HEALTH EFFECTS EVALUATION OF THEATRICAL SMOKE, HAZE, AND PYROTECHNICS

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Prepared by:

Jacqueline M. Moline, M.D., M.Sc.
Anne L. Golden, Ph.D.
Department of Community and Preventive Medicine
Mount Sinai School of Medicine

and

Joseph H. Highland, Ph.D.
Kenneth R. Wilmarth, Ph.D.
Alan S. Kao, Ph.D.
ENVIRON International Corporation

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EXECUTIVE SUMMARY

A. Introduction

At the request of Actors' Equity Association (AEA) and the League of American Theaters and Producers (LATP), investigators from the Mount Sinai School of Medicine and ENVIRON Corporation conducted a study to determine whether the use of smoke, haze, and pyrotechnics special effects in theatrical musical productions is associated with a negative health impact in Actors. This effort was initiated in response to ongoing concerns by Actors that the use of these theatrical effects may have a deleterious impact on their health.

B. Previous Work

Previous studies of possible health effects associated with the use of theatrical effects have been conducted at the request of AEA and LATP. The National Institute for Occupational Safety and Health (NIOSH) conducted Health Assessments of theatrical effects in 1990-91 and 1993, but these studies were limited in their scope. In the 1990-91 study, Actors in three musical productions using theatrical effects were compared to Actors in three dramatic productions that did not use any of these effects. While increased rates of occupational asthma were noted in the initial study, the follow-up study in 1993 of a subgroup of the performers failed to find an increase in asthma. Symptoms associated with irritative effects of the respiratory tract were noted.

A subsequent investigation was conducted by Consultech Engineering Company at the request of AEA. Consultech conducted a survey of Actors and a review of medical utilization through insurance records. A questionnaire inquiring about health effects as a result of exposure to theatrical effects was placed in the AEA's monthly newsletter, but was only completed by a small number of Actors. The low response rate for the questionnaire limits the applicability of its results. The insurance data review indicated that there might be greater use of medical resources among Actors in productions using these effects.

Because of limitations in these prior investigations, the question of whether these substances present a health hazard to theatrical performers remained.

C. Study Methodology

The goal of this study was to determine whether associations exist between exposure to theatrical effects (i.e., smoke, haze, and pyrotechnics) and health effects, taking into account the specific work environment and activities involved in a professional theatrical musical production. Based on a review of the toxicological literature on the components of these effects and previous information regarding theatrical exposure levels, it was determined that the likelihood that systemic toxicity could occur from exposure to any of these substances was extremely low. Therefore, considering symptoms previously reported by Actors and the results

of the toxicological review, the health endpoints selected for investigation in this study were those related to local irritant effects of the respiratory tract and eyes.

The study is comprised of two primary components – an epidemiologic assessment and an exposure assessment (Figure ES-1). The epidemiologic assessment included the collection of data from Actors regarding the symptoms they reported experiencing and background information (e.g., demographics, performance schedule, and other activities). The epidemiologic assessment also included a medical evaluation to collect clinical data on a subgroup of Actors before and after a performance. The data for the epidemiologic assessment was collected in three phases:

- In Phase 1, baseline questionnaires were distributed to all Actors and Stage Managers in a current Broadway musical. The questionnaire responses were used to collect background, symptom, and medical information from the participants, as well as information on their activities onstage and their theatrical experience.

- Phase 2 was designed to collect longitudinal data on daily symptoms over the course of the study. Actors were asked to complete daily checklists describing their activities and symptoms for three one-month periods.

- Phase 3 of the study involved a medical evaluation, which consisted of vocal quality assessments, pulmonary function tests, and direct visualization of the vocal cords. The evaluation was performed before and after a matinee performance. The medical evaluation is a unique aspect of this study in that it allows for a direct comparison of the upper airway, voice, and respiratory tract in the same person before and after a performance.

The second component of the study was a detailed exposure assessment, which was conducted to characterize potential exposures to Actors in the theatrical environment. A sampling strategy was developed to collect sufficient data to evaluate both time-integrated exposures (over the course of an entire performance) and potential peak levels of exposure (the maximum levels of exposure an individual may experience during a performance). Potential exposures were estimated by collecting personal breathing zone and general air samples from various locations in the theaters in both live performance and rehearsal settings. These air sampling data were combined with time and motion information (e.g., time on stage, inhalation rates associated with on-stage activities) developed for the productions to determine potential exposure to individual Actors. Two types of exposure estimates were developed:

- A "preliminary exposure matrix" was developed using time and activity data from the baseline questionnaires and stage-wide average concentration data. The purpose of this exposure matrix was to provide preliminary estimates of exposure so that initial analyses of all 439 of the Actors participating in the study could be conducted.

- A "detailed exposure matrix" was developed to provide a more accurate characterization of exposure on a subset of 218 Actors for the epidemiological analysis. Use of the

detailed exposure matrix provided the ability to distinguish between integrated and peak exposures.

The results of the epidemiologic and exposure assessments were combined in developing conclusions regarding associations between exposures to theatrical effects and health effects in performers.

D. Results and Discussion

This study was conducted in 1997-99 with 439 adult Actors performing in 16 Broadway musicals. No significant acute change in voice quality, pulmonary function, or vocal cord appearance was found among Actors exposed to theatrical smoke, haze, or pyrotechnic agents. However, Actors with exposures to elevated or peak levels of glycols reported more symptoms than Actors with less exposure. In addition, some mild chronic effects in Actors with greater exposure to peak levels of glycols and mineral oil were observed. These findings may reflect a negative health impact of exposure to theatrical agents or other factors (e.g., physical demand).

1. Phase 1 – Baseline Questionnaires

Glycols. There are associations between symptoms reported in the baseline questionnaires and increasing glycol exposure levels, based on the preliminary exposure estimates developed for all 439 study participants. To examine the nature of these associations, symptom reporting was evaluated in the subset of 218 Actors for whom detailed integrated dose and peak exposure estimates were measured (using time exposed to two times and five times the Broadway average exposure level as a measure of peak exposure). Based on this analysis, symptom reporting – in particular respiratory, throat, and nasal symptoms – was found to be associated with peak exposures and not integrated dose.

Peak levels of glycol exposure are associated with reported symptoms of mucus membrane irritation. This is consistent with the chemical and physical properties of glycols, since they have irritative and drying properties at high doses. There are consistent, statistically significant associations between an overall increase in throat symptoms with increasing glycol exposure. Similarly, symptoms such as coated vocal cords, hoarseness, and voice change were associated with increasing glycol exposure, as were symptoms of nasal irritation.

Mineral Oil. As opposed to glycols, which are generally used to generate localized effects, mineral oil is usually used to produce a uniform, low level haze effect across the stage. Thus, the distribution of mineral oil is similar for all Actors on stage regardless of their locations, with no exposure to short bursts of high concentration. Two shows (Cats and Sound of Music), however, utilized mineral oil in a peak concentration during one scene. In this study, exposure to mineral oil was not associated with increased respiratory or nasal symptom reporting, as glycol exposure was. There was, however, a statistically significant increase in irritated throat symptoms among those Actors with the

highest mineral oil exposures in the detailed exposure analysis (those with more than 10 minutes at peak mineral oil exposure, principally Actors from Rent).

Pyrotechnics. Overall, there were no significant or consistent associations observed between symptoms and pyrotechnics use. This may reflect the relatively low current use of pyrotechnics on Broadway, both in the number of shows utilizing pyrotechnics and the magnitude of the exposure, or that under the conditions of use in participating shows, no adverse effects occur. An increase in nose and sinus symptoms was noted for the preliminary pyrotechnics exposure assessment, which is consistent with irritative effects of particulates. However, there was no association with the detailed measurements.

Multiple Effects. We also investigated whether Actors exposed to more than one theatrical effect had increased rates of symptoms compared to Actors exposed to a single special effect. There was no evidence of an additive or multiplicative effect from exposure to more than one agent.

2. Phase 2 – Daily Checklists

Symptoms reported frequently in Phase 1 were also commonly reported on the Daily Checklists during Phase 2. Interestingly, there was no variation in symptom frequency by month of the year or season, making heating or air conditioning in the theaters less likely factors in symptom frequency in Phase 2. This suggests that integrated exposure levels, which are dependent on ventilation in the theater, are not associated with symptom frequency (as opposed to peak concentrations, which are generally independent of ventilation). No consistent statistically significant associations were found between occurrence of symptoms and exposure to glycol, mineral oil, or pyrotechnics, although a positive association between glycol use and most of the symptoms was noted. The strongest predictors of daily symptoms in Phase 2 were the number of performances, performances on a weekend, physical demand of the role(s) played, and perceived levels of stress at work and away from work. These associations were much stronger than any contribution to symptom occurrence from theatrical effects.

The finding of strong associations between weekend performances (i.e., Friday through Sunday) and daily symptoms may be due to several factors. Typically, most Actors perform five shows over these three days; thus, the weekend is the most demanding part of their workweek. Increased numbers of performances also place greater physical and vocal demands on Actors. For example, Actors in Rent, a show with high vocal and physical demand, have the highest rate of reported symptoms. Stress level, another significant factor in Phase 2 symptom rates, is also very high among Actors in Rent. Conversely, Actors in Smokey Joe's Café, the show with the highest vocal demand but average physical demand and the lowest stress level at work, report low rates of symptoms for Phase 2.

3. Phase 3 – Medical Evaluations

The Phase 3 medical evaluations included examinations of vocal cord appearance and function, voice analysis, and pulmonary function. Each test was performed before and after a matinee performance. The comparison of each Actor before and after a show was designed to measure acute changes in these measurements due to exposure to theatrical effects. In addition, data from the pre-performance evaluations were analyzed independently to determine whether exposures were associated with signs of chronic irritation. Most Actors were evaluated on Wednesday, after one or two days off from performing on Broadway.

Acute Effects. No statistically significant acute changes after a performance were detected in vocal cord appearance and function, perceptual voice rating, or pulmonary function regardless of exposure to theatrical effects. The lack of acute change in exposed Actors in vocal cord appearance is consistent with no adverse effect from these exposures or may in part reflect the short-term humectant properties of glycols and mineral oil, which may inhibit acute irritant effects. Additionally, Actors performing on Broadway generally have tremendous vocal capacity, which may allow them to compensate for mild irritation and/or inflammation. Limited changes were observed from the comparison of the computerized voice analysis with peak glycol exposures, which suggests a potential minor impact on voice quality from these exposures.

Chronic Effects. In the analysis of Phase 3 data from the pre-performance examinations, Actors whose performance requires longer exposure to peak levels of glycols had a statistically significant increased rate of certain vocal cord appearance parameters (indicating inflammation of the throat or vocal cords). There was no adverse impact from mineral oil or pyrotechnics use. Rates of other vocal cord abnormalities (such as nodules or polyps) were not increased by exposure to any theatrical effect. There was no negative impact on vocal cord function associated with exposures to glycol, mineral oil, or pyrotechnics. Similar to the analysis of acute effects, minor impacts on vocal quality were associated with peak glycol exposures.

There was no clinically significant adverse impact on pulmonary function due to either acute or chronic use of glycol or pyrotechnics. This is consistent with the findings from the second NIOSH study, where there was no increase in rates of asthma or other pulmonary disorders in Actors in smoke shows compared to non-exposed Actors. It is also consistent with the chemical properties of glycol at the concentrations measured in the theaters, where these compounds can exert irritant effects on mucus membranes, but not on the lower respiratory tract. On the other hand, Actors with the highest exposure to mineral oil had a statistically significant decrease in one pulmonary function parameter – forced vital capacity. This finding was surprising, as decreases in forced vital capacity are usually associated with interstitial lung processes or with interference with taking a deep breath from external pressures, such as pleural thickening or obesity. While an effect was noted, it is important to note that the Actors still have pulmonary function within the normal range. As with glycol exposure, there was no evidence of airway obstruction.

The results of this study of the effects of theatrical smoke, haze, and pyrotechnics indicate that there are health effects associated with exposure of Actors to elevated or peak levels of glycol smoke and mineral oil. However, as long as peak exposures are avoided, Actors' health, vocal abilities, and careers should not be harmed. In order to minimize Actor exposures to peak glycol concentrations, the use of glycols should be such that an Actor's exposure does not exceed 40 mg/m^3. Mineral oil, for the most part, does not appear to have significant effects on Actors, provided that the exposures are minimized and uniform, rather than in concentrated bursts. For chronic exposures to mineral oil, the existing standards established for oil mists (5 mg/m^3 as an eight-hour time-weighted average) should also be protective for Actors in theatrical productions. In addition, the use of mineral oil should be such that an Actor's exposure does not exceed a peak concentration of 25 mg/m^3. Pyrotechnics as currently used on Broadway does not have a significant effect on Actors' health.

E. Conclusions

The major findings of this study are summarized below:

- No evidence of serious health effects was found to be associated with exposure to any of the theatrical effects evaluated in this study.

- Peak exposures to elevated localized air concentrations following a release of glycol smoke are associated with increased reporting of respiratory, throat, and nasal symptoms, and findings of vocal cord inflammation.

- Elevated exposures to mineral oil haze are associated with increased reporting of throat symptoms.

- No health effects were associated with the current use of pyrotechnic effects in any of the productions included in the study.

- There was no evidence of an additive or multiplicative increase in effect from exposure to more than one of the types of theatrical effects evaluated in this study.

- Other factors besides theatrical effects were also found to be associated with increased symptom reporting. These factors include perceived levels of stress (at work and away from work), performance schedule, and physical demand of the role(s) played.

- Based on the observed association between increased signs and symptoms of respiratory irritant effects and exposure to elevated levels of glycols and mineral oil, it is recommended that exposures to these materials by Actors performing in musical productions not exceed peak or ceiling concentrations of 40 mg/m^3 for glycols and 25 mg/m^3 for mineral oil. Time-weighted average exposures to mineral oil should be kept below 5 mg/m^3. Based on the results of this study, no change in the current use of pyrotechnics is necessary. As long as peak exposures are avoided, health, vocal abilities, and careers of Actors should not be harmed.

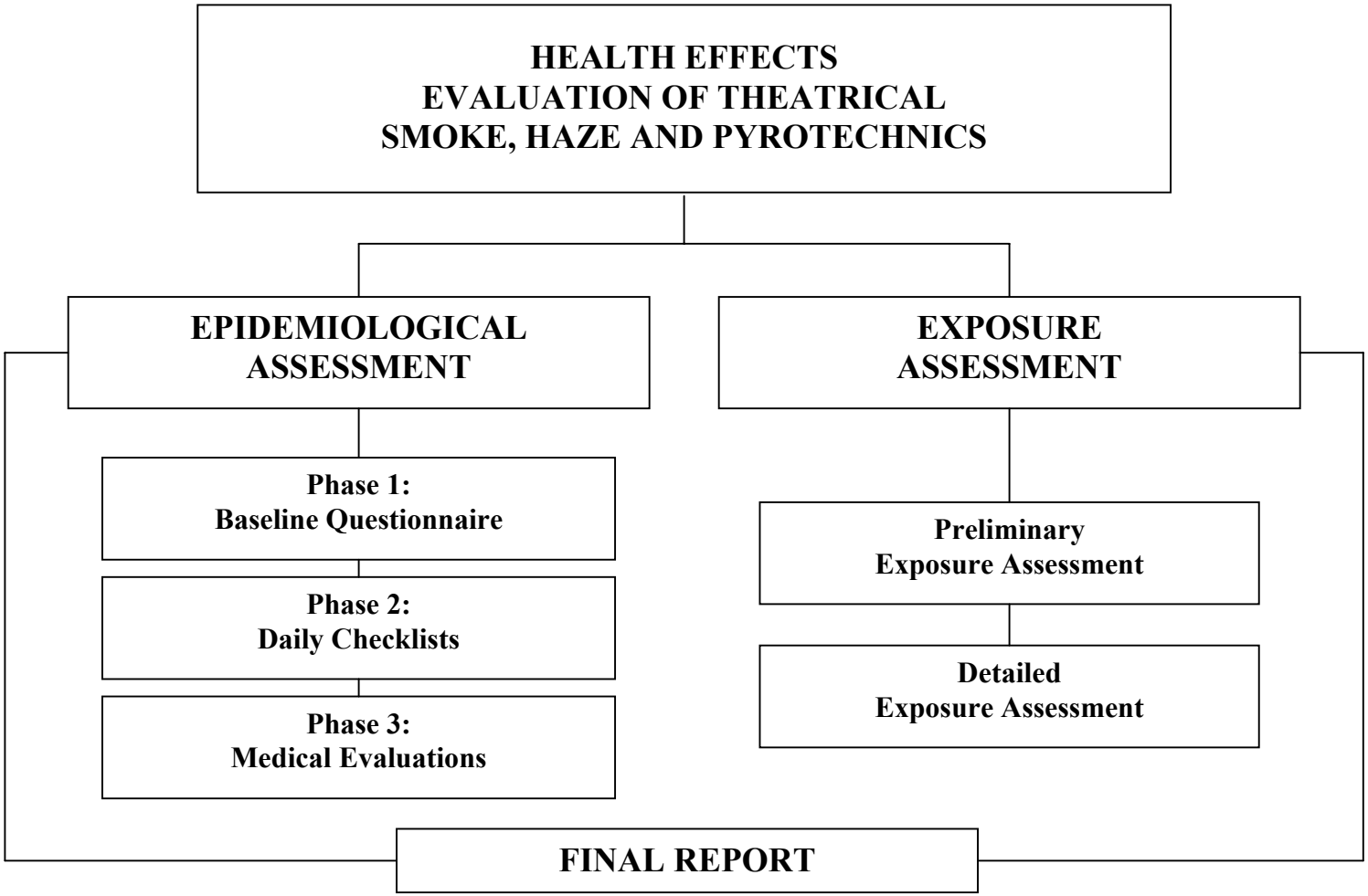

Figure ES-1: Flowchart of Health Effects Evaluation

I. INTRODUCTION

A. Background

At the request of Actors' Equity Association and the League of American Theaters and Producers, investigators from the Mount Sinai School of Medicine and ENVIRON Corporation have undertaken a study to determine whether theatrical smoke, fog, haze and pyrotechnics special effects currently used in theatrical productions are associated with health impact in Actors. The effort was initiated because of ongoing concerns by Actors that the use of these theatrical effects may have a deleterious impact on their health.

Previous Health Assessments conducted by the National Institute for Occupational Safety and Health (NIOSH) were limited in their scope; Actors in three musical productions using theatrical effects were compared to Actors in three dramatic productions which did not use any of these effects. While increased rates of occupational asthma were noted in the initial study, a follow-up study of a subgroup of the performers failed to find an increase in asthma. Symptoms associated with irritative effects of the respiratory tract were noted. Subsequently, Consultech Engineering Company conducted a survey of Actors and reviewed medical utilization through insurance records. A questionnaire inquiring about health effects as a result of exposure to theatrical effects was placed in the AEA's monthly newsletter, but was completed by only a small number of Actors, limiting its applicability. The insurance data review indicated that there might be greater use of medical resources among Actors in productions using these effects. Because of limitations in these prior investigations, the question of whether these substances present a health hazard to theatrical performers remained.

B. Study Methodology

Beginning in Fall 1997, a detailed study of the theatrical environment and the impact on Actors' health began. The goal of the study was to determine whether associations exist between exposure to theatrical effects (i.e., smoke, haze, and pyrotechnics) and health effects, taking into account the specific work environment and activities involved in a professional theatrical musical production.

