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Ethylene Oxide and Hydrogen Peroxide Gas Plasma Sterilization: Precautionary Practices in U.S. Hospitals

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Abstract

Objective—Evaluate precautionary practices and extent of use of ethylene oxide (EtO) and hydrogen peroxide gas plasma (HPGP) sterilization systems, including use of single chamber EtO units.

Design—Modular, web-based survey.

Participants—Members of professional practice organizations who reported using EtO or HPGP in the past week to sterilize medical instruments and supplies. Participating organizations invited members via email which included a hyperlink to the survey.

Methods—Descriptive analyses were conducted including simple frequencies and prevalences.

Results—A total of 428 respondents completed the module on chemical sterilants. Because most respondents worked in hospitals (87%, n=373) analysis focused on these workers. Most used HPGP sterilizers (84%, n=373), 38% used EtO sterilizers, with 22% using both. Nearly all respondents using EtO operated single chamber units (94%, n=120); most of them reported that the units employed single use cartridges (83%, n=115). Examples of where engineering and administrative controls were lacking for EtO include: operational local exhaust ventilation (7%; n=114); continuous air monitoring (6%; n=113); safe handling training (6%; n=142); and standard operating procedures (4%; n=142). Examples of practices which may increase HPGP exposure risk included lack of standard operating procedures (9%; n=311) and safe handling training (8%; n=312).

Conclusions—Use of precautionary practices was good but not universal. EtO use appears to have diminished in favor of HPGP which affords higher throughput and minimal regulatory constraints. Separate EtO sterilization and aeration units were still being used nearly one year after U.S. EPA prohibited their use.

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Keywords

chemical sterilization; ethylene oxide; hydrogen peroxide gas plasma; precautionary practices; hospitals

Introduction

Sterilization has been done for many decades in healthcare settings and is essential to ensure surgical instruments and medical supplies do not transmit infectious pathogens to patients. Although steam sterilization is highly effective and environmentally friendly, the introduction of heat and/or moisture sensitive medical devices prompted the development of low temperature chemical sterilization methods. Ethylene oxide (EtO) was first used as a chemical sterilant in healthcare settings in the 1950s.[1] Because of stringent health, safety and environmental regulatory requirements and lengthy processing times, 'safer' and more expedient alternatives have since been introduced. These include hydrogen peroxide gas plasma (HPGP), vaporized hydrogen peroxide, and immersion and vapor phase peracetic acid.[2] Sterilizers utilizing steam, EtO, and HPGP are predominantly used in high throughput applications typically found in hospital central sterile supply (CSS) departments. These and other chemical sterilants are also used to a lesser extent in point-of-use applications.

EtO sterilization systems commonly found in hospitals utilize EtO from 2 sources: 1) single use cartridges of 100% EtO, and 2) compressed gas cylinders or tanks of 100% EtO or EtO mixed with chlorofluorocarbons (CFCs) or carbon dioxide (CO_2). Use of EtO mixtures has decreased following the ban of ozone-depleting CFCs in the mid-1990s and stability and pressure issues associated with CO_2. Single use cartridges eliminate exposure risks associated with piping leaks and cylinder changes because they are punctured automatically while enclosed in the sterilizer unit.[1] Cycle times, including sterilization and aeration, can range from 10.5 to 14.5 hours.[2]

EtO sterilization requires a lengthy (8 to 12 hours) aeration to purge EtO from treated materials so that they do not harm patients or workers. When sterilization and aeration are done in separate units, healthcare workers can be exposed to EtO when transferring off-gassing loads from the sterilizer to the aerator. As a means of lowering ambient workplace EtO levels and reducing long-term non-cancer and potential cancer risks associated with exposure to EtO, the U.S. Environmental Protection Agency (EPA) required hospitals and healthcare facilities to use a single chamber process for EtO which combines sterilization and aeration in a single unit.[3] This requirement became effective on March 1, 2010, following an initial announcement in March 2008 which allowed time for employers to comply.[4] Additionally, state or local regulations may require that EtO emissions from the aeration process be treated with an air pollution control device.

