Evaluating OSHA's Ethylene Oxide Standard: Exposure Determinants in Massachusetts Hospitals

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ABSTRACT

Objectives. This study sought to identify determinants of workplace exposures to ethylene oxide to assess the effect of the Occupational Safety and Health Administration's (OSHA's) 1984 ethylene oxide standard.

Methods. An in-depth survey of all hospitals in Massachusetts that used ethylene oxide from 1990 through 1992 (96% participation, N=90) was conducted. Three types of exposure events were modeled with logistic regression: exceeding the 8-hour action level, exceeding the 15-minute excursion limit, and worker exposures during unmeasured accidental releases. Covariates were drawn from data representing an ecologic framework including direct and indirect potential exposure determinants.

Results. After adjustment for frequencies of ethylene oxide use and exposure monitoring, a significant inverse relation was observed between exceeding the action level and the use of combined sterilizer–aerators, an engineering control technology developed after the passage of the OSHA standard. Conversely, the use of positive-pressure sterilizers that employ ethylene oxide gas mixtures was strongly related to both exceeding the excursion limit and the occurrence of accidental releases.

Conclusions. These findings provide evidence of a positive effect of OSHA's ethylene oxide standard and specific targets for future prevention and control efforts. (*Am J Public Health.* 2001;91:412–417)

The Occupational Safety and Health Administration (OSHA) was established in 1970 to develop and enforce regulations that would provide workplaces that are "free from recognized hazards."[1] The most controversial of OSHA's regulatory activities have been the 35 agent-specific and generic health standards promulgated since 1970.[2,3] Yet there has been relatively little systematic evaluation of the implementation and effect of these health standards.[4–8] A central methodologic challenge is the measurement of health outcomes with long latencies or multifactorial etiologies (e.g., cancers, asthma).[4,8] Evaluation of the relations between exposures and regulatory interventions, however, circumvents the challenges of measuring such health outcomes. To date, exposure-focused strategies for evaluating OSHA regulatory effects have been underutilized.[7]

With the joint goals of evaluating a specific OSHA health standard and developing research methods in this area, we performed an in-depth evaluation of the implementation and effect of OSHA's 1984 ethylene oxide standard.[9–13] Ethylene oxide is used for the sterilization of heat- and moisture-sensitive medical supplies. The National Institute for Occupational Safety and Health (NIOSH) estimated that 270 000 US workers are potentially exposed to ethylene oxide, with the largest concentration being in the health care industry.[14] Ethylene oxide is a known human carcinogen, a potential reproductive hazard, an allergic sensitizer, and a potent neurotoxin.[15,16] An OSHA 6(b) ethylene oxide health standard with a work-shift 1-ppm permissible exposure limit and 0.5-ppm action level was promulgated in 1984[17] and revised in 1988 to add a 5-ppm short-term excursion limit.[18]

A previous report documented a continuing decline in measured work-shift and short-term ethylene oxide exposures in the workplace but also found a widespread occurrence of accidental ethylene oxide exposures that have escaped detection by personal monitoring.[12] In this article, we present a systematic analysis of potential determinants of the occurrence of 3 exposure events in Massachusetts hospitals: (1) exceeding the action level, (2) exceeding the excursion limit, and (3) experiencing uncontrolled or accidental releases in the absence of personal monitoring. Covariates investigated included direct determinants, such as the use of various engineering controls. Traditional industrial hygiene perspectives alone, however, cannot fully capture the various social, cultural, political, and economic influences that also may be relevant. Accordingly, we developed a 4-level ecologic framework to explore the potential influence of public policy, organizational, group, and individual characteristics. Ecologic approaches have been productively applied to evaluate the role of OSHA-specified and nonregulatory determinants of providing medical surveillance for ethylene oxide exposure[10] as well as to evaluate the effects of other health and safety interventions.[19–21]

Methods

Study Design and Population

A 3-phase survey of ethylene oxide health and safety was conducted among all hospitals in Massachusetts (N=159), with the sterilization department (or central sterile) manager as