Methodologies to determine whether these theatrical effects adversely impact the health of Actors were approved by the Board of Directors of the Equity-League Health Trust Fund in May 1997. Data collection continued until Summer 1999. A review of the toxicological literature on the components of smoke, fog, haze and pyrotechnics was performed to identify health endpoints of potential concern. An investigation of whether these substances had been reported in the medical literature to cause acute and/or chronic health problems was made. As a result of this literature review, presented in detail in Chapter II, as well as projections of actual theatrical exposures, it was determined that it was extremely unlikely that systemic toxicity could occur from any of these substances. Based on symptoms previously reported by Actors as well as a review of the potential exposures, the health endpoints chosen for investigation were those related to local irritant effects of the respiratory tract and eyes.

The epidemiologic assessment was comprised of three components. A description of the methodology employed is found in Chapter III. In Phase 1, baseline questionnaires were distributed to all Actors and Stage Managers in a current Broadway musical. Participants who completed the baseline questionnaire were asked to complete daily Checklists (Phase 2) describing current theater conditions and symptoms for three one-month periods. Actors were also invited to participate in Phase 3, the medical evaluation, consisting of vocal quality assessments, pulmonary function tests, and direct visualization of the vocal cords before and after a matinee performance. Data collected in Phases 1 and 2 provide background symptom and medical information from the participants, as well as their activities onstage and theatrical experience and longitudinal data on daily symptoms over the course of the study. The medical evaluation is a unique aspect of our study in that it allows for a direct comparison of the upper airway, voice and respiratory tract before and after a performance.

In order to characterize potential exposures to Actors in the theatrical environment, a detailed exposure assessment was conducted as part of the study. Details on the methodology employed can be found in Chapter IV. A sampling strategy was developed to collect sufficient data to evaluate both time-integrated exposures (over the course of an entire performance) and potential peak levels of exposure (the maximum levels of exposure an individual may experience during a performance). Potential exposures were estimated by collecting personal breathing zone (PBZ) and general air (GA) samples from various locations in the theaters in both live performance and rehearsal settings. These air sampling data were combined with time and motion information (e.g., time on-stage, inhalation rates associated with on-stage activities) developed for the productions to determine potential exposure to individual Actors.

C. Report Organization

This report is organized in the following fashion. First, a description of the toxicological properties of theatrical smoke, haze, and pyrotechnics is presented to lay the foundation for the acute and chronic endpoints chosen for investigation. Detailed descriptions of the methodologies employed in the epidemiological assessment and the exposure assessment appear in Chapters III and IV, respectively, including the methods by which the two major components of the study were integrated. The results of the health effects evaluation are presented in Chapter V. Finally, Chapter VI contains a discussion of the results and recommended guidelines for the use of current products and for the evaluation and safe use of alternative products.

II. TOXICOLOGICAL PROPERTIES OF COMPONENTS OF THEATRICAL SMOKE, HAZE, AND PYROTECHNICS

A. Introduction

This chapter presents a review of the scientific literature on the toxicological properties of components of theatrical smoke, fog, haze, and pyrotechnic effects. A brief background on the principles of toxicity assessment is presented, followed by a discussion of the chemical composition and the health effects that have been associated with the chemical components of theatrical effects products, both in human studies and animal studies. Separate sections describe effects associated with brief exposure (acute toxicity and irritancy) and effects associated with longer term exposure (systemic toxicity – subchronic and chronic effects) to five glycols (identified in "smoke" products), mineral oil (identified in "haze" products), and pyrotechnics products.

B. Principles of Toxicological Assessment

1. General Concepts about Risks of Toxic Effects Associated with Exposure to Chemical Substances

Almost all substances, even those that we consume in high amounts each day, can be made to produce a toxic response under some conditions of exposure. The science of toxicology attempts to identify the probability that the potential toxic properties of a chemical will be expressed under actual or anticipated conditions of human exposure. Thus, the risk of a substance is determined by its inherent toxic properties, the manner in which these properties change with changing exposure, and the actual conditions of human exposure to the substance. The term "safe" in its common usage, means "without risk". When one evaluates the potential risks associated with a chemical exposure, however, it is not possible to identify the conditions under which a given chemical exposure is likely to be absolutely without risk to any member of a population. The science of toxicology, however, can identify the conditions of exposure under which risks of chemical exposure are so low that they can generally be considered of no practical consequence.

2. Components of a Toxicological Assessment

A toxicological assessment is performed in order to evaluate the safety of a chemical exposure and involves a series of steps. The first step is to identify the chemical composition of the material in question. This can come from information supplied by the manufacturer, or from chemical analysis of the material itself.

The second step is to evaluate the toxic properties of the components of the material, determine the conditions of exposure (amount, or dose, and duration) that are associated with different forms of toxicity that each component may cause, and evaluate how the severity and

frequency of adverse effects changes as the level of exposure changes. This last aspect is termed dose-response assessment. A major purpose of a dose-response assessment is to determine conditions of exposure (dose and duration) that are likely to be free from adverse effects in the population of interest.

There are two principal sources of information about the toxic properties of a chemical: investigations of exposure in human populations or individuals (epidemiological or clinical studies), and experimental studies using laboratory animals or other biological systems. Studies in humans and in the laboratory setting may investigate both local irritant effects (effects at the site where the chemical contacts the body, such as skin, eye, or respiratory system irritation); and effects within the body (effects distant from the site of contact, also known as systemic effects). Toxicological studies can evaluate the effects of brief exposures (acute effects) and the effects of repeated exposures (subchronic or chronic effects).

Each source of information has strengths and weaknesses. The major strength of epidemiologic and clinical studies is that they are performed in the species of interest, humans, and avoid the uncertainties of extrapolating from animals to humans. Differences in anatomy, physiology, and metabolic activity can affect the way different species respond to exposure to a chemical. Epidemiologic and clinical studies of humans have the disadvantage that it is generally not possible to completely control exposure or other individual factors that may affect the study outcome.

Experimental animal studies have the advantage that the potential effects of other chemical exposures can be carefully controlled (e.g., rats do not smoke or drink alcohol), and it is possible to investigate exposures that could not be performed with humans (because of potential safety concerns).

Most toxicity assessments consider both human data (where such data exist) and data from animals, and use the dose-response information to estimate exposure levels that would not be associated with adverse effects. Once such "acceptable" levels of exposure have been established, it is possible to compare those levels to measurements or estimates of actual levels of exposure in the population of interest.

3. Application of Toxicological Assessment in the Current Study

In the toxicity assessment that follows, the available human and animal studies of chemicals of interest were reviewed to evaluate the levels and conditions of exposure at which adverse effects have been observed. Available information about levels of exposure in the theatrical setting that have been measured in past studies were also considered. This review was combined with the results of this epidemiological study in establishing guidelines for future use of these products.

C. Toxicological Properties of the Components of Theatrical Smoke, Haze, and Pyrotechnics

The theatrical effects being evaluated in this study are mixtures of glycols to generate smoke effects, mineral oil to produce haze effects, and various pyrotechnics effects. The glycol solutions currently used to generate smoke effects consist of mixtures of 1,3-butylene glycol, diethylene glycol, propylene glycol, and triethylene glycol. Although it is not a component of any glycol solutions known to be used currently for generating theatrical smoke, ethylene glycol is included in this discussion. The structures of these chemicals are shown in Figure II-1. The common uses of these chemicals and their toxicological properties are briefly below.

1. Propylene Glycol (PG)

Because of its low toxicity and useful properties, propylene glycol has a variety of industrial and consumer uses. Like the more common ethylene glycol (the main component of automobile antifreeze), it is completely miscible with water, and because such a water-glycol mixture has a lower freezing point than pure water, it can be used in antifreeze, and is a major component of aircraft deicing fluid. Because it tends to attract water from the air (it is hygroscopic), and it has low toxicity, it is widely used as an emollient in cosmetic and pharmaceutical creams, and as a humectant in tobacco, dentifrices and certain processed foods (e.g., shredded coconut) and animal feeds ("moist" dog food).

The Food and Drug Administration has affirmed the status of PG as "Generally Recognized as Safe" (GRAS) for a variety of uses in foods, and it may be present in seasonings and flavorings at up to 97%, in confections and frostings at up to 24%, in alcoholic beverages and in nuts and nut products at up to 5%, in frozen dairy products at up to 2.5%, and in all other food categories at up to 2% (FDA 1982). It is also used as a chemical intermediate (HSDB 1997).

The toxicology of PG has been reviewed extensively (FEMA 1985; ATSDR 1993; Cavender and Sowinski 1994; Cosmetic Ingredient Review Expert Panel 1994; BIBRA 1996). The following represents a brief summary of toxicology information that is most pertinent to the current concerns. More detailed information is available in the sources cited above.

a) Acute Toxicity and Irritancy

PG has a very low degree of acute toxicity. The oral LD_{50} (the dose lethal to 50% of an exposed population) for various animal species ranges from about 18 to 30 grams/kg body weight (HSDB 1997). For a 70 kg human, this would correspond to ingestion of more than one quart of the pure material.

It has a very low degree of skin and eye irritation, though some sensitive individuals (suffering from dermatitis) may display some skin irritation from direct contact with the pure liquid. Because of its wide use in cosmetics, in more than 4000 products and at concentrations of up to 50% in a few cases, the effect of PG on the skin has been extensively studied (CIREP 1994). PG showed no evidence of significant irritancy or allergic sensitization potential in several studies in animals, but a low incidence of irritancy and allergic reactions have been

reported in humans, particularly when exposure was to high concentrations of the chemical (>50%) under occlusive conditions (CIREP 1994).

Exposure of rats to a high concentration (160 mg/m^3) of a fine aerosol of PG (median aerodynamic diameter of around 2 μm) 6 hr/day, 5 days/week, for 90 days resulted in nasal hemorrhage and ocular discharge (possibly due to dehydration of the nasal passages and eyes) starting during the second week of exposure and diminishing over the weekends when no exposure occurred (Suber et al. 1989). By comparison, the highest air concentration measured in a previous NIOSH study of theatrical fog was less than 2 mg/m^3. In a very early study, exposure of children to atmospheres containing PG at 94 mg/m^3 (presumably as an aerosol) caused no effects on respiratory mucous membranes (Harris and Stokes 1943).

b) Systemic Toxicity

PG shows a low degree of systemic toxicity. Metabolism of PG in the body produces lactic and pyruvic acids, which are normal components of human metabolism. Only when exposure levels are extremely high are adverse effects likely. Very high oral doses (more than 700 mg/kg/day for several days) have been associated with abnormal heart rhythm in a 15 month old child receiving a vitamin preparation. Another child receiving a vitamin preparation containing 4-8 g PG/day developed seizures. In both cases, the adverse effects disappeared when exposure stopped. CNS effects were also seen in adults receiving 60-80 grams (2 to 3 ounces) of PG/day orally and in infants receiving intravenous injections of vitamin preparations containing PG at about 3 g/day (BIBRA 1996). Absorption of large amounts of PG by burn patients treated with an antibiotic cream caused increased osmotic pressure in the blood. This effect on osmotic pressure may be the cause of the CNS effects seen in several cases involving very high oral doses like those described above.

Cats appear to be more sensitive to PG than other species. Daily oral doses of 80 or 443 mg/kg/day for 94 days were without adverse effects in one study in cats, but in other studies in which oral doses of 675 mg/kg/day to 4,800 mg/kg/day were given, damage to the blood cells (Heinz bodies) was produced, and there were some mild effects on the liver and spleen (Bauer et al. 1992; BIBRA 1978, both as cited in BIBRA 1996). The blood effects were reversible when the cats were fed a control diet (BIBRA 1996). Dogs showed similar effects only when doses were in the range of 4,000 to 5,000 mg/kg/day; not at 2,000 or 3,000 mg/kg/day (BIBRA 1996).

b.1) Reproductive Toxicity. No adverse effects on reproduction or embryonic development have been reported in animals exposed to PG by oral, inhalation, or subcutaneous injection at doses up to levels that are toxic to the parents. Not surprisingly, at extremely high dose levels when more than 20% of a rat's diet was replaced with PG (a dose of more than 8 g/kg/day – equivalent to about one pint per day for a human), reproduction was impaired (BIBRA 1996).

b.2) Genotoxicity. PG has been tested for its ability to cause genetic mutations or other genetic damage in mice, rats, mammalian cells *in vitro*, bacteria, and yeast. No convincing evidence of genotoxicity was seen in any of these tests (ATSDR 1993; CIREP 1994; BIBRA 1996).

b.3) Carcinogenicity. No indication of carcinogenicity was seen when rats were fed PG at up to 5% in their diet for 2 years; or exposed to air containing the chemical at up to 350 mg/m^3 for 18 months; or when it was painted onto the skin of mice twice weekly for 2 years (BIBRA 1996). There was also no evidence of carcinogenicity in several more limited studies (BIBRA 1996).

2. Ethylene Glycol

Ethylene glycol (EG) is widely used as the main ingredient in automotive antifreeze. It is also used in hydraulic fluid and heat exchangers, and as a chemical intermediate and solvent. Its toxicity has been widely studied and reviewed (ATSDR 1993; BIBRA 1993b; Cavender and Sowinski 1994; IRIS 1997).

a) Acute Toxicity and Irritancy

EG has a relatively low degree of acute toxicity, but probably higher than the other glycols reviewed here. Its oral LD_{50} in rats, mice, guinea pigs, rabbits, and dogs ranges from about 5 to 15 g/kg, but cats and humans seem to be more sensitive, with a lethal level of about 1.6 g/kg (BIBRA 1993b).

EG is generally non-irritating to the skin, though a few dermatitis patients did experience an irritant response to undiluted EG, and a couple of cases of allergic reaction to repeated exposure to EG in an occupational setting have been reported. Most individuals with normal skin did not respond, however (BIBRA 1993b).

Direct contact with the eye caused inflammation but no permanent damage in humans, and similar responses were seen in rabbits (BIBRA 1993b). Although continuous exposure to EG vapor at 12 mg/m^3 for 90 days caused moderate to severe eye irritation in rabbits and rats starting within 8 days in two of the rats, no eye irritation was seen in rats, rabbits, guinea pigs, or dogs exposed to EG vapor at 57 mg/m^3, 8 hr/day, 5 days/week for 6 weeks (Coon et al. 1980, as cited in BIBRA 1993b).

In a study of human volunteers, individuals exposed for 28 days (approximately 20-22 hr/day) under sedentary conditions to an EG aerosol (droplet size 1-5 :m) at around 20-50 mg/m^3, reported only nose and throat irritation (Wills et al. 1974). The irritation became more severe when the concentration was increased to 188 mg/m^3, but could be tolerated for 15 minutes before the individuals had to leave the exposure chamber. When the concentration was again increased to 244 mg/m^3, it could be tolerated for only a minute or two, and 308 mg/m^3 was intolerable – the individuals were forced to leave after just one or two breaths because of the severe irritation. When the concentration exceeded 200 mg/m^3, symptoms included a burning sensation along the trachea and a burning cough (Wills et al. 1974).

b) Systemic Toxicity

Apart from the local irritation described in the previous section, the main effects of excessive exposure to EG are on the central nervous system (signs of drunkenness, nausea, vomiting, coma, and convulsions) and the kidney (damage to the tubular epithelium). Most of the toxic effects of ethylene glycol are due to its high water solubility, leading to increased

serum osmolality, and to its metabolic conversion to glycolic acid and oxalic acid. The latter cause metabolic acidosis, and the oxalic acid forms calcium oxalate which crystallizes in and damages the kidney tubules.

In the human inhalation study of Wills et al. (1974) described above, no clinical signs of systemic toxicity (including kidney toxicity) were seen, and psychological tests showed no effects on the central nervous system. Some individuals occasionally reported slight headaches and low backaches, but it is unclear if those symptoms were treatment related. The authors of this study concluded, in part, that EG was poorly absorbed via inhalation because no increase in serum EG was detected compared to individuals not exposed to the chemical.

In various animal species, the most sensitive sign of excessive exposure to EG is kidney damage. In rats, dose levels of 250-500 mg/kg/day in studies of up to 2 years duration have been associated with the development of kidney damage (see ATSDR 1993; BIBRA 1993b; IRIS 1997). Similar effects have been reported, generally at higher doses, in mice, rabbits, and monkeys. No other organ system showed signs of toxicity at lower dose levels.

b.1) Reproductive Toxicity. EG has been studied extensively to assess its reproductive toxicity via oral, inhalation, and dermal routes of exposure (BIBRA 1993b; ATSDR 1993). In several studies in rats and mice, EG has shown evidence of reproductive toxicity, including delays in fetal development and malformations following oral or whole-body inhalation exposure. These effects occur at dose levels at or above those associated with systemic toxicity (kidney effects). Mice appear to be more sensitive than rats to these effects, with signs of fetotoxicity evident at oral doses of 500 mg/kg/day or more in mice, but only at 1000 mg/kg/day or more in rats (Neeper-Bradley et al. 1995).

Because whole-body inhalation results in substantial oral exposure due to the grooming behavior of the animals, a study was also conducted using nose-only exposure (Tyl et al. 1995a). Under these conditions, signs of fetotoxicity (reduced fetal body weight) and malformations (fused ribs and other skeletal variations) were seen only at the highest, maternally toxic exposure level (2,500 mg/m^3, 6 hr/day on days 6-15 of gestation). No evidence of fetotoxicity was seen at 1,000 or 500 mg/m^3, though toxicity in the pregnant animals was seen at both 1,000 and 2,500 (but not 500) mg/m^3.

EG did not produce signs of developmental toxicity when applied to the skin of pregnant mice at dose levels up to 3549 mg/kg/day (0.1 ml of undiluted EG/mouse/day) (Tyl et al. 1995b).

b.2) Genotoxicity. EG has been studied in a variety of tests for genotoxicity, with generally negative results (see BIBRA 1993b; ATSDR 1993). In a few cases some suggestion of positive results were reported at high (cytotoxic) concentrations, possibly due to osmotic effects, which are known to cause false-positive responses in some assay systems. Overall, EG has not been found to be genotoxic

b.3) Carcinogenicity. EG has been tested for carcinogenic potential in rats and mice in several two-year feeding studies at up to 5% in the diet and by dermal application. No convincing evidence of carcinogenicity was seen in these studies (BIBRA 1993b).

3. Diethylene Glycol (DEG)

Diethylene glycol is used as a chemical intermediate in the manufacture of certain plastics and other products, as a component of antifreeze, as a solvent, for dehydration of natural gas, and has been used as a humectant for tobacco, casein, synthetic sponges, paper products, cork products, and book-binding adhesives (HSDB 1997).

a) Acute Toxicity and Irritancy

Like the other glycols reviewed here, DEG has a low degree of acute toxicity. Its LD_{50} in rats, mice, rabbits, hamsters, and guinea pigs is reported to be in the range of 8 to 27 g/kg/day (BIBRA 1993c; Cavender and Sowinski 1994). Again, cats seem to be somewhat more sensitive, with an oral LD_{50} in the range of 3.7 to 5.3 g/kg. Undiluted DEG was slightly irritating to the skin of rabbits, but was not reported to be irritating to the eyes of rabbits, dogs, or cats, and concentrations of 20% or less were not irritating to the skin of humans (BIBRA 1993c). Nasal discharge and lacrimation (tearing) were reported in a study in which rats were exposed to an aerosol of DEG (4,400 to 4,600 mg/m^3, droplet diameter 2.6-3.1 μm; Cascieri et al. 1991, as cited in BIBRA 1993c).

b) Systemic Toxicity

Despite its low acute toxicity, DEG has been the cause of several human fatalities due to its inappropriate use in pharmaceutical preparations, with death resulting from extensive kidney damage leading to kidney failure after ingestion of total doses of about 1.3 g/kg body weight – about 3 ounces in a 150 pound adult (BIBRA 1993c). In experimental animals, kidney damage, and to a lesser extent liver damage are seen in animals receiving doses of 1 g/kg/day or more (BIBRA 1993c). An increase in urinary oxalate concentration was seen in rats at a dose level as low as 100 mg/kg/day; no effects were seen at 50 mg/kg/day (BIBRA 1993c).

b.1) Reproductive Toxicity. Like several other glycols, DEG shows signs of fetotoxicity in mice when administered in drinking water, but adverse effects were seen only at a dose level equivalent to about 6 g/kg/day at which toxicity was also seen in the parents (Williams et al. 1990). No effects were seen in rabbits given DEG by gavage at up to 1 g/kg/day on days 7-19 of gestation (Hellwig et al. 1995).

b.2) Genotoxicity. DEG has generally given negative results in genotoxicity studies, though slight increases in chromosome damage have been reported at high oral dose levels (3 g/kg/day or more) in a couple of studies (BIBRA 1993c).

b.3) Carcinogenicity. DEG when administered at very high dose levels (2 or 4% in the diet – about 1.5 and 3 g/kg/day) has been shown to cause bladder tumors in rats secondary to the production of bladder stones (Fitzhugh and Nelson 1946; Weil et al. 1965, both as cited in BIBRA 1993c). At lower dose levels not associated with stone production, tumors are not seen, and similar bladder tumors can be produced by implantation of inert particles. Because of the requirement for bladder stones as a precursor to cancer development in response to DEG exposure, and such stones develop only at extremely high dose levels (equivalent to about 100

g/day or more in a human) DEG is not anticipated to cause cancer in humans at the levels of exposure likely to result from its normal use.

