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Reducing Ethylene Oxide and Glutaraldehyde Use

Environmental Best Practices for Health Care Facilities | November 2002

JCAHO Environment of Care Standards 1.3, 2.3, 4.0

Where are Ethylene Oxide and Glutaraldehyde Used?

Although many environmentally preferable technologies exist for sterilizing equipment and surfaces within hospitals, these technologies can damage some medical instruments that are susceptible to moisture and heat. In such cases, hospitals typically use ethylene oxide (EtO) to sterilize moisture- and heat-sensitive instruments and glutaraldehyde as a high-level disinfectant. Health care employees who commonly use glutaraldehyde-based products work in many departments, from gastroenterology, urology, and cardiology to x-ray, laboratory, and pharmacy. This fact sheet provides background information on the uses and hazards of both chemicals, describes environmentally preferable alternatives, and provides detailed case study and cost information to help your hospital evaluate alternatives to EtO and glutaraldehyde.

The first step in assessing the impacts of EtO and glutaraldehyde is to conduct an inventory of who, how, and where the chemicals are used in your hospital. Completing the usage inventory will enable you to prioritize your actions, monitor progress in eliminating the use of the chemicals, and ensure that affected employees are included in training and monitoring programs. In addition, an inventory may create opportunities for gathering feedback from hospital personnel on EtO, glutaraldehyde, and which alternatives might be best. Common locations to look for EtO and glutaraldehyde are mentioned in the following sections.

Why Eliminate EtO?

Ethylene oxide (EtO) poses several health hazards requiring special handling and disposal of the chemical and training in its use. It is identified by the National Toxicology Program as a known human carcinogen (see http://ntp-server.niehs.nih.gov/) and has several other acute and chronic health effects:

- Inhaling EtO can cause nausea, vomiting, and neurological disorders.
- In solution, EtO can severely irritate and burn the skin, eyes, and lungs.
- EtO is a probable teratogen and may pose reproductive hazards.
- EtO may damage the central nervous system, liver, and kidneys, or cause cataracts.

EtO is also extremely reactive and flammable, increasing the risk of chemical accidents that could injure hospital employees and patients. For example, even static electricity can cause EtO to ignite; therefore, employees using it should be well trained and aware of its potential dangers. A small selection of hydrogen peroxide- and peracetic acid-based sterilants can be used to replace EtO for many applications throughout your hospital. The following case study discusses the costs and benefits of switching to non-EtO alternatives.

MHMH's 3-Step Approach to Eliminating EtO

1 *Determine which medical instruments are sterilized using EtO.*

2 *Evaluate methods of eliminating EtO sterilization for each instrument.**

3 *Establish a "working group" to facilitate the decision making process and ensure that sterilization standards are not compromised.*

*Usually achieved by alternative technologies or a new or alternative device approved for sterilization with non-EtO technologies

case study | Finding Alternatives to EtO at Mary Hitchcock Memorial Hospital[1]

Facing increasing regulatory pressure and a growing awareness of the occupational exposure hazard of using EtO, Mary Hitchcock Memorial Hospital (MHMH) in Lebanon, New Hampshire began evaluating non-EtO sterilization unit alternatives. MHMH adopted two alternative technologies: Sterrad, a plasma phase hydrogen peroxide-based sterilizing agent and Steris, a peracetic acid-based technology. The primary difference between the two alternatives is that Steris is a "just-in-time" technology that requires sterilized items to be immediately used after being removed from the unit. This aspect makes it impractical in some applications, specifically for trauma cases where the need for a specific instrument cannot be predetermined. In most cases,

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MHMH Sterilization Cost Comparison

Ethylene Oxide (EtO)		Non-EtO Alternatives	
Capital Costs			
New emissions control equipment for existing EtO unit	$25,000	2 Sterrad units	$212,000
Renovation and construction	$20,000	2 Steris units	$35,000
"Lost time" from construction disruption	$20,000	New and/or replacement of instruments over 2 yrs	$50,000–$75,000
2 Sterrad units[2]	$212,000		Cost Total: $297,000–$322,000
	Cost Total: $277,000		
Annual Operating Costs[3]			
Emissions control	$10,000	Sterrad operating costs	$2,000
Spill response and staff training	$5,000	Steris operating costs	$1,000
Alarm system maintenance, testing, EtO monitoring	$5,000	EtO outsourcing ($80/load, approx. 60 loads/year)	$4,800
Sterrad operating costs	$2,000		Cost Total: $7,800
	Cost Total: $22,000		