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the primary respondent. The survey design, procedures, study population, and 96% participation rate have been described in detail previously.[9–11] Ninety hospitals completed the detailed exposure history required for the analyses presented below.[9,12]

Variables Measured

The 3 exposure event outcomes and monitoring frequencies (for the action level and excursion limit) and the rationale for the focus on 1990 to 1992 have been described in detail previously.[10–12]

Ethylene oxide use and equipment variables. Ethylene oxide use queries included type of ethylene oxide used: 88% Freon (or substitute propellant) mixed with 12% ethylene oxide (henceforth referred to as 88:12) or 100% ethylene oxide cartridges (no responses for the use of glass ampules or "other" [open-ended]). Ninety-eight percent of the hospitals in the study reported use of ethylene oxide since before 1984, when the ethylene oxide standard was passed. Frequency of ethylene oxide use was determined by asking: "On average, how many ethylene oxide loads are processed in your hospital per week?"

To characterize the ethylene oxide sterilization equipment and engineering controls at each hospital, we made yes-or-no determinations for the following: (1) Does the hospital have a combined sterilizer–aerator? (2) Is the slot vent over the sterilizer door functioning? (3) Is the sterilization equipment isolated from the rest of the work space in its own ventilated room? (4) Does the equipment have an alarm "which will indicate when the *ventilation* of ethylene oxide equipment is not working?" (5) Does the ethylene oxide equipment room or department have a dedicated exhaust system?

Public policy variables. Central sterile managers were asked whether their hospitals were publicly or privately operated. OSHA has jurisdiction (i.e., the standard is legally binding) only in private Massachusetts workplaces.

Organizational variables. Organizational-level variables were measured to explore potential structural and management influences on ethylene oxide exposure. Hospital size was measured by the number of patient beds.[22] Almost all hospitals were acute care facilities (85 of 90). Structural safety support was assessed by asking whether the hospital had a formal health and safety committee (88 of 90) and whether the committee had ever helped the sterilization department with any ethylene oxide health and safety concerns (in 58 of 82 hospitals, respondents could confidently answer the question). Accordingly, only whether committees ever helped with ethylene oxide concerns was included in analyses.

Group-level variables. Central sterile managers were asked to provide demographic information on workers in the sterilization department, including counts of workers employed in the department and full-time equivalents and the number of part-time workers, women, and racial/ethnic minorities (analyzed as a percentage of the total). Managers also were asked whether any sterilization workers were represented by a union. Ethylene oxide health and safety norms were measured as previously described.[10]

Individual-level variables. The central sterile manager is the individual most directly responsible for ethylene oxide health and safety in the hospital setting. Central sterile manager variables included composite measures of the individual's years of experience in central sterile work and the number of certifications and memberships in central sterile professional groups.[10]

Statistical Analysis

Data were entered, cleaned, and managed as previously described.[9] The Fisher exact test, the Wilcoxon rank sum test, and logistic regression analyses were performed with Intercooled Stata, Version 5.0 (Stata Corp, College Station, Tex). All P values were 2-sided. The 3 multivariate models were built starting with independent variables that were significantly associated with each exposure event in bivariate analyses. In addition, the frequency of ethylene oxide use was retained in all steps of model building, and the frequencies of personal work-shift (action level) and short-term (excursion limit) monitoring were retained in all models of the action level and excursion limit events, respectively. All other variables measured were rotated through the base models 1 at a time and retained if significantly associated with the outcome.

Results

Exposure Event Outcome Variables

Of those hospitals that performed action level monitoring from 1990 to 1992, about one quarter exceeded the action level 1 or more times (17 of 75). The action level usually was exceeded only once (11 of 17, median=1), with the 3 highest frequencies at 6, 9, and 12 times. Of those hospitals that performed excursion limit monitoring, about one fourth exceeded the excursion limit 1 or more times (17 of 72). The excursion limit usually was exceeded only once (9 of 17, median=1), with the 3 highest frequencies at 6, 7, and 25 times. Seven hospitals reported exceeding both the action level and the excursion limit, 10 exceeded the action level only, and 10 exceeded the excursion limit only. This partial overlap indicates that these 2 exposure events were adequately distinct to warrant separate analyses of potential determinants for each.