4. 1,3-Butylene Glycol (BG)

a) Acute Toxicity and Irritation

BG has been studied less extensively than PG, but shows a similar pattern of effects. It has a low degree of acute toxicity; the oral LD_{50} in rats and mice is in the range of 13-30 g/kg, and it can even be used as a source of calories replacing dietary carbohydrates. It appears to be mildly irritating to the skin and irritating to the eye (BIBRA 1990). At very high doses, close to the lethal level, sedation, incoordination, and other signs of CNS depression are seen (BIBRA 1990).

b) Systemic Toxicity

b.1) Reproductive Toxicity. No adverse effects on reproduction or embryonic development have been reported in animals exposed to BG at doses up to levels that are toxic to the parents. As with PG, however, at extremely high dose levels (4 g/kg/day or more), reproduction was impaired (BIBRA 1990).

b.2) Genotoxicity. BG showed no evidence of genotoxicity in tests for chromosome damage and dominant lethal mutations (BIBRA 1990).

b.3) Carcinogenicity. No indication of carcinogenicity was seen when rats were fed BG at up to 10% in their diet for 2 years (BIBRA 1990).

5. Triethylene Glycol

Triethylene glycol (TEG) is used to dry natural gas, as a chemical intermediate, as a solvent, and as a humectant for tobacco (HSDB 1997).

a) Acute Toxicity and Irritation

Like the other chemicals described, TEG shows a low degree of acute toxicity. Unlike ethylene glycol and diethylene glycol, TEG is not, apparently metabolized to oxalic acid (Lefaux 1968, as cited in BIBRA 1993). TEG's oral LD_{50} in guinea pig, mouse, rat, and rabbit is in the range of 8.8-22 g/kg. (BIBRA 1993).

TEG is at most only slightly irritating to the skin and eye (BIBRA 1993). Inhalation exposure of humans 8 hr/day while sleeping for 6 weeks at 2.5-3 mg/m^3 caused no respiratory irritation, but nasal discharge and lacrimation (tearing) suggestive of minor irritation was reported in monkeys exposed for 4 hours to "maximum attainable concentrations" (4,400 to 4,600 mg/m^3, droplet diameter 2.6-3.1 : m) of TEG aerosol (BIBRA 1993).

b) Systemic Toxicity

Most studies report no adverse effects in animals given TEG at doses of up to about 3 g/kg/day, but signs of liver, kidney and stomach damage at higher doses by oral administration

(BIBRA 1993). One early study in monkeys reported slight reductions in growth and in the numbers of white blood cells in monkeys receiving 0.6 g/day (about 300 mg/kg/day), but no effect on kidneys, spleen, bone marrow, or urine composition (Robertson et al. 1947, as cited in BIBRA 1993). One poorly reported Soviet study reported effects at lower doses, but the validity of this study cannot be confirmed (Tolstopyatova et al. 1987, as cited in BIBRA 1993).

By inhalation, no adverse effects were reported in rats exposed continuously for up to 13 months to air supersaturated with TEG vapor (4 mg/m^3), resulting in an estimated daily dose of about 5 mg/kg/day (Robertson et al. 1947, as cited in BIBRA 1993). In the same study, these authors reported a slight reduction in body weight, but no other effects, in monkeys exposed to the same concentration of TEG (4 mg/m^3).

b.1) Reproductive Toxicity. TEG was tested by the National Toxicology Program using a two-generation continuous breeding protocol (Bossert et al. 1992; Chapin and Sloane 1997). Animals received TEG in drinking water at 0.3, 1.5, and 3% (w/v). These concentrations resulted in daily intakes of approximately 0.59, 3.3, and 6.8 g/kg/day. A slight reduction in pup weight per litter was noted at the mid- and high-dose in the first generation, but this was not seen in the second generation, and the authors concluded that TEG was not a reproductive toxicant. The F_1 males and females receiving the highest dose of TEG showed increased liver weights, but no other signs of toxicity.

In other studies of reproductive toxicity, similar signs of fetotoxicity, but no overt teratogenicity were seen at dose levels close to or above the maternally toxic level in rats and mice (BIBRA 1993). The lowest dose level associated with such effects in reliable studies was 3.3 g/kg/day (the mid-dose in the Bossert et al. (1992) study). No effect on reproduction was seen in a early study in which rats were exposed continuously to a "supersaturated" TEG vapor (4 mg/m^3) for 13 months (Robertson et al 1947, as cited in BIBRA 1993).

b.2) Genotoxicity. Soviet studies reported dominant lethal mutations and chromosome damage in rats receiving 1/50 and 1/5 of the oral LD_{50} of TEG, respectively (Barilyak et al. 1987, as cited in BIBRA 1993), but the validity of these studies is questionable because of poor and incomplete reporting of methods and results. TEG was reported to be mutagenic in the Ames assay (NTP 1992, as cited in BIBRA 1993).

b.3) Carcinogenicity. No evidence of carcinogenicity was seen in an early, somewhat limited 2-year study in rats (Fitzhugh and Nelson, 1946, as cited in BIBRA 1993).

6. Mineral Oil

A haze-like effect may also be produced by generating an aerosol of mineral oil. This substance is the same as is used medicinally as a laxative and as a vehicle for drugs (white mineral oil, liquid paraffin, liquid petrolatum). It is also used in various food-contact uses (e.g., in lubricants for food machinery, in paper and paperboard, etc.). Aside from its laxative effect and possible interference with absorption of fat-soluble vitamins at high dose levels (up to 45 ml), oral exposure to mineral oil is essentially innocuous (Merck 1989; ACGIH 1998).

According to the Material Safety Data Sheets provided by the manufacturers (Reel EFX Diffusion Fluid; MDG Neutral Fluid), the mineral oil used to generate "haze" in the theatrical setting is a highly purified medicinal grade of mineral oil (White Mineral Oil, NF). It is consequently free of certain components/contaminants of some other petroleum-based products (e.g., metalworking fluids) that raise concern of health effects such as cancer or dermatitis (Mackerer 1989). In particular, medicinal-grade white mineral oil is free of polycyclic aromatic hydrocarbons (PAHs), which are known carcinogens found in some petroleum-based products. As a result, white mineral oil is considered by the International Agency for Research on Cancer (IARC 1984) to display "no evidence" of carcinogenicity. Medicinal-grade mineral oil is also free of aromatic compounds, and is composed primarily of hydrocarbons with 15 to 50 carbons (IARC 1984). Hence it is also essentially free of certain other potentially toxic components or contaminants of some other petroleum-based products, such as benzene (a human carcinogen) and *n*-hexane (a neurotoxicant).

A possible concern associated with the inhalation of any petroleum product is the occurrence of lipoid pneumonia. Lipoid pneumonia has been reported in humans following heavy exposure to oil mist in an industrial setting in the absence of adequate ventilation, and lung inflammatory reactions and lipoid granuloma have been reported in studies in which animals were exposed repeatedly at concentrations in air of 100 mg/m^3 and above (ACGIH 1998). Such effects have not been seen where the airborne concentration is maintained below the American Conference of Governmental Industrial Hygienists' Threshold Limit Value (TLV) for mineral oil mist of 5 mg/m^3. By comparison, in its survey of theatrical use of atmospheric effects, NIOSH (1994) found only at most "trace" levels of mineral oil (more than 0.04 but less than 0.13 mg/m^3) in the only theater production included in the study in which it was being used (Miss Saigon).

7. Pyrotechnics

In addition to the glycol smokes and oil hazes, some theatrical productions use pyrotechnics to generate atmospheric effects, including noise, light flashes/sparkles, and smoke. These products are similar in composition and emissions to fireworks commonly used to celebrate the Fourth of July, and other events. The composition varies according to the effect desired (light, noise, smoke).

The smoke generated by these pyrotechnics is typically a cloud of fine particulate matter. A literature search on various health-related databases (including TOXLINE and MEDLINE) revealed little information on the composition and potential health effects of smoke from these devices. Most citations identified were related to military devices whose composition differs substantially from the devices used in theaters. The only relevant studies identified were two related studies of respiratory effects of smoke from fireworks (Bach et al. 1975; Smith and Dinh 1975), and a NIOSH (1983) Health Hazard Evaluation Report of the use of theatrical pyrotechnics at the MGM Grand Hotel and Casino in Las Vegas.

The Bach et al. (1975) and Smith and Dinh (1975) studies measured particulate air pollution and respiratory function in individuals during a New Year's Eve celebration in Hawaii when there was extensive firework use. The peak concentration of respirable particulates was

over 3.8 mg/m^3. The authors reported a significant decrease (26%) in maximal mid-expiratory flow (FEV(25-75%)) in two subjects with a history of chronic respiratory disease, but no significant change in a group of normal healthy individuals. The emissions were identified as potassium chloride (KCl) particulates and sulfur dioxide (SO_2).

The NIOSH (1983) report indicated that smoke generated by pyrotechnics caused respiratory and/or eye irritation in 16 workers (about 10% of those exposed), symptoms suggestive of bronchitis in 9 of these, and some reports of skin rashes. Air monitoring during the show revealed time-weighted average (TWA) breathing zone concentrations of up to 1.81 mg/m^3, and peak concentrations during use of the pyrotechnic effects were likely near or above 10 mg/m^3. Based on discussions with the manufacturer of the pyrotechnic products, NIOSH concluded that the smoke would have contained a mixture of particulates including aluminum and titanium dioxides, carbon, and strontium carbonate, which NIOSH described as "rather inert chemically and considered nontoxic;" strontium and potassium chlorides and potassium sulfate, "all neutral salts with no anticipated toxicity;" and strontium hydroxide and potassium carbonate, "both of which would be alkaline." NIOSH noted that alkaline dusts are more irritating than "nuisance" dusts, and suggested that these may have contributed to the skin, eye, and respiratory irritation. They also suggested that the sulfate particulates may have contributed to the symptoms of bronchitis.

NIOSH recommended a thorough review of, and possibly changes in, the ventilating system to remove the smoke from the breathing zone, but noted that MGM had reduced the use of pyrotechnics in the show and this had greatly reduced the smoke problem. Unfortunately, air measurements after these changes were instituted were not performed, so it is not possible to determine the level of pyrotechnic smoke that was free of irritant effects.

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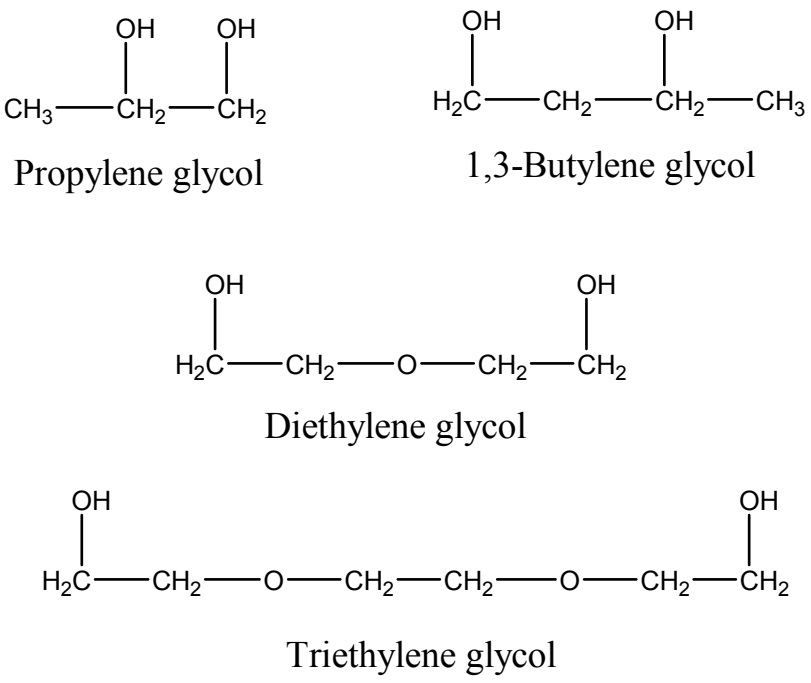


Figure II-1. Structure of Glycols Used in Theatrical Smoke

III. EPIDEMIOLOGICAL ASSESSMENT METHODOLOGY

A. Introduction and Background

The goal of the epidemiological assessment was to determine whether theatrical smoke, haze, and pyrotechnic effects are associated with acute respiratory and related health effects among Actors performing in Broadway musicals. More specifically, the data collected allowed us to evaluate whether reported symptoms and clinical findings related to acute irritant effects on the aerodigestive tract are associated with exposure levels estimated from an integrated exposure-activity matrix.

This study does not attempt to assess every potential health outcome that might be related to the use of theatrical effects. Rather, it comprehensively focuses on the most likely adverse outcomes as determined from previous investigations in this population and a review of the toxicological literature. The epidemiologic methodology does not allow us to conclude that a given individual's symptoms were directly caused by exposure to these theatrical effects. Rather, the data collected will enable us, with a reasonable degree of certainty, to (1) conclude whether exposed Actors, as a group, exhibit higher rates of these symptoms and/or objective clinical findings compared with unexposed Actors, (2) estimate the excess risk of developing these symptoms or conditions that may be associated with exposure to theatrical effects, and (3) estimate levels and patterns of exposure that increase the risk of developing these symptoms or conditions as well as exposure levels that do not increase the risk of health effects.

The study was designed to meet the following specific aims:

1. To determine whether theatrical effects currently used in Broadway productions are associated with acute irritative respiratory and related health effects among Actors.

2. To determine whether Actors working in productions which utilize a combination of theatrical effects have different rates of adverse effects compared with Actors in productions using a single effect.

3. To determine whether measurable changes in voice quality, upper airway appearance, and respiratory function occur after a performance in Actors exposed to theatrical effects compared with Actors in productions without these effects.

4. To develop a model that will allow us to evaluate the association between exposures anticipated in a production and the incidence of symptoms among Actors that can be attributed to these exposures.

B. Study Methods and Materials

1. Development of Study Questionnaires and Evaluations

The development of the study data collection instruments was the result of coordinated efforts by Stage Managers, Actors and the study investigators. The Stage Managers initially provided detailed information on their individual shows in a standardized questionnaire that included descriptions of each scene by name, number, length, and source of effects used, if any. Focus groups of Actors were convened to provide information regarding common parlance to describe their activities in the theater and on-stage, and for descriptions of health symptoms they experienced. Questionnaires used in previous studies of upper respiratory and pulmonary health effects in occupationally exposed groups, including the questions used in the earlier NIOSH studies, served as templates for the medical and environmental questions.

Pilot field-testing of Phase 1 (Baseline Questionnaire) and Phase 2 (Daily Checklists) of the study was carried out in the fall of 1998. Actors from different productions were asked to complete working draft versions the study questionnaire and checklist and to critique their content, format and procedures. The Actors' suggestions were incorporated into subsequent revisions to the questionnaire and checklist. Copies of the final versions of the questionnaire and checklist are included in the Appendix.

Pilot testing of the Phase 3 medical evaluation took place in the spring of 1999. The components of the Phase 3 evaluation – videoendoscopy/videostroboscopy, computerized vocal analysis, perceptual vocal rating and pulmonary function tests – were selected following a review of the medical literature and in consultation with Dr. Peak Woo, an otolaryngologist specializing in vocal disorders at the Grabscheid Voice Center at the Mount Sinai Medical Center, and occupational medicine specialists involved in studies of irritant exposures. Three Actors underwent pre- and post-performance testing to evaluate the feasibility, timing and overall experience of the evaluations.

For each Phase of the study, consideration was given to procedures and incentives that would make the Actors' and Stage Managers' participation as convenient and agreeable as possible. Beyond refreshments served at the administrations, a pen/highlighter with the Study Coordinator's name and phone number and a checklist clip were given out with the study forms to serve as reminders to the study participants.

2. Recruitment of Study Participants

Figure III-1 presents a flowchart that outlines the recruitment of study participants and the type of data collected during each of the three phases of the epidemiological assessment.

Prior to the start of the study, Actors Equity Association (AEA) informed the Stage Managers of all Broadway musicals about the purpose of the study and the methods of data collection. The Study Coordinator contacted the supervising Stage Manager at each show to schedule a date for an informational meeting and Phase 1 administration with the cast at their respective theaters. In order to maximize potential participation rates, AEA made attendance at

the informational meeting mandatory, although participation in the study was voluntary. A poster describing the purpose of the study and the date of the meeting was placed in a visible location at each theater. The AEA staff and the Stage Managers played an integral role in publicizing the study and assisting in the retention of study participants.

Recruitment of study participants began on January 22, 1998 with the first Phase 1 administration at Les Miserables. At the Phase 1 meetings, the Principal Investigators described the purpose and components of the study. Informed consent was obtained from cast members who were willing to participate, according to the guidelines of the Mount Sinai School of Medicine Institutional Review Board. Questionnaires for Phase 1 and the first checklist for Phase 2 were distributed, and detailed instructions were provided to participants. Study personnel were present to assist with any questions. Participants were asked to provide a copy of their resumes so that prior theatrical and non-theatrical work experience could be quantified.

Because some cast members were unavailable at the time of the initial Phase 1 administration, and to include new cast members who had joined a show after the start of Phase 1, a second opportunity to enroll in Phase 1 was scheduled for each show. These sessions were held either in the individual theaters or in an AEA conference room.

The Study Coordinator contacted all Phase 1 participants two weeks after they received the first Phase 2 checklist. Staff from AEA also encouraged participation in weekly theater visits. To ensure confidentiality, Actors were provided with sealed envelopes in which to place the completed checklists; the checklists were subsequently collected by the Study Coordinator at each theater. Prior to distribution of the second and third Checklists at months 4 and 7, respectively, the Study Coordinator obtained cast lists from the Stage Managers to determine whether Phase 1 participants were still performing in the show. Individual envelopes were delivered to the theater for each participant for the second and third checklists. The Study Coordinator, AEA staff and stage managers again encouraged continued participation in Phase 2 with phone calls and theater visits.

Recruitment for Phase 3 began in May of 1998. Individual letters were sent to Actors who had participated in Phase 1 describing the elements of Phase 3 and available dates for the evaluations. The Study Coordinator visited the theaters to encourage participation. AEA also sent letters out to cast members to encourage participation. The Phase 3 evaluations were held in the rehearsal space at AEA on matinee days, either Wednesday or Saturday. Because of the close proximity to the theaters, all Actors were able to return for the post-performance evaluations within thirty minutes of the end of the matinee performance.

