U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE CENTER FOR DISEASE CONTROL NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH CINCINNATI, OHIO 45226

HEALTH HAZARD EVALUATION DETERMINATION REPORT NO. 77-118-453

Englewood Hospital Englewood, New Jersey January 1978

I. TOXICITY DETERMINATION

A Health Hazard Evaluation was conducted by the National Institute for Occupational Safety and Health (NIOSH) in the operating and recovery room area of the Englewood Hospital. On October 13, 1977, environmental samples were collected to determine concentrations of waste anesthetic gases.

Findings on the day of this survey indicate a significant decrease in exposure compared with measurements made in the same area during a previous study approximately a year earlier. Time weighted average exposures of anesthesiologists to nitrous oxide, calculated only for the time samples were being taken, ranged from 22 to 140 ppm, compared with 80 to 330 ppm for the previous study. Eight-hour time weighted average exposures to nitrous oxide ranged from 4 to 40 ppm, and most area samples were below 25 ppm. Airborne concentrations of halogenated anesthetics were below the limit of detection of the analytical method.

Nitrous oxide concentrations were slightly above the NIOSH Recommended Limit of 25 ppm. Since information on adverse health effects due to exposure to waste anesthetic gases is still not completely definitive and many unknown factors still exist, recommended permissible levels of exposure are not defined as safe levels but rather as levels attainable by current technology. These levels should prevent the effects caused by acute exposure and significantly reduce the risk associated with long term, low level exposure.

II. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Services, Information and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office at the Cincinnati address.

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Copies of this report have been sent to:

a) Englewood Hospital, Englewood, New Jersey

b) Hospital Professional and Allied Employees of New Jersey

c) U.S. Department of Labor, Region II

d) NIOSH, Region II

For the purpose of informing the approximately 150 "affected employees", the employer shall promptly "Post" for a period of 30 calendar days the determination report in a prominent place near where exposed employees work.

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 a representative of the Hospital Professional and Allied Employees of New Jersey regarding exposure of personnel to waste anesthetic gases in the operating room and recovery room area.

This request follows a previous evaluation conducted by NIOSH in the Englewood Hospital in November, 1976, during which concentrations of waste anesthetic gas were found to exceed recommended standards (Health Hazard Evaluation Determination Report No. 76-113-385, April, 1977). Following that evaluation, additional measures were taken by the hospital engineering and administrative staff to reduce exposures to waste anesthetic gas. There were no specific alleged health problems at the time this request was submitted.

IV. HEALTH HAZARD EVALUATION

A. Process Description

The anesthetic circuit is composed of the anesthesia machine and the breathing system. The anesthesia machine vaporizes the potent anesthetic (halothane or enflurane) and combines it with nitrous oxide and oxygen, which are pumped to the machine from outside the room or supplied from cylinders affixed to the machine. 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 terminating in an endoctracheal tube or face mask.

The anesthetic gas mixture is delivered at a rate higher than the patient's metabolic needs. When a breathing bag is used, excess gases are vented out of the breathing system through the pop-off valve. The volume of gases and vapors escaping through the pop-off valve are highly variable since it depends on the patient's breathing pattern and metabolic rate. When a ventilator is in use the pop-off valve on the anesthesia machine is closed and the ventilator assumes the function of the pop-off valve. The pop-off valve and the ventilator are potential sources of waste anesthetic gas. Other sources are the face mask or endotracheal tube, cracks or holes in the hoses, tube fittings or seals, or from spilled liquid anesthetic.

Measures have been implemented since the 1976 visit to reduce concentrations of waste anesthetic gases. Scavenging techniques are now common practice to remove gas from the area of the pop-off valve and ventilator. A continuous program for leak testing machines and tubing has been established. Equipment has been obtained to measure nitrous oxide concentrations and a program is being established to periodically monitor this gas.

B. Evaluation Design 🕡 🖔

On October 13, 1977, breathing zone and general area air samples were obtained for halothane, enflurane, and nitrous oxide. The breathing zone samples were obtained by attaching sampling equipment to operating room personnel. Anesthesiologists were sampled during operating room procedures whenever they were willing to wear the equipment, which consisted of a charcoal tube sampler for halothane and enflurane, and a bag sampler for nitrous oxide. Some charcoal tube samplers were placed on other operating room personnel. Area samples were obtained by placing sampling equipment at various locations, generally five to ten feet from the anesthesia machine. The charcoal tubes were shipped to a laboratory for analysis by gas chromatography and bag samples were analyzed on site by infrared spectrophotometry. A more detailed description of the sampling and analytical methods can be found in Health Hazard Evaluation Determination Reports 75-22-228²³ and 75-76-232²⁴

C. Evaluation Criteria

No new information or evidence has been forthcoming to alter the discussion of the evaluation criteria on waste anesthetic gases presented in the earlier report. For persons who may not have access to this information, the criteria is presented below.

