LONG-TERM ETHYLENE OXIDE EXPOSURE TRENDS IN US HOSPITALS: INTERVENTION NEEDED TO PRESERVE GAINS MADE FOLLOWING THE 1984 OSHA STANDARD

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Abstract

Objectives: Long-term trends in ethylene oxide worker exposures were assessed for the purposes of (1) exposure surveillance and (2) evaluating the potential impacts of OSHA’s 1984 and 1988 ethylene oxide (EtO) standards.

Methods: Exposure data were obtained from a large commercial vendor and processor of EtO passive dosimeters. Personal samples (87,628 workshift and 45,816 short-term) from 1,876 US hospitals were analysed for time trends from 1984 through 1998 using regression modelling.

Results: EtO exposures declined steadily for the first several years following the 1984 and 1988 OSHA standards. From 1996-1999, however, the probability of exceeding OSHA’s short-term Excursion Limit increased. Workshift exposures may also be increasing over this time period. Random effects models predict continuing increases in both short-term and workshift personal exposures, indicating that selection bias is not likely to account for the observed trends.

Conclusions: These early warning signs indicate the need for renewed intervention efforts to protect healthcare workers from EtO’s carcinogenic, allergic sensitising, reproductive, and other hazards.

Introduction

The need for expanded research efforts on how best to translate occupational health and safety (OHS) knowledge into exposure prevention and control in the workplace is widely recognized. (1) Two areas with particularly high potential in this regard are surveillance and intervention effectiveness research, both of which have been identified by broad stakeholder input as National Occupational Research Agenda priorities. (2, 3) This report presents an integrated surveillance and intervention effectiveness research approach to analysing long-term ethylene oxide (EtO) exposure trends in US hospitals.

Exposure or hazard surveillance is relatively underdeveloped in relation to occupational health outcome surveillance, which has a much longer history. (2, 4) While both exposure and health outcome surveillance are relevant to addressing the unacceptably high burden of occupational disease, (5) health outcome surveillance is infeasible for many occupational disease outcomes, such as those with multi-factorial etiologies or long latency periods. Nevertheless, exposure surveillance continues to be underutilized as a surveillance strategy as well as an effectiveness measure in government policy evaluation and other intervention research. (4, 6, 7) One reason for this is the lack of data sources. While the US Occupational Safety and Health Administration’s (OSHA) Integrated Management Information System (IMIS) data on occupational exposures is broad-based both geographically and in terms of the range of hazards represented, (8) data on personal exposures to specific agents over time can be thin. The National Institute for Occupational Safety and Health’s (NIOSH) National Occupational Exposure Survey also has broad coverage, but little in the way of quantitative measurements. While NIOSH is planning new exposure surveillance initiatives, (9) substantial quantitative exposure databases on specific hazards are only rarely reported on. One strategy for addressing this data gap is to improve relations between researchers and data gatherers (employers) in order to make use of vast amount of exposure data routinely collected by employers and other groups. (4, 7)

From an intervention effectiveness research perspective, the literature is dominated by reports on the development, implementation, and evaluation of worksite-level intervention programs. (10) Evaluations of policy-level interventions, such as OSHA standards, are relatively few, but provide valuable guidance for the implementation of current policy as well as new policy-making. (10, 11) Finally, legislative mandates requiring government agencies to demonstrate the need for OHS
regulations, their effectiveness, and the achievement of performance benchmarks point to the potential utility of integrating exposure surveillance and intervention effectiveness research approaches. This report presents such an integrative effort in the context of exposure trends following OSHA’s 1984 Ethylene Oxide (EtO) standard, and was made possible by recently obtained access to a very large database of exposure measurements collected by a commercial distributor and processor of EtO monitoring devices.

Methods

Context

EtO is a known human carcinogen, a potential reproductive hazard, an allergic sensitizer, a potential asthmagen, and a potent neurotoxin that continues to be used widely for the sterilization of heat- and moisture sensitive medical supplies. An OSHA section 6(b) EtO health standard was promulgated in 1984, including a Permissible Exposure Limit (PEL) of 1 ppm and an Action Level (AL) of 0.5 ppm for EtO workshift exposures (time-weighted average ppm over 8 hours). In 1988, OSHA implemented an additional Excursion Limit (EL) of 5 ppm for EtO short-term exposures (time weighted average ppm over 15 minutes). Convenient passive exposure monitoring technologies for EtO that were developed and marketed to meet the needs for OSHA-mandated exposure monitoring were widely adopted by employers, and quickly became dominant over active sampling.