Sterilization using HPGP is considered an environmentally safer and more time-efficient alternative to EtO with cycle times of 75 minutes.[2] One of the first sterilizer systems using HPGP approved by the U.S. Food and Drug Administration was the Sterrad™ system.[5] Under normal conditions, operator contact with either the liquid or plasma hydrogen peroxide is negligible; liquid hydrogen peroxide is contained in a sealed cassette which is

punctured only after the sterilizer door is closed. By-products include water and oxygen which are nontoxic and eliminate the need for aeration.[2]

Acute exposure to EtO may result in respiratory irritation, headache, nausea, coughing, shortness of breath, and cyanosis.[6] Chronic exposure to EtO has been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.[6] Occupational exposure in healthcare facilities has been linked to an increased risk of spontaneous abortions and various cancers.[7–9] Injuries (e.g., tissue burns) to patients have been associated with EtO residues in implants used in surgical procedures.[10] The International Agency for Research on Cancer (IARC) has determined that EtO is carcinogenic to humans.[11,12] The National Institute for Occupational Safety and Health (NIOSH) recommends that EtO be regarded as a potential occupational carcinogen in the workplace.[9] Guidelines for the safe use and handling of EtO including recommended engineering controls, personal protective equipment (PPE), and work practices have been published by NIOSH and the Occupational Safety and Health Administration (OSHA).[13,14]

Occupational exposure to hydrogen peroxide primarily occurs via inhalation and contact with the skin and eyes. In a food sterilization process, inhalation of hydrogen peroxide vapors caused irritation of the eyes, nose and throat of exposed workers.[15] Irritation and redness of the skin can develop following contact with liquid solutions; burns with blisters have developed following exposure to concentrated solutions. Eye contact with liquid hydrogen peroxide causes irritation and redness; corneal ulcerations have developed following contact with concentrated solutions.[16] Inadequate evidence exists of the carcinogenicity of hydrogen peroxide in humans.[17]

The primary objective of this study was to describe exposure control practices used to minimize exposures to EtO and HPGP, characterize the extent of use of EtO and HPGP sterilization, and assess compliance with EPA's requirement for employers to use a single chamber process for EtO.

METHODS

Survey Methodology

The NIOSH Health and Safety Practices Survey of Healthcare Workers was a voluntary, anonymous, modular web-based survey conducted in early 2011. The study population primarily included members of professional practice organizations representing central supply technicians. Participating organizations invited members via email which included a hyperlink to the survey. Practices associated with the use of high level disinfectants in point-of-use applications were addressed in a separate hazard module and reported elsewhere.[18] Methods used to develop, test and implement the survey, along with its strengths and limitations, have been published previously.[19]

Survey Instrument

The web survey instrument included a screening module, 7 hazard modules addressing selected chemical hazards commonly found in healthcare settings, and a core module. Participants were eligible to complete the hazard module on chemical sterilants if they

responded ‘yes’ to the screening question asking whether they used EtO or HPGP to chemically sterilize medical or dental devices, instruments or supplies during the past 7 calendar days (hereafter referred to as the past week). It was possible for respondents to complete the chemical sterilants hazard module and not the core module. In those cases, demographic information is unavailable.

Most questions were presented to all respondents. However, questions addressing PPE, medical surveillance, and personal exposure monitoring were presented only to respondents who used automated EtO sterilizers with compressed gas cylinders or manual sterilizers utilizing glass ampules containing liquid EtO because these systems present the greatest potential for EtO exposure. The format of the questions varied including multiple choice, multi-part, yes/no and numeric. The questions sought information relative to the past week unless otherwise noted. To minimize response error, photos were included of various types of respirators.

Data Analysis

Data were analyzed using SAS 9.3.[20] Simple frequencies and prevalences are presented. Stratification was used to further describe and compare and contrast extent of use and process characteristics of EtO and HPGP. Results include responses to questions in the chemical sterilants module and selected questions in the core module that describe demographic, employer and occupation characteristics. Age was estimated by subtracting respondents’ year of birth from the year the survey took place, 2011. States where respondents worked were aggregated into 4 U.S. Census regions (Northeast, Midwest, South and West). No a priori hypotheses were proposed therefore statistical tests were not performed.

