

**FINAL PERFORMANCE REPORT
(Option 2 Summary report format):**

**“Evaluating Exposures Under OSHA’s 1984 EtO Standard”
CDC/NIOSH Research Grant 5 R01 OH3932-04**

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who was PI on the grant until moving to Australia)

ABSTRACT

The three specific aims of the study were: (1) to characterize EtO exposures in various industries, over time, etc.; (2) to identify potential determinants of EtO overexposures, and (3) to assess compliance with the EtO standard using traditional OSHA compliance assessment for a given workplace over a given period of time versus a new method that estimates the probability that a typical measurement would exceed OSHA limits. Each of these aims has been addressed in published works or in publications in process. Each of these aims is addressed in turn below.

SIGNIFICANT FINDINGS

Aim 1: To characterize EtO exposures

Long-term trends in ethylene oxide (EtO) worker exposures were assessed for the purposes of exposure surveillance, and evaluating the impacts of OSHA's 1984 and 1988 EtO standards. Exposure data were obtained from a large commercial vendor and processor of EtO passive dosimeters. Personal samples (87,582 workshift and 46,097 short-term) from 2,265 US hospitals were analysed for time trends from 1984—2001, and compared to OSHA enforcement data (OSHA's Integrated Management Information System data on the number of EtO standard inspections, citations, and proposed penalty amounts). Exposures declined steadily for the first several years following the OSHA standards. Workshift exposures continued to taper off and have remained low and flat through 2001. Since 1996, however, the probability of exceeding the short-term Excursion Limit has increased. This trend coincides with a steep decline in enforcement of the EtO standard. Results indicate the need for renewed intervention efforts from all stakeholders in order to preserve the gains made following the passage of the OSHA standard. This work has been accepted for publication in the American J Public Health [LaMontagne, et al. in press, January 2004] and has been presented in various scientific meetings and conferences (listed below). This work will also be presented at the 15th Annual Conference of the International Society for Environmental Epidemiology (ISEE), September 24-26 2003, Perth, Australia. [LaMontagne, et al. in press]

The work described in the preceding paragraph focuses on policy outcomes (e.g., whether there have been exceedances of specific OSHA exposure limits in a given workplace over a given period of time). We are continuing to conduct analyses of exposure trends at the level of the individual as well. These outcomes are continuous (e.g., time-weighted average pip of EtO exposure) and their analysis is complicated by the high frequency of measurements that are below the analytical limits of detection (overall in the range of 70% of the measurements). We are currently preparing a methodological paper on how varying treatments of measurements below the limit of detection (or non-detectable/ND measurements) affect exposure summary measures. It is anticipated that this will be published in a peer-reviewed occupational health journal.

Aim 2: To identify potential determinants of EtO overexposures

We used data from the Massachusetts hospital EtO study funded by a previous NIOSH R03 to investigate the determinants of workplace exposures in order to assess the impact of OSHA's 1984 EtO standard. In the Massachusetts hospital study, an in-depth survey of all EtO-using

hospitals in Massachusetts was conducted for the 1990-1992 period (96% participation, N = 90). Three types of exposure events were modelled using logistic regression: exceeding the 8-hour Action Level (AL), exceeding the 15-minute Excursion Limit (EL), and worker exposures during unmeasured accidental releases. Covariates were drawn from data representing an ecological framework including direct as well as indirect potential exposure determinants. After adjustment for frequencies of EtO use and exposure monitoring, a significant inverse relationship was observed between exceeding the AL 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 EtO gas mixtures was strongly related to both exceeding the EL and the occurrence of accidental releases. These findings provide evidence of a positive impact of OSHA's EtO standard as well as specific targets for future prevention and control efforts. This work has been published in the American Journal of Public Health [LaMontagne and Kelsey 2001] and was presented in various scientific meetings (listed below).

We have further investigated the determinants of EtO exposures using the large dataset from the commercial monitoring company described above. These analyses, conducted in collaboration with Professor Stephen Rappaport and Dr. Douglas Taylor, assessed within versus between worker variability in exposures. Because these analyses require multiple exposure measurements over time on the same individual, we have used a restricted sub-sample of 25 hospitals that have at least 10 years of measurements available, 20 or more workers monitored, and the total number of measurements is greater than 100. Preliminary findings indicate that the estimated within-worker variance was typically much greater than the between-worker variance, indicating that exposures were dictated more by source-related and environmental factors than subject-related factors among sterilization workers in these hospitals. Further analyses will be conducted. We anticipate that this work will be published in a public health journal. A separate complete technical report on the work completed to date on this specific aim is provided under separate cover (entitled 'Analysis of exposure to ethylene oxide among hospital workers').