3. Participation and Compliance

a) The Baseline Questionnaire

Actors from the 17 Broadway musicals playing during the study period were invited to participate in Phase 1 of the study – the Baseline Questionnaire. The previous two studies of Broadway Actors had clearly demonstrated that inviting Actors in all ongoing Broadway musicals would be essential to enroll an adequate number of study participants who represent the range of exposures to theatrical effects. Because of the anticipated closings of some productions

during the study period as well as turnover among the performers, it was inevitable that Actors enrolled at baseline might not complete the longitudinal phase (Phase 2) of the study. For these reasons, a large baseline population was important for the success of the project. Based on the number of Actors and Stage Managers working in musical productions when the study began, we anticipated that approximately 500 Equity members would be available for invitation into the first phase of the study. Assuming a response rate of 75%, 375 individuals were expected to complete the questionnaire.

The number of individuals participating in Phase 1 was actually higher than our prediction. A total of 407 questionnaires were completed at these initial visits. Because of turnover among Actors in shows and the unavailability of some Actors at the initial meetings, repeat administrations of the Phase 1 questionnaire were held; an additional 80 questionnaires were completed. Accordingly, the number of participants completing Phase 1 was 487.

At the initial administrations of the questionnaire, Stage Managers and children were invited to participate. Questionnaires were received from 42 Stage Managers and 6 children. It was decided that the study analyses would be restricted to the data collected from adult Actors. Children were not included in the study analyses because few children are performing on Broadway, there was a low initial response rate among the children, and it was decided by AEA that no children would be asked to have the Phase 3 medical evaluations. The Stage Managers were not included because the nature of their work results in inconsistent exposure patterns and levels, and their activities are not comparable to those that result in increased inhaled exposures (e.g., singing and dancing) among Actors. Consequently, a total of 439 adult Actors from 16 shows comprise the study population used for the statistical analyses. (No completed questionnaires were received from Actors in the 17th show, Bring in Da' Noise/Bring in Da' Funk). The distribution of this final study population is presented in Table III-1 as the number and proportion of participants from each of the 16 Broadway musicals included in the statistical analyses.

The responses obtained from the baseline questionnaire provided essential information about the characteristics of the study population, as well as prevalence rates of illness and symptoms in this population. These data also allow for comparisons of the current study with previously conducted prevalence surveys of Actors exposed to theatrical effects.

b) Physical Demand of the Actor's Performance

Another integral purpose of the baseline questionnaire was collection of data needed to derive accurate exposure estimates for all study participants, i.e., quantification of intake rates via inhalation and exposure duration. Information about an individual's on-stage physical activities reported on the baseline questionnaire was combined with air concentration exposure measurements taken at all shows to develop an exposure matrix that characterized the level of exposure to glycol, mineral oil and pyrotechnics for each Actor. By using this matrix, physical demands were included in the exposure assessment, incorporating, for example, the increased metabolic and respiratory rates inherent in a physically demanding role. The inhalation rate standards for physical activities used in these calculations were validated by an exercise physiologist consulting for the study. Details of the exposure matrix development are given in Chapter IV.

c) Vocal Demand of the Actor's Performance

It was necessary to derive an objective measure of the vocal requirements of each Actor for the role(s) he or she currently performs in the show. A professional theatrical voice coach scored the vocal demands for each Actor enrolled in the study, based upon the Actor's responses in the baseline questionnaire and from her knowledge and analysis of the roles in Broadway musicals. The components of the vocal demand calculation included the vocal category, role type (principal, ensemble), the tessitura (high, medium or low), the singing style (belt, legit), the years of training and singing experience, and the number of scenes in which the Actor sang.

d) The Daily Checklists

The goal of Phase 2 of the study – the longitudinal follow-up with completion of three Daily Checklists – was to investigate differences in the incidence rates of health effects associated with different levels of exposure. In any longitudinal study, attrition of participants from the initial cohort occurs. To ensure that information was available from a sufficient and representative number of study participants, all Actors who participated in Phase 1 were invited to continue in Phase 2, and given the first of the three Checklists on the day they completed the Questionnaire. Checklist 1 was returned by 69% (n=301) of the 439 Phase 1 participants.

The Checklists were to be completed for three one-month periods, with two months hiatus in between. Therefore, the time period for Checklist data collection spanned seven to nine months in each show, with inevitable turnover among cast members. Two shows, High Society and The Life, closed prior to completion of all three Checklists. There was also attrition from the study cohort by Actors who elected to withdraw from the study or failed to complete the Checklists despite intervention from study personnel and Equity staff members. In our proposal, we estimated that 280 Actors would comply with recording the Daily Checklist information. By the time the last checklist was completed in September of 1999, Checklist 1 was completed by 301 Actors, Checklist 2 was completed by 153 Actors, and Checklist 3 was completed by 100 Actors. Table III-1 shows the proportion of Phase 2 checklist data that came from each of the participating shows. The proportions of Phase 1 and Phase 2 participants from each show were similar. Moreover, the proportions of participants with different levels of exposure to glycols, mineral oil and pyrotechnics were comparable in all phases of the study (Table III-2).

This longitudinal phase of the study provided information regarding occurrence of self-reported symptoms in three one-month periods among Actors with differing levels of exposure to either single or multiple theatrical effects in a given production. The collection of data over a several-month period permitted the effect of seasonal variation in theater conditions, including heating and air-conditioning, to be assessed. On the Checklists, the Actor was asked to record daily performance data, for example, day of performance, number of performances, role(s) played, and the perceived level of effects used. Information was also collected on other factors including physical or vocal conditioning activities; cigarette smoking; perceived stress level at work and away from work on a scale of 0 (none) to 5 (high); and concurrent medical conditions and medication use. The outcome measures were occurrence of specific symptoms, and whether they were new or ongoing symptoms.

e) The Medical Evaluations

Phase 3 of the study enabled us to objectively determine whether changes in the aerodigestive tract could be detected using clinical measurements before and/or following a performance. Actors were recruited from shows across the range of exposures in order to achieve adequate representation at each exposure level. The exposure groups and number of participants in each group were determined from the on-stage activity data generated by the Baseline Questionnaire and the measurements made during preliminary industrial hygiene evaluations.

Phase 3 evaluations were conducted with Actors who had completed Phase 1 and at least one checklist in Phase 2 of the study. A total of 95 Actors enrolled in Phase 3, although five Actors did not complete the post-performance evaluation. Table III-1 shows the distribution of Phase 3 participants by show and Table III-2 shows the distribution by exposure level. Phase 3 evaluations were conducted from May 20, 1998 through May 5, 1999 over sixteen days (12 Wednesdays and 4 Saturdays). The majority of evaluations (79%) were conducted on a Wednesday, which usually follows a one- or two-day break from performing in the show.

The four elements of the Phase 3 evaluation were (1) a computerized acoustic voice analysis, (2) perceptual vocal rating, (3) pulmonary function tests (spirometry), and (4) videoendoscopy/videostroboscopy of the vocal cords. Actors were examined before and after a matinee performance, either on Wednesday or Saturday in the rehearsal space of Actors' Equity Association. Pre-performance examinations were done between one and three hours prior to the matinee; post-performance examinations commenced within 30 minutes of the matinee curtain.

e.1) Voice recording and computerized acoustic analysis. For the computerized voice analysis, the Actor was seated in front of a microphone that was placed on a holder to maintain a constant microphone to lip distance. The Actor was instructed to produce a steady vowel "ee" at a constant frequency and amplitude to the best of his or her ability. The next component included voicing at comfortable pitch and comfortable loudness (modal phonation), voicing at high pitch and comfortable loudness, voicing at low pitch and loudness, and phonation at comfortable pitch and loud phonation. To maintain consistency, the testing were administered by two qualified speech language pathologists with experience in phonatory function testing. Each component of the test was analyzed by a computerized speech laboratory system (CSL, Kay Elemetrics Lincoln Park, New Jersey). The computer program samples the sustained vowel, analyzes the acoustic signal and generates a numerical description of the acoustic signal. Statistics on the sustained vowel include jitter, shimmer, fundamental frequency, and noise to harmonic ratio (i.e., poorer quality signal across cycles).

e.2) Perceptual rating of speech sample. The Actor read aloud at comfortable pitch and loudness the Rainbow Passage, using a fixed microphone to lip distance. The speech sample was recorded on a DAT recorder (Digital AudioTape, SONY Corporation, New York). Each Rainbow Passage recording was coded and collated onto two DAT tapes for perceptual rating. The raters consisted of one otolaryngologist and three certified speech pathologists with prior experience and training in the perceptual rating of voice. Perceptual rating was based on the GRBAS scale (grade, roughness, breathiness, asthenia and strain). The rater was blinded as to the Actor's identity, exposure status, and to the rating of the other raters.

e.3) Pulmonary function tests. Study subjects underwent spirometric testing using a Cosmed Pony Spirometer (Vacumetrics, Ventura, California) according to standard guidelines. A trained technician performed all spirometric tests without knowledge of the Actor's exposure status. Forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), peak expiratory flow rate (PEFR), and peak expiratory flow 25-75 (PEF_{25-75}) were recorded. Two measurements were taken at both evaluations; the best values from each evaluation for each parameter were used in the analysis. The percentage predicted value for each spirometric value was calculated according to Knudson, which takes into consideration the subject's race, age, sex and height.

e.4) Videoendoscopy/videostroboscopy of the vocal cords. For the examination of the vocal cords, the Actor was seated comfortably and the nasal passage was anesthetized by topical application anesthetic. A fiberoptic laryngoscope (Olympus Corporation ENF-P3) was passed through the nose into the oral pharynx and the larynx was visualized. The Actor then produced sustained phonation of "ee" at modal voice, high voice, low voice and loud voice. During sustained phonation, the videostroboscopic examination was performed using constant and stroboscopic light, and recorded on S-VHS tape. With the scope in place, the subject was asked to count sequentially in a comfortable speaking voice from one to ten. To record a sample of the singing voice, the Actor was asked to sing the last two stanzas of the Star Spangled Banner. The examination took approximately five minutes to complete. To maintain consistency, a qualified otolaryngologist with extensive experience in performing nasal endoscopy and videostroboscopy performed all of the vocal cord examinations.

Three otolaryngologists who have experience in videostroboscopy and videoendoscopy of the larynx rated each taped videostroboscopic examination. For each examination, the video was coded and put into a series of before and after videoendoscopy examinations. The raters were blinded as to the Actor's identification and their exposure status. For each examination, a standard videolaryngoscopy and videostroboscopy form was completed, consisting of a systematic rating of glottis configuration, vocal fold smoothness, vibratory amplitude, mucosal wave and other features relevant to observation of vocal vibratory function. Clinical parameters such as the presence of a vocal cord nodule, edema, laryngitis, excessive muscle tension, and excessive mucous production were also indicated, if present.

4. Statistical Analyses

a) Measures of Health Outcomes Used in Statistical Analyses

a.1) Phase 1 Symptom Scores. The individual symptoms listed in the Phase 1 questionnaire were collapsed into composite "symptom scores" that reflect the frequency with which groups of related symptoms were reported. In order to focus the analysis on a manageable number of variables, only symptoms that were reported by at least 15% of the Actors were included in a symptom score. (Reliable statistical analysis could not be performed for rarely reported symptoms, and examination of the correlation among symptoms indicated that Actors reporting rare symptoms also reported the common symptoms that were included in the scores). Within a category of symptoms, the results of the correlation analyses were used to group the

most closely related symptoms. Each Actor's values were calculated for the resulting set of 14 Phase 1 composite symptom scores listed in Table III-3. Scores were calculated for general classes of symptoms (e.g., Any Symptoms, Any Eye Symptoms, and Any Throat Symptoms) as well as more specific subgroups of symptoms (e.g., Dry or Burning Eyes). All Phase 1 symptom scores were standardized to range from 0 to 2 (to reflect occasional or frequent occurrence), in order to make the scores comparable to one another and more robust for statistical analyses.

a.2) Phase 2 Symptom Scores. The second phase of the study provided information regarding occurrence of self-reported symptoms during three one-month periods. Composite symptom scores were developed in a manner comparable to the scores for Phase 1; however, as shown in Table III-3, because fewer symptoms were asked on the Checklist, only seven symptom scores were developed for Phase 2 – Any Symptoms; Any Chest Symptoms; Any Throat Symptoms; Excess Phlegm+Vocal Change; Hoarse Voice+Vocal Change; Any Nose Symptoms; and Any Eye Symptoms. For every checklist day completed, the Actor received daily values for each of the seven symptom scores, standardized to range from 0 to 1 (none present to all present) to ensure comparability of the scores and statistical utility.

The last column of Table III-3 also shows the positive correlation between the scores for prevalent symptoms from the Phase 1 questionnaire and the corresponding average daily symptom scores from the Phase 2 Checklist data. All of these correlation coefficients are statistically significant, indicating that Actors who experienced symptoms during the month before entering the study are likely to report similar incident symptoms during follow-up period.

a.3) Phase 3 Clinical Findings. The variables that define the clinical findings of the tests performed during the Phase 3 evaluations are outlined in Table III-4.

The computerized analysis of the acoustic signal provided numerical descriptions for four characteristics of the sustained vowel sound – jitter, shimmer, fundamental frequency, and noise to harmonic ratio – in modal voice, high voice, and low voice. Because gender-specific norms are available for the modal voice only, analyses were restricted to the modal voice variables.

Spirometry to assess lung function and capacity provides continuously distributed values for forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), peak expiratory flow rate (PEFR), and peak expiratory flow 25-75 % range (PEF_{25-75}). Traditionally, FVC measures any restriction to lung function, FEV_1 and PEFR measure large airway lung function, and PEF_{25-75} is a measure of small airway function.

An Actor's voice was recorded before and after a performance and was rated for overall grade (perceptible hoarseness), roughness (irregularity of vibration), breathiness (turbulence), asthenia (weakness), or strain (hyperfunction) – the GRBAS scale. Each characteristic was rated with an ordinal categorical variable on a scale of normal (0) to extremely abnormal (3).

Vibratory function and appearance of the vocal cords on videostroboscopic examination during sustained phonation was graded before and after the performance. The rating of glottis configuration, vocal fold smoothness, vibratory amplitude, mucosal wave and other features relevant to vocal vibratory function were each coded on an ordinal scale of normal (1) to

abnormal/absent (4 or 5, depending on the range for that finding). Clinical parameters visualized by the fiberoptic laryngoscope, such as the presence of a vocal cord nodule, edema, laryngitis, pharyngitis, tracheitis, excessive muscle tension, and excessive mucus production, were coded as present (1) or absent (0). For ease of analysis, four composite variables were created to count the number of abnormal findings for the four types of categorical outcome variables: vibratory, fiberoptic, pathologic, and inflammatory findings.

b) Exposure Variables Used in Statistical Analyses

For each theatrical effect category (glycols, mineral oil, and pyrotechnics), three types of exposure variables were calculated for statistical analysis. Details of the derivation of these variables from the exposure matrix, as well as comparisons of the exposure variables derived by the different methods, can be found in Chapter IV.

In our initial analysis, the symptom scores and clinical findings for all the Actors were compared with their exposure values from the "preliminary" and "detailed" exposure matrices. The comparison of symptom scores with the preliminary exposure values for all the Actors was conducted to determine whether any broad associations were apparent across the entire study population. Then, comparison of symptom scores and clinical findings with the exposure values for the subset of 218 Actors was conducted to evaluate the nature of any associations identified from the preliminary comparison (e.g., was it related to peak exposures or integrated dose). The detailed "peak exposure" time estimates measure the duration of time per performance that an Actor might spend at elevated levels of exposure, i.e., greater than two times or five times the Broadway average for that effect. The detailed "integrated dose" estimates the Actor's total exposure over the course of a performance.

c) Statistical Analyses Relating Phase 1 and Phase 2 Symptoms to Exposures

c.1) Bar Charts of Average Symptom Scores by Show. The "by show" average (or mean) values for the Phase 1 and the Phase 2 symptom scores among Actors in each show was calculated. Means and the standard deviations for each type of symptom score were calculated and presented in a series of bar charts (Figures V-1 to V-14). The height of a bar reflects the average value of the symptom score among Actors in a show. Shows with similar levels of exposure are grouped together in the graphs; exposure level categorization (None, Low, High) – based on the average preliminary measurements for each of the exposures used in a show – allowed us to examine whether one type of theatrical effect or some combination of effects was related to increased occurrence of symptoms. The cut-points for categorization were as follows: for glycol, "Low" is between 0 and 8 μg/show and "High" is greater than 8 μg/show; for mineral oil, "Low" is between 0 and 4 μg/show and "High" is greater than 4 μg/show; for pyrotechnics, "Low" is between 0 and 0.1 μg/show and "High" is greater than 0.1 μg/show.

c.2) Graphs of Individual's Symptom Scores by Their Measured Exposure Level.

To evaluate the association between symptoms reported at baseline (Phase 1) and increasing exposure level, graphs were produced that show the best-fitting curves that are consistent with the observed data. Optimal transformation regression procedures were used to plot the symptom score against exposure level, and then produce segments of the curve that best describe the relationship within very small intervals along the continuum. For each graph, this

"piecewise" procedure results in a smoothed, optimized visual representation of how a symptom score changes as exposure level increases (Figures V-15 to V-56). In each figure, for graphs a., b., and d., the unit of exposure is μg/show, and for graph c., the unit of exposure is minutes spent at more than two times the Broadway average.

Phase 2 symptoms were evaluated longitudinally, i.e., trends in symptoms as reported each day in a Checklist. The results were evaluated graphically by plotting the daily symptoms scores by several time-related or "temporal" factors: season, month, day of the week, number of performances, and day of performance, i.e., weekday (Monday to Thursday) versus weekend (Friday to Sunday). Graphs were compared across categories (None, Low, High) of the Actors' glycol, mineral oil and pyrotechnics exposure levels. (These graphs are not included in the report; available upon request.)

c.3) Multivariable Regression Analysis of Symptom Scores. Multivariable linear regression analyses were conducted to determine the nature and magnitude of the relationship between exposure to glycols, mineral oil or pyrotechnics and the prevalence or incidence of symptoms in Phase 1 and Phase 2. The linear regression coefficient *(β)* measures the strength and the direction of the association between increasing level of an exposure (μg/show) and a symptom score (increasing score or decreasing score). The statistical significance of the association is expressed as the *p-value*. By convention, a result is "statistically significant" if the likelihood is less than 5% that the observed association occurred by chance, i.e., p-values less than 0.05 are statistically significant.

A number of other variables were considered as potential confounders of the relationships of interest between symptoms and the exposure variables. These "covariates" were retained in the multivariable regression model using a modified backward selection process, i.e., all covariates were initially included and those with a significance level of 0.15 were retained in order to assure that important confounders would not be ignored. Covariates considered for inclusion in the models were the Actor's age and gender, months performing in the show, vocal demand, years of professional experience, respiratory infections, seasonal allergies, cigarette smoking, and environmental factors. In addition, regression models to assess the independent impact of each theatrical exposure (glycol, mineral oil or pyrotechnics) on symptoms were simultaneously controlled for the other two exposures. The potential correlation among cast members in the same show was taken into account by always including a fixed effect term for show.

d) Statistical Analyses Relating Phase 3 Clinical Findings to Exposures

d.1) Multivariable Linear Regression Analysis of Phase 3 Continuous Variables.
Linear regression models were used to identify predictors of the continuously distributed outcomes and, in particular, to assess whether exposure to any of the theatrical effects was predictive of these outcomes. The continuous outcome variables were the pulmonary function tests (FEV_1, FVC, PEF_{25-75} and FEV_1/FVC ratio) and the voice parameters (fundamental frequency, jitter, shimmer, and noise-to-harmonic ratio). Chronic effects of exposures were examined using pre-performance values for the outcomes, while acute effects were examined with models to predict change in the outcomes from before to after the performance. The change

model was fit by using the post-show measurement as the outcome and the pre-show measurement as one of the covariates.