In a 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 and congenital abnormalities in offspring among female workers and wives of male workers. Risks of hepatic and renal diseases are also increased among exposed personnel. In addition, psychologic function may be impaired. A few studies have suggested an increased risk of cancer. Effects on the central nervous system (CNS) 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.

That same NIOSH publication recommends maximum exposures of 25 parts per million (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 Vaisman² and Askrog and Harvald³ were among the first to identify an 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)⁴. The results of this study indicate "that female members of the operating room-exposed group were subject to increased 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 investigator⁵, however, showed increased fetal death rates in two groups of rats following exposure of 1,000 and 100 ppm of nitrous oxide. Doenicke et al⁶ 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 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 study⁴, as well as surveys by Knill-Jones et al⁸ and Corbett et al⁹, indicated an increased rate of congenital abnormalities in children of women with occupational exposures to anesthetic gases, and to wives of men with similar exposures. While most animal exposure studies have been conducted at anesthetic levels, one study¹⁰,11,12 indicated liver, kidney, and brain tissues changes in pups born to rats exposed to subanesthetic concentrations of halothane during pregnancy.

The same epidemiological and toxicological studies that indicated an increase in spontaneous abortion and congenital abnormalities also indicated an increase in liver and kidney abnormalities. This increase, however, was less pronounced in both rate and severity.

In a study published by NIOSH, ¹³ "nitrous oxide and halothane in respective concentrations as low as 50 parts per million (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;²,¹⁴ and damage to cerebral cortical neurons has been seen in rats after subanesthetic exposure to halothane. Oimby et all⁶ 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 enflurane as suspected carcinogens.

Literature reviews regarding halothane ^{17,18,19,20} indicate the most widely accepted mechanism of bio-transformation is the production of trifluoro-acetic acid with resulting urinary excretion of trifluoroacetic acid and bromide. The literature regarding enflurane ^{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 effects apparently related to subanesthetic exposure to anesthetic gases, no cause and effect relationship has yet been shown.

D. Evaluation Results

Table I shows the results of the 41 samples taken for nitrous oxide. Concentrations ranged from below the limit of detection (approximately 2 ppm) to 155 ppm, with 29 samples below 25 ppm. Time weighted averages for personal samples are shown below for both the duration of measured exposure and also on an eight-hour basis. The 8-hour TWA assumes no exposure during the time measurements were not taken.

Time Weighted Average Concentration(ppm)

Anesthesiologist	Total Sampling Time	Time Sampled Basis	8-Hour Basis
#1	1 hr. 25 min.	58 .	10
#2	1 hr. 25 min.	22 ်	4
#3	4 hr. 50 min.	53	. 32
#4	1 hr. 25 min.	55	10
#5	2 hr. 15 min.	140	40
#6	30 min.	75	5

All 21 samples taken for halogenated anesthetic were below the limit of detection for currently available analytical techniques (0.01 mg per sample). This would correspond to airborne concentrations of less than approximately 0.1 ppm for halothane or enflurane.

V. CONCLUSIONS AND RECOMMENDATIONS

The most significant finding of this evaluation is the large decrease in concentration of both nitrous oxide and halogenated anesthetic in the operating room and recovery room area since the initial evaluation conducted in November, 1976. Time weighted average exposures (time sampled basis) at that time ranged from 80 to 330 ppm nitrous oxide, compared with 22 to 140 in this study; and halogenated anesthetic samples ranged up to 7.6 ppm, compared with less than 0.1 ppm in this study.

Two of the six anesthesiologists sampled had 8-hour TWA nitrous oxide exposures slightly above the 25 ppm recommended standard. All halogenated anesthetic concentrations were below the 0.5 ppm recommended standard. These calculations were based on the assumption that these doctors spent their non-sampled time in areas with a zero concentration of nitrous oxide. Observations indicated that this non-sampled time was spent generally outside operating rooms although frequently near enough that there could have been a measurable concentration of anesthetic gas. It is conceivable that actual 8-hour TWA exposures could have been higher than those calculated, although judging from the concentrations of nitrous oxide found in area samples and other factors, they would not be significantly higher.

