

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGYTM

EDITORIAL

- Antibiotic Resistance in ICUs: A Multifaceted Problem Requiring a Multifaceted Solution** 328
ROBERT GAINES, MD

ORIGINAL ARTICLES

- Focused Microbiological Surveillance and Gram-Negative Beta-Lactamase-Mediated Resistance in an Intensive Care Unit** 331
E.A. BRYCE, MD, FRCP(C); J.A. SMITH, MD, FRCP(C)

- A Cluster of Fever and Hypotension on a Surgical Intensive Care Unit Related to the Contamination of Plasma Expanders by Cell Wall Products of *Bacillus stearothermophilus*** 335
ANTONI TRILLA, MD; CARLES CODINA, DPHARM; MONTSERRAT SALLES, RN; JOSEP M. GATELL, MD; MAGDA ZARAGOZA, RN; FRANCESCO MARCO, MD; MIQUEL NAVASA, MD; JAUME MULET, MD; JOSEP RIBAS, DPHARM; MARIA T. JIMENEZ DE ANTA, MD; MIGUEL A. ASENJO, MD

- Impact of a Coordinated Tuberculosis Team in an Inner-City Hospital in New York City** 340
BARKAT A. FAZAL, MD, MPHTM; EDWARD E. TELZAK, MD; STEVE BLUM, PHD; CATHY L. POLLARD, PA-C; MORDECAI BAR, MD; JEROME A. ERNST, MD; GLENN S. TRETT, MD

- Prevalence of PPD Positivity Among New Employees at a Hospital in New York City** 344
KENT A. SEPKOWITZ, MD; PETER FELLA, RN; PEDRO RIVERA, RN; NERINDA VILLA, BS; JACK DEHOVITZ, MD, MPH

PRACTICAL HEALTHCARE EPIDEMIOLOGY

- Infection Control in Long-Term-Care Facilities** 348
LINDSAY E. NICOLLE, MD; RICHARD A. GARIBALDI, MD

MOLECULAR HOSPITAL EPIDEMIOLOGY

- Mupirocin Resistance: Clinical and Molecular Epidemiology** 354
SUZANNE F. BRADLEY, MD; MARY A. RAMSEY, MS; TERESA M. MORTON, PHD; CAROL A. KAUFFMAN, MD

GLOBAL ASPECTS OF INFECTION CONTROL

- The Impact of US-Style Infection Control Programs in an Asian Country** 359
HSIEH-SHONG LEU, MD, MSC

SPECIAL REPORT

- Respiratory Protection Standard: Comments on OSHA's Proposed Revision** 365
MICHAEL D. DECKER, MD, MPH

Continued inside.

The Real Facts About Glutaraldehyde

Glutaraldehyde solutions have been proven effective for over 30 years. The praise in medical circles for glutaraldehyde's efficacy and safety led to quick acceptance. Glutaraldehyde's ability to reliably disinfect and sterilize medical instruments generated high confidence. And lasting confidence. Recently, however, that confidence is being questioned in certain corners. To make an informed judgement, consider the facts presented below.

High Level Disinfection or Sterilization?

Currently, there is universal acceptance of high level disinfection for semi-critical devices such as flexible endoscopes.¹ This acceptance comes from both government and professional organizations, including the FDA, CDC, AORN, APIC, SGNA, and ASGE. As one group stated, "The apparent consensus is that high-level disinfection, if meticulously and consistently done, gives a high degree of patient safety; this appears to be the current standard worldwide."¹

"Although the value of sterilization of semi-critical items may seem obvious, evidence that sterilization reduces the risk of infection is lacking."² The incidence of post-endoscopic infections has been estimated to be 1 in approximately 1.8 million gastrointestinal procedures.³

Fast Acting, Compatible, Reusable and Cost Effective

Glutaraldehyde is the most commonly used liquid chemical germicide for heat-sensitive medical devices such as endoscopes. It provides *quick high level disinfection* for fast instrument turnaround time. However, manufacturers' recommendations for specific high level disinfection times vary with formulation and usage. Their complete product directions should be referred to before use.