From 1990 to 1992, 32 of the 90 hospitals reported the occurrence of 1 or more uncontrolled accidental ethylene oxide releases. One or more workers were definitely (e.g., medical attention was required) or potentially (e.g., they were in the vicinity during leak or release) exposed during accidental releases at most of these hospitals (29 of 32). Twenty-five of these 29 hospitals also had experienced evacuations in response to real or suspected leaks detected by ethylene oxide alarms or by other means.

Bivariate Analyses

Independent variable descriptive data are presented in Tables 1 and 2. Two potential determinants were associated with the outcome of exceeding the action level in bivariate analyses. The use of a combined ethylene oxide sterilizer–aerator showed an inverse relation with an odds ratio (OR) of 0.33 (Fisher exact test, P=.06, n=75), and hospitals where the action level was exceeded were larger than hospitals where the action level was not exceeded (median=301 vs 206 beds, Wilcoxon rank sum test, P=.03, n=75).

For the outcome of exceeding the excursion limit, 3 potential determinants were identified. The use of 88:12 was strongly related to exceeding the excursion limit (OR=7.78, P=.03, n=72). Hospitals where the excursion limit was exceeded were larger than hospitals where the excursion limit was not exceeded (median=300 vs 200 beds, Wilcoxon rank sum test, P=.06, n=72) and had performed excursion limit monitoring more frequently than hospitals where the excursion limit was not exceeded (median=28 vs 16, P=.05, n=72).

Only 1 potential determinant was associated with the outcome of unmeasured accidental worker exposures: the use of 88:12 (OR=6.59, P=.008, n=90).

Multivariate Analyses

Of the 90 hospitals included in multivariate analyses, 22 used only 100% ethylene oxide, 58 used only 88:12, and 10 used both. Because the use of 100% ethylene oxide represented the lowest exposure event risk in the excursion limit (OR=0.46, P=.26) and accidental exposure (OR=0.45, P=.16) bivariate analyses, users of only 100% ethylene oxide served as the reference category for dummy coding over the 3 categories.

For the outcome of exceeding the action level, the use of a combined sterilizer–aerator was the only potential determinant to remain significantly related to the outcome after adjustment for the frequencies of ethylene oxide

TABLE 1—Summary Measures of Ordinal and Continuous Independent Variables: Massachusetts Hospitals, 1990–1992

	Median	Range	N[a]
Work-shift personal monitoring frequency (action level) among hospitals that conducted work-shift monitoring	19	2–3744	75
Short-term personal monitoring frequency (short-term excursion limit) among hospitals that conducted short-term monitoring	18	1–2808	72
Average no. of ethylene oxide loads processed per week	7	1–182	90
Hospital size (no. of patient beds)	230	30–1082	90
Health and safety norms (score of 0–55) (n = 90, median = 50)	50	35–55	90
Number of full-time equivalents in sterilization department	7.6	1.5–45.0	90
% Women sterilization workers ([women/total] × 100)	80	0–100	90
% Minority sterilization workers ([non-Whites/total] × 100)	6	0–100	90
% Part-time sterilization workers ([part-timers/total] × 100)	10	0–67	88
Central sterile manager years of experience	8.0	0.08–25.7	90
Manager certifications and professional memberships (score of 0–8)	4.5	0–7	90

[a]When data were not obtainable for a particular variable (monitoring not performed, respondent did not have an answer, or records were not available to answer the question), these observations were deleted from regression analyses (maximum N = 90 hospitals).

