

HETA 86-489-1789
APRIL, 1987
ST. JAMES ANNEX
BUTTE, MONTANA

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I. SUMMARY

In September 1986 the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate exposures to nitrous oxide and ethrane in the Saint James Hospital day surgery annex, in Butte, Montana.

On February 2, 1987, two breathing zone and two general room air samples were collected for ethrane. Four nitrous oxide samples were also collected; two were breathing zone samples and two were general room samples. Direct reading measurements were taken during surgical procedures in order to locate leaks in the anesthesiologist's equipment, leaks in the pop-off valve scavenging equipment, and other sources of anesthetic waste gas contamination.

All four of the ethrane samples exceeded the evaluation criteria of 0.5 parts per million (ppm) for halogenated anesthetic agents used in combination with nitrous oxide. The evaluation criteria for the halogenated anesthetic agents when used alone is 2 ppm. The levels found on the two breathing zone samples were both 2.2 PPM. The two general room samples were 2.8 and 1.3 ppm. The two breathing zone air samples analyzed for nitrous oxide were 175 ppm and less than 25 ppm. The general room air samples were 25 ppm and 50 ppm. All high and low pressure connections were checked for leaks, as well as all parts of the scavenging system. No leaks were observed. The probable reason for the build up of high levels of the nitrous oxide and ethrane is not enough general ventilation in the operating room. There are about 8 to 10 air changes per hour in this operating room. There should be a minimum of 20 air changes per hour in an operating room. If this were accomplished in this facility, the levels of all these gases would probably be below the evaluation criteria.

On the basis of the environmental data, it was concluded that a health hazard existed in the operating room at the Saint James Annex Day surgery from overexposures to nitrous oxide and ethrane. Recommendations on improvements in the ventilation system are included in this report.

Keywords: SIC: 8070 (Hospitals) surgery, nitrous oxide, ethrane.

II. INTRODUCTION

NIOSH received a request from the Director, Nursing Services, in September of 1986 to evaluate the operating room in the day surgery department at Saint James Annex in Butte, Montana. An environmental evaluation was conducted on February 2, 1987. Environmental results were discussed with the requestor on March 9, 1987. The delay in performing this evaluation was due to the conflicts in the schedule of the surgery department and NIOSH. The delay was a mutual agreement between the two parties.

III. BACKGROUND

The Saint James Annex referred to as St. James East is an outpatient facility that performs day surgery procedures. A large number of these procedures are mask inductions. Mask inductions are procedures performed without intubation of the patient, only the mask is used. This procedure is commonly used for tonsil operations and surgery on infants that cannot be intubated. Mask inductions procedures usually produce higher levels of waste anesthetic gas. Only one operating room is routinely used for these procedures.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

Four nitrous oxide breathing zone air samples were collected by using vacuum pumps and 20 to 40 liter metallic bags attached to the worker. The samples were analyzed immediately on the surgical floor using infrared spectrometry. Ethrane samples were collected on workers using organic vapor charcoal sampling tubes and vacuum pumps. These samples were analyzed according to NIOSH method 1003. All the operating room personnel were interviewed.

V. EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended exposure limits, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

	<u>Recommended Exposure Limits</u>		
	<u>8-Hour Time-Weighted</u>		
	<u>Exposure Basis (PPM)</u>		
Nitrous Oxide		25.0 (NIOSH)	
Ethrane	2.0a	0.5 (NIOSH)	75* ACGIH

ppm - parts of vapor or air per million parts of contaminated air.

* - 1985 ACGIH TLV

a - when used without nitrous oxide

OSHA does not have standards for these compounds.

Toxicological

In the NIOSH criteria document for a recommended standard for occupational exposure to anesthetic gases, NIOSH states: "Current scientific evidence obtained from human and animal studies suggests that chronic exposure to anesthetic gases increases the risk of both spontaneous abortion among female workers and congenital abnormalities in the offspring of female workers and the wives of male workers. Risks of hepatic and renal diseases are also increased among exposed personnel. In addition, physiological Health Hazard Evaluation Report No. 86-489 Page 4

function may be impaired. A few studies have suggested increased risk of cancer. Effects on the central nervous system due to acute exposures to anesthetic gases have been associated with headaches, nausea, fatigue, irritability, etc." Control procedures and work practices presented in that document, however, should prevent the effects caused by acute exposure and significantly reduce the risk associated with long-term, low level exposure. A dose response relationship for halogenated anesthetic toxicity has not been defined. (Reference 2)

That same NIOSH publication recommends maximum exposures to 25 ppm nitrous oxide (eight-hour time-weighted average) and 2 ppm halogenated anesthetic when used alone, or 0.5 ppm when used with nitrous oxide. These recommendations are based upon available technology in reducing waste anesthetic gas levels.