Each multivariable regression model contained the individual Actors' exposure measurements (as μg/show) for glycol, mineral oil and pyrotechnics in order to simultaneously control for the effects of all of these exposures. Additionally, important covariates were retained in the model using a modified backward selection process. In the first step, all candidate variables were included. Once all candidate variables had $p<0.30$ (other than those automatically retained), the selection procedure was stopped. The liberal significance level of 0.30 was used because of the small number of participants in Phase 3, in order to assure that any important confounders would not be ignored.

d.2) Logistic Regression Analysis of Phase 3 Categorical Variables. Logistic regression models were used to examine categorical outcome variables. For each clinical category (vibratory, fiberoptic, pathologic, inflammatory), a binary variable was created indicating whether the number of abnormalities increased from the pre-show to the post-show measurement. These were used as the outcome variables in logistic regression models assessing change between pre-show and post-show conditions. The purpose was to examine acute effects of exposure, where the predictors of interest were μg/show of glycol, mineral oil and pyrotechnics exposure (considered one at a time), adjusting for the number of conditions present at the pre-show measurement. Adjustment was not made for other factors due to limited sample size and sparse data in some of the categories. To consider chronic effects of exposure to these agents, additional logistic regression models were fit which used the pre-show assessments as the outcome variables. Due to limitations in overall sample size as well as in the number of subjects exhibiting multiple conditions, these outcome variables were dichotomized as any conditions versus none. Cigarette smoking was included in every model.

Figure III-1. Flowchart of Epidemiological Assessment

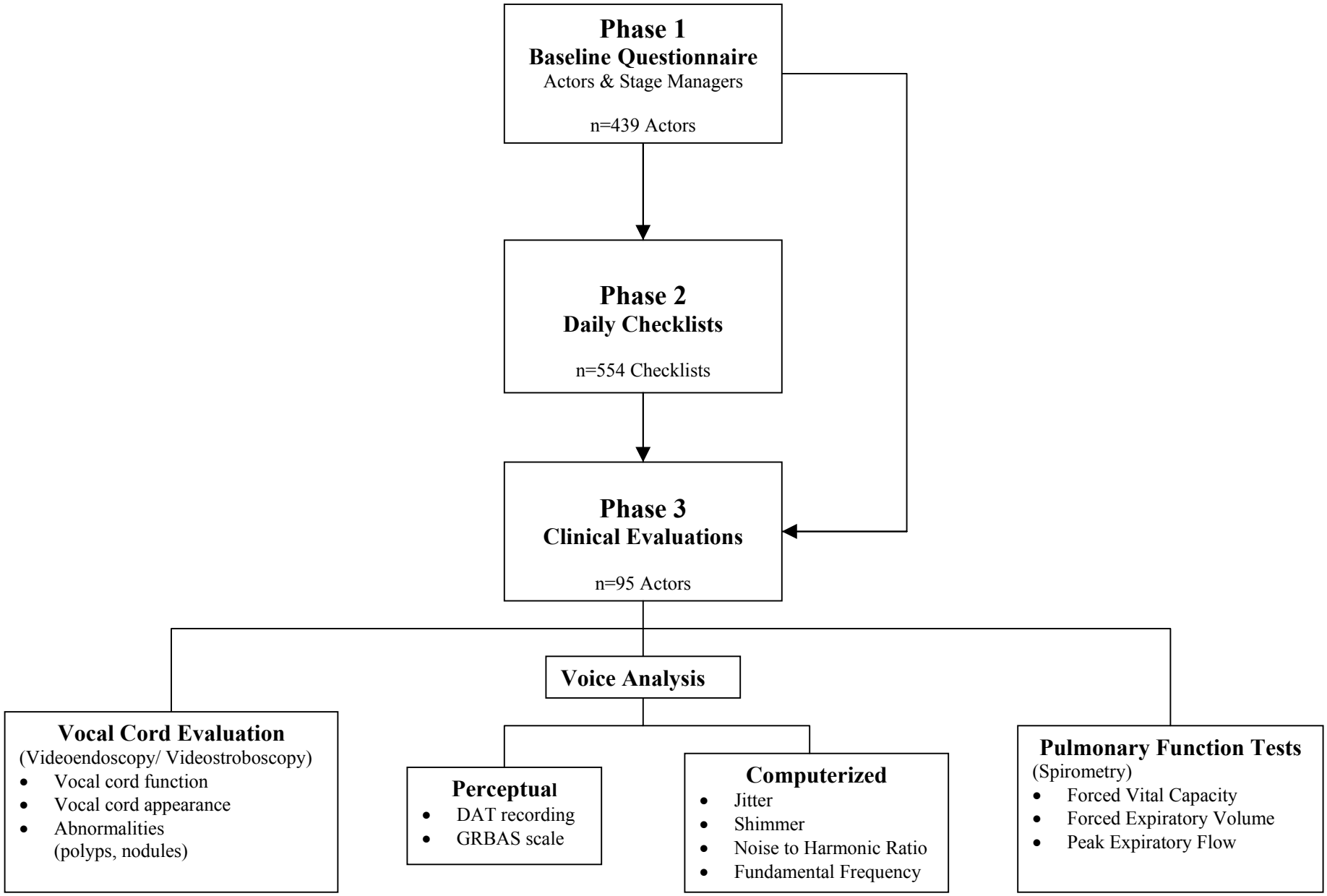


Table III-1. **Proportion of Study Participants from Each Broadway Musical**			
Show Code Number and Name	**Phase 1 % of Total (n)**	**Phase 2 % of Total (# person-days)**	**Phase 3 % of Total (n)**
1. High Society	2.1 (9)	0.8 (112)	0 (0)
3. Cats	8.0 (35)	8.7 (1,260)	8.4 (8)
4. Chicago	3.2 (14)	2.7 (392)	1.1 (1)
5. Beauty and the Beast	8.4 (37)	8.3 (1,204)	11.5 (11)
6. Jekyll and Hyde	6.2 (27)	8.7 (1,260)	7.4 (7)
7. Les Miserables	4.8 (21)	6.2 (896)	7.4 (7)
8. Miss Saigon	9.8 (43)	12.1 (1,764)	9.5 (9)
9. Rent	3.4 (15)	2.9 (420)	4.2 (4)
10. The Scarlet Pimpernel	6.4 (28)	7.5 (1,092)	13.7 (13)
11. Smokey Joe's Cafe	3.0 (13)	0.8 (112)	0 (0)
12. Ragtime	10.5 (46)	11.0 (1,596)	11.5 (11)
13. The Life	3.9 (17)	1.3 (196)	0 (0)
14. The Phantom of the Opera	8.0 (35)	9.2 1,344)	9.5 (9)
15. Titanic	8.2 (36)	6.7 (980)	4.2 (4)
16. The Sound of Music	7.7 (34)	9.4 (1,372)	11.5 (11)
17. The Lion King	6.6 (29)	3.8 (560)	0 (0)
TOTAL	**100 (439)**	**100 (14,560)**	**100 (95)**

Table III-2. **Proportion of Participants in Each Phase of the Study by Preliminary Exposure Measurement Category**			
Exposure Category	**Phase 1** %	**Phase 2** %	**Phase 3** %
GLYCOL:			
None	58.3	50.0	46.4
Low	21.4	23.7	30.5
High	20.3	26.3	23.2
MINERAL OIL:			
None	44.4	43.7	53.7
Low	27.8	29.4	25.3
High	27.8	26.9	21.0
PYROTECHNICS:			
None	66.5	63.7	68.4
Low	17.5	19.0	13.7
High	15.9	17.3	17.9

Table III-3. **Composite Symptom Scores Calculated for Phase 1 and Phase 2 Statistical Analyses**				
Composite Score	**Individual Symptoms in Score**	**Phase 1**	**Phase 2**	**Correlation between Phase 1and Phase 2 Scores**
1. ANY	CHEST + ANY THROAT + ANY NOSE + ANY EYES	✓	✓	**0.49**
2. CHEST	Short of breath + Coughing + Phlegm + Wheezing	✓	✓	**0.42**
3. ANY THROAT	Dry throat + Irritated throat + Sore throat + Hoarse voice + Excess mucus/phlegm + Coated cords + Change in voice maneuverability	✓	✓	**0.44**
4. ONLY THROAT	Dry throat + Irritated throat + Sore throat + Hoarse voice	✓	--	--
5. ANY CORD11 (M+C+V)	Excess mucus/phlegm + Coated cords + Change in voice maneuverability	✓	✓	**0.41**
6. ANY CORD1 (M+C)	Excess mucus/phlegm + Coated cords	✓	--	--
7. ANY CORD2 (C+V)	Coated cords + Change in voice maneuverability	✓	--	--
8. ANY CORD3 (H+V)	Hoarse voice + Change in voice maneuverability	✓	✓	**0.46**
9. ANY NOSE	Stuffy nose + Runny nose + Post-nasal drip + Sneezing + Congested sinuses + Sinus infection + Sinus headache	✓	✓	**0.47**
10. ONLY NOSE	Stuffy nose + Runny nose + Post-nasal drip + Sneezing	✓	--	--
11. ONLY SINUS	Congested sinuses + Sinus infection + Sinus headache	✓	--	--
12. ANY EYES	Dry eyes + Burning eyes + Itchy eyes + Watery eyes	✓	✓	**0.34**
13. EYES1 (D+B)	Dry eyes + Burning eyes	✓	--	--
14. EYES2 (I+W)	Itchy eyes + Watery eyes	✓	--	--

Table III-4. **Variables Used to Define Clinical Findings for the Phase 3 Statistical Analyses**			
Procedure	**Variable Name**	**Components**	**Type of Variables**
Computerized acoustic analysis of voice	• Fundamental Frequency (FF) • Standard Deviation of FF (SD) • Jitter (%) • Shimmer (%) • Noise to Harmonic Ratio (NHR) • Realtime pitch and speaking FF	• Modal, high and low range parameters were determined. Only the modal values were analyzed (norms available).	Continuous
Perceptual rating of speech sample	• GRBAS scale	• Grade (general) • Roughness • Breathiness • Asthenia • Strain	Categorical/ Ordinal
Pulmonary function by spirometry	• FEV_1 • FVC • PEFR • PEF_{25-75}	• Forced expiratory volume in 1 second • Forced vital capacity • Peak expiratory flow rate • Peak expiratory flow in 25-75% range • Ratios of FEV_1/FVC and FEV_1/PEFR (airway obstruction)	Continuous
Videoendoscopy/ videostroboscopy of the vocal cords	• Stroboscopic abnormality • Vibratory abnormality • Fiberoptic observation • Pathologic finding • Inflammatory finding	• Abnormal appearance of vocal folds • Abnormal movement of vocal folds • Erythema, arytenoid edema, vocal cord edema, pharyngitis • Nodule, polyp, reflux, vocal cord compression • Pharyngitis, laryngitis, tracheitis	Categorical/ Ordinal

IV. EXPOSURE ASSESSMENT

A. Introduction and Background

An important component of the overall epidemiological assessment is the characterization of potential exposure of Actors to the smoke, haze, and pyrotechnic effects used in theatrical productions. The exposure assessment conducted for this Study is comprised of two components: (1) a characterization of the on-stage air concentrations of the constituents of concern and (2) a quantification of the intake rates (via inhalation) and exposure durations (i.e., time on-stage) for the exposed Actor population.

This chapter presents the results of air sampling that was conducted to quantify on-stage air concentrations. The goal of the air sampling strategy was to collect sufficient air concentration data to characterize both the time-integrated exposure to individual agents (i.e., total amount of the product an Actor was exposed to over the course of a show) and potential peak levels of exposure to these agents (i.e., the maximum levels of exposure an individual may experience during a performance). Potential exposures to these agents were estimated by collecting personal breathing zone (PBZ) and general area (GA) air samples from various locations in the theaters in both live performance and rehearsal settings. The air sampling was conducted in two phases:

- A preliminary sampling phase, in which certain representative air samples were collected from the stage during live performances and used to characterize average concentrations across the stage during certain scenes; and

- A detailed sampling phase, in which additional samples during rehearsals and crew calls were collected from locations on the stage that were not accessible during a live performance, and the spatial and temporal variations of concentrations during a scene were characterized.

The preliminary sampling was conducted to collect limited air concentration data from all of the shows included in the Study. These preliminary data support the analyses involving all of the Actors participating in the Study. The detailed sampling was conducted to develop more comprehensive air concentration data and provide a more accurate characterization of individual Actor exposures for a subset of the shows. These detailed data provide more accurate exposure data on a subset of the Actors for use in the epidemiological assessment, as they provide a more refined estimate of integrated exposures and a characterization of peak exposures.

These air sampling data were combined with time and motion information (e.g., time on-stage, inhalation rates associated with on-stage activities) to estimate the potential exposure doses received by individual Actors over the course of a performance. In addition, this approach allows for the identification of different exposure scenarios such as high-level, short duration exposure (i.e., "peak" exposures) to specific agents for individual Actors or groups of Actors in a production. The results were incorporated into an "exposure matrix," which quantifies the

potential inhaled dose for an individual to specific products used during a theatrical performance. As will be described in this Chapter, a "preliminary exposure matrix" was developed for all of the Actors participating in the Study (using the preliminary sampling data) and a "detailed exposure matrix" was developed for a subset of these Actors (using the detailed sampling data).

B. Experimental Design and Methodology

Based on initial site visits to the theaters and discussions with theater personnel, it was determined that each theater production represents a unique working environment in which potential exposures to smoke, haze, and pyrotechnics will depend on numerous factors. These factors include the specific selection and usage patterns of the materials, placement and movement of the cast on-stage, physical design of the release point(s) for the effects, positioning of stage props and scenery drops, and overall design of the theater and house ventilation system. All of these parameters are theater- and show-specific. In addition, potential exposures may occur in backstage areas where cast members spend time during the performance while not on stage. Therefore, the air sampling strategy included measurements for potential constituents of concern at points both on- and off-stage. Rather than attempting to extrapolate exposures from one theater to another, sampling was conducted in each theater to incorporate the site-specific variability in work practices, product usage, and physical design.

It should be emphasized that this air sampling was conducted as part of an epidemiological investigation of the potential association between exposure to theatrical smoke, haze, and pyrotechnic exposure and health effects in Actors. As such, this study does not attempt, nor is it intended to be, a comprehensive evaluation of all potential exposures or hazards associated with working in the theater.

1. Selection of Constituents for Sampling

A review of the product usage associated with theatrical effects was used as the basis for selection of agents for which sampling was conducted. The theatrical effects used in Broadway productions at the time the air sampling was conducted are summarized in Table IV-1. The actual constituents will vary among productions based on specific product selection in the theater. The general categories of compounds that were measured are:

- Glycols for smoke generation;
- Mineral oil used for a haze effect; and
- Particulates associated with the use of pyrotechnic devices.

Based on their potential to represent confounders with respect to the clinical endpoint of concern in the Study (i.e., mucosal irritation), background dust levels, temperature, and relative humidity were also measured.

Based on a review of previous studies and consultation among the investigators, it was determined that the presence of dry ice and liquid nitrogen fog would not be significant contributory factors to the symptom reporting associated with exposure to glycols, mineral oil, or pyrotechnics.

With the exception of one theater (Lunt-Fontanne), there were no observable signs of chronic moisture problems or water damage that would lead to the suspicion that molds and fungi represent a significant problem in these theaters. After considering the general absence of evidence that would indicate microbiological air quality issues of concern, consensus among all of the project investigators was that sampling of the theaters for airborne microbiological contaminants would not be required.

2. Air Sampling Procedures and Analytical Methodology

All sampling was conducted using established and validated methodologies and instrumentation (including proper documentation of instrument calibration and appropriate field blanks and controls). All sample analysis was conducted by American Industrial Hygiene Association (AIHA) accredited laboratories[1] using validated analytical methodologies. The sampling and analytical methods are summarized in Table IV-2. As described later in this chapter, certain method calibration and validation activities were conducted for glycols and mineral oil by ENVIRON in a controlled environment, which consisted of a closed sound stage equipped with box fans to achieve a well mixed environment. These activities were conducted at Lightwave Research/High End Systems, Inc. (HES) in Austin, Texas.

a) Glycols

Glycol aerosols are generated by heating a glycol/water solution and feeding the vapor through a critical flow orifice. Upon entering the atmosphere, the vapor condenses rapidly to form fine droplets, producing a visible aerosol. The particles subsequently revolatilize into the vapor phase. A schematic diagram of the smoke generation process is shown in Figure IV-1. Fluids are composed of various mixtures of individual glycols (propylene, butylene, diethlyene, and triethylene glycol) and water. The specific glycols measured at the time of the Study are summarized in Table IV-3. Based on preliminary testing conducted by ENVIRON at HES, it was observed that, once generated, the glycol aerosol is very dynamic with respect to particle size and abundance. The glycols rapidly evaporate from the surface of the droplets, resulting in reduced particle size and, eventually, complete vaporization of the aerosol. The behavior of individual aerosols is dependent upon the composition of the glycol solution and environmental factors, including temperature and relative humidity.[2]

Due to the dynamic nature of the glycol aerosols, it was determined that the most practical method for glycol quantitation would be a variation of NIOSH Method 5523. In this method, a sampling pump (Gilian GilAir-5 or SKC Aircheck Model 224-44XR) was used to draw air through an XAD-7 OVS tube to collect both the particulate and vapor phase of the glycol aerosol. Preliminary data generated on several stages and a review of previous NIOSH reports suggested that in order to characterize the stage environment adequately, a sensitivity for the method below that reported by NIOSH (1992) would be required. Following conversations with the NIOSH investigators involved in developing the method, laboratory-based breakthrough and recovery testing from spiked samples was conducted that has extended that validated range

[1] Laboratory Corporation of America (LabCorp), Richmond, Virginia for glycols and Advanced Applied Sciences, Inc. (A2SI), Harrisburg, Pennsylvania for mineral oil.

[2] Eric Tishman, personal communication

of the method to a limit of quantitation (LOQ) of 4.0 μg of each individual glycol per sample. No breakthrough was observed at flow rates of 2.0 liters per minute (lpm) for up to sixty minutes sampling time.

Previous studies conducted by NIOSH (1992) identified the presence of low levels of aldehyde decomposition products following the heating of glycol fluids at high temperature (exceeding the normal operating temperature of currently used machines). However, these decomposition products were only detected under controlled laboratory conditions. No evidence of thermal decomposition products was observed by NIOSH in PBZ or GA air sampling conducted in the theaters. Therefore, it was judged that monitoring for these agents would not be required. Instead, the normal operating temperature of the smoke generating equipment in each theater was verified by ENVIRON to ensure that the heating element was operating in a temperature range not associated with generation of these products.

b) Mineral Oil

Oil mist effects are generated by "cracking" a USDA approved food or pharmaceutical grade mineral oil through a dispersion system using high-pressure air. Data provided by the manufacturers of these units indicated that the equipment produced a fairly uniform particle size distribution with aerodynamic diameters ranging from 0.1 to 1.0 :m. ENVIRON independently confirmed the particle size distribution was between 0.1 and 1.0 :m by using an airborne particle counter (MetOne Model A2408 Six Channel Laser Particle Counter) to measure the oil particles generated in a closed sound stage at HES using MDG Atmosphere and MAX 3000 fog generators.

The method selected for measuring air levels of oil mist on the stages involved the use of portable real-time aerosol monitors (MIE *personal*DataRAM Model PDR-1000). These instruments were used to conduct real time monitoring of particle concentrations with an integration time of 15 seconds. The small size of the monitors allowed them to be hidden on-stage during live performances without being noticed by the audience. When placed on the stage, the aerosol monitors recorded oil mist levels over the course of the entire performance. This information was used in estimating scene-specific levels of oil mist for developing the exposure matrix.

