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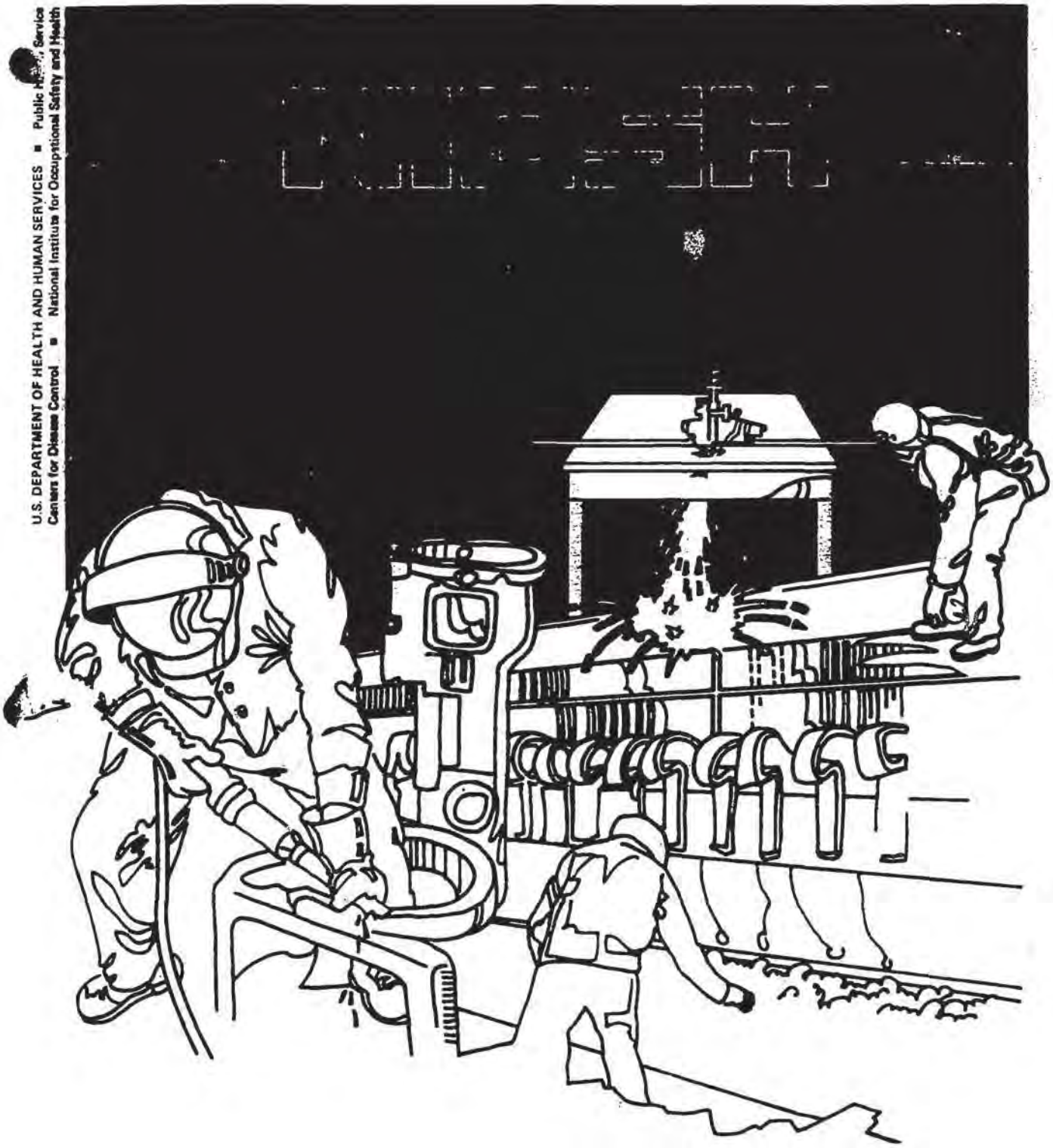

# Health Hazard Evaluation Report

HETA 82-016-1206
MANHATTAN EYE, EAR & THROAT HOSPITAL
NEW YORK, NEW YORK

## PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any 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 Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

HETA 82-016-1206
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Manhattan Eye, Ear & Throat Hospital
New York, New York

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## I. SUMMARY

On November 12, 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation at Manhattan Eye, Ear & Throat Hospital in New York City. The request submitted by District 1199 National Union of Hospital and Health Care Employees listed ethylene oxide (EtO), cyclopropane, nitrous oxide ($N_2O$), and halothane as potentially toxic substances of concern. Exposed personnel include all of the operating room staff (ie. surgeons, nurses, technicians, and anesthesiologist). Health problems reported in the request include spontaneous abortions among operating room personnel and their spouses, and infertility of male employees.

Potentially toxic substances of concern include $N_2O$ and halogenated anesthestic waste gases in the operating rooms (OR's). On November 23 and 24, 1981, NIOSH industrial hygienists and epidemiologists visited the hospital and conducted an environmental and medical evaluation.

Eighteen personal air samples for $N_2O$ showed exposure levels between 30 and 144 ppm, all above the NIOSH recommended criteria of 25 ppm during an anesthesia administration period. Twenty-eight personal exposures measured for halothane, enflurane, and ethylene oxide (EtO) showed levels of 0.15 to 3.51 parts per million parts of air (ppm), 0.32 to 7.33 ppm, and 4.0 to 66.7 ppm. Six halothane exposures were in excess of the NIOSH recommended level of 0.50 ppm for an anesthetic administration period when used in combination with $N_2O$. Six enflurane exposure were in excess of the NIOSH recommended level of 0.5 ppm for an anesthetic administration period. TWA ethylene oxide levels were 4.0 and 5.5 ppm. Short term levels measured during sterilizer door opening were 41.6 and 66.7 ppm, respectively. Ethylene oxide exposure levels should be lowered, since NIOSH currently considers EtO as a potential occupational carcinogen and recommends that levels be reduced to the lowest extent possible.