Human Subjects Review

The NIOSH Institutional Review Board determined that the activities in this project were surveillance and did not meet the criteria of research according to 45 CFR 46.1101(b)(2) and CDC Guidelines for Defining Public Health Research and Public Health Nonresearch.[21]

RESULTS

Respondent Characteristics

There were 428 respondents who sterilized medical instruments and supplies using EtO (n=142) and/or HPGP (n=313) during the past week. Of these, 373 (87%) reported that they most often sterilized in hospitals, predominantly in the CSS department (92%) or in other hospital areas (8%). The remaining respondents who sterilized in non-hospital settings (e.g. outpatient care centers, physician and dental offices) were excluded from the analysis because there were relatively few in each setting for meaningful interpretation of the data.

Nearly all (98%) of the 373 respondents who worked in hospitals completed the core module and are characterized by demographic and other descriptive information. Respondents were predominantly female (72%), non-Hispanic (91%) and older than 40 years of age (81%). The majority of respondents were white (81%); some reported that they

were black (15%), Asian (3%) or another race (4%). Education level varied, with most reporting up to Grade 12 (38%) or having either a vocational certificate (26%) or Associate's degree (20%). One-sixth (17%) were members of labor unions.

Respondents primarily categorized themselves as technicians/technologists including central supply processing technicians, sterile technicians and surgical technologists (90%); nurses (7%) and other healthcare workers (Table 1). Two-thirds of respondents (67%) had 6 or more years of experience in their current occupation, and 61% reported working for their current employer for 10 years or less. Seventy-one percent of employers had 250 or more employees. Most employers (57%) were non-profit; 31% were for-profit with the remaining employers being publicly-owned establishments. Respondents worked in states equally represented by the 4 major U.S. Census regions and over half (57%) worked in a large city.

Training, Professional Certification, Availability of Employer Procedures and Familiarity with OSHA Guidelines

Nearly all respondents using EtO were trained (94%), reported that their employer had standard procedures for sterilizing with EtO (96%), and were familiar with OSHA guidelines (94%) (Table 2). Of those trained, 40% reported that it had been more than 12 months ago. By comparison, a slightly lower proportion of respondents who used HPGP was trained (92%) and reported that their employer had standard procedures (91%). Of the HPGP users who had received training, almost half (46%) reported that it had been more than 12 months ago. Most respondents using EtO and/or HPGP reported that they had achieved professional certification (88%). Primary sources included the International Association of Healthcare Central Service Materiel Management and the Certification Board for Sterile Processing and Distribution.

EtO and HPGP System Characteristics

When asked about the type of sterilization system used, 84% of respondents reported HPGP, 38% EtO, and 22% used both (Table 3). Most (94%) respondents using EtO operated single chamber units, though a small number (6 respondents) reported using separate sterilization and aeration units. Of those who operated single chamber units, most (83%) reported that the EtO source was single-use cartridges instead of compressed gas cylinders. All 6 respondents who operated separate units for EtO sterilization and aeration reported that the sterilizer units used single-use cartridges. Five of these respondents reported that transferring loads from the sterilizer to the aerator lasted no more than 2 minutes and 1 reported that it lasted more than 6 minutes (Table 3).

Additional characteristics are presented separately for EtO and HPGP sterilization processes, including number of years the respondent had been chemically sterilizing medical instruments and supplies, number of days sterilizing and number of loads processed in the past week, and whether the number of loads processed were typical (Table 3). Marked differences were noted—EtO sterilization systems were used by respondents for more years, but for fewer days and loads in the past week compared to HPGP. Of the respondents using EtO, over a third (37%) sterilized for 11 or more years, nearly half (48%) sterilized for 2 or fewer days in the past week, and 56% processed 3 or fewer loads per week. By comparison,

most respondents (83%) using HPGP sterilized for 10 or fewer years, 56% sterilized for 5 or more days in the past week, and over half (52%) processed more than 11 loads per week. Between 80% and 90% of each group reported that the number of loads processed was the same as usual; however, a slightly greater proportion of respondents using HPGP reported that the number of loads processed was fewer than usual (13% vs 7%).