TABLE 2—Dichotomous Independent Variable Frequencies: Massachusetts Hospitals, 1990–1992:

	Yes/Total (%)[a]
Use of positive-pressure sterilizers supplied with 88:12 or other chlorofluorocarbon and ethylene oxide gas mixture	68/90 (76)
Use of negative-pressure sterilizers supplied with 100% ethylene oxide cartridges	32/90 (36)
Use of combined sterilizer–aerator	52/90 (58)
Functioning slot vent over sterilizer door	79/88 (90)
Ethylene oxide sterilization equipment isolated from rest of department workspace	37/90 (41)
Alarm to indicate failure of ventilation of ethylene oxide equipment	63/90 (70)
Dedicated exhaust for ethylene oxide equipment room or for department	87/89 (98)
Private vs public hospital	80/90 (89)
Health and safety committee ever helped with ethylene oxide concerns	58/82 (71)
Presence of a sterilization worker union	15/90 (17)

Note. 88:12 = 88% Freon (or substitute propellant) mixed with 12% ethylene oxide.
[a]When data were not obtainable for a particular variable, these observations were deleted from regression analyses (maximum N = 90 hospitals).

use and action level monitoring (Table 3). The magnitude of the inverse relation between combined sterilizer–aerator use and exceeding the action level was increased by adjustment for these 2 potential confounders.

The use of 88:12 or both 88:12 and 100% ethylene oxide in a given hospital was strongly related to exceeding the excursion limit compared with those hospitals that used only 100% ethylene oxide (Table 3). The frequency of excursion limit monitoring was not related to exceeding the excursion limit after adjustment for ethylene oxide type and frequency of ethylene oxide use. The parameter estimates for ethylene oxide type are large but unstable. The use of only 88:12 (relative to only 100%) was not significant at the .05 level. A likelihood ratio test of a nested model without the ethylene oxide type dummy variables compared with the full model presented in Table 3 yields a *P* value of .04, indicating that the ethylene oxide type variable group meets our inclusion criteria of $P \leq .05$. A likelihood ratio test for the full model (or model χ^2) yields a *P* value of .09. This model was chosen for presentation, however, because it was necessary to account for the frequency of excursion limit monitoring, which was significant in bivariate analyses, and the frequency of ethylene oxide use, another important potential confounder. A model including only the dummy variables for ethylene oxide type yields a likelihood ratio test *P* value of .04.

Only ethylene oxide type was significantly related to the occurrence of accidental exposures after adjustment for the frequency of ethylene oxide use (Table 3).

Discussion

Performance-based OSHA rule making is intended to set the most protective standards feasible without strictly specifying the means by which employers are to achieve them. This provides flexibility and room for innovation by employers, manufacturers, and other stakeholders in achieving compliance. In this way, OSHA standards can play a stimulatory role in the development of new exposure prevention and control technologies.[23] The findings reported in this article, combined with previous findings, provide evidence of a very successful performance-based ethylene oxide standard in terms of (1) widespread implementation of a range of exposure control technologies, (2) complementary roles for OSHA and NIOSH in setting standards and supporting compliance efforts, (3) technology-forcing effects of the ethylene oxide standard, (4) the effectiveness of new exposure controls, and (5) the continuing need for the ethylene oxide standard. These points are addressed in turn below.

NIOSH began research on workplace ethylene oxide hazards in the 1970s. In 1977, NIOSH published its first public communication alerting workers, employers, and others to the health hazards of ethylene oxide exposure.[24] Seven years later, the ethylene oxide standard incorporated various engineering and other exposure prevention and control recommendations from NIOSH, ethylene oxide users, ethylene oxide equipment manufacturers, and others into a nonmandatory appendix.[17] These recommendations have continued to evolve since the passage of the standard,[25] in part supported by a steady stream of NIOSH research[14,26–32] and public communications[24,33–36] on the subject over a 23-year period. Our results show widespread implementation by 1993 of most of the ethylene oxide engineering controls that NIOSH and others[27,34,35] had previously shown in smaller-scale studies to be effective in controlling ethylene oxide exposures (Table 2). This is an important finding in its own right. Implementation of exposure controls has coincided with decreases in exposure levels over time[12,25] in a general sense. The exposure event modeling analyses presented in this article represent an advance in characterizing relations between specific determinants and exposures from a population-level policy perspective.