A questionnaire survey found no statistically significant increase in the rate of spontaneous abortion, nor in the incidence of involuntary infertility, as compared to both an unexposed group of compatible workers and the U.S. general population. However, these results should be interpreted cautiously due to the small size of the exposed group and the well-documented adverse reproductive effects from anesthetic gas exposure. Other worker - reported non-reproductive symptoms including headache (34%), fatigue (30%), and some skin (13%) and throat (15%) irritation were found to occur. Adherence to NIOSH's recommendations should alleviate most of these problems.

Based on the high levels of anesthetic gas levels measured, NIOSH concludes that a health hazard exists at Manhattan Eye, Ear, and Throat Hospital at the time of our survey. Recommendations to help control the hazard are included in Section VIII of this report.

KEYWORDS: SIC 2519, anesthetic waste gas, spontaneous abortions, ethylene oxide.

## II. INTRODUCTION/STATEMENT OF REQUEST

On November 12, 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation at Manhattan Eye, Ear & Throat Hospital in New York City. The request submitted by District 1199 National Union of Hospital and Health Care Employees listed ethylene oxide (EtO), cyclopropane, nitrous oxide ($N_2O$), and halothane as potentially toxic substances of concern. Exposed personnel include all of the operating room staff (i.e., surgeons, nurses, technicians, and anesthesiologist). Health problems reported in the request include spontaneous abortions among operating room personnal and their spouses, and infertility of male employees.

Potentially toxic substances of concern include nitrous oxide and halogenated anesthestic waste gases in the operating rooms (OR's) and ethylene oxide in the central supply area. On November 23 and 24, 1981, two NIOSH industrial hygienists and two epidemiologists visited the hospital and conducted an environmental and medical evaluation.

Interim survey results from the November 23 and 24 site visit were submitted to the hospital and union in a letter dated December 16, 1981.

## III. BACKGROUND

### A. Process Description and Workforce

Manhattan Eye, Ear and Throat Hospital (here after abbreviated MEET) is a voluntary private hospital, approximately 150 years old, located in New York city. The hospital specializes in treating eye, ear, and throat illnesses. MEET's operating rooms(or's) are centrally located on two separate floors of the building, the 6th and 7th. There are 5 OR's used primarily for ear, throat and some types of plastic surgery, and a recovery room located on the 6th floor. The recovery room receive patients from both 6th and 7th floor OR's. On the 7th floor there are 5 OR's used primarily for eye surgery, and the central supply area which consist of ethylene oxide (EtO) sterilizers and an aerator. All surgical instruments, and equipment at MEET are stored and maintained in the central supply area.

Approximately 80 hospital staff employees are assigned to the operating rooms, recovery room and central supply, excluding surgeons and anesthesiologists. A typical operating team includes a surgeon and assistant surgeon, a scrub nurse, a circulating nurse, anesthesiologists or anesthetists, and if needed a technician. Between two and five aides work daily in central supply to operate the sterilizers and aerator, and maintain surgical equipment. Each operating floor has its own nursing staff, which does not rotate from floor to floor. Other

personnel, however, including anesthesiologists, nurse anesthetists, attendents, and nurses on the second shift rotate between floors as needed. A personnel listing provided by the hospital identified several worker catagories: registered nurses (R.N.'s), licensed practical nurses (L.P.N's), technicians, aides, attendants, anesthesiologists, and nurse anesthetists (C.R.N.A.S).

Anesthetic gases used at the hospital include $N_2O$ in combination with halothane or ethrane. The concentrations and flow rates used during the survey are listed in Table V for each OR. There are two basic components making up the anesthetic curcuit of an anesthesia gas machine, the anesthesis mechanism and the breathing system. The anesthesis mechanism vaporizes the anesthetics (halothane or enflurane) and combines them with $N_2O$ and $O_2$. These gases are supplied from cylinders to the anesthesia mechanism. The breathing system contains a soda lime canister for absorbing exhaled carbon dioxide, a breathing bag (ventilator), control valves for regulating gas flow, flexible hoses and "Y" fitting for attaching the face mask or endotracheal tube.

Prior to the operation, an anesthetic gas mixture is administered to the patient via the anesthetic circuit at a rate greater than the patient's metabolic needs. A pop-off valve or pressure relief valve found on the anesthetic circuit vents off excess gases into the hospital's central exhaust system. Defective pop-off valves can be major sources of waste gas leakage. Other sources of leakage can be face masks, endotracheal tubes, worn or rotted hoses, improper fitting of seals or connections, and spillage of liquid anesthetics during vaporizer refilling.

B. Environmental Controls

Environmental controls in each OR include radiant heat supplied by steam pipes in the building walls, two 20,000 BTU air conditioners in each OR, and the scavaging systems equipped on the anesthetic gas carts.

## IV. EVALUATION DESIGN AND METHODS

Initially a review of recent literature dealing with anesthetic waste gases was conducted, and as much information as possible was obtain through telephone correspondence with MEET on demographic data, hospital procedures, work force and schedules, and health effects prior to the site visit. Based on this information a survey protocol was developed, which was carried out during November 23 and 24, 1981.