Data Cleaning

From 1984 to 1999, a total of 236,781 EtO samples were processed and entered into the vendor’s database. These were cleaned through a series of steps in order to generate an analytical dataset for assessment of time trends in relation to workshift and short-term personal samples.

NIOSH has previously determined that the greatest concentration of potentially EtO-exposed workers is in the healthcare/hospital sector, where EtO is used for the sterilization of heat- and moisture-sensitive medical supplies. This is reflected in the database obtained, wherein most of the measurements were identified as coming from hospitals. We have restricted analyses reported here to hospitals in order to: (1) make the industrial context homogeneous, and (2) focus on the employment sector where the bulk of OSHA and NIOSH EtO intervention efforts have been focused as a best-case scenario of potential policy-level intervention impacts on EtO exposures.

Ninety-one “test” samples (created by the vendor) were removed. One sample was removed due a nonsensical date (year = 1909). All area samples were dropped. Measurements taken in 1999 were dropped because it represents an incomplete year of data. Finally, many samples were not clearly identifiable by sample duration (time in minutes) as either workshift or short-term. Workshift
samples were defined as samples with a duration from 6-10 hours (8 hours +/- 2 hours). OSHA specifies that short-term samples are to be 15 minutes in duration. Short-term samples were defined as those falling within 15 minutes +/- 5 minutes. In summary, these cleaning steps resulted in analytical datasets of 87,582 workshift and 46,097 short-term samples from the hospital sector from 1984 through the end of 1998.

**Study Population**

The workshift measurements were taken from 20,775 hospital workers in 1,717 hospitals across the United States. On average, each worker was tested 4.216 times, up to 375 times. The short-term measurements were taken from 12,402 workers in 1,329 hospitals. On average, each worker was sampled 3.717 times, up to 343 times. Within a given hospital, EtO exposure measurements of the same type (workshift or short-term) were anywhere from a few hours to 13 years apart. On average, workshift samples were one month apart, and short-term samples were a month and a half apart.

**Statistical Analysis**

Exposure measurement results are reported as exceeding OSHA specified limits or not for a given workplace (hospital) by calendar year. Accordingly, we report results for exceeding the AL, the PEL, and the EL. We have focussed on the hospital as the unit of analysis (rather than the individual worker) because the primary aim of OSHA policy is create safer workplaces and because this provides the greatest power for assessing time trends. While some information is lost using these simple metrics, they are nonetheless the most relevant to policy implications and have been reported commonly in other exposure time trend analyses. Time trends were analysed descriptively and using logistic regression for each of the three exposure limit outcomes. Analyses were conducted using Stata version 6.0 (Stata Corp, College Station, TX). Independent variables included time in years as well as a quadratic term for time to test for potential non-linearities. Previous descriptive analyses have suggested that exposure levels declined at a faster rate for the first several years after the effective dates of the two OSHA standards, followed by a progressive flattening over subsequent years. All regressions were also adjusted for the interval of time since the previous sample of the same type was taken in that hospital. This takes into account the fact that a long time lag between samples is likely to be associated with a larger difference in EtO exposure levels. Finally, all standard errors were adjusted for clustering by hospital.

In addition to standard logistic regression techniques, random effects regression was also conducted. Random effects regression was used to assess trends within hospitals over fixed effects on the basis of the surveillance and policy analysis goals of the analyses: random effects regression is more appropriate for inference to hospitals that are like those in the sample in general, whereas fixed effects regression is more appropriate for making inferences specific to hospitals included in the sample.

**Results**

Aggregate summary statistics for the 1984—1998 period are presented in Table 1. While the mean percentages of hospitals exceeding the three EtO exposure limits over time were low (from 1.5-4.0%), Figure 1 shows that these percentages declined steeply over the first several years following the 1984 workshift exposure limit OSHA standard and the 1988 short-term exposure limit OSHA standard. The last two years of data suggest an increase in the percentage of hospitals exceeding both workshift and short-term OSHA exposure limits, which were further examined analytically.
When analysed using regression modelling, coefficients for time (in calendar year) indicate that the probabilities of exceeding each of the three OSHA limits decreases significantly over the first several years following the standards (Table 2). The coefficients for the squared terms, included to test for non-linearities in these trends, are also significant, though smaller in magnitude.