TABLE 3—Potential Determinants of Ethylene Oxide Overexposures: Multivariate Logistic Regression Models of Action Level, Excursion Limit, and Accidental Overexposures, 1990–1992

	OR	95% CI	*P*>*z*
Outcome = exceeding action level 1 or more times (n = 75)			
Use of combined sterilizer–aerator (yes = 42/75)	0.25	0.07, 0.90	.03
No. of ethylene oxide loads sterilized per week (median = 7, range = 1–182)	1.04	0.96, 1.12	.34
No. of action level badges collected (median = 19, range = 2–3744)	1.00	0.99, 1.00	.14
Outcome = exceeding short-term excursion limit 1 or more times (n = 72)			
Use of only 88:12 ethylene oxide mixture vs use of only 100% ethylene oxide (yes = 46/72, only 100% ethylene oxide [reference category] = 19/72)	7.24	0.76, 69.27	.09
Use of 88:12 and 100% ethylene oxide vs use of only 100% ethylene oxide (yes = 7/72)	15.20	1.13, 204.73	.04
No. of ethylene oxide loads sterilized per week (median = 7, range = 1–182)	1.01	0.97, 1.04	.70
No. of excursion limit badges collected (median = 17, range = 1–2808)	1.00	0.99, 1.00	.27
Outcome = workers accidentally exposed 1 or more times (n = 90)			
Use of only 88:12 ethylene oxide mixture vs use of only 100% ethylene oxide (yes = 58/90, only 100% ethylene oxide [reference category] = 22/90)	5.95	1.26, 28.10	.02
Use of 88:12 and 100% ethylene oxide vs use of only 100% ethylene oxide (yes = 10/90)	9.92	1.47, 67.09	.02
No. of ethylene oxide loads sterilized per week (median = 7, range = 1–182)	0.99	0.94, 1.05	.82

Note. OR = odds ratio; CI = confidence interval; 88:12 = 88% Freon (or substitute propellant) mixed with 12% ethylene oxide.

Work-Shift Exposures (Action Level)

Our results provide evidence of a populationwide effect of combined sterilizer–aerators in reducing work-shift exposures to ethylene oxide. Combined sterilizer–aerators are an example of a process redesign and engineering control that was not available when the ethylene oxide standard was promulgated in 1984. This feature, developed by each of the leading sterilizer manufacturers, preempts the need to transfer freshly sterilized goods from the sterilizer to a separate aerator. This transfer process had been a common source of worker exposure.[35] A 1992 OSHA-commissioned evaluation of the ethylene oxide standard found that its passage had stimulated the development of combined sterilizer–aerators and other efficient and inexpensive technologies to monitor and control ethylene oxide exposures.[25] Combined sterilizer–aerators were first widely marketed in the mid to late 1980s[25] and were recommended in 1989 by NIOSH in widely disseminated ethylene oxide health and safety guidelines.[34,35] A NIOSH field survey published in 1989 included 1 hospital that used a combined sterilizer–aerator; that hospital stood out as having nondetectable worker exposures and area concentrations.[35]

Short-Term (Excursion Limit) and Accidental Exposures

Our analyses also showed that the use of positive-pressure sterilizers is associated with elevated risks of exceeding the excursion limit and experiencing accidental exposures. Higher-dose exposures to ethylene oxide are of particular concern with respect to both acute and chronic health risks.[12,13] Important design differences between sterilizers that use chlorofluorocarbon and ethylene oxide gas mixtures and sterilizers that use 100% ethylene oxide likely account for the observed associations.

Machines that use chlorofluorocarbon and ethylene oxide require piping between the external gas-mixture source (supplied in large pressurized cylinders) and the sterilizer. The pressurized piping is a known source of leakage.[35] In addition, the sterilization chamber of gas-mixture sterilizers operates under positive pressure; thus, door gasket leaks, mishaps in door opening or closing, overpressure releases from relief valves, and other circumstances can result in ethylene oxide being released into the work or containment area.

In contrast, sterilizers that use 100% ethylene oxide cartridges operate by placement inside the sterilization chamber of a single-use cartridge (approximately 100 g), which is automatically punctured when the door is sealed. The 100% ethylene oxide sterilization chamber also runs under negative pressure; thus, chamber leaks result in the movement of air from the work space into the sterilizer, from which it can be effectively vented from the work area.