A. Environmental

1. Nitrous Oxide

In order to characterize employee exposure, 18 personal breathing zone and 5 area air samples for $N_2O$ were collected in 20 liter mylar bags using personal sampling pumps. The flow rates on the pumps were adjusted to collect a representative sample of $N_2O$. Analyses of these samples were performed after each mylar bag was filled using a Wilks Miran infared analyzer, which gives a direct read out in parts of $N_2O$ per million parts of air (ppm).

To determine if cryo machines were leaking $N_2O$, several direct atmospheric $N_2O$ measurements were taken using a Wilks Miran infrared analyzer equipped with a probe on connection probe beside two of the cryo machines during a simulated use period.

2. Halothane and Enflurane

Twelve personal breathing zone air samples for halothane and enflurane were collected on charcoal tubes using personal sampling pumps operating at 200 cubic centimeter per minute cc/min. Laboratory analyses was performed on these samples using a gas chromatograph with a flame ionization detector according to NIOSH Method No. P & CAM 127 with slight modifications, such as: samples were separated into A and B portions and desorbed in 1 mL carbon disulfide containing 1 uL/mL benzene as an internal standard. A 12' x 1/8" stainless steel column, packed with 0.1% SP-1000 on 80/100 mesh Carbopack C, was used with oven temperature programming from 80°C at a rate of 8°C/minute.

3. Ethylene Oxide

In order to characterize central supply personnel exposure, four personal breathing zone air samples for ethylene oxide were collected on charcoal tubes using personal sampling pumps operating at 50-200 cc/min. The higher flow rates were used to measure short term exposures which occurs during loading and unloading of the EtO sterilizers.

Analysis was performed using a gas chromatograph with a flame ionization detector in accordance with NIOSH Method S-286 with minor modifications such as: samples were separated into A and B sections and each section desorbed with 2 mL carbon disulfide containing 0.1 uL/mL heptane as an internal standard. A Hewlett-Packard 7731A gas chromatograph with a flame ionization detector was used to perform the analysis. The gas chromatograph was equipped with a 12' x 1/8" stainless steel column packed with 10% TCEP on 80/100 mesh Chromosorb P AW. The column oven was operated isothermally at 110°C.

B. Medical

In order to investigate the major potentially work-related health effects as reported in the hazard evaluation request - increased risk of spontaneous abortion and involuntary infertility, a five-page self-administered questionnaire was designed to obtain information on the individual's health history, occupational history, reproductive history, and reported frequency of other symptoms associated with occupational exposure to anesthetic gases. Specific questions were included on the survey form to allow for stratification of the sample by various factors such as age and sex, smoking and alcohol usage, years of exposure to anesthetic waste gases at this hospital, and history of exposure to procedures involving the cryo machine, which would involve exposure to unscavenged nitrous oxide ($N_2O$).

The sample (exposed workers) surveyed consisted of personnel from both shifts and seven job categories (Table I) - all of whom were determined to have regular daily exposure to one or several of the waste gases. Female registered nurses made up the bulk of the sample group (51%). Attendants assigned to the operating room were not included since their jobs consisted of transporting patients to and from the operating rooms before and after surgical procedures and, therefore, they were not considered to be at high risk. Conversely, it was reported that recovery room attendants function much the same as the technicians and nurses in that area, and therefore, they were considered to have significant exposure and included in our sample. Additionally, employees of the Central Supply Room (CSR) were also included in the sample, since they receive general background exposure to waste gases. Generally, the sample was evenly divided between those assigned to the 6th and 7th floors (Table II).

There is no cross rotation of assignments between nurses assigned to the Recovery Room or Operating Rooms. Likewise, nurses assigned to the 6th floor O.R. do not rotate to the 7th floor, and vice-versa. The exception to this are the 2 nurses assigned to the second shift, who do rotate floors. Also, the circulating nurse and scrub nurse assigned to an O.R. suite exchange responsibilities halfway through each shift and, therefore, have similar "doses" of waste gas exposure patterns.

In order to evaluate the results of the questionnaire responses, a comparison or non-exposed group was selected. This group was matched with the study group for age, sex and race, and was selected from various areas of the hospital where no anaesthetic waste gas exposure occurs, for example, the ambulatory care clinics, security office, and the pharmacy.

## V. EVALUATION CRITERIA AND TOXICOLOGICAL EFFECTS

Excessive occupational exposure to the various anesthetic gases in use at Manhattan Eye, Ear and Throat Hospital has also been shown to cause headache, fatigue, irritability, nausea and loss of appetite, dizziness, irritation (itching) of the skin and throat, and heart palpitations.[5,8]

### A. Anesthetic Waste Gases

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 function may be impaired. 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.[1]

NIOSH recommends maximum exposures of 25 parts per million (ppm) $N_2O$ (time-weighted average concentration during anesthetic administration) and 2 ppm halogenated anesthetic when used alone, or 0.5 ppm when used with $N_2O$. These recommendations are based upon available technology in reducing waste anesthetic gas levels.