Though not directly a product of this grant, the insights into EtO exposure hazards and controls gained through this study and its predecessors were applied to the problem of EtO explosions in commercial sterilization facilities. Dr. LaMontagne participated in the development of a NIOSH Hazard Alert that was published and widely disseminated to address this problem (<http://www.cdc.gov/niosh/2000119.html>). [NIOSH 2000] The Principal Contributors to the Alert were Palassis J, Mattheissen C, Santiago A, Hadley J, LaMontagne AD, and Harris A.

Aim 3: To assess compliance with the EtO standard using traditional OSHA compliance assessment for a given workplace over a given period of time versus a new method that estimates the probability that a typical measurement would exceed OSHA limits.

We continue to work with Professor Stephen Rappaport and his colleague Dr. Douglas Taylor on the comparison of traditional OSHA methods of compliance assessment for a given workplace with his alternative method of estimating the probability that a typical measurement will exceed OSHA limits. Because these analyses require multiple exposure measurements over time on the same individual, we have used a restricted sub-sample of 25 hospitals that have at least 10 years of measurements available, 20 or more workers monitored, and the total number of measurements is greater than 100. Preliminary findings

indicate that while the probability of non-compliance (i.e., the likelihood that a random observation would exceed the Action Level of 0.5 ppm) is decreasing over time—roughly halved from 1985—2000, the probability of overexposure (i.e., the likelihood that a typical worker would be exposed, on average, above the Action Level) has decreased more dramatically—on the order of 10-fold.

Further analyses will be conducted. We anticipate that this work will be published in a public health journal. A separate complete technical report on the work completed to date on this specific aim is provided under separate cover (entitled ‘Analysis of exposure to ethylene oxide among hospital workers’).

BROADER IMPLICATIONS/FINDINGS OF THE STUDY

As well as addressing this particular study’s specific aims, this work has contributed to the development of strategies and methods for OHS intervention research. This study has been used in the broader context of OHS intervention research in two review/concept papers, [LaMontagne in press, Goldenhar, et al. 2001] a one-day workshop for government OHS regulators on how to improve OHS policy through intervention research (see listed below), and in a number of presentations at scientific and policy meetings (listed below).

SCIENTIFIC PRESENTATIONS

- Sep 2003 15th ANNUAL CONFERENCE OF THE INTERNATIONAL SOCIETY FOR ENVIRONMENTAL EPIDEMIOLOGY, September 24-26 2003, Perth, Australia. AD LaMontagne poster presenter on “Long-term EtO exposure trends in US hospitals in relation to OSHA regulatory activity,” co-authored by JM Oakes and RN Lopez-Turley. [LaMontagne, et al. in press]
- May 2003 EVALUATING GOVERNMENT OCCUPATIONAL HEALTH & SAFETY INTERVENTIONS: A ONE-DAY NOHSC WORKSHOP, 14 May 2003, Canberra ACT, Australia. AD LaMontagne invited sole developer, speaker, and workshop facilitator. Sponsored by the Australian National Occupational Health & Safety Commission (NOHSC) and provided for a group consisting of two OHS Regulatory agency staff from each Australian state and territory. See http://www.nohsc.gov.au/ResearchCoordination/ohs_interventions.htm.
- Dec 2002 20th ANNUAL MEETING OF THE AUSTRALIAN INSTITUTE OF OCCUPATIONAL HYGIENE, Geelong, Australia. AD LaMontagne invited Plenary Speaker on “Intervention research in occupational health & safety.”
- Sep 2002 SYMPOSIUM ON PRIORITIES IN OCCUPATIONAL HEALTH, Massey University, Wellington, New Zealand. AD LaMontagne invited speaker on “Improving OHS policy through intervention research.”
- Sep 2002 CURRENT ISSUES IN REGULATION: ENFORCEMENT AND COMPLIANCE, a conference presented by the Australian Institute of Criminology, the Regulatory Institutions Network at the Australian National University and the Division of Business and Enterprise, University of South

Australia (Melbourne). AD LaMontagne speaker on “Long-term exposure trends following US OSHA’s 1984 ethylene oxide standard,” paper co-authored by JM Oakes and RN Lopez-Turley.

