

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CINCINNATI, OHIO 45202

HEALTH HAZARD EVALUATION DETERMINATION
REPORT NO. 75-76-234

MT. SINAI HOSPITAL
NEW YORK, NEW YORK

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I. TOXICITY DETERMINATION

On July 15-17, 1975, the exposures of medical and technical personnel to waste anesthetic gases were evaluated at Mt. Sinai Hospital. It has been demonstrated in animal experiments and from epidemiologic studies that anesthetic gases and vapors, including nitrous oxide and halothane, are potentially toxic at subanesthetic concentrations. Since present technology for the removal of waste anesthetic gases from operating rooms does not completely eliminate the gases, certain techniques and work practices must be adhered to in order to minimize the exposures of operating room personnel. It has been reported that concentrations of 30 ppm of nitrous oxide and 0.5 ppm halothane are attainable during the routine use of inhalation anesthetics, where the anesthesia equipment is leak-proof and scavenging techniques have been established which collect and dispose of the waste gases. It has been demonstrated that environmental concentrations of nitrous oxide and halothane measured in cystoscopy rooms and three operating rooms at Mt. Sinai Hospital, greatly exceed these recommended levels. Recommendations for effective control of these gases are included herein.

II. DISTRIBUTION AND AVAILABILITY

Copies of this determination report are available upon request from the Hazard Evaluation Services Branch, NIOSH, U.S. Post Office Building, Room 508, 5th and Walnut Streets, Cincinnati, Ohio 45202. Copies have been sent to:

- a) Mt. Sinai Hospital, New York, New York
- b) U.S. Department of Labor, Region II
- c) NIOSH, Region II

For the purposes of informing the affected employees, the employer will promptly "post" the Determination Report in a prominent place(s) near where exposed employees work for a period of 30 calendar days.

III. INTRODUCTION

Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) authorizes the Secretary of Health, Education, and Welfare, following a written request by an employer or authorized

representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The National Institute for Occupational Safety and Health received such a request from the Chairman of the Department of Anesthesiology of Mt. Sinai Hospital regarding exposure of operating room medical and technical personnel to waste anesthetic gases in the cysto diagnostic rooms, Guggenheim Basement. The survey request followed employee complaints of headache, nausea, fatigue, anorexia, and conjunctivitis which were believed to be related to exposure to halothane and nitrous oxide in the cystoscopy rooms.

IV. HEALTH HAZARD EVALUATION

A. Conditions of Use

The Cystoscopy Unit at Mt. Sinai Hospital occupies a section of the Guggenheim Basement including six cysto diagnostic rooms and a recovery room. This area has been designated as the Cystoscopy Unit since 1974 when it was converted from an x-ray department, but has never been used to its fullest capacity because of alleged problems with the ventilation system. At the time that the request was generated, the Unit was only being used for cases that did not require general anesthesia. All other cases were being referred to other hospitals, or were being done in one of the regular operating rooms on the sixth floor. The ventilation system in the Cystoscopy Unit was recently upgraded. However, many employees felt that it was still inadequate and that their daily exposures to anesthetic gases were producing headaches, nausea, fatigue, anorexia, and conjunctivitis.

Both medical and technical personnel may be exposed to anesthetic gases. During a surgical procedure, there may be one or two anesthesiologists present, one or two surgeons, nurses, an x-ray technician, surgical technician, and often some medical students. Their principal source of exposure to waste anesthetic gases is leakage from the anesthesia circuit. Exposures are highly variable, depending on the length of the surgical procedure, type of operation, and on their proximity to the anesthesia equipment.