### B. Ethylene Oxide

Numerous studies involving animals have shown several types of chromosomal aberrations in the bone marrow, following the inhalation or ingestion of ethylene oxide (EtO) at levels of 50 ppm - the current OSHA legal standard. Data from a study conducted in Sweden of 31 persons occupationally exposed to 1 ppm EtO for an average of 15 years revealed that the lymphocyte counts were insignificantly increased. Also noted were three cases of anisocytosis and one case of lymphatic leukemia in those exposed.[10]

Recent data from Stanford Research Institute demonstrates that EtO was found positive in the Ames mutagenicity test. Additional studies have confirmed that EtO is readily absorbed via the respiratory tract and thus reacts with components of the body tissue. Human experiences have indicated toxic dermatitis with large bullae from even brief contact. The eyes of workers exposed to EtO vapor occasionally have shown slight irritation of the conjunctive, however, no injuries to the cornea have been reported.[11]

The current (OSHA) Standard for occupational exposure to EtO is 50 ppm parts of air, which corresponds approximately to 90 $mg/m^3$, as an 8 hour time-weighted average concentration, with no ceiling level stipulated. The current Threshold Limit Value (TLV), is also 50 ppm. At the time these criteria were developed, studies involving carcinogenicity were not available. Since then EtO has caused statistically significant increases in mononuclean cell leukemia in female Fischer 344 rats, and peritoneal mesothelioma in male Fischer 344 rats.[12] This animal experimental evidence of carcinogencity is compatible with two human epidemiologic studies of Swedish workers showing an excess in cancer deaths.[13,14] Therefore, NIOSH recommends that EtO be regarded in the workplace as a potential occupational carcinogen. Safe levels of carcinogens have not been demonstrated. Based on the assumption that the probability of developing cancer should be reduced by decreasing exposure, NIOSH recommends that employers take all reasonable steps to reduce exposure to the lowest extent possible, and has suggested that the OSHA standard of 50 ppm as a TWA should be reexamined.[15]

## VI. RESULTS AND DISCUSSION

### A. Environmental

#### 1. Nitrous Oxide

Eighteen personal $N_2O$ exposure levels were found to range from 30 ppm to 144 ppm (Table III), all of which exceed the NIOSH recommended criteria of 25 ppm during an anesthesia administration period. Five area $N_2O$ sample showed levels that ranged from 15 to 38 ppm. Only the one 38 ppm recovery room area $N_2O$ sample exceeded NIOSH recommended criteria.

The results of measurements taken approximately one inch away from the front and back of the cryo machines showed that substantial leakage was occuring. The levels measured were all above 280 ppm $N_2O$ which was the upper limit of our analytical instrument. The manufacturer has documented $N_2O$ leakage well above 1000 ppm when the cryo machine is in use, and indicated that starting in mid 1980, all new amoil cryo units were fitted with a scavenging system.

2. Halothane

Twelve personal samples taken for Halothane showed exposure levels range from 0.15 to 3.51 ppm (see Table IV). Six of them exceed the NIOSH recommended criteria of 0.5 ppm for any anesthetic administration period, when used in combination with $N_2O$.

3. Enflurane

Twelve personal samples taken for enflurane showed exposure level ranging from 0.32 to 7.33 ppm (see Table IV). Six of these exposure levels are in excess of the current NIOSH recommendation of 0.50 ppm for any administration period, when used in combination with $N_2O$.

4. General Discussion

Two potential sources of waste gas leakage specifically noticed at Manhattan Eye, Ear and Throat are leakage from the amoils cryo-ophthalmic unit, and induction of young children with halothane. Unscavenged halothane is blown freely across the face of young children instead of administered with a mask to prevent the children from becoming frightened during induction. The second potential source of leakage are the amoils cryo units, each consisting of a console control with a pencil attachment. The console control regulates the flow of $N_2O$ gas from a detached cylinder into the cryo pencil where $N_2O$ laten heat allows for instantaneous freezing and defrosting of the pencil tip. The cryo units pencil tip is very useful in two primary types of ophthamologic surgery, cateract removals and retinal buckels. According to the manufacture the units were originally designed to utilize $CO_2$ gas, and therefore, were not fitted with scavaging systems.

Several operating room conditions which were thought to play major roles in effecting exposure levels on a given day are listed in Table V. In general, there seems, to be no correlation between the use of the cryo machine and $N_2O$ exposure levels in the OR's. However, survey time did not permit enough $N_2O$ sampling to support a definite conclusion concerning how much, if any, the use of cryo machines increases $N_2O$ levels in OR. In OR #4 between 8:45 am and 10:00 am, sampling for $N_2O$, halothane, and enflurane was conducted during one anesthesia administration period and showed levels of 144 ppm, 10.5 $mg/m^3$ and 55.3 $mg/m^3$, respectively. During the next sampling period in OR #4 between 10:30 am and 12:00 am $N_2O$, halothane, and enflurane exposure levels dropped drastically to 62 ppm, 2.5 $mg/m^3$, and 3.7 $mg/m^3$. These sampling results in OR #4 are in agreement with the condition listed in Table III. The drop in exposure levels can be attributed to anesthetic gas flow shut off during administration of local anesthesia. Measured enflurane levels were much higher than halothane levels because enflurane not halothane, was used during the 8:45 am to 10:00 am operation.

The highest halothane exposures levels measured during the day (28.3 and 25.5 mg/m$^3$) were in OR #5 between 8:15 am and 12:00 am. During this time period two children were operated on, and induced with unscavenged halothane as was discussed earlier; therefore, high halothane exposures were expected. The lower halothane exposure levels (4.7 mg/m$^3$) measured in OR #6, where a child was undergoing surgery, can be explained by the fact that the sampler was not started until half of the surgery was completed; therefore sampling was not conducted during the halothane induction of the child. In OR #3, where 1 child was operated on in the afternoon, the halothane exposure level (4.9 mg/m$^3$) was greater than the enflurance level, but not near as high as those in OR #5. This is probably because the sampler remained on the anesthesiologists for the entire day, 8:30 am to 4:00 pm, measuring a TWA exposure, and would not characterize higher short term exposures which might have occured during the day. In fact, all personal samples for halogenous anesthetic waste gases taken, except those in OR #4, are TWA's, and therefore, indicate slightly low exposures than actually occured during each anesthesia administration period. The sampler could not be changed before and after each operation because of manpower limits.

