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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

EDITORIAL

Nosocomial Pertussis in the Nineties
JAMES D. CHERRY, MD, MSc 553

ORIGINAL ARTICLES

Containment of Pertussis in the Regional Pediatric Hospital During the Greater Cincinnati Epidemic of 1993
CELIA D.C. CHRISTIE, MD; ANNE MARIE GLOVER, RN, BA; MARY JANE WILKE, RN; MARY L. MARX, BA; SHIRLEY F. REISING, PHD; NANCY M. HUTCHINSON, RN, MSN 556

Vertical Transmission of *Citrobacter diversus* Documented by DNA Fingerprinting
BRENDA S. HARVEY, MD; THEARITH KOEUTH, BSc; JAMES VERSALOVIC, PHD; CHARLES R. WOODS, MD; JAMES R. LUPSKI, MD, PHD 564

An Outbreak of Needlestick Injuries in Hospital Employees Due to Needles Piercing Infectious Waste Containers
ANNE M. ANGLIM, MD, MS; JUNE E. COLLMER, RN, MSN, CPNP; T. JOEL LOVING, MS; KENNETH A. BELTRAN, BS; BETTY J. COYNER, RN, MSN; KARIM ADAL, MD, MS; JANINE JAGGER, MPH, PHD; NIKOLAS J. SOJKA, DVM; BARRY M. FARR, MD, MSc 570

Recovery of Vancomycin-Resistant Enterococci on Fingertips and Environmental Surfaces
GARY A. NOSKIN, MD; VALENTINA STOSOR, MD; ISABELL COOPER, BS, MT (ASCP); LANCE R. PETERSON, MD 577

Percutaneous Injury Analysis: Consistent Categorization, Effective Reduction Methods, and Future Strategies
DONNA J. HAIDUVEN, BSN, MSN, CIC; ESTHER S. PHILLIPS; KARL V. CLEMONS, PHD; DAVID A. STEVENS, MD 582

Molecular Heterogeneity of *Acinetobacter baumanii* Isolates During Seasonal Increase in Prevalence
CELIA D.C. CHRISTIE, MD; DOROTHY MAZON, RN; WALTER HIERHOLZER, JR, MD; JAN EVANS PATTERSON, MD 590

CONCISE COMMUNICATIONS

Epidemiologic Investigation of an Outbreak of Coagulase-Negative *Staphylococcus* Primary Bacteremia in a Newborn Intensive Care Unit
LUIS F.A. CAMARGO, MD; TÂNIA M.V. STRABELLI, MD; FLORACY G. RIBEIRO, RN; ELIZA R. IWAHASHI, MD; MUNIR EBAID, MD; HÉLIO H.H.C. FILHO, MD; SUMIKO I. SINTO, BS; CAIO M.F. MENDES, MD; DAVID E. UIP, MD 595

Treatment of Hickman Catheter Sepsis Using Antibiotic Lock Technique
ELIZABETH A. KRZYWDA, RN, BSN; DEBORAH A. ANDRIS RN, BSN; CHARLES E. EDMISTON JR, PHD; EDWARD J. QUEBBEMAN MD, PHD 596

Continued inside.

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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.† 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 claims[4], 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.†† 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.††† 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]

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"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*.[5,9] 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 disinfected 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 laparoscopes, endoscopes and respiratory therapy equipment in their Department of Health and Human Services "Guidelines for Prevention and Control of Nosocomal 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 valve (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.

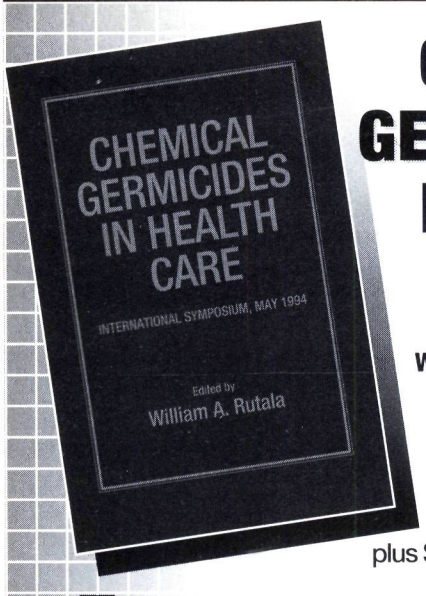
†††††Please note that some state and local authorities may have additional restrictions on drain disposal of specific wastes.

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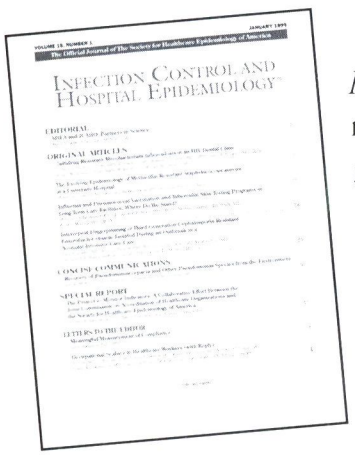
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CONTENTS

Continued from cover

PRACTICAL HEALTHCARE EPIDEMIOLOGY
Hospital Epidemiology in Smaller Hospitals
JOHN M. BOYCE, MD 600

READERS' FORUM
A Letter from Oliver Wendell Holmes, 1809-1894: In Menory of the Centennial of His Death
ELIZABETH C. GATHRIGHT 607

EDITOR SOUGHT 599, 616

MEDICAL NEWS
GINA PUGLIESE, MD 612

New TB Respirators Expected to Save Millions 555
Guidelines for Prevention of Intravascular Device-Related Infection 569
HICPAC Guidelines 576
Congress's Office of Technology Assessment Will Close 581
VRE Common 599
Court Rejects HIV-Positive Surgical Technician 606
PHS Guidelines for Prevention of Opportunistic Infections 611
Delays in Identification of *M tuberculosis* 612
Two Cases of HIV-2 Detected Among Blood Donors in US 612
ACIP Expands Hepatitis B Recommendations 612
Topical Microbicides to Prevent STD 613

SHEA NEWS
C. GLEN MAYHALL, MD 616

SHEA Announces New Course on Clinical Epidemiology and Quality Improvement 616

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