Halothane (2-bromo, 2-chloro, 1,1,1-trifluoroethane) and nitrous oxide are the commonly used anesthetic agents at Mt. Sinai Hospital. Enflurane, also a halogenated hydrocarbon, is used occasionally, however, it was not used during this evaluation. Nitrous oxide and oxygen are piped in from outside the rooms at controlled flow rates. These are combined in approximately a 5:2 ratio of nitrous oxide to oxygen. Halothane, which is a liquid, is vaporized in the anesthesia machine to form a mixture in the range of 0.75% to 2.0% halothane in combination with the nitrous oxide/oxygen mixture. This entire anesthetic mixture is delivered to a face mask or endotracheal tube at a rate of 4 to 6 liters per minute. The exact concentrations of anesthesia gases are varied during a procedure, with higher concentrations required during induction than during maintenance of anesthesia. There is also variation depending on the individual anesthesiologist's technique.

The breathing system consists of a soda lime canister (to absorb exhaled carbon dioxide), breathing bag or ventilator, valves for assuring unidirectional gas flow, flexible hoses, and a Y-piece or T-piece terminating in an endotracheal tube or face mask. A face mask is used most often in cystoscopy and pediatric cases. The anesthetic gas mixture is delivered at a rate greater than the patient's metabolic need. Where a breathing bag is used, excess gases are vented out of the breathing system through the pop-off valve. If there is no scavenging system, this is the major source of leakage of waste anesthetic gases into the room. While a ventilator is in use, the pop-off valve of the anesthesia machine is closed and the ventilator assumes the function of the pop-off valve. This also can be a major source of leakage. Other sources are the face mask or endotracheal tube, cracks or holes in the hoses, through fittings or seals, from spilled liquid halothane, and even from the scavenging system itself when in use.

Scavenging components were present on most of the breathing systems at Mt. Sinai Hospital. In the Cystoscopy Unit, attempts were made to dispose of the waste gases into the general room exhaust grille via lengths of rubber hose. Fresh air is brought in from outside, and the actual ventilation, as measured by the Engineering Department at Mt. Sinai, provided 12 to 17 air changes per hour. In many of the operating rooms on the sixth and seventh floors of Mt. Sinai Hospital, scavenging was accomplished by direct connection of the pop-off valve or ventilator to the central vacuum system of the hospital.

B. Evaluation Design

1. Environmental

A preliminary observational study was conducted on July 15, 1975 by a team of three NIOSH industrial hygienists. Breathing zone and general area samples were obtained in the Cystoscopy Unit on July 16 to evaluate the exposures of operating room personnel to nitrous oxide and halothane. The Cystoscopy rooms had not been routinely used for cases requiring general anesthesia, however, arrangements were made to schedule six operations for that day. Three Cystoscopy rooms were utilized. Each operation was 20-40 minutes in duration, and no room was occupied for two successive procedures. During each operation, one or two anesthesiologists, a surgeon, and a nurse wore Sipin pumps and charcoal tubes to monitor their exposures to halothane. In addition, several area samples were obtained. The charcoal tubes were changed after each surgical procedure and were sent to the Analytical Research Laboratories, Inc., in Monrovia, California, where they were analyzed for halothane by gas chromatography. Sample results are presented in Table 1.

The exposures of anesthesiologists and surgeons to nitrous oxide were also monitored. Each wore a MSA pump modified for bag filling with a 30-liter Mylar bag attached. Air was drawn from the breathing zone via a 3-foot length of Tygon tubing. The bag was removed after each operation, capped, and a new bag was attached. Analysis followed almost

immediately, using a Wilks Miran I Infrared Analyzer. Analyses were performed at a wavelength of 4.48 micro meters and a pathlength of 5.25 meters unless otherwise noted in the table of results. Nitrous oxide concentrations are also shown in Table 1.

Further sampling was conducted on July 17 in three regular operating rooms which had a different ventilation system for disposal of waste anesthetic gases. Anesthesiologists wore sampling apparatus to monitor their exposures to both nitrous oxide and halothane. Samples for halothane analysis were also collected in the breathing zone of surgeons and nurses and in various locations in the operating rooms. Sampling and analytic methods were identical to those used for the samples collected on the previous day. The concentrations of nitrous oxide and halothane measured in the three operating rooms are presented in Table 2.