5. Ethylene Oxide

Ethylene oxide exposure levels were 7.2 and 10.0 mg/m$^3$, short term exposure levels were 75 and 120 respectively (Table VI). The time weighted average (TWA) exposure levels were well below the current OSHA standard of 98 mg/m$^3$ TWA. However, in light of the most recent research, implicating EtO as a potential carcinogen, NIOSH has recommended that exposure levels be kept as low as reasonably possible.

6. Work Practices

Through observation of work practices during the survey, it was noted that many staff members in the OR and adjacent areas tend to remain in the area during meals and breaks, thereby increasing their overall exposures to background anesthetic gas levels. In addition, because sterilizer and aerator operators did not allow enough time between opening and unloading procedures to permit residual EtO to be exhausted from the chambers, they received unnessarily high short term exposures during the task. This probably occurred due to a lack of understanding on the part of employees as to correct operating procedures, and the seriousness of EtO as a health hazard.

B. Medical Results

Of the 119 questionnaires distributed to potential participants, eighty-six were returned and suitable for analysis (Table VII), while 4 workers refused to participate, producing an overall response rate of 73%.

1. Reproductive Effects

In terms of adverse reproductive effects associated with exposure to anesthetic gases, specifically, increased risk of spontaneous abortion and infertility,[2,3] the following data was tabulated. Among the exposed group, only 1 of 23 pregnancies (4.3%) was reported to have terminated in a spontaneous abortion, while there were 20 (or 87%) normal live births, and 2 induced abortions. The comparison group reported 13 pregnancies resulting in 12 normal live births, 1 induced abortions, and no spontaneous abortions. The denominator used to calculate these rates was "number of pregnancies since working at this hospital".

Since congenital birth defects have been previously associated with anesthetic gas exposure,[4,5,6] this outcome was also analyzed. Neither the exposed group nor the control reported any birth defects (Table VIII).

Similar proportions of the exposed and control groups, 17% and 18% respectively, reported infertility (all were women). While all four of the exposed workers sought professional help, neither of the two control workers did.

2. Non-Reproductive Effects

Acute and chronic symptoms other than those of a reproductive nature have been identified in the literature as being associated with occupational anesthetic waste gas exposure.[7,8] In this study headache was the most often reported symptom among both groups (34% and 31%) followed by fatigue, and to a lesser degree, irritation of the skin and throat (Table IX). Except for fatigue, however, none appeared to be associated with jobs involving exposure to anesthetic gases.

Other chronic health effects associated in the literature with exposure to anesthetic waste gases include hepatic disease, renal disease and cancers.[7,8,9] The survey response revealed no difference between the two groups for kidney or liver disorders and only one person in the exposed group (none in the control group) reported a diagnosed cancer.

C. Discussion

1. Reproductive Effects

a. Birth Defects

Among offspring of parents with occupational waste gas exposure the rate of congenital birth defects has been reported to be excessive.[5,6,10] This study found no such excess in frequency of birth defects among exposed workers. The sample used, however, was very small and, therefore, for a group this size there would have to be approximately an 8-fold increase in congenital malformations occuring at a 3% expected rate to achieve statistical significance.

b. Spontaneous Abortion

The "expected" rate of spontaneous abortion among the U.S. general population has been set at approximately 15%; however, among females exposed to anesthetic waste gases and spouses of gas-exposed males, the rate is higher. Reported frequency of spontaneous abortion among both the exposed and control groups was well below the "expected", i.e., 4.3% and 0%, respectively. When looked at separately for men and women in the sample, rates were still low at 0% and 15%, respectively. Once again it is difficult to achieve statistically significant results with such a small sample size, since one would require a 3-fold increase, an expected rate of approximately 15%, in order to identify an excess.

c. Involuntary Infertility

There are multiple problems associated with measuring fertility. First, identifying an isolated cause for infertility is very difficult since there are interrelated physiological, anatomical, and psychological factors which were not addressed in this evaluation. Second, there are several methodological approaches - each with its own limitations - for measuring involuntary infertility[13]. Our sample size and number of births among the group were too small to allow us to apply most of the formulas. However, a comparison of rates between the exposed and non-exposed groups which excluded non-respondents, counted non-respondents as "yes" responses, and counted non-respondents as "no" responses, were all not significant. (See Table X).

In addition, 44% of the exposed females report never having been pregnant. Although this may seem high, 54% of the female controls have never been pregnant. Lacking data on cultural and religious beliefs and socio-economic status, one may still conclude through comparison with the non-exposed females that exposure to anesthetic gases is not resulting in unusually high infertility.

2. Non-Reproductive Effects

In this study headache was the most frequenty reported complaint of both groups (34% and 31%), suggesting that this symptom is related more directly to the stress of the job than to a particular chemical exposure. Fatigue was more common among the exposed than unexposed group (30% vs. 8%), but this could be due to the fact that operating room personnel tend to stand most of their workshift. The frequency of other complaints as listed in Table IX do not differ significantly between the two groups.

## VII. CONCLUSIONS

Although the questionnaire survey did not document any major adverse health effects attributable to occupational exposure to anesthetic waste gases, environmental measurements did show exposure levels in excess of those currently recommended by NIOSH. Therefore recommendations have been included aimed at reducing exposures.

## VIII. RECOMMENDATIONS

1. Old unscavenged cryo units should be replaced with new models which are equipped with their own scavenging systems. According to the manufacturer, 10 years is the average life of a cryo unit, and hospital officals indicated that most of the cryo machines were at least 9 years old.