The decreasing numbers of hospitals conducting personal exposure monitoring in the most recent years represent the potential for selection bias as an explanation for any ostensible upward exposure trends. Random effects modelling enables assessment of exposure trends over time within hospitals. This second approach to analysis of the effect of time yields qualitatively the same results as simple logistic regression, ruling out selection bias as a central explanatory factor for the apparent recent upward trends. Log likelihood ratios indicate that the random effects models are better fits than the corresponding simple logistic regressions for all three outcomes (Table 2). The probabilities of exceeding the three exposure limits decreased sharply over the first several years following the OSHA standards (Table 2). Further, the recent upward trend in exceeding the short-term limit is clearly discernable when viewed as random effects model-predicted probably over time, but is not convincing when viewed similarly for workshift exposure limits (Figure 2).

Discussion

The observed results are relevant in implementation evaluation terms (how organizations respond to OSHA exposure monitoring requirements over time in naturalistic settings) as well as what they indicate in terms of surveillance and effectiveness evaluation (how have exposures changed over time, particularly in relation to OSHA regulation?). These are discussed in turn below.

Our results indicate widespread implementation of exposure monitoring requirements of the EtO standard by hospitals across the country. In a previous detailed study of the implementation of the EtO standard in Massachusetts hospitals, we observed that most hospitals were one or more years late in conducting initial exposure monitoring relative to OSHA-required dates. (18) The steep upward trend in the number of hospitals conducting monitoring from 1984 through 1990 in this report suggests that this was also the case nationally. This occurred despite the high visibility of OSHA’s EtO rulemaking (e.g., was closely followed in healthcare material management professional journals) and the considerable outreach efforts on the part of both OSHA and NIOSH (reviewed elsewhere(22)). This suggests the need for additional strategies to improve the implementation of OSHA standard requirements by industry.

In terms of the observed exposure trends, this report verifies previously documented downward EtO exposure trends for the first several years following the 1984 and 1988 standards,(17, 18) but does so using a single, internally consistent, much larger, and much more broadly representative EtO exposure data source. The exceptionally high statistical power afforded by this new data source has also enabled the detection of a recent upward trend in exposures exceeding the EL and also possibly the workshift limits. Most, if not all, previous studies of OSHA-regulated hazardous exposures have shown steady declines or a flattening of exposures over the similar time scales of 15 or more years following regulation.(23) Because of the potential policy and practice implications of this unusual and disturbing finding, careful examination of the strengths and limitations of the evidence is warranted.

There are several points to consider in relation to the data source. The benefits of analyzing employer-collected data described in this study include: (1) the quantity of the data dwarfs all other sources described in published reports to date; (2) further, the large number of exposure measurements were drawn from a large number of hospitals that were widely geographically distributed across the U.S.; (3) the opportunity to gain insights into a primary goal of OSHA regulation: changes in organizational behaviour to assess and improve OHS conditions. Limitations
include potential biases due to the non-random nature of the sampling, and the limited information on potential determinants of exposure levels (e.g., no information on job tasks or titles through which sub-group variation could be assessed). The lack of information on job tasks and titles is offset to some extent by the specific focus on hospitals, where there is a small number of task groups: operation of sterilization equipment, changing of EtO gas cylinders, and working in the vicinity of the sterilization equipment. In practical terms, the size of the database and knowledge from other studies of the prevalent practice in hospitals of routine over worst-case monitoring(18) suggest that the data presented in this report probably more closely represent nationwide exposure conditions than other available sources. By comparison to OSHA’s IMIS database—the most commonly used source for long-term exposure trend studies(8, 23)—all available EtO samples in OSHA’s Consultation and Compliance IMIS databases for the period from May 1, 1979 through September 30, 1999 total up to: 2,376 measurements, of which ~75% are personal (and 25% area) measurements across all industries (not just hospitals).

These strengths and limitations of the data are most important in interpreting the significance of the observed upward exposure trends in recent years. The random effects analysis demonstrated that the upward trend was observable within hospitals, and therefore not accountable for by selection bias. It is also possible that the recent upward trends are explained by changes in prevalent sampling practices. We do not have data to assess this and therefore cannot strictly rule out a systematic change in sampling practices within hospitals. In order for this to account for the observed trends, however, hospitals across the country would have had to move consistently from routine periodic monitoring to worst case monitoring over the same calendar years. We believe this to be extremely unlikely, and are not aware of any evidence to suggest that this might be the case. While qualified by the limitations outlined above, we believe the most likely explanation is that the observed upward trend represents an increase in EtO exposures in hospitals in recent years. If this is the case, then a finding from the previous Massachusetts hospital study suggests that there may also be a parallel increase in accidental releases of EtO that result in short-term high level exposures to small groups of workers that are not detected by personal monitoring.(18) In that study, it was observed that even though a minority of hospitals across Massachusetts had exceeded OSHA limits over the 1990-1993 period, many more had experienced accidental releases that were not captured by personal monitoring. Short-term high dose exposures are of particular concern due to EtO’s dose-rate effect in terms of adduct-formation, which is relevant to EtO health effects ranging from carcinogenicity and reproductive toxicity, to allergic sensitization and asthma.(12, 18)

Investigation of possible reasons for upward exposure trends is beyond the scope if this report. Possibilities include decreased NIOSH/OSHA outreach, decreased OSHA enforcement, the diversion of employer attention to EtO hazards due to more recent emphases on other hazards in hospital settings (e.g., bloodborne pathogens, tuberculosis, glutaraldehyde). These are the subject of continuing study.