2. Medical

The primary reason that the Cystoscopy Unit was not being fully utilized at the time of the request was that there were numerous complaints from the nursing staff including nausea, headache, fatigue, anorexia, and conjunctivitis, which they felt were due to anesthesia gas exposure. Non-directed medical interviews were conducted with eight of the personnel in the Cystoscopy Unit. Two of the eight employees had no health complaints which they related to their jobs. Complaints of the other six workers included the above signs and symptoms as well as light-headedness, lethargy, general malaise, and dizziness. Most nurses and technicians felt that their symptoms were related to their exposure to anesthesia gases, especially to halothane. The employees had learned of studies showing increased risks of hepatic and renal disease, spontaneous abortion, and congenital abnormalities in children of exposed personnel associated with anesthetic gas exposure, and were concerned about their own daily exposures.

C. Evaluation Criteria

1. Toxicologic Effects

Until recently, nitrous oxide was considered to be a simple asphyxiant without other significant physiologic effects. No standard has been set for occupational exposure to halothane either. Both of these chemicals have been selected for use in surgical procedures because of their abilities to produce narcosis or unconsciousness in sufficient concentrations. Much less is known about the effects of subanesthetic concentrations. Animal experiments, epidemiologic studies, and a recent NIOSH investigation are now providing evidence that chronic exposure to low concentrations of inhalation anesthetics may be a health hazard.

The teratogenic effects of nitrous oxide have been demonstrated in developing chicks and rats when pregnant animals were exposed to nitrous oxide in anesthetic concentrations.^{1,2} Other animal experiments have shown the

embryotoxicity in the rat of chronic exposure to low concentrations of nitrous oxide.³ Nitrous oxide has also been associated with hematopoietic effect, including leucopenia and bone marrow depression.⁴

Halothane has similarly been shown to have teratogenic effects on developing chick embryos.¹ Subanesthetic halothane exposures have produced increased liver:body weight ratios and centrilobular hepatic fatty metamorphosis in other toxicologic experiments.^{5,6}

There is also evidence from human exposures that anesthetic agents are potentially toxic. Since other halogenated hydrocarbons are known to be capable of producing liver damage, the hepatotoxicity of halothane has undergone comprehensive review. A committee on Anesthesia of the National Academy of Sciences-National Research Council reviewed several reports associating halothane anesthesia with post operative hepatic necrosis, but concluded that this was limited to certain hypersensitive individuals and that the actual incidence was very low.⁷

Epidemiological studies have also provided evidence on the toxicity of nitrous oxide and halothane. Increased incidences of headaches, fatigue, irritability, spontaneous abortion, and abnormal pregnancies were reported in a study of Russian anesthesiologists who used primarily nitrous oxide and ether.⁸ Obstetric histories were obtained from 563 married women anesthesiologists and 828 women physician controls in the United Kingdom. It was determined that anesthesiologists working during pregnancy had an increased ratio of spontaneous abortions to live births and an increased frequency of congenital abnormality in live births. Women anesthesiologists also had a higher incidence of infertility than the control group.⁹ The most comprehensive study was conducted by the American Society of Anesthesiologists Ad Hoc Committee on Effects of Trace Anesthetic Agents on Health of Operating Room Personnel.¹⁰ Questionnaires were mailed to 49,585 exposed operating room personnel and 23,911 control persons. The exposed and unexposed groups were compared to determine whether there were important differences in occurrence rates of spontaneous abortions, congenital abnormality rate, cancer rate, hepatic disease rate, and renal disease rate. Spontaneous abortion rates were found to be higher among women working in the operating room than in comparable unexposed women. The congenital abnormality rate was found to be higher both for exposed women and for wives of exposed men than for their unexposed counterparts. Exposed women were also found to have an increased risk of developing cancer and renal disease than the control groups. Both male and female operating room personnel had significantly higher frequencies of hepatic disease than unexposed groups. Although it was recognized that other variables could account for these increased risks in disease rates, it was concluded that the exposure to waste anesthetic gases in the operating room was the probable cause.¹⁰