2. Due to poor ventilation in the old OR suites, NIOSH supports the hospital's intentions to move into a new operating facility, which was under construction during the survey.

3. Once in the new operating facility there are several actions that can be taken to insure that waste gas exposure is minimized. For example, scavaging equipment should be used in all OR's to remove the contaminant from the area of the pop-off valve. To reduce gas escape from other parts of the anesthesia machine, anesthesia equipment should be checked and maintained on a regular basis. Face masks, tubing, breathing bags, and endotrachial tubes should be visually checked for cracks and other leak sources. Both high and low pressure components should be leak tested. The high pressure components, from nitrous oxide and oxygen supply up to flow meter control valves, can be tested by applying soap solution to all connections and observing any bubbles. This should be done quarterly. Low pressure components, including breathing bags and tubing, can be tested using the precedure presented in Appendix I of the NIOSH criteria document on waste anesthetic gases (1) and are shown below:

    (a) Assemble the anesthesia machine as in the usual manner for clinical anesthesia with breathing tubes, Y-piece, breathing bag, and high pressure hoses or cylinders connected.

(b) Occlude the Y-piece securely with the thumb or palm of hand.

(c) Pressurize the breathing system to 30 cm water, observed on the absorber pressure gauge. This may be accomplished by using the oxygen flush valve.

(d) Add a sufficient flow of oxygen through the low-range flowmeter to maintain a constant pressure of 30 cm water in the breathing system. The oxygen flow required to maintain the pressure is a measure of the leak rate. This test may be abbreviated by using an oxygen flowrate of 100 ml/minute. If pressure in the system increases, the breathing system is below the maximum allowed leak rate.

(e) Determine the presence of check valves downstream from the flowmeters by consulting the manufacturer or a serviceman. These valves must be tested differently. With oxygen flowing as indicated in (d), briefly turn off in turn each flowmeter, which is equipped with a check valve, until there is a rise in pressure on the absorber gauge. An increase in pressure indicates absence of leakage in the circuit tested.

The low pressure leak rate should be below 100 ml per minute.

Small components such as breathing bags and hoses can be leak tested separately by pressurization, immersion in water, and observation of any bubbles. In situations where this is not practical, it is recommended that fittings and seals be checked periodically to make sure gaskets and o-rings are in place properly, that connections are tight and not worn, and that moisture or chemical action has not caused corrosion or degradation of materials. Typical places to check, and where leaks have been found in other studies, include the seals at the domed unidirectional valves, seals at the top, bottom, and center of the $CO_2$ absorber, and fittings where the breathing tubes connect to the machine and to the Y-piece.

In addition to a scavenging system and proper equipment maintenance, the anesthetists can reduce exposure by good work practices. Improper practices, such as poor choice of face mask, insufficiently inflated endotracheal tubes, and spillage of volatile anesthetic agents when filling vaporizers, are chief contributors to exposure.

And finally, general ventilations in OR suites should be in compliance with ASHRAE ventilation codes, 62-1981.

4. Since NIOSH feels that EtO should be considered as mutagenic and potentially carcinogenic to humans, occupational exposure should be minimized by eliminating all unnecessary and improper uses of EtO in medical facilities. When less hazardous sterilization alternatives are available, they should be substituted for EtO sterilization. Where the use of EtO must be continued, proper techniques of exhausting the gas from the sterilizer, the aerator, and the sterilized item storage binds. NIOSH document #77-200, Special Occupational Hazard Review with Control Recommendations, Use of Ethylene Oxide as a Sterilant in Medical Facilities, should be consulted for details concerning control technology. Medical surveillance, informing employees of the hazard, and training employees in proper operational procedures, record keeping, and environmental monitoring activities should be implemented.

## IX. REFERENCES

1. National Institute for Occupational Safety and Health. Criteria for a recommended standard--occupational exposure to waste anesthetic gases and vapors. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1977. (DHEW publication no. (NIOSH) 77-140).

2. International Federation of Chemical, Energy and General Worker's Union, ICEF 58, ruede Moillebaw, P.O. Box 277 CH-1211, Geneva, 19 Switzerland.

3. Thiess, A.M., Observations of the Adverse Health Effects from Ethylene Oxide, Arch. Fur. Toxikol; 20, 127-140, 1963 (German).

4. Snellings, W.M., C.S. Weil and R.R. Maronpot: Final report on Ethylene oxide two-year Inhalation Study on Rats, Project Report 44-20, Bushy Run Research Center January 28, 1981. Submitted by Union Carbide Corporation to the U.S. Environmental Protection Agency under Section 8(c) of the Toxic Substance Control Act, on behalf of cosponsors of the study (February 1981).

5. LaBorde, J.B. and C.A. Kimmel: The Teratogenicity of Ethylene Oxide Administered Intravenously to Mic. Toxicol Appl. Pharmacol. 56:16-22(1980).

6. Hogstedt, C., O. Rohlen, B.S. Berndtscon, O. Axelson and L. Ehrehberg: A Cohort Study of Mortality and Cancer Incidence in Ethylene Oxide Production Workers. Br. J. Ind. Med. 26:276-280(1979).

7. Ethylene Oxide Current Intellegent Bulletin No. 18, 1981.

8. USDHEW (NIOSH) Ethylene Oxide (EtO), Current Intelligence Bulletin #35, May 22, 1981.

9. Cohen, E., et al., Anesthesiology, Vol 35, p. 343, 1971.

10. Knill-Jones, R.P., et al. "Anesthetic Practice and Pregnancy-Controlled Survey of Male Anesthetists in the United Kingdom," Lancet, Oct. 25, 1975, p. 807.