Conclusions

Hospital worker exposures to EtO declined sharply in the several years following OSHA’s workshift and short-term exposure limit standards. In recent years, however, there is an early warning sign of upward exposure trends. This indicates the need for employers, regulators, researchers, and others to devote renewed attention to the assessment and control of EtO exposures in order to protect the substantial gains made following OSHA’s EtO standards. Intervention should follow according to the findings of such confirmatory investigations, with different stakeholders intervening according to their complementary roles (e.g., employers improving engineering controls, regulators increasing outreach education and enforcement activity, unions and other worker advocates increasing educational activities).
The goal of public health surveillance is to provide early warning of potential problems in order to enable their timely control.\(^{(24)}\) For occupational health hazards whose health effects are not amenable to surveillance—a characteristic of EtO that is also shared by most other hazardous occupational exposures, only exposure or hazard surveillance has the potential to effect timely feedback and control. Occupational exposure or hazard-focused surveillance efforts should be expanded for this reason as well as for their value in providing insights into the effectiveness of OSHA regulations and other interventions, and for meeting government performance requirements.\(^{(4, 6)}\)

**Acknowledgements**

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References


Table 1. EtO Personal Breathing Zone Samples in US Hospitals: Summary Statistics
for 1984—1998

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<th>Workshift Samples</th>
<th>Short-Term Samples</th>
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<td>Obs</td>
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<tr>
<td><strong>Hospitals</strong></td>
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<td>Samples per Hosp</td>
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<td><strong>Hospital Workers</strong></td>
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<td>Samples per Worker</td>
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<td><strong>EtO Samples</strong></td>
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<td>% PEL or STEL</td>
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</tr>
<tr>
<td>% AL</td>
<td>87582</td>
<td>0.040</td>
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Table 2. Effect of Time on Probability of Exceeding OSHA EtO Exposure Limits (Coefficients Shown)

<table>
<thead>
<tr>
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<th>Workshift Samples</th>
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<th>Short-Term Samples</th>
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<td>EtO AL</td>
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<tr>
<td>Year</td>
<td>-3.143***</td>
<td>-3.683***</td>
<td>-7.343***</td>
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<td></td>
<td>(0.863)</td>
<td>(0.505)</td>
<td>(1.063)</td>
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<tr>
<td>Year^2</td>
<td>0.016***</td>
<td>0.019***</td>
<td>0.039***</td>
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<tr>
<td></td>
<td>(0.005)</td>
<td>(0.003)</td>
<td>(0.006)</td>
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<tr>
<td>Log Likelihood</td>
<td>-6,045</td>
<td>-13,135</td>
<td>-5,395</td>
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<tr>
<td>Random Effects</td>
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<tr>
<td>Year</td>
<td>-2.960***</td>
<td>-3.534***</td>
<td>-6.581***</td>
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<tr>
<td></td>
<td>(0.492)</td>
<td>(0.299)</td>
<td>(0.665)</td>
<td></td>
</tr>
<tr>
<td>Year^2</td>
<td>0.015***</td>
<td>0.018***</td>
<td>0.035***</td>
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<tr>
<td></td>
<td>(0.003)</td>
<td>(0.002)</td>
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<td>86,167</td>
<td>44,788</td>
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NOTE: Regressions are adjusted for the interval of time since the previous sample of the same type was taken in that hospital. Parentheses contain robust standard errors adjusted for clustering on hospitals.

* p 0.05    ** p 0.01    *** p 0.001
Figure 1
Observed Proportions of EtO Personal Samples Exceeding OSHA Limits, by Calendar Year

Proportion

Calendar Year (19__)
Figure 2
Random Effects Model Predicted Probabilities of EtO Personal Samples
Exceeding OSHA Limits, by Calendar Year

Calendar Year (19__) vs. Probability

- Workshift Samples: Probability of Exceeding PEL
- Workshift Samples: Probability of Exceeding AL
- Short-Term Samples: Probability of Exceeding STEL