The aerosol monitors are initially calibrated to Arizona road dust. In order to utilize the monitors to measure oil mist, three of these instruments were calibrated under controlled conditions (closed sound stage) at target oil mist concentrations ranging from 0.25 to 30.0 mg/m^3. Samples were collected onto 37-mm PVC filters (5 :m) and analyzed by infrared spectrophotometry (IR) in conjunction with a bulk oil sample. Based on these data, a calibration factor of 1.47 was determined for the three aerosol monitors evaluated. Figure IV-2 shows the agreement of this calibration factor. This calibration factor was applied to other similarly-calibrated aerosol monitors used over the course of this Study. Mass sampling for oil mist at selected locations in the theaters was also conducted using long-term integrated samples collected on PVC filters over the duration of the show. These samples were placed in the same location as the aerosol monitors and were used to provide validation of the previously developed calibration factor.

c) Pyrotechnics

The same real-time aerosol monitors (i.e., MIE PDR-1000) used to measure mineral oil concentrations were utilized to determine levels of particulates in the air associated with specific pyrotechnic releases around the stage. Gravimetric sampling was impractical in this environment as the level of particulate matter emitted from these cues is usually too low for determination with personal sampling pumps. The use of a Hi-Vol filter system was also not a practical alternative in this environment based on the nature of use, which involves localized bursts that rapidly (within two to five minutes) dilute across the stage.

d) Total Dust

Total dust samples were collected in each theater using NIOSH Method 0500. Gravimetric analysis was conducted on (37 mm, 5 μm PVC filters) at a flow rate of 2.0 lpm. Sampling was conducted over the entire course of the performance. Two or three samples were collected around the stage, based on availability of sampling locations.

e) Temperature and Relative Humidity

Combination temperature and relative humidity gauges (Fisher Scientific Certified and Traceable Digital Hygrometer/Thermometer) were placed at two points on the stage (stage left and stage right) during both live performances and rehearsal sampling. Temperature and humidity measurements were collected as follows:

- Temperature and humidity readings were taken during the 30 minutes before the start of the show. This reflects the time when Actors may first be present on or around the stage.

- At intermission, readings were taken and included both the current temperature and relative humidity as well as the minimum and maximum values for these parameters that occurred over the first act of the performance.

- At the end of the show, readings were taken and included both the current temperature and relative humidity as well as the minimum and maximum vales for these parameters that occurred over the second act of the performance.

In addition to temperature and relative humidity measurements taken during the sampling visits, stage personnel were instructed in taking these readings in order to obtain seasonal data for a one-year period based on measurements taken for eight successive shows (one full week) per season.

3. Preliminary and Detailed Air Sampling

As discussed previously, the air sampling was conducted in two phases in order to obtain (1) limited air sampling data from all of the shows included in the Study (preliminary air sampling), and (2) comprehensive air sampling data from a subset of the shows to provide a more accurate characterization of temporal and spatial variations, and to determine peak concentrations of air exposures across a stage (detailed air sampling). The preliminary air sampling was generally conducted during live performances at two to three locations on a stage.

Two of the 16 shows did not use any glycol, oil, or pyrotechnic effects. Preliminary air sampling was conducted at one of these shows (The Scarlet Pimpernel) to verify the absence of the constituents of concern; no sampling was conducted at the second show (High Society).

Based on the results of the preliminary air sampling, nine of the 16 productions were selected for more detailed air sampling. These nine shows, which are identified in Table IV-4, were mutually selected by Mt. Sinai and ENVIRON based on the types of theatrical effects used and the participation rate of the Actors in the clinical portion of the Study. It should be noted that efforts were made to ensure the detailed sampling included the shows with Actors believed to have the highest exposures.

The detailed air sampling consisted of additional sampling during live performances combined with sampling in a crew call and/or rehearsal environment. The rehearsal sampling provided the opportunity to collect samples from locations on the stage that were not accessible during a live performance. Prior to the start of the each rehearsal, house ventilation and lighting were turned on and operated under the same conditions as during a live performance. During the rehearsal, scenes involving cue releases were reconstructed with the same timing and movement of props and scenery drops as during a live performance. Certain samples were collected during the rehearsal from identical locations as the preliminary sampling during a live performance to confirm that the stage conditions of the rehearsal were comparable to those of a live performance.

a) Glycols

Glycols are used in theatrical productions to simulate battle smoke, fires, or other short-term effects. As opposed to mineral oil, which is generally released over a sustained period of time and has a long "hang time," glycol smoke is released in short bursts (typically 5 to 15 seconds) and rapidly dissipates. As a result, concentrations of glycols will be highly variable across the stage, concentrated near the point of release. The amount of time required for the glycol smoke to reach background levels is dependent on the duration of the cue release, but was found to typically range from five to ten minutes. For example, preliminary air sampling data from eight points across the stage of Les Miserables (including two points directly over a cue release point) indicated that higher localized concentrations of a contaminant were present near its point of release immediately following a cue. However, within a few minutes of the cue release (i.e., two to five minutes), glycol levels diminished rapidly in both time and distance from the release point and the glycol dispersed to a relatively even (and lower) concentration across the stage. Glycol levels at all points on the stage were below the limit of detection by eight to ten minutes following release of the material.

a.1) Preliminary Sampling of Glycols. The preliminary air sampling of glycol aerosols during a live performance involved the placement of sampling pumps and collection media at various points across the stage. The placement of samples during a live show was heavily dependent upon the availability of props and scenery to hide the equipment as well as our ability to access the collection media at short intervals. In order to characterize potential acute exposures associated with being in close proximity of a cue release point, programmable pumps were used to collect data prior to a cue, during the cue release and for some period of time following the cue from the same point on the stage. A passive blank was included with

these filters to correct for any deposition occurring during the time on stage when active sampling was not occurring. Depending on the number of cues, the available sampling locations, and other constraints, samples were collected for selected portions of scenes and acts.

a.2) Detailed Sampling of Glycols. More detailed evaluation of potential short-term exposures to glycols was conducted in a more controlled rehearsal environment. Under these conditions, with complete access to all locations on the stage, an improved characterization of the spatial variation of glycol across the stage was possible. Each of the stages was divided into four, six, or nine sections (depending on the stage configuration), and air sampling data were collected across the stage to allow a characterization of the air concentration in each of these stage sections throughout the show, particularly during scenes in which glycol cues were involved.

Based on this preliminary sampling, serial samples were collected over a 10 to 20 minute period following release of material in a series of two to three samples from representative points across each section of the stage. For example, a 20-minute exposure was evaluated for a fixed location on one stage by collecting a series of three samples. The first sample, which was collected during the first four minutes following the cue release, captured the peak concentrations. The second and third samples, which were collected between four to eight and eight to 20 minutes following the cue release, were used to quantify the decay in the glycol concentration over time. Sampling was carried out to 20 minutes to ensure background levels were reached. For each scene in each show, the number of samples and the timing of their collection depend on the nature of the cue, the movement of cast during the scene, and the length of the scene.

The majority of the air samples were collected by study investigators. In certain shows, Actors and crew members were also present to assist in the sample collection. The total number of people on-stage during the rehearsal sampling was generally less than are present during a performance, which likely results in a decrease in the air exchange rate for the stage. Thus, the effects may have dispersed less quickly than in actual performances, resulting in longer persistence. This was not judged to result in an underestimation of actual Actor exposures.

To estimate a theoretical "peak" glycol exposure for each show, samples were collected over a 30-second sustained release of specific glycol cues near the point of release. This was conducted at the conclusion of each rehearsal. The purpose of this exercise was to determine the maximum potential concentration that could be inhaled under a worst case exposure scenario (e.g., an Actor directly exposed to the aerosol as it emerges from the release point). Under normal use scenarios, the cue only persists for 5 to 10 seconds, a period of time that is too short to measure reliably the aerosol concentration. Sustaining the cue release for 30 seconds and collecting a sample directly over the point of release provides an estimate of a maximum concentration associated with a first breath to which an Actor could be exposed under a worst-case scenario.

b) Mineral Oil

Mineral oil is predominantly used in theaters to generate a hazy environment for enhancing lighting effects. The aesthetic goal is to achieve a diffuse/uniform effect across the

stage. The oil mist is often used as a preset cue prior to the opening act and/or at intermission. Some productions use oil mist to simulate night fog for a particular scene. For haze effects, one to three oil mist generators are placed off the stage and are equipped with fans to assist in mixing of the material into the air. A sustained release of oil mist results in a well-mixed exposure environment on-stage during the show.

b.1) Preliminary Sampling of Mineral Oil. Based on preliminary air sampling with three to six aerosol monitors placed at representative positions across the stage, there is only limited spatial variability in the observed levels of mineral oil across a stage for most productions. As such, repeated sampling with two to three aerosol monitors and associated IR analysis of filters were used to produce data for use in exposure modeling. The monitors were started prior to turning on the oil mist generators. This enabled us to establish background levels of dust in the theater to subtract out from our measurements. Over the course of each act, there was a steady decline in the particulate (oil) levels for each monitor. Any interfering dust or other particulate contaminants (e.g., pyrotechnics) were detected as an overlaid spike on this decay curve. Because the aerosol monitors collect real-time data over the course of the entire performance, they can be used to estimate both acute and overall exposures.

b.2) Detailed Sampling of Mineral Oil. For most productions in which oil is used to generate a haze effect, the sampling conducted during live performances at two or three locations was judged to be a sufficient characterization of levels across the stage (i.e., increasing the number of monitoring locations would not yield additional information). In two shows (Cats and Sound of Music), oil is used in one scene to produce a more localized effect. Because of the nature of this effect, oil concentrations are more concentrated near the point of release for the cue and will be more variable across the stage. To estimate oil exposures for these scenes, the scenes were reconstructed in a rehearsal environment, and ten aerosol monitors were placed across the stage at locations representative of Actor positions.

c) Pyrotechnic Effects

As discussed previously, real-time aerosol monitors were used for the evaluation of pyrotechnic effects. For preliminary air sampling, two to three aerosol monitors were placed on-stage in close proximity to Actor positions during the cue release. More detailed monitoring was conducted in rehearsal environments, in which selected scenes were reconstructed and eight to ten aerosol monitors were placed across the stage at locations representative of Actor positions.

d) Theater Dust

In order to evaluate the potential for dust generation associated with the movement of stage sets and fabric backdrops used in a production, total particulate mass was measured concurrent with the preliminary air sampling. In general, samples were collected for each act from stage right and stage left.

C. Development of Exposure Matrix

The purpose of the exposure matrix is to provide a quantitative measure of an Actor's potential exposure to theatrical special effects (i.e., mineral oil, glycol aerosols, and pyrotechnic particulates) during a performance. The exposure matrix combines air sampling data with

physical activity demand and stage location information for each Actor to provide a quantitative measure of the dose received by an Actor during a performance. Both preliminary and detailed exposure matrices were developed, depending on the nature of the air sampling and time and activity data utilized. The intent of the preliminary exposure matrix is to allow some initial analyses to be conducted involving all of the Actors participating in the Study. The detailed exposure matrix was developed to provide a more accurate characterization of exposure on a subset of the Actors for the epidemiological analysis.

The parameters used to develop the preliminary and detailed exposure matrices are described in detail below and are summarized in Table IV-5. Briefly, the preliminary exposure matrix was based on the following: (1) Actor responses from the Baseline Questionnaire with respect to the type of activities performed during a show and the amount of time spent on-stage, and (2) stage-wide average concentrations for each scene as determined from either the preliminary or detailed air sampling. The detailed exposure matrix was based on the following: (1) refined information regarding the amount of time and location of Actors on-stage during scenes that use effects (obtained through the scratch tape review), and (2) extensive air sampling data collected from the stages of the shows (from performances, rehearsals, and/or crew calls).

1. Evaluation of On-Stage Time and Activity

The dose potentially received by an Actor is dependent on the amount of time an Actor is present on-stage during a particular scene and the Actor's breathing rate (which is a function of the Actor's activity) during that time. Actor time and activity data were obtained from the Baseline Questionnaires and "scratch" tapes that were produced for selected shows (see Table IV-4).

a) Characterization of Exposure Duration and Location

For the preliminary exposure matrix, exposure durations were determined from information provided by Actors on the Baseline Questionnaire. In these questionnaires, each scene was divided into four quarters, and Actors indicated whether they were on-stage during each quarter of each scene. By combining these data with information provided by the stage managers regarding the length of each scene, ENVIRON estimated the amount of time spent on-stage by each Actor in each show.

For the detailed exposure matrix, the exposure duration parameter was refined for scenes in which a cue is released and other appropriate scenes (e.g., scene following cue release) through a review of "scratch" tapes for selected shows. The scratch tapes consisted of a video recording of a live performance, with the audio cue calling by the stage manager dubbed into the tape. Using the scratch tapes, individual Actors can be tracked during specific scenes of interest and the amount of time and position for each Actor while on-stage was determined. Where appropriate, the blocking and choreography "book" was used to supplement this information.

The scratch tapes were reviewed with stage managers or other appropriate stage personnel (e.g., dance captain). The scratch tape review was conducted by pausing the tape at 15 second intervals during a scene of interest and identifying the Actors present at that time and their location. In this manner, an Actor's time on-stage during a particular scene was determined by summing the number of 15-second intervals in which the Actor was identified on the scratch

tape. For scenes that did not involve cues and where the stage was assumed to be a "well mixed" environment (as characterized by preliminary air sampling data), the exposure durations determined from the Baseline Questionnaires were used.

b) Characterization of Intake Rates

Intake (inhalation) rates were based on the activities performed by the Actors, as reported on the Baseline Questionnaire. USEPA (1997) compiled and analyzed numerous peer-reviewed studies on inhalation rates for various activities. Studies included inhalation rates for people performing both indoor and outdoor activities. USEPA's recommended inhalation rates for different activity levels are summarized in Table IV-6. Based on these data, short-term inhalation rates were estimated for each of the activity codes used this Study. These short-term inhalation rates are summarized in Table IV-7.

For the preliminary exposure matrix, an Actor's intake rate was based on the information provided on the Baseline Questionnaire. In the questionnaire, the Actor provided up to three activity codes per scene, with a fraction assigned to each activity code. The fractions and the inhalation rates in Table IV-7 were used to develop a weighted average inhalation rate for each scene and each Actor. For the detailed exposure matrix, the activity observed from the scratch tape for each Actor in each 15-second interval within a scene was used in combination with the inhalation rates in Table IV-7 to develop a refined weighted average inhalation rate for each Actor in each scene.

2. Characterization of Potential Exposure Doses

For both exposure matrices, exposure estimates were calculated based on the following parameters:

1. Exposure Duration (i.e., the amount of time an Actor is on-stage during a scene);
2. Intake Rate (i.e., inhalation rate based on the activities being performed during each scene); and
3. Exposure Concentration (i.e., air concentrations during each scene).

An Actor's exposure was determined from the product of these three parameters:

$$\text{Exposure Dose } (\mu g) = \text{Duration (hr)} \times \text{Intake Rate } (m^3/hr) \times \text{Concentration } (\mu g/m^3)$$

For the preliminary exposure matrix, scene-specific average concentrations across the stage were developed and combined with the exposure duration and intake rate data derived from the Baseline Questionnaires. This exposure matrix was developed for every Actor that completed a Baseline Questionnaire. The preliminary exposure matrix consists of the following information for each Actor:

- Total Integrated Exposure Dose (μg);
- Total Amount of Time Spent On-Stage (min); and
- Total Volume of Air Inhaled while On-Stage (m^3) (a measure of physical activity).

For the detailed exposure matrix, location-specific concentrations from the detailed air sampling were combined with the exposure duration and intake rate data derived from the scratch tape reviews. For every 15-second interval in which an Actor was on-stage, the inhalation rate associated with the Actor's activity during that interval was combined with the exposure concentration for the portion of the stage where the Actor was located. This exposure matrix was developed for the subset of Actors that were evaluated in the scratch tape review. The detailed exposure matrix consists of the following information for each Actor:

- Total Integrated Exposure Dose (μg);
- Total Amount of Time Spent On-Stage (min);
- Time Spent Above Peak Exposure Level(s) (min) (based on factors of 1, 2, 5, and 10 times the average concentration across all Broadway productions)
- Maximum Potential Exposure Concentration ($\mu g/m^3$); and
- Total Volume of Air Inhaled while On-Stage (m^3) (a measure of physical activity).

These data were intended to provide sufficient characterization of each Actor's exposure to theatrical effects for the purposes of this Study.

D. Results and Discussion

1. Preliminary Air Sampling

The preliminary air sampling was generally conducted during live performances at two to three locations on a stage. For the nine shows that were included in the detailed air sampling phase, the live performance data were supplemented with data subsequently collected from rehearsals during the detailed sampling. Two of the 16 shows did not use any glycol, oil, or pyrotechnic effects. Preliminary air sampling was conducted at one of these shows (Scarlet Pimpernel) to verify the absence of the constituents of concern; no sampling was conducted at the second show (High Society).

Based on the preliminary air sampling, an average air concentration for the entire stage was determined for each scene in which an effect is used. All Actors who appeared on-stage during a particular scene were assumed to be exposed to the average concentration for that scene. Thus, some Actors may have actually had much different exposures, as was subsequently determined in the detailed air sampling analysis. These scene-average concentrations are summarized in Table IV-8. Typical scene-average total glycol concentrations ranged from 0.1 mg/m^3 (Beauty & the Beast, Phantom of the Opera) to 7 mg/m^3 (Les Miserables, Jekyll & Hyde, Sound of Music). Scene-average mineral oil concentrations generally ranged from less than 0.1 mg/m^3 (Smokey Joe's Café) to 4 mg/m^3 (Rent, Sound of Music). One show, Cats, had higher average oil concentrations (up to 68 mg/m^3) during one scene at the end of the performance. Scene-average pyrotechnics concentrations generally ranged from less than 0.01 mg/m^3 to 0.5 mg/m^3.

2. Detailed Air Sampling

As discussed previously, nine of the productions were selected for more detailed air sampling (see Table IV-4). The detailed air sampling consisted of additional sampling during live performances combined with air sampling in a crew call and/or rehearsal environment. Because the rehearsal sampling provided the opportunity to collect samples from locations on the stage that were not accessible during a live performance. Using the detailed air sampling data, the stages for most productions were divided into nine sections (e.g., upstage left, center, and right [USL, USC, USR], midstage left, center, and right [MSL, MSC, MSR], and downstage left, center, and right [DSL, DSC, DSR]), and short-term (15 second) concentrations were extrapolated from the sampling data for each section of the stage during each scene in which an effect is used. The ranges of these concentrations are summarized in Table IV-9.

Based on the detailed air sampling, time-weighted average concentrations for the entire performance were also calculated, as summarized in Table IV-10. These data were used to calculate average time-weighted concentrations for all theaters across Broadway that use glycol, oil, and pyrotechnics effects. The Broadway time-weighted average concentrations were 0.73 mg/m^3 for glycols, 0.74 mg/m^3 for mineral oil, and 0.010 mg/m^3 for pyrotechnics.

a) Glycols

Glycols are used in theatrical productions to create short-term, localized smoke effects. Based on the nature of its use, concentrations of glycols were found to be highly variable across the stage, concentrated near the point of release. Figure IV-3 shows glycol concentrations measured at various on-stage locations during a scene from Les Miserables in which a glycol cue is released from upstage right. As Figure IV-3 shows, glycol concentrations are highest in the first four minutes near the point of release (i.e., upstage right). Comparably high concentrations were also measured during the first four minutes downstage right. However, concentrations during the first four minutes upstage and downstage left were low, with intermediate levels at upstage and downstage center. After the first four minutes, the glycol disperses rapidly across the stage to uniform and relatively low concentrations across the stage.