11. Knill-Jones, R.P., et al., "Anesthetic Practice and Pregnancy," Lancet, June 17, 1972, p. 1326.

12. USDHEW (NIOSH) Criteria for a Recommended Standard... Occupational Exposure to Waste Anesthetic Gases and Vapors, Public Health Service, Pub. No. 77-140, March, 1977.

13. Corbett, T., et al., "Birth Defects among Children of Nurse-Anesthetists," Anesthesiology, Vol. 41, 1974, p. 341.

14. Cohen, Ellis, et al., "Occupational Disease among Operating Room Personnel: A National Study," Anesthesiology, Oct., 1974, p. 321.

15. USDHEW, Occupational Diseases: A Guide to their Recognition, Public Health Service, Pub. No. 77-181, June, 1977.

16. Corbett, T., et al., "Incidence of Cancer among Michigan Nurse-Anesthetists, "Anesthesiology, Vol. 38, 1973, p. 260.

17. Hernminki, K., et al., "Congenital Malformations by Parental Occupation in Finland," Int. Arch. Occup. Environ. Health, Vol. 46, 1980, pp. 93-8.

18. Hook, E.B., "Some General Considerations Concerning Monitoring," in Hook, E.B., Janerick, D. and Porter, I. Monitoring Birth Defects and Environment (Academic Press: New York), 1971.

19. Bloom, A.D. (Ed.) Guidelines for Studies of Human Populations Exposed to Mutagenic and Reproductive Hazards, March of Dimes Birth Foundation, 1981.

20. Levine,R. et al., "A Method for Monitoring the Fertility of Workers," J.O.M., Vol. 22, 1980, pp. 781-91.

21. NIOSH, Final Report on Lincoln Medical and Mental Health Center, Bronx, N.Y., HE 80-158.

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## XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. Manhattan Eye, Ear, & Throat Hospital
2. NIOSH, Region II
3. OSHA, Region II

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

TABLE I

Operating Room Conditions on Sample Day

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Operating Room Number | Cryo Machine Use | Number of Operations | Patient | Anesthestic Gas Flow |
|---|---|---|---|---|
| 1 | Morning<br>10-20 minutes | 4 | Adults | 5 Lpm total<br>50% $N_2O$/47%$O_2$<br>3% Enflurane |
| | Afternoon<br>10-20 minutes | 4 | Adults | "" "" |
| 3 | Morning<br>15-20 minutes | 2 | Adults | 2 Lpm total<br>50% $N_2O$/46%$O_2$<br>3-4% Enflurane |
| | Afternoon<br>15-20 minutes | 1 | Child | "" ""<br>except 3-4% Halothane |
| 4 | Morning<br>5-10 minutes | 1<br>1 | Adults<br>Adult Loc* | 5 Lpm total<br>50% $N_2O$/47%$O_2$<br>2-3% Enflurane |
| | Afternoon<br>0 minutes | 1<br>1 | Adult Loc<br>Adult | "" "" |
| 5 | Morning<br>0 minutes | 2 | Child | 2 Lpm total<br>50% $N_2O$/47%$O_2$<br>2.3% Halothane |
| 6 | Afternoon<br>0 minutes | 1 | Child | 4 Lpm<br>50% $N_2O$/49%$O_2$<br>1% Halothane |

* = Loc-Local anestheia

TABLE II

Stratification of Exposed Workers by Job Title, Race and Sex (N=47)

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Job Title | Female | | | | Male | | | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | W | B | H | A** | W | B | H | A | |
| Registered Nurses* | 9 | 2 | 0 | 10 | 0 | 2 | 0 | 1 | 24 |
| Licensed Practical Nurses | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 4 |
| Technicians | 1 | 2 | 0 | 0 | 0 | 4 | 0 | 0 | 7 |
| Attendants (R.R.) | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 3 |
| Anaesthesiologists (MDs) | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 |
| Aides | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| Other | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| TOTAL | 11 | 11 | 1 | 11 | 4 | 8 | 0 | 1 | 47 |

* includes CRNAs (certified nurse anesthetists)

** White, Black, Hispanic, Asian

TABLE III

Stratification of Exposed Workers by Work Area (N=47)

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Area | Number of Employees | Percent of Total Employees |
|---|---|---|
| O.R. - 7th floor | 14 | 29.7 |
| O.R. - 6th floor | 15 | 31.9 |
| R.R. | 4 | 8.5 |
| CSR | 6 | 12.8 |
| "Floaters" (rotate between floors) | 8 | 17.0 |
| TOTAL | 47 | 99.9 |

TABLE IV

Personal and Area Air Samples Nitrous Oxide ($N_2O$)