Reports by Vaisman (Reference 3) and Askrong and Harvald (Reference 4) were among the first to identify increased incidence of spontaneous abortion in women exposed to anesthetic gases and in wives of men exposed to anesthetic gases. Results of a more recent and comprehensive nationwide survey of occupational disease among operating personnel were published in 1974 by the American Society of Anesthesiologists (ASA). (Reference 1) The results of this study indicate "that female members of the operating room-exposed group were subject to increase risks of spontaneous abortion, congenital abnormalities in their children, cancer, and hepatic and renal disease. This increased risk of congenital abnormalities was also present among the unexposed wives of male operating room personnel. No increase in cancer was found among the exposed males, but an increased incidence of hepatic disease similar to that in the female was found."

While several investigators have reported increased rates of resorption in animals, particularly rats, most of these studies involved concentrations of anesthetic gases well above the levels found in occupational exposure. One investigator (Reference 5) showed increased

fetal death rates in two groups of rats following exposures of 1,000 and 100 ppm of nitrous oxide. Doenicke, et al., (Reference 6) concluded from their study of anesthetized pregnant rats that halothane demonstrates an abortive effect directly proportional to the concentration inhaled, again referring to anesthetic concentrations; but nitrous oxide does not produce an abortive effect. Bruce (Reference 7) reports no significant difference, including implantations and resorptions per pregnancy, in his exposure of rats to 16 ppm halothane.

Several epidemiological studies that indicate increased spontaneous abortions also indicate an increased rate of congenital abnormalities. The ASA study (Reference 1) as well as surveys by Knilljones, et al., (Reference 8) and Corbett, et al. (Reference 9) indicated an increased rate of congenital abnormalities in children of women with occupational exposures to anesthetic levels. One study (Reference 10, 11, 12) indicated liver, kidney, and brain tissue changes in pups born to rats exposed to sub-anesthetic concentrations of halothane during pregnancy.

The same epidemiological and toxicological studies, (Reference 10, 11, 12) have indicated an increase in spontaneous abortion and congenital abnormalities. This increase, however, was less pronounced in both rate and severity.

In a study published by NIOSH (Reference 13), "nitrous oxide and halothane in respective concentrations as low as 50 ppm and 1.0 ppm caused measurable decrements in performance on some psychological tests taken by healthy male graduate students. Nitrous oxide alone caused similar effects. The functions apparently most sensitive to these low concentrations of anesthetics were visual perception, immediate memory, and a combination of perception, cognition, and motor responses required in a task of divided attention to simultaneous visual and auditory stimuli." Headache, fatigue, irritability, and disturbance of sleep have also been reported (References 2, 14); and damage to cerebral cortical neurons has been seen in rats after sub-anesthetic exposure to halothane. (Reference 15) Quimby, et al., (Reference 16) reported permanent learning deficits in rats exposed to anesthetic concentrations of halothane during early development (from conception).

Mortality and epidemiological studies have raised the questions of possible carcinogenicity of anesthetic gases, but sufficient data are lacking to list nitrous oxide, halothane, or ethrane as suspected carcinogens.

Literature reviews regarding halothane (References 17, 18, 10, 20) indicate the most widely accepted mechanism of bio-transformation is the production of trifluoroacetic acid and bromide. The literature regarding enflurane (References 21, 22) does not indicate any one accepted mechanism, but increased serum and urinary fluoride levels were found in patients receiving enflurane anesthesia. While epidemiological and toxicological studies have indicated several symptoms apparently related to sub-anesthetic exposure to anesthetic gases, no cause and effect relationship has yet been shown.