Administrative and Engineering Controls for EtO

Respondents who used both types of EtO sterilizer systems (i.e., single chamber unit and separate sterilization and aeration units) were asked about specific engineering and administrative controls including the presence of local exhaust ventilation (LEV) above the sterilizer door, continuous EtO air monitors near the sterilizer, and whether gas cylinders were located in a different room than the sterilization process (Table 4). Seven percent of respondents using single chamber EtO sterilizers reported that LEV was not present above the door of the unit, while an additional 19% who did not know. Six percent of respondents using single chamber EtO sterilizers reported that a continuous EtO monitor was not located near the sterilizer and 6% did not know. Over a third of respondents (37%) reported that the gas cylinders for the single chamber sterilizers were located in the same room as the sterilizer. Of the 6 respondents who reported using EtO sterilization systems with separate aeration chambers, 4 reported that LEV was present above the sterilizer door (2 did not know) and 3 reported that a continuous EtO monitor was present near the sterilizer (3 did not know).

Respiratory Protection for EtO

Only respondents using EtO units with compressed gas cylinders (n=19) were queried regarding the use of respiratory protection. Mistakenly excluded from these questions were the 6 respondents who used separate units for sterilization and aeration. None of the 19 respondents reported using a respirator while operating the EtO unit, although 4 reported using a surgical mask. Primary reasons for not wearing respirators included “an engineering control was being used” (50%), “exposure was minimal” (33%), and “not part of our protocol” (28%).

Medical Surveillance and Exposure Monitoring

Questions about participation in a medical surveillance program and exposure monitoring were presented only to respondents who used EtO and, of these, only to those (n=19) who operated units using compressed gas cylinders. The 6 respondents using EtO systems with separate sterilization and aeration were inadvertently excluded as noted above. A medical surveillance program, as defined in the survey, may include a work history, physical exam, and blood and/or urine tests. There was no medical surveillance of the 19 respondents. Eight of the respondents (42%) reported that their employer did not provide such a program, 9 (47%) were unaware whether their employer had a program, and 2 (11%) opted out of participating in their program.

Respondents (n=19) were asked whether or not exposure monitoring had been conducted in the past 12 months to assess personal or co-worker exposure to EtO. Thirty-seven percent

reported “it had”, 42% reported “it had not” and 21% were unaware whether or not it had been done.

DISCUSSION

This survey is one of the first to characterize precautionary practices and extent of use of EtO and HPGP sterilization systems in hospitals. The timing of the survey (January–March 2011) also afforded the opportunity to evaluate compliance with EPA’s requirement that a single chamber unit be used when sterilizing medical equipment with EtO which became effective on March 1, 2010.

With the exception of the 6 respondents who reported using separate units for EtO sterilization and aeration, all of the EtO and HPGP sterilization systems used in hospitals were automated closed-system processes which, under normal operating conditions and proper maintenance, represent minimal exposure risk to healthcare workers. Our survey did not ask respondents whether or not there were any equipment malfunctions in the recent past that activated alarms or resulted in acute health problems, whether or not environmental monitoring had been conducted for HPGP sterilizers, and information about the performance and maintenance of LEV systems. This information should be included in future studies.

Our survey showed that more than twice as many respondents reported using HPGP vs EtO sterilizers. This was not unexpected considering the regulatory constraints for EtO, coupled with sterile processing advantages of HPGP (much shorter processing times and harmless by-products including water vapor and oxygen). Operational advantages of HPGP were borne out in the data—respondents using HPGP sterilizers processed a much greater number of loads and spent more days per week sterilizing than those using EtO sterilizers.