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| LOCATION | JOB TITLE | SAMPLING TIME | $N_2O$ PPM TWA (over period sampled) |
|---|---|---|---|
| OR 1 | Scrub Nurse | 0800-1140 | 31 |
| | Circulating Nurse | 0800-1130 | 32 |
| | Scrub Nurse | 1215-1504 | 39 |
| OR 3 | Scrub Nurse | 0800-1230 | 56 |
| | Circulating Nurse | 1310-1530 | 92 |
| | Circulating Nurse | 0800-1120 | 39 |
| | Scrub Nurse | 1205-1420 | 106 |
| | Anesthesiologist | 0830-1220 | 72 |
| | Anesthesiologist | 1250-1530 | 140 |
| OR 4 | Anesthesiologist | 0845-1000 | 144* |
| | Anesthesiologist | 1030-1200 | 62 |
| | Anesthesiologist | 1330-1530 | 66 |
| OR 5 | Scrub Nurse | 0800-1200 | 28 |
| | Circulating Nurse | 0800-1130 | 82 |
| Recovery Rm. | Rec. Rm. Tech. | 0930-1120 | 30 |
| | Rec. Rm. Tech. | 1245-1445 | 72 |
| | Rec. Rm. Tech. | 1445-1645 | 41 |
| | Area in corner | 1300-1645 | 38 |
| OR 6 | Anesthesiologist | 1300-1630 | 31 |
| 7th floor Office | Area | 0930-1100 | 22 |
| | | 1100-1430 | 20 |
| 7th floor Nurses' Station Hallway | Area | 0930-1200 | 23 |
| | | 1200-1500 | 15 |
| OSHA Standard | | | -- |
| NIOSH Criteria | | | 25ppm |

* Sample collected during one anesthesia administration period.

TABLE V

Personal and Area Air Samples for
Halogenated Anesthestic Waste Gases

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Location | Job Title | Sample Times | Halothane (ppm) | Enflurane (ppm) |
|---|---|---|---|---|
| OR 3 | Scrub/Circulating Nurse | 0800-1600 | 0.42 | 0.32 |
| OR 3 | Scrub/Circulating Nurse | 0800-1600 | 0.77 | 0.45 |
| OR 1 | Circulating Nurse | 0800-1130 | 0.15 | 1.10 |
| OR 1 | Scrub/Circulating Nurse | 0800-1545 | 0.17 | 1.26 |
| OR 5 | Scrub Nurse | 0815-1200 | 3.51 | 0.33 |
| OR 5 | Circulating Nurse | 0815-1130 | 3.16 | 0.41 |
| OR 4 | Anesthesiologist | 0845-1000 | 1.30 | 7.33* |
| OR 4 | Anesthesiologist | 1030-1540 | 0.31 | 0.49 |
| OR 3 | Anesthesiologist | 0830-1600 | 0.98 | 0.65 |
| Recovery Rm. | Technition | 0930-1630 | 0.48 | 2.73 |
| OR 6 | Anesthesiologist | 0100-1630 | 0.58 | 0.93 |
| OSHA Standard | | | --- | --- |
| NIOSH Criteria | | | 0.5 | 0.5 |

* Sample collected during one anesthesia administration period.

TABLE VI

Personal and Area Air Samples for Ethylene Oxide (ETO)

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Location | Job Title | SAMPLE TIMES | ETO (ppm) |
|---|---|---|---|
| Central Supply | Nurses Aid | 0900-1540 | 4.0 |
| Central Supply | Nurses Aid | 0900-1540 during the opening of the sterilizer | 5.5 |
| Central Supply | Nurses Aid | 1540-1545 | 66.7 |
| Central Supply | Nurses Aid | 1540-1545 during the opening of the sterilizer | 41.6 |
| OSHA Standard | | | 50ppm |
| NIOSH Criteria | | | as low as possible using currently available control technology |

TABLE VII

Summary of Survey Distribution and Collection

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| | Exposed | Non-Exposed |
|---|---|---|
| Total no. questionnaires given out | 66 | 53 |
| Total no. questionnaires returned | 51* | 39 |
| Rate of Return | 77.2% | 73.4% |

* 4 Forms were incomplete and not used in data analysis

TABLE VIII

Reported Pregnancy Outcome in Study and Control Groups

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| | EXPOSED GROUP (N=47) | CONTROLS (N=38) |
|---|---|---|
| Total no. pregnancies | 75.0 | 58.0 |
| Mean (Avg.) no. pregnancies | 1.6 | 1.5 |
| Total no. pregnancies* | 23.0 | 13.0 |
| No. live births | 20 (87%) | 12.0 (92%) |
| No. spon. abortions | 1.0 (4.3%) | 0.0 |
| No. induced abortions | 2.0 (8.7%) | 1.0 (7.7%) |
| No. still births | 0.0 | 0.0 |
| Reported congenital defects | 0.0 | 0.0 |
| Mean Age | 40.6 yrs. | 38.8 yrs. |

* No. of pregnancies since working at this hospital; the denominator used for calculating outcome rates.

TABLE IX

Frequency of Reported Symptoms and Health Problems

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Symptom | Exposed | Percent | Control | Percent |
|---|---|---|---|---|
| Headache | 16 | (34) | 12 | (31) |
| Lightheaded/dizzy | 4 | (9) | 4 | (10) |
| Fatigue | 14 | (30) | 3 | (8) |
| Nausea | 3 | (6) | 1 | (3) |
| Loss of appetite | 2 | (4) | 1 | (3) |
| Skin irritation | 6 | (13) | 5 | (13) |
| Throat irritation | 7 | (15) | 7 | (18) |
| Heart palpitations | 3 | (6) | 4 | (10) |
| Liver problem | 0 | (0) | 0 | (0) |
| Kidney problem | 0 | (0) | 0 | (0) |
| Leukemia | 0 | (0) | 0 | (0) |

TABLE X

Statistical Significance of Responses to Fertility Question

Manhattan Eye, Ear & Throat Hospital
New York, New York
HETA 82-016

November 24, 1981

| Grouping | Chi-Square($X^2$)** | P-Value |
|---|---|---|
| Excluding Non-Respondents | 0.186 | 0.60* |
| Including Non-Respondents as Having Difficulty | 0.078 | 0.80* |
| Including Non-Respondents as Not Having Difficulty | 0.281 | 0.65* |

* not statistically significant

** 1 degree of freedom

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