2. Environmental Standards

Since there is insufficient data to correlate exposure concentrations to toxic effects, no standard limiting exposure to waste anesthetic gases has yet been put into effect. Exposure guidelines have therefore been formulated based on limiting exposure through technology designed to remove the

waste gases and vapors from the operating room environment. A group of professors from Stanford University, working under a NIOSH contract, evaluated methods for eliminating waste anesthetic gases and vapors.⁸ They concluded that effective control of the waste gases could reduce concentrations to less than 30 ppm of nitrous oxide and less than 0.5 ppm halothane during the routine use of inhalation anesthetics.

D. Evaluation Results and Discussion

The results of environmental sampling are presented in Tables 1, 2, and 3.

The concentrations of nitrous oxide measured in the Cystoscopy Rooms at Mt. Sinai Hospital ranged from 20 ppm to 3000 ppm with a median value of 155. Only one measurement was below the recommended concentration of 30 ppm. The highest concentration was measured from a sample obtained in the breathing zone of an anesthesiologist during a panendoscopy. Except in the case of one area sample, the exposure concentrations of anesthesiologists exceeded concentrations measured in the breathing zone of surgeons and area sample concentrations. Concentrations of halothane ranged from 0.04 ppm to 29.3 ppm with a median of 1.0. About two-thirds of the measured levels equalled or exceeded the recommended concentration of 0.5 ppm. The highest concentration was again measured in the breathing zone of an anesthesiologist during a panendoscopy. The second highest concentration was measured in the breathing zone of the same anesthesiologist while he was filling the vaporizer with halothane. In five of the six procedures, the anesthesiologist was exposed to a higher concentration than any of the other personnel in a room. No conclusions can be made regarding the abilities of different rooms to be adequately ventilated.

Nitrous oxide concentrations measured in three operating rooms on the regular surgical floors ranged from 150 ppm to 3000 ppm with a median of 430. The highest concentration was measured in the breathing zone of an anesthesiologist during a breast biopsy, where the ventilator was vented but the expired air was not. The concentrations of halothane in these rooms ranged from 0.3 to 7.0 ppm with the highest concentration monitored in the breathing zone of an anesthesiologist in a Pediatric Room where a face mask was being used to deliver the anesthesia gases. Only three of seventeen measurements were below 0.5 ppm, the level which has been reported to be achievable in operating room air. In the Ophthalmology Room, where the waste gases were disposed of directly into the central vacuum system, concentrations of halothane and nitrous oxide were still very high. However, during the administration of anesthesia, a face mask was used for an extended period of time before the endotracheal tube was inserted, which could account for the high concentrations of gases.

E. Conclusions and Recommendations

Environmental data indicate that operating room personnel at Mt. Sinai Hospital are exposed to concentrations of halothane and nitrous oxide which could have potentially toxic effects. Since there are no defined

"safe" levels of exposure, employee exposures must be limited by the application of effective control measures including scavenging of gases at the anesthesia machine, "low leakage" practices by the anesthetist, and equipment maintenance. In spite of the fact that there is scavenging equipment and what should be an adequate number of air changes in the rooms, concentrations of halothane and nitrous oxide exceed those concentrations which have been reported to be achievable in the operating room environment. This may be due to leakage from the anesthetic circuit, poor anesthesia work practices, leakage from the scavenging equipment, or inadequate room ventilation.

The diffusion of gases through cracks in rubber and plastic material is one possible source of leakage which could be investigated by pressurization, immersion in water, and observation of any bubbling. There may also be poor fittings, missing or damaged gaskets. In order to determine leakage from the anesthesia machine and CO₂ absorber a non-leaking breathing bag and tubing must be used, then the increase in anesthesia gas concentrations with time should be monitored in an operating room.