With respect to exceeding the excursion limit, several aspects of positive-pressure sterilizers could plausibly account for the observed association. By 1993, almost all 100% ethylene oxide sterilizers had built-in local exhaust ventilation over the sterilizer door. Although newer positive-pressure sterilizers have local exhaust ventilation over the door, some older sterilizers do not. Positive-pressure sterilizers tend to be larger and more expensive than 100% ethylene oxide sterilizers (which are often called portable); thus, they are replaced less frequently and tend to be older. Older sterilizers—even those retrofitted with emission control devices—may have less efficient emission controls. In addition, positive-pressure sterilizers have far greater potential for emissions from ethylene oxide supply gas piping, from the sterilization chamber, and from other sources.[35] Finally, our population-level results are consistent with the findings of NIOSH, which conducted a series of small-scale, in-depth studies of ethylene oxide emissions and control strategies in the health care setting.[35] NIOSH also found that 100% ethylene oxide sterilizers were inherently safer by design than those that used chlorofluorocarbon and ethylene oxide mixtures.

Similarly, several characteristics of positive-pressure sterilizers likely explain our observed association with worker exposures during accidental ethylene oxide releases. Mechanical and other problems associated with accidental releases have been previously described almost exclusively in positive-pressure sterilizers. These problems include clogging of valves with polymerized gas mixture, ruptured door seals, and cylinder-changing mishaps.[24,35,37–39] Although our survey did not include questions on the cause of accidental releases, examples of each of the above causes were included in anecdotal reports from study respondents.

From a prevention perspective, we believe that this evidence is strong enough to justify targeted intervention efforts to improve the safety of positive-pressure sterilizers. Continuing improvements in sterilizer design, regularly scheduled maintenance, quality control of supply cylinders (to prevent polymer buildup), and other measures could greatly reduce exposure potential for short-term excursions and accidental releases. Specifically, attention should be paid to better educating workers, supervisors, and managers about exposure potentials and their risk and protective factors, improved excursion limit monitoring during higher-risk activities such as cylinder changes and equipment maintenance, use of continuous-reading ethylene oxide alarms, and appropriate emergency response planning.[12] Opportunities also exist for greatly reducing ethylene oxide use and, thus, accompanying costs and exposure risks.[12,13,38,40,41]

The current study and other recent developments highlight the continuing need for the ethylene oxide standard and complementary NIOSH efforts. The phaseout of ozone-depleting chlorofluorocarbon diluent gases may lead to increasing use of ethylene oxide–carbon dioxide gas mixtures in hospitals. Importantly, ethylene oxide–carbon dioxide mixtures run at much higher positive pressures than do ethylene oxide and chlorofluorocarbon, thus potentially increasing the frequency and magnitude of short-term emissions and accidental releases. In addition, many hospitals are installing devices to control environmental emissions of ethylene oxide. A recent spate of catastrophic ethylene oxide explosions has been linked to inadequate matching of retrofitted emission control devices with large-scale commercial sterilization units.[13,36] Careful attention to this potential problem will help to prevent similar incidents from occurring in hospital sterilization operations.

Conclusions

Combined sterilizer–aerators have been associated with lower work-shift exposures on a populationwide basis, suggesting a technology-forcing role and a continuing positive effect of OSHA's ethylene oxide standard almost a decade after its initial passage. The identification of a strong risk factor for short-term and accidental exposures highlights the continuing need for the ethylene oxide standard and provides specific targets for prevention and control efforts. After a recent congressionally mandated in-depth regulatory flexibility review, the ethylene oxide standard was continued without change.[13,42]

Exposure-focused evaluations are an underutilized approach to measuring OSHA and NIOSH effects. Although relatively few such studies have been performed to date,[43–46] a renewed exposure emphasis in standards evaluation would help to surmount many of the challenges of assessing occupational disease outcomes, yield greater insights for improved primary preventive efforts than health outcome–focused studies, and help OSHA and NIOSH to more efficiently fulfill the requirements of the Government Performance and Results Act.[7,8] □

Contributors

A. D. LaMontagne led the conception and planning of the study, conducted the analyses, and wrote the paper. K. T. Kelsey assisted in the conception and planning of the study and data analysis and contributed to the writing of the paper.

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