Theoretical "peak" glycol exposures for each show were determined by collecting sustained releases of specific glycol cues near the point of release. These levels represent the maximum potential concentration that could be inhaled under a worst case exposure scenario (e.g., an Actor directly exposed to the aerosol as it emerges from the release point). The theoretical peak glycol exposures are summarized in Table IV-11. Because Actors often are not situated directly in front of a release point as a glycol cue is being released, the maximum concentration to which an Actor is exposed may be less than the theoretical peak exposure level. Table IV-11 also summarizes the estimated maximum glycol concentrations to which Actors are exposed based on the detailed air sampling. Thus proximity to high concentrations may not result in inhalation of the maximal levels.

b) Mineral Oil

The use of mineral oil as a preset cue to generate a uniformly hazy appearance across the stage for enhancing lighting effects results in generally similar measurements at all locations on the stage. Figure IV-4 shows typical oil levels during a performance of Rent at three on-stage

sampling locations (stage left, center, and right). For this show, a preset oil cue is released from stage left for a 20-minute period before the beginning of the first act of the performance. As Figure IV-4 illustrates, the levels of mineral oil quickly reach a uniform concentration (higher than background) at all three sampling locations across the stage. The cue release is discontinued before the beginning of the first act (time=0 min), and concentrations begin to decrease exponentially at all three locations. After the first act is completed (approximately time=80 min), the oil cue is released again from stage left to re-establish the hazy effect. Again, as the cue release is discontinued before the beginning of the second act (approximately time=100 min), the oil concentrations again begin to decrease exponentially at all three sampling locations.

This uniformity of oil concentrations across the stage was observed at all other productions that use mineral oil with the exceptions of one scene each in Cats and Sound of Music. In Cats, mineral oil is used in one scene (Journey/Addressing the Cats) to generate a more localized smoke effect, rather than a uniform haze effect across the stage. The scene involves a giant flying tire, which moves across the stage with oil being released from beneath the tire for a one-minute period. During this time, Actors are situated beneath the tire, above the tire, and at other on-stage locations away from the tire. Figure IV-5 shows oil concentrations measured during this scene from various locations on-stage. As Figure IV-5 shows, oil concentrations vary widely across the stage during this one-minute cue release period. Oil concentrations are highest beneath the tire, approximately one order of magnitude higher than at other on-stage locations (e.g., above the tire, away from the tire). After the cue release is discontinued, however, the oil disperses across the stage and oil concentrations become uniform at all locations on the stage.

In Sound of Music, one scene (Sound of Music) involves a similar short-term release from upstage right. The scene involves a single Actor, who is located near the cue when it is released. The Actor spends the majority of the scene downstage, where concentrations are more uniform. The cue is much shorter in duration than the cue described above for Cats. The detailed air sampling was conducted to incorporate the potential elevated exposure during the beginning of this scene. This is reflected in the 50-fold increase in the peak oil concentration (Table IV-9) over the upper end of the preliminary air sampling (Table IV-8), which is more indicative of the average concentration across the entire stage during that scene.

The wide spatial differences in concentrations observed for these particular scenes, which were not captured in the preliminary air sampling, demonstrate the need for detailed sampling in order to characterize on-stage exposures accurately.

c) Pyrotechnics

In general, the upper range of the detailed measurements for pyrotechnics were higher than those measured during the preliminary air sampling. This is a reflection of the localized nature of these peak concentrations and our inability to gain access to the most representative sampling locations on-stage during the preliminary air sampling phase. Because the air concentrations drop rapidly with distance, the preliminary sampling locations were unable to capture the peak concentrations.

3. Other Measurements

a) Total Dust

In order to evaluate the potential for dust generation associated with the movement of stage sets and fabric backdrops used in a production, total dust samples were collected concurrent with the preliminary air sampling. Total dust was not measured in detectable levels (detection limit = 0.05 mg/show) at any of the productions sampled. Based on these data, dust levels at all of the theaters are less than approximately 0.3 mg/m^3.

b) Temperature and Relative Humidity

Temperature and relative humidity data collected throughout the course of the Study between January 1998 and May 1999 are summarized in Figures IV-6 and IV-7. These data indicated that average stage temperatures during performances are relatively constant from theater to theater, ranging from approximately 68 to 72EF. The minimum temperatures range from 62 to 68EF, and the maximum temperatures range from 73 to 77EF. The difference among the theaters is not significant. The average day-to-day variation in temperature was a change of less than one percent from the previous day.

Relative humidity on-stage varies more significantly from theater to theater. Average stage relative humidities range from approximately 40 to 52 percent. The minimum relative humidities range from 22 to 44 percent, and the maximum relative humidities range from 50 to 70 percent. The theaters with the highest average relative humidities are the Plymouth (Jekyll & Hyde), Imperial (Les Miserables), Majestic (Phantom of the Opera), and Nederlander (Rent). The theaters with the lowest average relative humidities are the Winter Garden (Cats), Barrymore (The Life), Martin Beck (Sound of Music), Ford Center (Ragtime), and Lunt-Fontanne (Titanic). The average day-to-day variation in relative humidity was a change of one to four percent from the previous day's value.

4. Exposure Matrices

The exposure matrices combine the air sampling data with physical activity demand and stage location information for each Actor to provide a quantitative measure of the dose received by an Actor during a performance. As discussed earlier, both preliminary and detailed exposure matrices were developed. The intent of the preliminary exposure matrix was to allow analyses to be conducted involving all of the Actors participating in the Study and provide a framework for the subsequent detailed exposure assessment. The detailed exposure matrix was developed to provide a more accurate characterization of exposure on a subset of the Actors for the epidemiological analysis.

a) Preliminary Exposure Matrix

Figures IV-8 through IV-10 show the distributions of preliminary exposure doses for Actors who are on-stage during a scene in which a glycol, oil, or pyrotechnics cue is used. Based on the preliminary exposure information, Actors are exposed to a wide range of doses across all shows. The potential glycol and pyrotechnics doses span three orders of magnitude; the potential oil doses span four orders of magnitude.

b) Detailed Exposure Matrix

Figures IV-11 through IV-13 show the distributions of detailed exposure doses for Actors who are on-stage during a scene in which a glycol, oil, or pyrotechnics cue is used. The detailed exposure information also supports the conclusion from the preliminary exposure matrix that Actors are exposed to a wide range of doses across all productions. The potential glycol, oil, and pyrotechnics doses span four orders of magnitude.

c) Comparison of Preliminary and Detailed Exposure Matrices

Figures IV-14 through IV-16 compare the Actor doses from the preliminary and detailed exposure matrices. These parity plots indicate good agreement between the exposure doses from the preliminary and detailed exposure matrices for oil, with larger differences for glycol and pyrotechnics.

For mineral oil, the agreement between doses from the preliminary and detailed exposure matrices is very good for all productions except for Cats (see Figure IV-15). This is a reflection of the use of mineral oil in most shows to produce a uniform haze effect across the stage. Because productions that use oil in this manner are able to achieve a uniform oil concentration across the stage, using a single on-stage measurement to represent the levels throughout the stage (as was assumed for the preliminary exposure matrix) will result in similar estimates of exposure as using multiple measurements at different on-stage locations (as was used for the detailed exposure matrix). The only instances in which the methodology used for developing the preliminary exposure matrix will not yield comparable results as the detailed exposure matrix are scenes that involve the use of mineral oil to produce more localized effects, such as in Cats and Sound of Music. The localized release of oil in Cats results in spatially variable oil concentrations on-stage (see Figure IV-5), which accounts for the difference between the preliminary and detailed exposure estimates for this production. The scene in which a localized release of oil is used only involves one Actor, which is also reflected in Figure IV-5. Because a single average oil concentration were used for the preliminary exposure matrix to provide estimates of exposure, the doses from the preliminary matrix generally are substantially different than the doses from the detailed matrix for these Actors in Cats and Sound of Music.

For glycols and pyrotechnics, there are more significant differences between the doses from the preliminary and detailed exposure matrices than was observed for mineral oil (see Figures IV-14 and IV-16). This is a reflection of the localized use patterns for glycol and pyrotechnic effects. Similar to the results for Cats, the localized release of glycols and pyrotechnics results in spatially variable oil concentrations on-stage, which accounts for the difference between the preliminary and detailed exposure estimates for these productions. These results demonstrate the need for more detailed sampling to develop accurate estimates of Actor exposures to glycols and pyrotechnics.

d) Time Exposed to "Peak" Concentrations

In order to assess exposures to elevated or "peak" concentrations, Figures IV-17 and IV-18 show the distribution in the amount of time Actors are exposed to various levels of mineral oil and glycols. Each figure shows the number of minutes Actors are exposed to concentrations that exceed the Broadway average concentration (see Table IV-10) and two, five, and ten times

the Broadway average concentration. These estimates are based on the detailed exposure matrices for mineral oil and glycols.

As shown in Figure IV-17, approximately 55 percent of the 218 Actors in the detailed exposure matrix spend at least 15 seconds exposed to total glycol concentrations that exceed the Broadway average of 0.73 mg/m^3, and approximately 40 percent spend time in glycol concentrations that exceed two times the Broadway average, or 1.5 mg/m^3. Approximately 40 percent spend time in glycol concentrations that exceed five times the Broadway average, or 3.6 mg/m^3, while 34 percent spend time in glycol concentrations that exceed ten times the Broadway average, or 7.3 mg/m^3.

As shown in Figure IV-18, approximately 46 percent of the 218 Actors in the detailed exposure matrix spend at least 15 seconds exposed to mineral oil concentrations that exceed the Broadway average of 0.74 mg/m^3, and approximately 38 percent spend time in oil concentrations that exceed two times the Broadway average, or 1.5 mg/m^3. Approximately 18 percent spend time in oil concentrations that exceed five times the Broadway average, or 3.7 mg/m^3, while only nine percent spend time in oil concentrations that exceed ten times the Broadway average, or 7.4 mg/m^3. The low amount of time spent by Actors in the higher peak mineral oil levels (e.g., five and ten times the Broadway average) is in agreement with the nature of the typical theatrical uses of mineral oil, i.e., to create a generally uniform hazy environment.

E. References

National Institute for Occupational Safety and Health (NIOSH). 1992. *Health hazard evaluation program*. Revised interim report No. HETA 90-355. Prepared for Actors' Equity Association and the League of American Theaters and Producers. October 1.

United States Environmental Protection Agency (USEPA). 1997. *Exposure factors handbook. General factors.* Volume I of III. EPA/600/P-95/002Fa. Office of Research and Development, Washington, DC. August.

TABLE IV-1
Summary of Theatrical Effects Used in Broadway Productions[a]

Show	Theater	Effect		
		Glycol	Oil	Pyro
Beauty & the Beast	Palace	U		U
Cats	Winter Garden		U	U
Chicago	Shubert		U	
High Society	St. James			
Jekyll & Hyde	Plymouth	U	U	U
Les Miserables	Imperial	U		
The Life	Barrymore	U		
The Lion King	New Amsterdam		U	
Miss Saigon	Broadway	U		
The Phantom of the Opera	Majestic	U	U	U
Ragtime	Ford Center		U	U
Rent	Nederlander		U	
The Scarlet Pimpernel	Minskoff			
Smokey Joe's Café	Virginia		U	
The Sound of Music	Martin Beck	U	U	
Titanic	Lunt-Fontanne	U		

Notes:
a Based on theatrical effects being used at the time of the air sampling for this Study.

TABLE IV-2 Sampling and Analytical Methods				
Target Analyte	**Method**	**Collection Medium**	**Sampling Flow Rate**	**Analytical Method**
Glycols	Modified NIOSH Method 5532	XAD-7	2 lpm	GC-FID
Mineral Oil	NIOSH Method 5026	37-mm PVC filter	3 lpm	Infrared Spectro-photometry
Total Dust and Pyrotechnics	NIOSH Method 0500	37-mm PVC filter	3 lpm	Gravimetric

TABLE IV-3 Specific Glycols Measured During Study				
Show	**Glycols**			
	BG	**DEG**	**PG**	**TEG**
Beauty & the Beast	U		U	U
Jekyll & Hyde			U	U
Les Miserables	U		U	U
Miss Saigon	U		U	U
The Phantom of the Opera		U	U	
The Sound of Music	U		U	U
Titanic			U	
Notes: BG=butylene glycol; DEG=diethylene glycol; PG=propylene glycol; TEG=triethylene glycol				

TABLE IV-4 Summary of Data Used to Develop Exposure Matrix				
Show	**Effects**	**Preliminary Sampling**	**Detailed Sampling**	**Scratch Tape Review**
Beauty & the Beast	Glycol, Pyro	U	U	U
Cats	Oil, Pyro	U	U	U
Chicago	Oil	U		
High Society	None			
Jekyll & Hyde	Glycol, Oil, Pyro	U	U	U
Les Miserables	Glycol	U	U	U
The Life	Glycol	U		
The Lion King	Oil	U		
Miss Saigon	Glycol	U	U	U
The Phantom of the Opera	Glycol, Oil, Pyro	U	U	U
Ragtime	Oil, Pyro	U	U	U
Rent	Oil	U	U	U
The Scarlet Pimpernel	None	U		
Smokey Joe's Café	Oil	U		
The Sound of Music	Glycol, Oil	U	U	U
Titanic	Glycol	U		
Notes:				

TABLE IV-5
Comparison of Preliminary and Detailed Exposure Matrix Parameters

Parameter	Preliminary Matrix	Detailed Matrix
Number of Actors	439	218
Exposure duration	Based on Actor responses to Baseline Questionnaire; temporal resolution equal to one quarter of each scene length.	For cue scenes, based on scratch tape review; temporal resolution equal to 15 seconds within a scene. For noncue scenes, same as Preliminary Matrix (i.e., based on Actor responses to Baseline Questionnaire)
Intake rate	Based on Actor responses to Baseline Questionnaire; up to three activities averaged per scene	For cue scenes, based on scratch tape review; activities were identified every 15 seconds within a scene. For noncue scenes, same as Preliminary Matrix (i.e., based on Actor responses to Baseline Questionnaire)
Exposure concentration	Based on stage-wide average concentrations for each scene collected from performance air sampling; concentration assumed to be constant at all locations on the stage throughout a scene	Based on 15-second average concentrations for portions of stage (stage divided into nine sections) from performance and rehearsal/crew call air sampling. These spatial concentration data were combined with Actor location information collected from the scratch tape review, in which the position on-stage of an Actor was identified every 15 seconds within a scene.
Notes:		

TABLE IV-6 Summary of Inhalation Rates for Short-Term Exposures		
Activity Level	**Indoor Activities**	**Outdoor Workers/Athletes**
Rest	0.3 m^3/hr	---
Sedentary Activities	0.4 m^3/hr	---
Slow/Light Activities	1.0 m^3/hr	1.1 m^3/hr
Moderate Activities	1.6 m^3/hr	1.5 m^3/hr
Heavy Activities	3.2 m^3/hr	2.5 m^3/hr
Reference: USEPA (1997)		

TABLE IV-7 Short-Term Inhalation Rates Used for Exposure Matrix Development		
Activity Code	**Activity**	**Inhalation Rate (m^3/hr)**
A	Singing and dancing	3.2
B	Singing and walking	2.5
C	Singing in place	1.6
D	Speaking and walking	1.5
E	Speaking in place	1.5
F	Walking only	1.0
G	Dancing only	1.6
H	Other strenuous activities	1.6
I	Other non-strenuous activities	0.8
J	Standing still, sitting, or lying in place (but not frozen)	0.8
K	Frozen	0.8
L	Smoking tobacco	1.1
M	Back stage/In wings right	0.8
N	Back stage/In wings left	0.8
O	Back stage/In wings center	0.8
P	Other activity	0.8
Q	No activity listed	0

TABLE IV-8 Range in Average Concentrations from Preliminary Air Sampling			
Show	**Total Glycols (mg/m^3)**	**Mineral Oil (mg/m^3)**	**Pyrotechnics (mg/m^3)**
Beauty & the Beast	0.16	---	0.01 to 0.05
Cats	---	6.5 to 68	0.17
Chicago	---	0.06 to 0.42	---
Jekyll & Hyde	0.15 to 6.3	0.03 to 1.3	---
Les Miserables	1.3 to 7.2	---	---
The Life	ND	---	---
The Lion King	---	0.08 to 0.80	---
Miss Saigon	0.94 to 2.9	---	---
The Phantom of the Opera	0.10 to 1.1	0.12 to 0.70	0.001 to 0.26
Ragtime	---	0.19 to 0.20	0.004 to 0.49
Rent	---	1.1 to 3.1	---
The Scarlet Pimpernel	---	---	---
Smokey Joe's Café	---	0.001 to 0.017	---
Sound of Music	6.9	0.099 to 3.7	---
Titanic	ND	---	---
Notes: Concentrations represent range in average concentrations during a scene used to represent entire stage. ND=While glycols are known to be used in this show, no detectable levels were measured.			

TABLE IV-9 Range in 15-Second Concentrations Extrapolated from Detailed Air Sampling				
Show	**Scene**	**Total Glycol (mg/m^3)**	**Mineral Oil (mg/m^3)**	**Pyrotechnics (mg/m^3)**
Beauty & the Beast	Prologue	---	---	0.007 to 2.6
	The Town	---	---	0.004 to 0.09
	Cottage	---	---	0.04 to 4.9
	Forest	---	---	0.03 to 0.1
	Be Our Guest	---	---	0.02 to 0.6
	Battle	0.26 to 0.37	---	---
	Rooftops	0.27 to 0.45	---	---
	Transformation	---	---	0.02 to 4.5
Cats	Mistoffellees	---	---	0.01 to 2.6
	Journey	---	0.04 to 600	---
Jekyll & Hyde	Lost/Facade	0.5 to 1.2	0.04 to 5.7	---
	Wharf	1.2	0.16 to 1.3	---
	Red Rat	1.2	0.50 to 1.1	---
	Exit Red Rat	0.5 to 1.2	0.42 to 0.72	---
	Alive	0.5 to 23	0.30 to 0.40	---
	Bishop Burn	1.2 to 11	0.20 to 0.30	---
	Murder Murder	3.7	0.21 to 7.3	---
Les Miserables	Chain Gang	1.5 to 17	---	---
	End of the Day	0.73 to 20	---	---
	Runaway Cart	0.75 to 4.9	---	---
	Paris	2.1 to 11	---	---
	ABC Cafe	1.0 to 1.8	---	---
	One Day More	1.2 to 2.3	---	---
	Mini-Barricade	1.2 to 1.6	---	---
	Javert	1.0 to 2.9	---	---
	First Attack	0.82 to 3.1	---	---
	Second Attack	1.5 to 16	---	---
	Sewers	1.5 to 2.3	---	---
	Finale	2.0 to 4.6	---	---