The scavenging system itself is often found to be a source of leakage because of poor maintenance or poor design. All scavenging components must be gastight. The air conditioning system is also of prime importance in providing a disposal pathway for the anesthesia gases. If, in fact, there are 12 to 17 air changes per hour in the Cystoscopy Rooms, this should be sufficient to remove waste gases from the room. The actual effectiveness of the general room ventilation could be checked by setting up several monitoring sites in a room. With high air exchange rates there should not be significant differences in concentrations at various locations.

The NIOSH publication, Development and Evaluation of Methods for the Elimination of Waste Anesthetic Gases and Vapors in Hospitals, provides comprehensive information on methods for determining sources of leakage and means for reducing leakage at the source as well as recommendations for work practices that can reduce gas leakage.

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Table 1

CONCENTRATIONS OF ANESTHETIC GASES IN CYSTOSCOPY UNIT

July 16, 1975

<u>Room/ Operation</u>	<u>Sample Period</u>	<u>Anesthetic</u>	<u>Job Title</u>	<u>Halothane (ppm)</u>	<u>N₂O (ppm)</u>
Room 4	10:00-10:03 10:10-10:13	Halothane	Anesthesiologist*	14.8	
Room 4/ Excision Urethral Lesion- Panendoscopy	10:30-11:00 10:30-11:01 10:30-11:00 10:27-10:54 10:30-11:01	Halothane, N ₂ O (5 L N ₂ O + 2 L O ₂)	Anesthesiologist Anesthesiologist Nurse Surgeon Area-service table	5.4 1.0 1.0 0.8 0.9	560 160 110
Room 5/ Panendoscopy	11:20-12:00 11:20-12:02 11:19-12:03 11:19-12:02 11:19-12:02 11:23-12:04 11:35-12:12	Halothane, N ₂ O (5 L N ₂ O + 2 L O ₂)	Anesthesiologist Anesthesiologist Nurse Surgeon Surgeon Area Area sample-hall	29.3 3.0 2.2 2.2 2.4 N.D.	3000** 400 900 20
Hall	11:35-12:12	NA	Area sample-hall	N.D.	900 20
Room 1/ Cystoscopy	12:12-12:36 12:12-12:36 12:14-12:37 12:15-12:36 12:40-15:13	Halothane, N ₂ O	Anesthesiologist Nurse Surgeon Area sample Area sample-hanging from i.v. rack	2.0 2.0 2.8 6.3 0.2	660 400 1350**
Room 5/ Retrograde	13:04-13:38 13:05-13:40 13:06-13:36 13:00-13:41	Halothane, N ₂ O	Anesthesiologist Nurse Surgeon Area-service table	1.9 0.4 0.4 0.4	600 120 90
Room 4/ Cystoscopy- Biopsy	13:55-14:17 13:55-14:17 13:56-14:14 13:55-14:18	Halothane, N ₂ O (5 L N ₂ O + 2 L O ₂)	Anesthesiologist Nurse Surgeon Area	0.5 0.4 0.04 0.2	210 80 70
Room 5/ Cystoscopy- Needle Biopsy- Prostate	14:37-15:15 14:37-15:15 14:37-15:15 14:37-15:10 14:40-15:15	Halothane, N ₂ O (5 L N ₂ O + 2 L O ₂)	Anesthesiologist Anesthesiologist Nurse Surgeon Area-on vent intake	0.8 1.5 0.4 0.5 0.4	100 150 40 80
Room 5	13:15-14:23 13:15-14:23	None, samples taken on following day	Area Area	N.D. N.D.	