Data from a variety of sources clearly indicate that reducing the bioburden challenge by thorough cleaning prior to high level disinfection or sterilization results in greater efficacy in less time. For example, the APIC Guideline for

Selection and Use of Disinfectants recommends 20 minutes at room temperature as the minimum exposure time for a 2% glutaraldehyde to achieve high level disinfection following cleaning. However, because manufacturers have no control over user's cleaning technique, and regulatory agencies currently do not recognize a protocol that considers the effects of cleaning on label claims⁴, specific label statements *cannot* be made with regard to the potential decrease in soak time and temperature following cleaning.

Glutaraldehyde can also be used to *sterilize* heat-sensitive instruments when ETO or steam sterilization is not appropriate.

Compared to other liquid chemical germicides used for high level disinfection and sterilization, alkaline glutaraldehyde has the best *compatibility with a wide range of materials*.² It is non-corrosive to instruments, including delicate endoscopic instrumentation. Furthermore, glutaraldehyde is reusable up to 14 or 28 days.¹ This makes it the most *cost effective* product available for high level disinfection.

In addition, glutaraldehyde may be used in automated endoscope reprocessors to reduce health care worker exposure, and reduce the variability of processing instrumentation in manual tray systems.

Effectiveness Can Be Tested Before Each Use

Glutaraldehyde solutions *can be tested and documented* prior to each use to verify that the effective concentration is still present. This provides the end user with a margin of safety by offering a reliable way to detect unintentional dilution or contamination of the glutaraldehyde solution.

Hard Evidence Favors Glutaraldehyde's Safety For Health Care Workers

Although glutaraldehyde can be irritating to the eyes, respiratory tract and skin, precautions can easily be undertaken to prevent these short term effects by donning appropriate protective clothing (such as high quality rubber latex gloves, protective eye wear and fluid resistant gowns) and the implementation of environmental controls that allow for adequate ventilation.¹⁰ However, even upon exposure at ambient temperatures to vapor concentrations in excess of the 0.2 ppm threshold limit value, *no evidence of acute or subchronic toxicity has been found in studies on animal models*.⁵⁻⁷

"Glutaraldehyde does not meet the criteria for classification as a mutagen . . . [or] . . . carcinogen . . . A number of studies have no evidence of teratogenicity."⁸ Studies conducted to date have shown glutaraldehyde *not to be a suspected carcinogen*. Although glutaraldehyde is frequently confused with formaldehyde, its chemical and toxicological properties are significantly different. OSHA, the International Agency for Research on Cancer (IARC), and the National Toxicology Program (NTP) do not list glutaraldehyde as a carcinogen.

In addition, studies conducted to date have shown glutaraldehyde *not to cause birth defects*.⁹ However, as a normal precaution, pregnant women working around glutaraldehyde or other chemicals should inform their obstetricians.

Prominent Endoscope Companies Recommend Glutaraldehyde^{††††}

For over 30 years, prominent endoscope companies such as Olympus, Karl Storz, Stryker Endoscopy, CIRCON ACMI, Pentax and Fujinon have recommended alkaline glutaraldehyde solutions as safe to use with their delicate endoscopic instrumentation.

Third party studies confirm this recommendation. "In particular, they (glutaraldehyde solutions) are preferred for the disinfection of gastrointestinal endoscopes."¹⁰

Glutaraldehyde Meets U.S. EPA Regulations For Non-Hazardous Waste

In compliance with U.S. EPA regulations, glutaraldehyde *may be disposed down the drain* as an ordinary domestic waste.^{††††} Further, by the time the drain-disposed solutions reach the wastewater treatment system, they are diluted to well below 10 ppm glutaraldehyde. At this low concentration, glutaraldehyde will not have detrimental effects on functioning wastewater treatment systems.

The fact is, sewage microorganisms readily biodegrade glutaraldehyde, initially to glutaric acid, a naturally occurring compound, and then ultimately to carbon dioxide and water.

The FDA Now Regulates Glutaraldehyde's Claims

The FDA now regulates the efficacy claims of high level disinfectants/sterilants. All manufacturers of high level disinfectants/sterilants used with medical devices are currently required to submit for 510(k) clearance with the FDA.