Precautionary practices primarily focused on EtO because OSHA and EPA have regulations specifying the types of equipment and procedures that are needed to minimize worker exposure and ambient workplace EtO levels.[3, 14] Most respondents sterilizing with EtO used single chamber units that employed single use cartridges which are considered “safer” systems relative to minimizing potential EtO exposure risk. Most respondents also reported that a continuous EtO air monitor was present near the sterilizer to warn of high EtO levels in the event of a leak or equipment problem, and that (operational) LEV was present above the sterilizer door to remove fugitive EtO emissions. Additionally, two-thirds of the relatively few respondents who operated EtO sterilizers with compressed gas cylinders reported that the cylinders were in a different room than the sterilizer, which is a recommended practice to minimize worker exposure in the event a leak occurs in the gas line, valves or connections. Nearly all respondents using EtO sterilizers were trained, certified, and aware of OSHA procedures, and stated that their employer had standard sterilization procedures.

As noted earlier, 6 respondents (5%) reported using separate units for EtO sterilization and aeration, which is not in compliance with EPA’s single chamber mandate. The problem with this type of equipment is the potential for relatively high EtO levels that typically occur during the transfer of (off-gassing) loads from the sterilizer to the aerator. Although use of

precautionary practices focused on EtO, practices which may increase HPGP exposure risk included lack of safe handling training and employee-reported standard procedures.

According to the OSHA ethylene oxide standard (29CFR 1910.1047) employers must perform initial exposure monitoring of workers, and periodic exposure monitoring if either 8-hour exposures are at or above the action level or short-term exposures are at or above the 15 minute excursion limit. Additionally, employers are required to have a medical surveillance program for workers who are or may be exposed to EtO at or above the action level for at least 30 days a year. Some respondents reported that their employer conducted exposure monitoring during the past 12 months; however, most reported that it had not been done or they did not know if it had. A small proportion of respondents reported that medical monitoring was provided by employers but they did not participate in the program; most reported that their employer did not have a medical surveillance program or they did not know if one was available. We did not ask respondents why exposure monitoring was not conducted or why medical monitoring was not provided. It is unclear whether employers did not have a medical surveillance program because EtO levels were below the action level or were not in compliance with the standard.

Limitations of the study need to be considered when interpreting survey findings. The survey was targeted to professional practice organizations whose members are likely to use or come in contact with the chemical agents under investigation. Response rate could not be calculated because the survey invitation specified the specific chemical agents under study; it is not known who decided not to participate because they did not use any of the chemicals and therefore were ineligible, versus those who used them but decided not to participate for other reasons. Because the survey was not a probability sample, the findings and conclusions are not generalizable to all healthcare workers who sterilize using HPGP or EtOs but are limited to healthcare workers who participated. Additionally, the delivery of and response to the survey was conducted electronically, limiting respondents to those who have e-mail and Internet access. Survey data are self-reported and responses were not confirmed via observation, records or other means. Information on use of specific exposure controls, and medical and exposure monitoring were lacking for respondents who used separate EtO sterilization and aeration units, albeit only reported by 6 respondents. Information on reasons for absence of exposure and medical monitoring was not collected and should be evaluated in future studies.

In conclusion, although the survey does not represent all healthcare workers who sterilize with HPGP and EtO, the survey provides valuable information on current use and precautionary practices used to minimize exposures in hospitals. Survey findings show: 1) use of precautionary practices for EtO and HPGP sterilization processes was good but not universal; 2) a few separate EtO sterilization and aeration units were still in use one year after EPA mandated switching to single chamber units; and 3) EtO use appears to have diminished in favor of HPGP which affords higher throughput and minimal regulatory constraints.

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Table 1

Occupation and Employer Characteristics of Respondents

Characteristic	% of Respondents
Occupation	(n*=360)
Technician/technologist	90
Nurse	7
Other	3
Years in current occupation	(n=358)†
< 1	4
1–5	29
6–10	20
11–20	24
21–30	16
>30	7
Years with current employer	(n=358)†
<1	7
1–5	34
6–10	20
11–20	29
>20	18
Employer ownership type	(n=349)†
Non-profit	57
For profit	31
State, city, county or district government	7
Federal government	5
Size of employer (# of employees)	(n=357)
<10	7
10–99	15
100–249	7
250–1,000	27
>1,000	44
Employer location by population density	(n=357)†
Large city (≥50,000 people)	57
Small city (<50,000 people)	22
Suburbs (areas adjacent to cities)	12
Rural	10
Employer geographic region‡	(n=284)†
South	25
Midwest	27
West	24
Northeast	23

[*] Number of respondents varied for individual items (i.e., number of eligible respondents less number who elected not to answer).