* - filling the vaporizer

** - pathlength of Wilks Miran I changed to 2.25 meters

N.D. - none detected - limit of detection = 0.8 µg per sample

Table 2

CONCENTRATIONS OF ANESTHETIC GASES IN OPERATING ROOMS

July 17, 1975

Room/Operation	Sample Period	Anesthetic	Job Title	Halothane (ppm)	N ₂ O (ppm)		
Ophthalmo. Rm 1/ Repair Retinal Detachment	7:55-10:10	Halothane, N ₂ O	Anesthesiologist	0.8	420	8:13- 9:30	
	8:12-10:10		Anesthesiologist	1.1	300	9:30-10:10	
						430	8:13- 9:30
						480	9:30-10:12
	8:07-10:23		Nurse	0.4			
	8:15-10:24		Assist. surgeon	0.7			
	8:15-10:22		Surgeon	0.3			
8:10-10:13	Area-table, side of room	0.6					
Ortho. Rm 1/ Breast Biopsy	11:13-12:00	Halothane, N ₂ O	Anesthesiologist	0.6	3000*		
	11:15-12:00		Anesthesiologist	5.0			
	11:05-12:00		Surgeon	1.2			
	11:17-12:00		Area-near exhaust vent	0.3		150	
Ped. Rm 11/ Orchiopexy	11:32-12:35	Halothane, N ₂ O	Anesthesiologist	7.0	1600*		
	11:35-12:45		Nurse	1.8			
	11:30-12:40		Surgeon	4.9			
	11:35-12:40		Area-table, side of room	1.9			
Ped. Rm 11/ Inguinal Herniorrhaphy	12:52-13:58		Anesthesiologist	1.7	700*		
	12:50-13:58		Nurse	3.0			
	12:57-13:58		Area-table side of room	1.8	300*		

* - pathlength of Wilks Miran I changed to 2.25 meters

Table 3

COMPARISON OF EXPOSURES BY JOB TITLE

<u>Job Title</u>	<u>Room</u>	<u>Halothane</u> (ppm)	<u>N₂O</u> (ppm)
Anesthesiologist	Cysto. 4	5.4	560
Anesthesiologist	Cysto. 4	1.0	160
Anesthesiologist	Cysto. 5	29.3	3000
Anesthesiologist	Cysto. 5	3.0	400
Anesthesiologist	Cysto. 1	2.0	660
Anesthesiologist	Cysto. 5	1.9	600
Anesthesiologist	Cysto. 4	0.5	210
Anesthesiologist	Cysto. 5	0.8	100
Anesthesiologist	Cysto. 5	1.5	150
Anesthesiologist	Ophthalmo 1	0.8	420
			300
Anesthesiologist	Ophthalmo 1	1.1	430
			480
Anesthesiologist	Ortho. 1	0.6	
Anesthesiologist	Ortho. 1	5.0	3000
Anesthesiologist	Ped. 11	7.0	1600
Anesthesiologist	Ped. 11	1.7	700
Surgeon	Cysto. 4	0.8	
Surgeon	Cysto. 5	2.2	
Surgeon	Cysto. 5	2.4	
Surgeon	Cysto. 1	2.8	400
Surgeon	Cysto. 5	0.4	120
Surgeon	Cysto. 4	0.04	80
Surgeon	Cysto. 5	0.5	40
Surgeon	Ophthalmo 1	0.7	
Surgeon	Ophthalmo 1	0.3	
Surgeon	Ortho. 1	1.2	
Surgeon	Ped. 11	4.9	
Nurse	Cysto. 4	1.0	
Nurse	Cysto. 5	2.2	
Nurse	Cysto. 1	2.0	
Nurse	Cysto. 5	0.4	
Nurse	Cysto. 4	0.4	
Nurse	Cysto. 5	0.4	
Nurse	Ophthalmo 1	0.4	
Nurse	Ped. 11	1.8	
Nurse	Ped. 11	3.0	
Area	Cysto. 4	0.9	110
Area	Cysto. 5		900
Area	Hall	N.D.	20
Area	Cysto. 1	6.3	1350
Area	Cysto. 5	0.2	
Area	Cysto. 5	0.4	90
Area	Cysto. 4	0.2	70
Area	Cysto. 5	0.4	80
Area	Ophthalmo 1	0.6	
Area	Ortho. 1	0.3	150
Area	Ped. 11	1.9	
Area	Ped. 11	1.8	300