[1] Background information adopted from Tellus Institute's "Healthy Hospitals: Environmental Improvements Through Environmental Accounting–Appendix B"
[2] Because EtO operations are limited to one load per day under MHMH's Title V permit, the addition of two non-EtO units were needed to meet the sterilization needs of the hospital.
[3] Contingent costs of an EtO "incident" or related fines are not included

Sterrad has proved to be an acceptable alternative to EtO; however, in some instances, manufacturers have not yet approved the use of EtO alternatives for sterilization of their products. Such limitations vary by vendor and are not specific to one instrument or medical device product type. For example, MHMH must still sterilize the following five instruments using EtO: angioscopes, choledocoscopes, surgiscopes, bone flaps, and hysterectoscopes.

Devices that have not been approved for sterilization using EtO alternatives are often constructed of complex mixed-media materials. To completely eliminate the need for EtO, MHMH is collecting data from other healthcare facilities to find alternative instruments (or in some cases, the same product by a different vendor) that have been approved for non-EtO sterilization alternatives.

Advanced Sterilization Products provided the following costs per sterilized square foot:

EtO/CO_2 mix = $12/foot^2
EtO/HCFC mix = $11.31/foot^2
Sterrad = $8.44/foot^2

MHMH conducted a detailed cost analysis to evaluate the difference between using EtO and non-EtO sterilization technologies (see "MHMH Sterilization Cost Comparison"); however, several costs and benefits of eliminating EtO were not quantified, including:

- Transaction cost of reduction effort
- Value of quicker average sterilization time
- Benefit of increased availability of instruments and sterilization process control, which ultimately translates to better infection control
- Instrument upgrade/replacement costs; some of which would have been necessary regardless of the EtO elimination effort
- Benefit of avoided EtO exposure incidents

Overall, MHMH staff are pleased with both Steris and Sterrad technologies. In addition, because the new technologies have shorter processing times and therefore higher productivity, MHMH is able to sterilize instruments that were previously being high-level disinfected. Also, the labor required to operate the technologies has proven to be less than expected, despite increased productivity.

Why Eliminate Glutaraldehyde?

Glutaraldehyde is most frequently used as a cold liquid high-level disinfectant for heat-sensitive equipment such as dialysis instruments; surgical instruments; suction bottles; bronchoscopes; endoscopes; and ear, nose, and throat instruments. There are other, less obvious areas where glutaraldehyde is used as well. For example, it is used as a tissue fixative in histology and pathology laboratories and as a hardening agent in the development of x-rays. Unlike EtO, glutaraldehyde is not a human carcinogen; however, several health effects have been reported among hospital workers exposed to glutaraldehyde:

- Asthma, and breathing difficulties
- Burning eyes and conjunctivitis
- Headaches
- Nosebleed, irritation, sneezing, and wheezing.
- Hives
- Nausea
- Rashes and allergic dermatitis
- Staining of the hands
- Throat and lung irritation

Several hydrogen peroxide-, peracetic acid-, and orthopalahaldehyde-based high-level disinfectant solutions can be used to replace glutaraldehyde throughout your hospital. The following case study discusses the costs and benefits of switching to glutaraldehyde alternatives.

case study | Kaiser Woodland Hills Medical Center Eliminates Glutaraldehyde

Prompted by increasing health concerns related to the use of glutaraldehyde, Kaiser Woodland Hills Medical Center

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(Woodland Hills) in Woodland Hills, CA eliminated it from its highest use area: the Gastroenterology Department. This department accounts for over 50% of the hospital's glutaraldehyde use. The department relies on eight automated endoscope reprocessors for high-level disinfection of endoscopes, which are in use about eight hours each day. The Environmental Health and Safety Director at Woodland Hills identified Cidex OPA (ortho-phthalaldehyde) as a possible glutaraldehyde alternative because of 1) its lower inhalation exposure risk, 2) reduced disinfecting time (12 minutes vs. APIC-approved 20 minute disinfection time and FDA-approved 45 minute disinfecting time for Cidex), 3) the solution is approved for use in almost all of their equipment without negating the warranty and 4) the cost of using Cidex OPA was significantly less than installing a more substantial ventilation system to minimize respiratory irritation from using glutaraldehyde. Cidex OPA, however, cost approximately $25 per gallon– three times more than glutaraldehyde.