In the opinion of this investigator, the staff and employees of Englewood Hospital have developed an effective program for reducing exposure to waste anesthetic gases. It is recommended that this program be continued in order to reduce exposure as far as possible and maintain that low level. Periodic environmental testing should be a part of the program to evaluate progress. While an absolutely safe level of exposure cannot be defined by currently available information, reducing exposure to the lowest possible level will prevent effects caused by acute exposure and significantly reduce the risk associated with long term, low level exposures.

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Table 1
Results of Samples for Nitrous Oxide October 13, 1977

Englewood Hospital Englewood, New Jersey

Location	Type *	Description	Time	Nitrous Oxide Concentrations (ppm
O.R. #1	Α .	S.W. corner, approx. 5 ft. from anesthesia	8:05 - 9:15	40
	A A	machine, table height same as above	9:15 - 10:00 10:10 - 11:00	5 N.D.**
	A A A	0 H	11:00 - 11:45 11:45 - 12:25 12:25 - 1:05	2 N.D. 35
·	A A P	" " " " " on anesthesiologist #1	1:05 - 1:45 1:45 - 2:15 8:05 - 8:45	20 80 110
0.0 "0	P	" " #2	8:45 - 9:30	10
O.R. #2	A	attached to anesthesia machine, approx. 2-4 ft from breathing zone of anesthesiologist	8:05 - 9:15	. 8
	A	same as above	9:15 - 10:15	4
	A A	ts at 11 11 11 11	10:15 - 11:20 11:20 - 12:25	4 4
O.R. #4	A	N.W. corner, approx. 10 ft. from anesthesia machine	11:20 - 12:05	4 .
	. A	same as above	1:20 - 2:15	12
O.R. #5	A	W.W. corner, on table, approx. 5 ft. from anesthesia machine	8:10 - 9:10	10
; ;	A A A	same as above	9:10 - 9:40 10:10 - 11:00 11:00 - 12:00	4 12 20
: :	P P	on anesthesiologist #2 " #2	8:10 - 9:10 9:10 - 9:35	30 2
0.R. #6	P P P	on anesthesiologist #3	8:25 - 9:20 9:20 - 9:55 9:55 - 10:40	15 12 115

Table 1 (cont.)

<u>Location</u>	Type	Description	<u>Time</u>	Nitrous Oxide Concentrations (ppm
	P P	same as above 3	10:40 - 12:35 12:35 - 1:15	70 27
0.R. #8	P P P	on anesthesiologist #4 " #5 " " "	8:15 - 9:40 8:15 - 9:35 11:05 - 12:00	55 155 115
Cystoscopy	Р	on anesthesiologist #6	8:20 - 8:50	75
Recovery Room	A .	breathing zone level, approx. 5 ft. from des	9:10 - 9:35 k	2
	· A	same as above	9:35 - 10:05	5
. •	. A	ii ii ii	10:05 - 10:35	5
	Ā	11 II II	10:35 - 11:05	2
j·	Ä	SI 14 IS	11:05 - 11:40	7
	Ä	и и и	11:40 - 12:15	12
	A	n n	12:15 - 12:40	8
,	A		12:40 - 1:10	10
	A	u u n	1:10 - 1:40	9
	. Д	ge H i H H	1.40 - 2.10	8

^{* &}quot;A" indicates area samples located in stationary position as described "P" indicates personal samples attached to person described

^{**} Not Detectable by currently available analytical techniques, i.e.< 2 ppm

Table 2
Location of Samples for Halogenated Anesthetic October 13, 1977

Englewood Hospital Englewood, New Jersey

Operating	Room	Туре	*	<u>Location</u>	<u>Time</u>
#1		P P P		Circulating Nurse Anestheologist	7:40 - 11:25 11:25 - 12:50 8:05 - 9:30
#2		Р	•	Circulating Nurse	7:55 - 11:30
#4		P P		n n n u	7:35 - 11:35 11:35 - 12:10
#5		P P P		" " Anestheologist	7:35 - 11:20 11:20 - 1:40 8:10 - 12:20
#6		Р Р Р		Circulating Nurse "Anestheologist	7:35 - 11:15 11:15 - 2:30 8:25 - 1:05
#7		P		Circulating Nurse	7:40 - 11:35
#8		Р Р Р		Circulating Nurse Anestheologist	7:45 - 11:30 8:15 - 9:35 11:30 - 12:15
		A A		Near center, South wall Near center South wall	8:15 - 11:40 11:40 - 12:30
Cystos	сору	P		Circulating Nurse Anestheologist	7:55 - 11:00 8:25 - 8:55

^{* &}quot;A" indicates area samples located in stationary position as described. "P" indicates personal samples attached to person described