[†] Percent totals do not add up to exactly 100 due to rounding.

[‡] Based on four U.S. Census regions: Northeast = CT, ME, MA, NJ, NH, NY, PA, RI, VT; Midwest = IL, IN, IA, KS, MI, MN, MO, NE, ND, OH, SD, WI; South = AL, AR, DE, DC, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV; West = AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY.

Table 2

Training, Employer Standard Procedures and Familiarity with OSHA Guidelines

Training/Standard Procedures	EtO		HPGP	
	n	% Yes	n	% Yes
Training on safe handling procedures	142	94	312	92
>12 months ago	133	40	286	46
≤12 months	133	60	286	54
Employer has standard procedures	142	96	311	91
Familiar with OSHA guidelines	142	94	_*	_*

EtO= ethylene oxide; HPGP=hydrogen peroxide gas plasma

*There are no OSHA guidelines for HPGP

Table 3

Sterilization Process Characteristics

Process Characteristics	% of Respondents	
Type of sterilization system used	(n*=373)†	
EtO	38	
HPGP	84	
EtO and HPGP	23	
Type of EtO system used		
Single chamber (sterilization and aeration occur in same unit)	94 (n=124)‡	
Separate units for sterilization and aeration	5 (n=120)‡	
Source of EtO for single chamber sterilizer	(n=115)	
Single use cartridges	83	
Gas cylinders	17	
Source of EtO for separate sterilization and aeration units	(n=6)	
Single use cartridges	100	
Gas cylinders	0	
Time (in minutes) transferring loads from sterilizer to aerator	(n=6)	
< 1	50	
1–2	33	
>6 minutes	17	
Process Characteristics by Type of Sterilization System	**EtO**	**HPGP**
Number of years sterilizing medical instruments and/or supplies	(n=142)‡	(n=312)
<1	6	6
1–5	37	47
6–10	19	30
11–20	18	14
>20	19	3
Number of days sterilizing medical instruments and/or supplies	(n=142)	(n=310)‡
1	33	11
2	15	13
3	15	9
4	9	10
5	15	29
6 or 7	13	27
Number of loads processed during past week§	(n¶=115)	(n=308)‡
EtO **HPGP**		
1 load <11 loads	31	47
2–3 loads 11–20 loads	25	25
4–5 loads 21–50 loads	22	18
6–10 loads 51–100 loads	16	7
>10 loads >100 loads	6	2

Process Characteristics by Type of Sterilization System	EtO	HPGP
Number of loads processed compared to usual	(n[¶]=115)	(n=251)
more loads than usual	6	5
fewer loads than usual	7	13
about the same number of loads as usual	87	82

EtO=ethylene oxide; HPGP=hydrogen peroxide gas plasma

[*] Number of respondents varied for individual items (i.e., number of eligible respondents less number who elected not to answer).

[†] Percents add to more than 100 percent because respondents could select more than one answer.

[‡] Percents do not add to exactly 100% due to rounding.

[§] Shorter processing times for HPGP compared to EtO was the basis for the higher load ranges

[¶] Does not include respondents who used separate sterilization and aeration equipment due to small number (n=6).

Table 4

Administrative and Engineering Controls For Single Chamber EtO Sterilizers

Administrative and Engineering Controls	n	% of Respondents		
		Yes	No	I don't know
Operational LEV above sterilizer door	114*	74	7	19
Continuous monitor located near sterilizer that provides warning when EtO leaks occur	113*	88	6	6
Gas cylinder located in different room than sterilizer	19†	63	37	–

LEV=local exhaust ventilation; EtO=ethylene oxide

*Number of respondents varied for individual items (i.e., number of eligible respondents less number who elected not to answer)

†Respondents who reported gas cylinders as the source for single chamber EtO sterilizers