"Chemical germicides should be registered with the U.S. Environmental Protection Agency

and cleared for marketing by the U.S. Food and Drug Administration."¹¹ The FDA 510(k) clearance process assures that similar glutaraldehyde products will have comparable high level disinfection claims.

Glutaraldehyde Is A Long-Running Success Story

Today, glutaraldehyde continues to pass one of the most important safety tests health care workers rely upon — the test of time.

How To Get More Information

If you would like to learn more about glutaraldehyde, ask your Johnson & Johnson Medical, Inc. Account Manager about our educational programs, including *The Use of Glutaraldehyde in the Health Care Environment*, a videotape that allows for 2 contact hours, and *Just The Facts*, a publication that discusses important issues about high level disinfection and sterilization. If you would like technical assistance, please call 1-800-423-5850.

[†]Rigid endoscopes are considered to be a critical device and should be sterilized versus high level disinfection before each use, if feasible. When sterilization is not feasible, high level disinfection is acceptable. This is consistent with the Center for Disease Control guidelines for decontamination and cleaning of endoscopes, endoscopes and respiratory therapy equipment in their Department of Health and Human Services "Guidelines for Prevention and Control of Nosocomial Infection," and the "APIC Guideline for Selection and Use of Disinfectants."

^{††} Provided the glutaraldehyde solution passes test strip verification of minimum effective concentration (MEC).

^{†††} During the 1970s, the American Conference of Governmental Industrial Hygienists (ACGIH) adopted a threshold limit value (TLV) ceiling limit of 0.2 ppm of glutaraldehyde for the atmosphere in work environments. The ceiling limit may be achieved by "any reasonable combination of engineering controls, work practices, and personal protective equipment." Code of Federal Regulations 29 C.F.R. 1910.1000 CH.XVII. Strive to achieve a minimum of 10 air exchanges per hour.

^{††††} While surfactant containing glutaraldehyde solutions are NOT generally recommended for use with rigid endoscopes used in electrosurgical procedures, major scope manufacturers have found surfactant containing glutaraldehyde solutions to be compatible with their flexible endoscopes.

^{†††††} Please note that some state and local authorities may have additional restrictions on drain disposal of specific wastes.

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CONTENTS

Continued from cover.

LETTERS TO THE EDITOR

- Hepatitis C Virus Infection in Healthcare Workers (with Reply)
Vincenzo Puro, MD; Nicola Petrosillo, MD; Giuseppe Ippolito, MD; Janine Jagger, MPH, PhD; Bruce P. Lanphear, MD, MPH;
Calvin C. Linneman Jr., MD 324
- Wound Infection Surveillance (with Reply)
James T. Lee, MD, PhD, FACS; Deborah S. Yokoe, MD, MPH; Richard Platt, MD, MS 326

MEDICAL NEWS

- Gina Pugliese, RN, MS 372
- Community Exposure Predicts Healthcare Worker TB Skin-Test Conversion 330
- Serosurvey Finds Surgeons at Greatest Risk for Hepatitis B 334
- Community Outbreak of Legionnaires' Disease from Hospital Cooling Tower 339
- Newly Identified Virus Kills Trainer and 14 Horses in Australia 347
- New Hepatitis Viruses Identified 353
- Diphtheria Epidemic in the Newly Independent States of the Former Soviet Union 358
- Clarification of Hepatitis B Vaccine Dose for Infants 364
- FDA Approves Latex Allergy Test 372
- NIOSH Develops Videotape on Aerosol Production During Surgery 372
- Columbia/HCA Creates AIDS Network 372
- California's Orange County Reports 14% Drop in TB Cases 372
- New Russian Law Requires HIV Testing of Visitors 372
- JCAHO Backs Away from Mandatory Indicators, Invites Other Performance Measurement Systems 373
- CDC Releases Draft Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women 373

SHEA NEWS

- C. Glen Mayhall, MD 376
- Healthcare Epidemiology: Measuring Performance and Implementing Improvement 376
- Dr. James Lee Heads Effort to Attract Surgeons to SHEA 376

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