria and standardized evaluation protocols, disinfectant misuse in health care settings adversely affects patient safety and remains an important challenge. The international infection control community has the collective expertise and scientific standing to help solve this problem by designing low-cost, simple and effective strategies to prevent disinfectant misuse.

To significantly reduce the risk of disease transmission from contaminated instruments, it is required to partner with international health organizations and national health authorities, institutions of higher education, patient advocacy groups such as WHO's Global Alliance for Patient Safety, and industry.

Global, regional and national associations for professionals in infection control can develop the blue print on "Liquid Chemical Sterilants/High Level Disinfectants Guidance for Industry, regulatory agency reviewers, disinfectant testing facilities and personnel responsible for instrument reprocessing".

This document on sporicidal formulations must include:

- Proper taxonomy to define concepts, introduce clarity and consistency.
- Recommendations to industry on their product's expected activity, quality control, labeling and instructions for safe handling, use and disposal.
- Scientific rationale and evidence-based recommendations for health authorities, health care workers, and hospital administrators.

This guidance document could be presented to the World Health Organization for dissemination to health ministers. Ministries of Health may use this document to create their own national standards for *"Manufacturing, quality control, bottling, labeling, classification, intended use, standardized testing, safe preparation, handling, use and disposal of disinfectants"*.

"Standards govern practically everything we do in our daily lives…Anyone intimately involved in standards development, however, is very aware of how standards come to fruition. While it sometimes may be a painful process, it can also be one of the most rewarding experiences in a person's career".[12]

It is necessary to reach top health officials to make them realize how innapropriate instrument reprocessing contributes to the burden of health care associated infections. Diverse educational interventions and materials can be used by regional and national organizations to disseminate relevant information to medical, nursing and dental schools, as well as private and public health care facilities. Manufacturers and distributors are important stake holders in this public health initiative.

A sustained international effort, led by infection control officers, policy makers, researchers, educators, and consultants, is required to avoid the marketing of ineffective products that may endanger human lives.

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