A mail survey of 30,650 dentists and 30,547 chairside assistants grouped according to occupational exposure to inhalation anesthetic/sedatives in the dental operator indicated increased general health problems and reproductive difficulties among anesthetic-exposed respondents. For heavily anesthetic-exposed male dentists, the increase in liver disease was 1.9-fold, kidney disease 1.2-fold, and neurological disease 1.9-fold. For wives of heavily anesthetic-exposed male dentists the increase in spontaneous abortion rate was 1.5-fold. Among heavily anesthetic-exposed female chairside assistants, the increase in liver disease was 1.6-fold, kidney disease 1.7-fold and neurological disease 2.8-fold. The increase in spontaneous abortion rate among heavily exposed assistants was 2.3-fold. Cancer rates in women heavily exposed to inhalation anesthetics were increased 1.5-fold but this finding was only borderline significant ($P = 0.06$). Separate analysis of the data for disease rates and birth difficulties by type of inhalation anesthetic indicates that in both dentists and chairside assistants chronic exposure to nitrous oxide alone is associated with an increased rate of adverse response. (Reference 23) It would not be correct to directly extrapolate nitrous oxide epidemiological data taken on dentists and dental assistants to surgical operations. Dentists and their assistants are much closer to their work and are breathing higher concentrations than surgeons, scrub nurses, and anesthesiologists.

In November 1986 NIOSH performed a computer search of the scientific literature on the anesthetic waste gases. Information received from this search did not add additional light on the toxicology of these agents.

VI. ENVIRONMENTAL RESULTS

All four of the environmental samples taken for ethrane exceeded the evaluation criteria; levels were 2.2, 2.2, 2.8, and 1.3 ppm. Three of the four samples taken for nitrous oxide exceeded the evaluation criteria, these levels were 25, less than 25, 175 and 50 ppm. The evaluation criteria for ethrane when used with nitrous oxide is 0.5 ppm., when used alone the evaluation criteria for ethrane is 2.0 ppm. The evaluation criteria for nitrous oxide is 25 ppm. Leaks were not found in the anesthesia administering machine, the pop-off valve scavenging system, or any other area of the operating room. This operating room had approximately 8 to 10 air changes per hour. If the general ventilation was increased so that there was about 20 air changes per hour the levels of waste anesthetic gas would probably decrease to an acceptable level. Informal interviews with the nurses, nurse anesthetist, and surgeon showed an interest in the toxicology of ethrane and nitrous oxide. None of the workers thought they had health problems that were work related.

VII. CONCLUSIONS

Overexposures to nitrous oxide, and ethrane were observed during this survey. Since no leaks were observed in the anesthesiologist machine or in the scavenging system the source of exposures are: (1) Waste anesthetic gas coming from the mask during induction and (2) Insufficient general ventilation to exhaust the waste anesthetic gas. With 20 air changes per hour and practicing low flow anesthesiology, it is possible to keep waste anesthetic gas exposures at very low levels with a poorly operating scavenging system.

VIII. RECOMMENDATIONS

1. Air monitoring with passive dosimetry should be continued in the day surgery.
2. The ventilation system should be improved to allow more general ventilation in this room. Twenty (20) to 26 air changes per hour would be optimum. (Reference 24)

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XI. DISTRIBUTION AND AVAILABILITY

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Copies of this report have been sent to:

1. St. James Hospital
2. U.S. Department of Labor/OSHA - Region VIII.
3. NIOSH - Denver Region.
4. Montana State Health Department
5. State Designated Agency.

For the purpose of informing affected employees, a copy of this report shall be posted in a prominent place accessible to the employees for a period of 30 calendar days.

Table I

Breathing Zone and General Room Air Concentrations
of Nitrous Oxide
St. James Hospital Annex
Butte, Montana
February 2, 1987

<u>Sample ID</u>	<u>Job</u>	<u>Sampling Time</u>	(ppm) <u>Nitrous Oxide</u>
H	Circulating Nurse	8:39a - 9:00a	25
E	Scrub Nurse	8:41a - 9:30a	25
B	General Room	8:45a - 9:30a	175
A	General Room	8:49a - 9:30a	<u>50</u>
Evaluation Criteria			25
Limit of Detection			1

Table II

Breathing Zone and General Room Air Concentrations
of Ethrane
St. James Hospital Annex
Butte, Montana
February 2, 1987

<u>Sample No.</u>	<u>Job</u>	<u>Sampling Time</u>	(ppm) <u>Ethane</u>
Ct 1	Circulating Nurse	8:39a - 9:40a	2.2
Ct 2	Scrub Nurse	8:41a - 9:30a	2.2
Ct 3	General Room	8:45a - 9:30a	2.8
Ct 4	General Room	8:49a - 9:30a	<u>1.3</u>
Evaluation Criteria			0.5
Limit of Detection			0.01