June 2001 NORA SYMPOSIUM 2001: LEADING RESEARCH IN OCCUPATIONAL SAFETY & HEALTH, Washington DC, USA. AD LaMontagne facilitated “Program Evaluation Perspectives” session by Professor Carol Weiss for Intervention Effectiveness Team Workshop for the National Occupational Research Agenda (NORA) initiative led by the US CDC’s National Institute for Occupational Safety & Health (NIOSH).

PUBLICATIONS

LaMontagne A, Oakes J, Lopez-Turley R (in press, January 2004). Long-term ethylene oxide exposure trends in US hospitals: intervention needed to preserve gains made following 1984 OSHA standard. *American J Public Health 94*.

LaMontagne A, Oakes J, Lopez-Turley R (in press). Long-term ethylene oxide exposure trends in US hospitals in relation to OSHA regulatory activity (abstract). *Epidemiology*.

LaMontagne AD, Kelsey KT (2001). Evaluating OSHA's ethylene oxide standard: exposure determinants in Massachusetts hospitals. *American J Public Health 91: 412-417*.

NIOSH (2000). ALERT: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities Cincinnati, OH: U.S. Department of Health & Human Services: National Institute for Occupational Safety & Health (NIOSH).

LaMontagne A (in press). Improving occupational health & safety policy through intervention research. *Journal of OHS - Aust NZ*.

Goldenhar LM, LaMontagne AD, Katz T, Heaney C, Landsbergis P (2001). The intervention research process in occupational safety & health: an overview from the NORA Intervention Effectiveness Research Team. *J Occup Environ Med 43: 616-622*.



Memorandum

Date: October 22, 2003

From: Michael J. Galvin, Ph.D., Program Official *for Steven J*
Office of Extramural Programs, NIOSH, E-74

Subject: Final Report Submitted for Entry into NTIS for Grant 5 R01 OH003932-04.

To: William D. Bennett
Data Systems Team, Information Resources Branch, EID, NIOSH, P03/C18

The attached final report has been received from the principal investigator on the subject NIOSH grant. If this document is forwarded to the National Technical Information Service, please let us know when a document number is known so that we can inform anyone who inquires about this final report.

Any publications that are included with this report are highlighted on the list below.

Attachment

cc: Sherri Diana, EID, P03/C13

List of Publications

LaMontagne AD, Oakes J, Lopex-Turley R. Long-Term Ethylene Oxide Exposure Trends in US Hospitals: Intervention Needed to Preserve Gains Made Following 184 OSHA Standard. American Health 94.

Goldenhar LM, LaMontagne AD, Katz T, Heaney C, Lansbergis P (2002). The Intervention Research Process in Occupational Safety & Health: An Overview From the NORA Intervention Effectiveness Research Team. J Occup Environ Med 43: 616-622

LaMontagne AD, Kelsey KT: Evaluating OSHA's Ethylene Oxide Standard: Exposure Determinants in Massachusetts Hospitals. Am J Public Health, in press, 2001

NIOSH Closeout Summary with Publications

Title: Evaluating Exposures Under OSHA'S 1984 ETO Standard
Investigator: Robert F. Herrick, Sc.D.
Affiliation: Harvard University
City & State: MA
Telephone: (617) 432-0674
Award Number: 5 R01 OH003932-04
Start & End Date: 5/1/1999–4/30/2003
Total Project Cost: \$594,352
Program Area: Intervention Effectiveness Research Methods
Key Words: health care workers

Final Report Abstract:

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Publications:

LaMontagne AD, Kelsey KT: Evaluating OSHA's Ethylene Oxide Standard: Exposure Determinants in Massachusetts Hospitals. *Am J Public Health*, in press, 2001

LaMontagne AD, Oakes J, Lopex-Turley R. Long-Term Ethylene Oxide Exposure Trends in US Hospitals: Intervention Needed to Preserve Gains Made Following 184 OSHA Standard. *American Health* 94.

Goldenhar LM, LaMontagne AD, Katz T, Heaney C, Lansbergis P (2002). The Intervention Research Process in Occupational Safety & Health: An Overview From the NORA Intervention Effectiveness Research Team. *J Occup Environ Med* 43: 616-622