Due to its toxicity, California legislation deemed Cidex OPA a hazardous waste beginning January 1, 2001. However, this legislation exempts healthcare facilities from tiered permitting regulatory requirements when treating Cidex OPA with glycine on site to render it a non hazardous waste. (If local publicly owned treatment works (POTWs) or sewer agencies have other prohibitions against sewerage of aldehydes, facilities must seek approval for this process as well.) To comply with California legislation, Woodland Hills treats Cidex OPA with 25 grams of glycine per gallon for 1-hour, which renders it a non-hazardous waste. Woodland Hills must utilize an external treatment tank for this process, since manufacturer warranties would be voided if the Cidex OPA were treated within the reprocessor. It spent

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Top Reasons to Eliminate Glutaraldehyde

Adapted from the Sustainable Hospitals Project

- *Glutaraldehyde is a potent occupational skin irritant and sensitizer.*
- *Glutaraldehyde is a recognized cause of occupational asthma.*
- *Patients, visitors, and hospital employees may be needlessly exposed to glutaraldehyde vapors in patient rooms and clinic areas where open bins or poorly ventilated reprocessing units are in use.*
- *Cost-competitive alternatives exist that meet infection control standards and reduce risks to patient, visitor, and employee health.*
- *Several regulatory organizations, including OSHA, NIOSH, and ACGIH, are re-evaluating their exposure limits for glutaraldehyde.*

The Sustainable Hospitals Project website includes a 4-step glutaraldehyde use survey that can help 1) identify where glutaraldehyde is used, 2) prioritize areas for improvement, 3) monitor progress, and 4) ensure affected employees are included in training and monitoring programs.

Overview of EtO and Glutaraldehyde Alternatives

Product (Vendor)	Application	Cost	Comments
EtO Alternatives			
Sterrad (Advanced Sterilization Products)	Enclosed sterilization processor with 45-minute cycle time	Processor $65,000 to $130,000 Hydrogen peroxide cassettes $216 to $265 per case ($43 to $53 per cassette, or $9 to $10 per cycle)	Generates hydrogen peroxide gas plasma from 58% hydrogen peroxide solution
Steris 20 (Steris Corporation)	Sterilization in 12 minutes at 50 to 55 °C; instruments "patient ready" in less than 30 minutes	Processor $18,200 Peracetic acid cups $128 per case ($7 per cup)	0.2% peracetic acid (diluted from 35%)
Glutaraldehyde Alternatives			
Cidex OPA (Advanced Sterilization Products)	High-level disinfection in 12 minutes at 20 °C	$25 per gallon	0.55% OPA solution: exposure limits not yet determined
Sporox II (Sultan Chemists)	High-level disinfection in 30 minutes at 20 °C	$25 per gallon	7.5% hydrogen peroxide
Sterilox (Sterilox Technologies Inc.)	Cycle time is 10 minutes for high-level disinfection	Rental of generator $15,000 year costing approximately $1–$3 per cycle, depending on use	System generates hypo-chlorus acid Currently used in Europe as liquid chemical sterilant; FDA pre-market clearance pending

Table adapted from Sustainable Hospitals Project web site. Costs provided are vendor list prices; actual costs may vary significantly under contract agreements.

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$700 to purchase the external treatment tank, which includes a mobile cart, treatment tank, pump, and tubing. Glycine costs approximately $5 per gallon, including the cost of the product and labor. This is more effort than what is required for glutaraldehyde; vendors often provide test strips that when dipped in solution, will change color to show whether it has fully degraded.

Despite the added treatment steps, Woodland Hills employees are very satisfied with the OPA-based product. Symptoms associated with using Cidex OPA are described as being very mild, with select staff indicating slight eyelid irritation and a "chalky" taste after prolonged use. However, Woodland Hills staff noted that the complaints received for OPA are much less frequent and significantly less severe than comments made regarding glutaraldehyde. Also, because Cidex OPA has a quicker cycle time than glutaraldehyde, Woodland Hills saves approximately 8 minutes with each disinfection cycle, or a savings of 1 hour for each 8-hour automated endoscope reprocessor shift. This allows greater turn-over of endoscopes, while requiring fewer reprocessors to disinfect them. This is especially important to consider for new facilities, since the cost of endoscopes is approximately $30,000 and reprocessors are often near $15,000. In addition, Woodland Hills has found that Cidex OPA does not lose efficacy as fast as the glutaraldehyde-based product. In their high-volume department, they are now able to disinfect approximately 60% more endoscopes during the life of the solution.

Accounting for Time

Perhaps the most significant savings when switching to a non-EtO or non-glutaraldehyde alternative is the value of time saved in sterilizing or disinfecting equipment. This value is difficult to quantify however, because the direct impact of shorter process times is dependent on several factors, including such things as on-hand inventory of equipment and cost of labor.

A Look at Ortho-Phthalaldehyde

(Adapted from the Michigan Health and Hospital Association Employee Safety and Disability Service Newsletter)

Also an aldehyde, ortho-phthalaldehyde (OPA) is chemically related to glutaraldehyde. According to the Michigan Health and Hospital Association (MHA), the disinfecting mechanism of OPA is thought to be similar to glutaraldehyde and is based on the powerful binding of the aldehyde to the outer cell wall of contaminant organisms.

A notable difference between the two commercial disinfectants is the percent of active ingredient in each product. Commercial OPA-based disinfecting products contain only 0.55% of the active ingredient, while most glutaraldehyde-based disinfecting products contain 2.4 to 3.2% active ingredient – 5 to 7 times that of OPA products.

Although OPA may pose similar occupational hazards to glutaraldehyde – including mild eye, skin, and respiratory tract irritation and skin and respiratory sensitization – the risk is significantly reduced due to the low percentage of OPA and relatively low vapor pressure of OPA-based commercial products. OPA does not currently have a recommended exposure limit; however, vendors recommend that similar protective equipment be used, including gloves and goggles.

For example, consider the Kaiser Woodland Hills glutaraldehyde case study: using Cidex OPA saved 1 hour of endoscope processing time each day. This can result in a significant increase in productivity by allowing equipment to be available for patient care sooner. A shorter process time also saves labor, as technicians do not have to wait as long for equipment to process, allowing them to do more with their time. Ultimately, quicker process times can mean that more patients get treated sooner. A careful analysis of how time affects your facility should be performed when considering non-EtO or non-glutaraldehyde alternatives. While difficult to calculate, these savings can easily make up for the higher cost of non-EtO and non-glutaraldehyde alternatives.

Resources

Cidex OPA Material Safety Data Sheet, Advanced Sterilization Products. http://www.cidex.com/ASPnew.htm

Massachusetts Toxics Use Reduction Institute. "Massachusetts Chemical Fact Sheet: Ethylene Oxide." www.turi.org/PDF/eo.pdf

Michigan Health and Hospital Association. "Glutaraldehyde Free High Level Disinfectant Introduced," March 2000. www.mhaservicecorp.com/esdm/newsletter_archive/pages_archive/Years_past/March2000nv.html

National Institute for Occupational Safety and Health. "Glutaraldehyde: Occupational Hazards in Hospitals." May 2001.

National Safety Council. "Ethylene Oxide Chemical Backgrounder." July 1997. www.nsc.org/library/chemical/EthylenO.htm

Occupational Safety and Health Administration. www.osha-slc.gov/SLTC/ethyleneoxide/index.html

Sustainable Hospitals Project. www.sustainablehospitals.org

Tellus Institute. "Healthy Hospitals: Environmental Improvements Through Environmental Accounting." July 2000. www.tellus.org/b&s/publications/R2-213-Nb.pdf

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