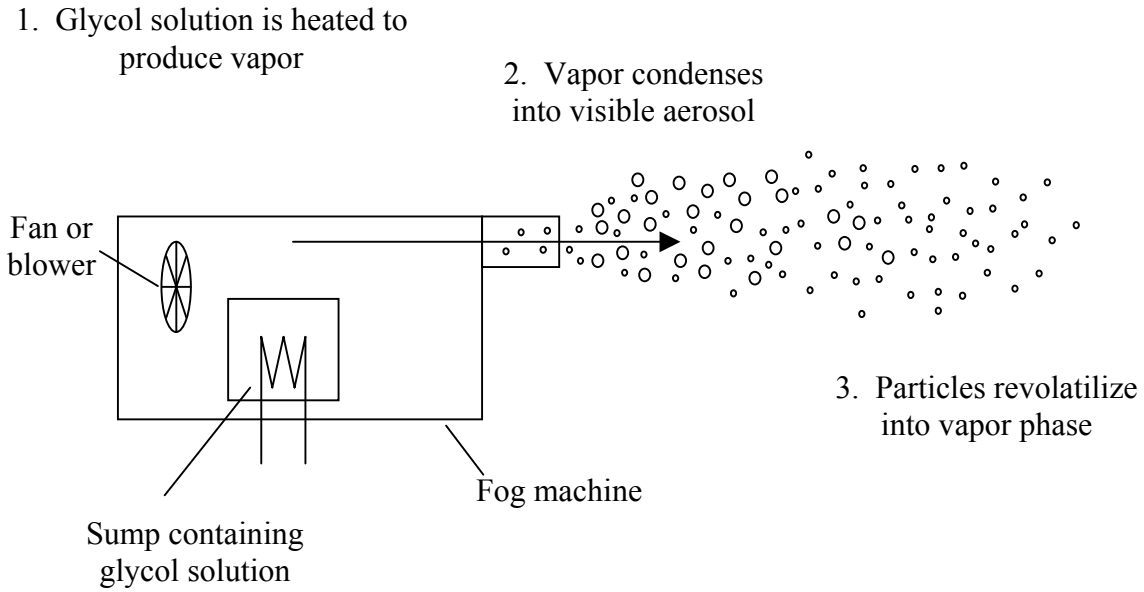
TABLE IV-9
Range in 15-Second Concentrations Extrapolated from Detailed Air Sampling

Show	Scene	Total Glycol (mg/m^3)	Mineral Oil (mg/m^3)	Pyrotechnics (mg/m^3)
Miss Saigon	Overture	1.5 to 3.5	---	---
	Dreamland	0.66 to 3.5	---	---
	Kim 3	0.66 to 1.2	---	---
	MOD	0.93 to 3.8	---	---
	This is the Hour	0.83 to 4.0	---	---
	Exodus	0.55 to 2.5	---	---
	Bangkok	1.3 to 4.6	---	---
	Nightmare	1.0 to 4.0	---	---
	American Dream	0.96 to 3.5	---	---
The Phantom of the Opera	Auction	---	0.48 to 0.76	0.001 to 1.6
	Dressing Room	0.08 to 37	0.24 to 0.35	---
	Buquet	0.10 to 37	0.21 to 0.34	---
	Masquerade	1.1	0.12 to 0.16	---
Ragtime	Prologue	---	---	0.001 to 0.032
	Journey On	---	---	0.001 to 0.048
	Reporter	---	---	0.001 to 0.017
	Mr. President	---	---	0.042 to 0.14
	Houdini	---	---	0.005 to 4.4
	Fire in the City	---	---	0.042 to 0.11
	Decent Men	---	0.10 to 0.40	---
Sound of Music	Sound of Music	---	0.02 to 190	---
	Wedding	---	0.75 to 6.5	---
	Final Abbey	0.24 to 32	1.5 to 2.1	---

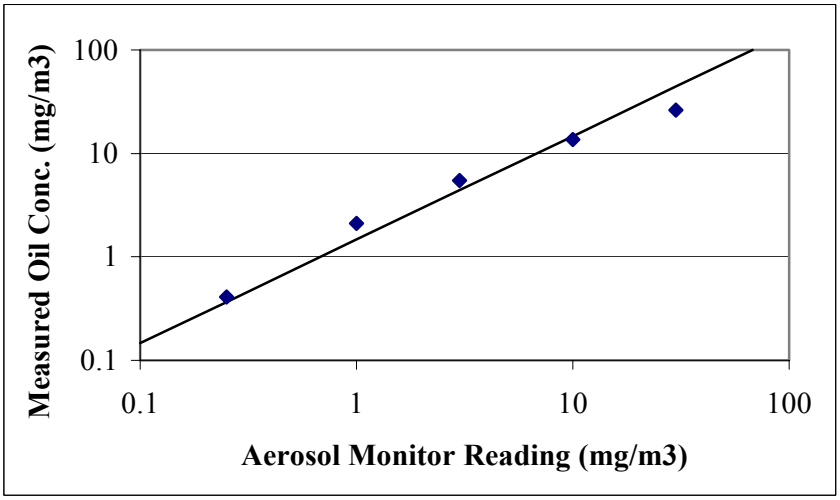
Notes:
Concentration data represent range in 15-second average concentrations during a scene across six to nine sections of the stage.

TABLE IV-10 Time-Weighted Full Show Average Concentration Data (Based on Detailed Sampling)			
Show	**Total Glycols (mg/m^3)**	**Mineral Oil (mg/m^3)**	**Pyrotechnics (mg/m^3)**
Beauty & the Beast	0.015	---	0.014
Cats	---	1.91	0.009
Jekyll & Hyde	0.90	0.18	---
Les Miserables	1.84	---	---
Miss Saigon	0.94	---	---
The Phantom of the Opera	0.20	0.32	0.006
Ragtime	---	0.009	0.012
Rent	---	1.14	---
Sound of Music	0.13	0.95	---
Broadway Average	**0.73**	**0.74**	**0.010**
Note: Concentrations represent stage-wide averages			

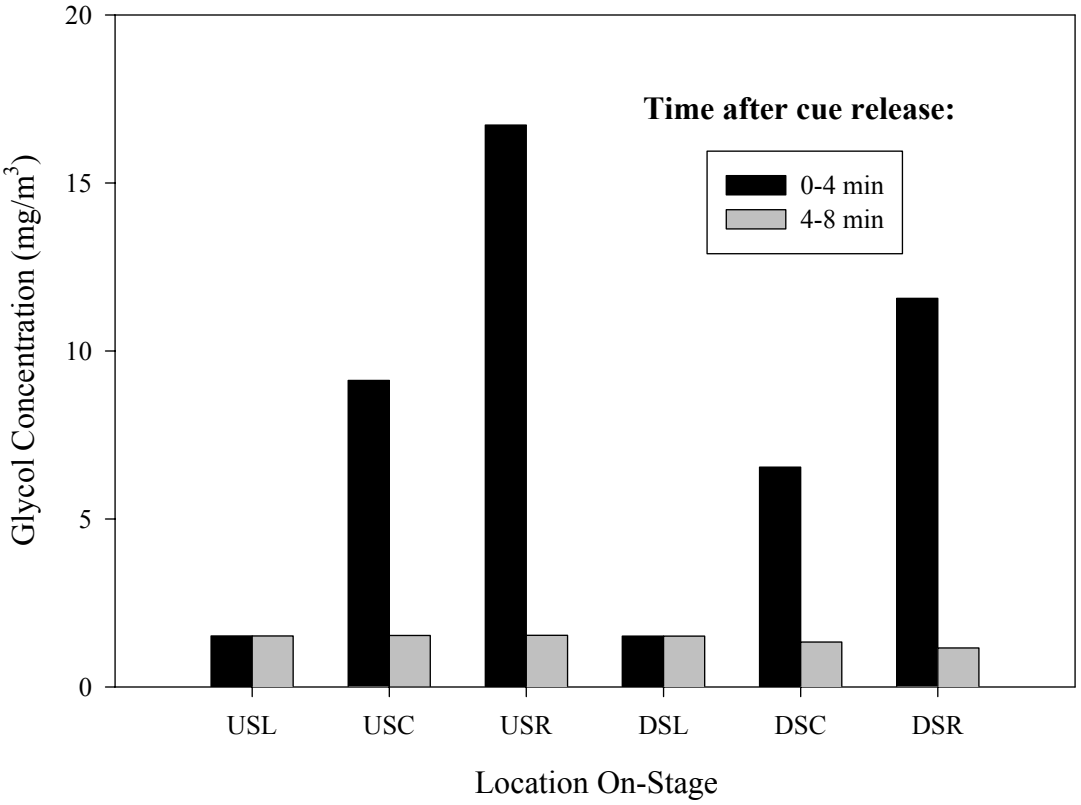
TABLE IV-11 Peak Glycol Concentrations		
Show	**Potential Peak Concentration (mg/m^3)**	**Maximum Measured Short-Term Exposure Concentration (mg/m^3)**
Beauty & the Beast	0.37	0.37
Jekyll & Hyde	150	23
Les Miserables	160	20
Miss Saigon	80	46
The Phantom of the Opera	80	37
Sound of Music	32	32
Note: Actual maximum concentrations received by an Actor may be somewhere in between the potential peak concentration and maximum measured short-term exposure concentration.		



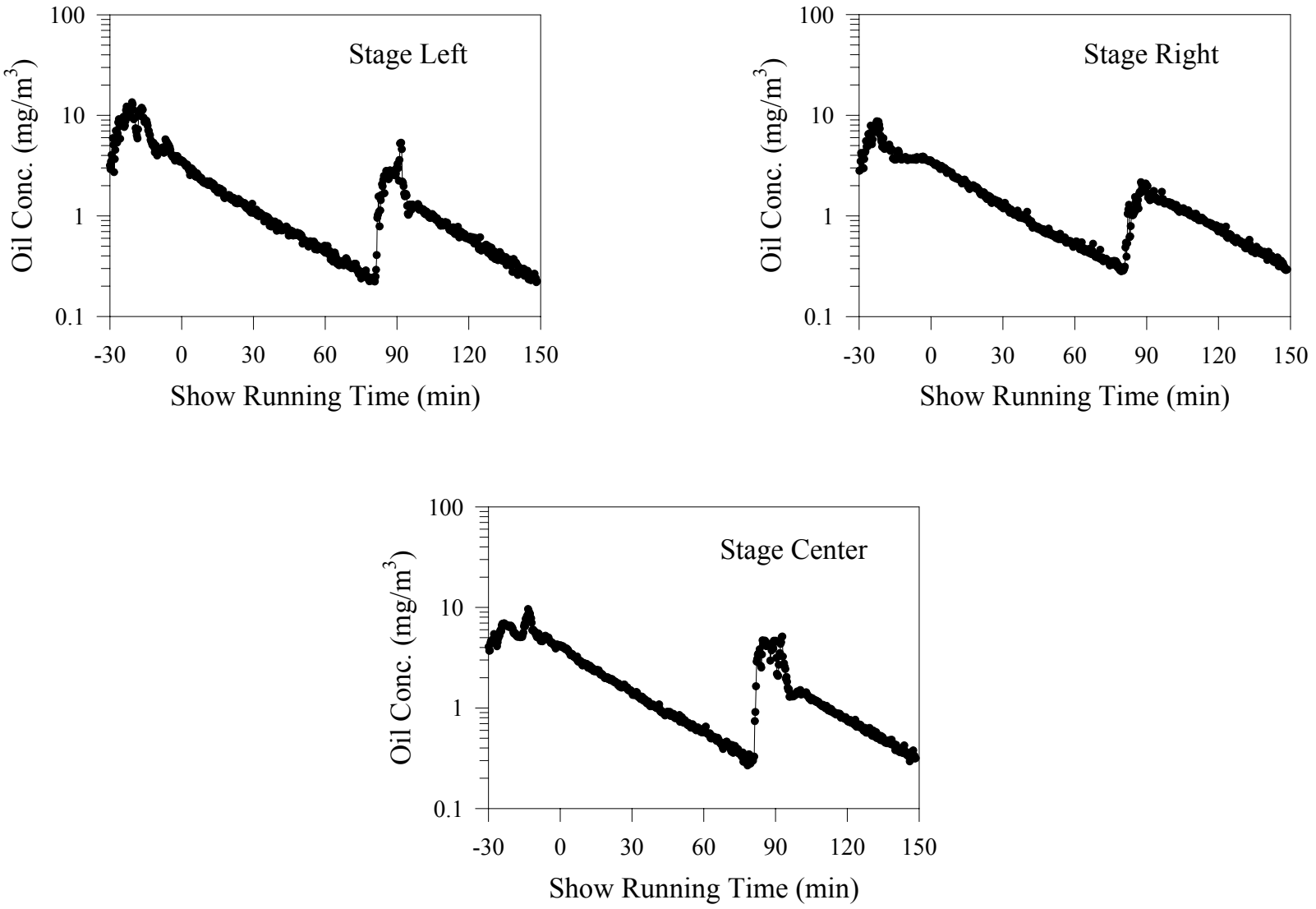
Figures IV-1. Schematic diagram of smoke formation using glycol-based fog machine



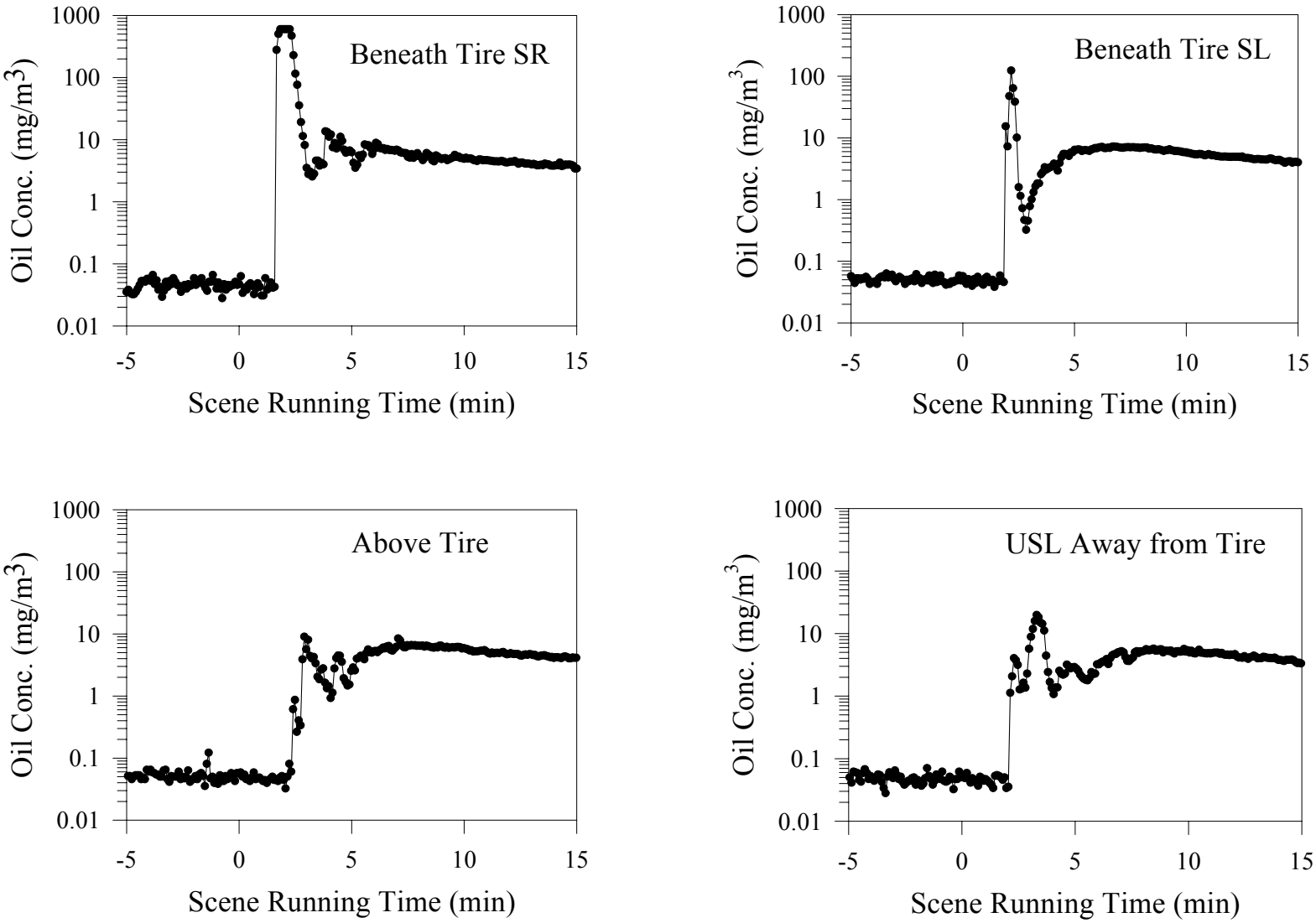
Figures IV-2. Calibration of portable aerosol monitors to mineral oil. Calibration factor of 1.47 developed to convert from Arizona road dust (for which units are precalibrated) to mineral oil.



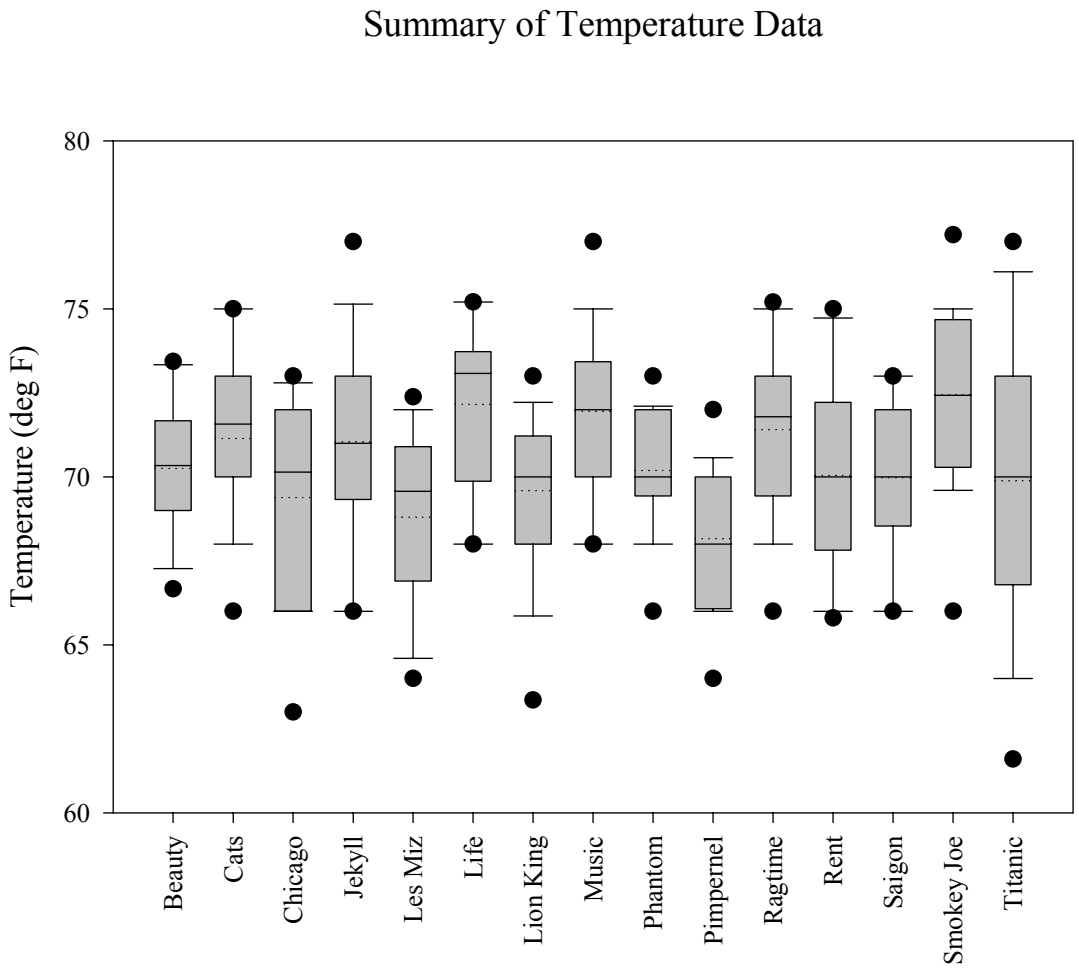
Figures IV-3. Total glycol concentrations measured from six on-stage locations during a scene from Les Miserables at two time periods following the release of a glycol cue. The glycol cue is released from upstage right (USR). The highest glycol concentrations immediately following the release of the glycol cue (time=0-4 min) are observed at USR and downstage right (DSR), with lower concentrations at upstage left (USL) and downstage left (DSL) and intermediate concentrations at upstage center (USC) and downstage center (DSC). After four minutes (time=4-8 min), concentrations are reduced to background levels across the stage.



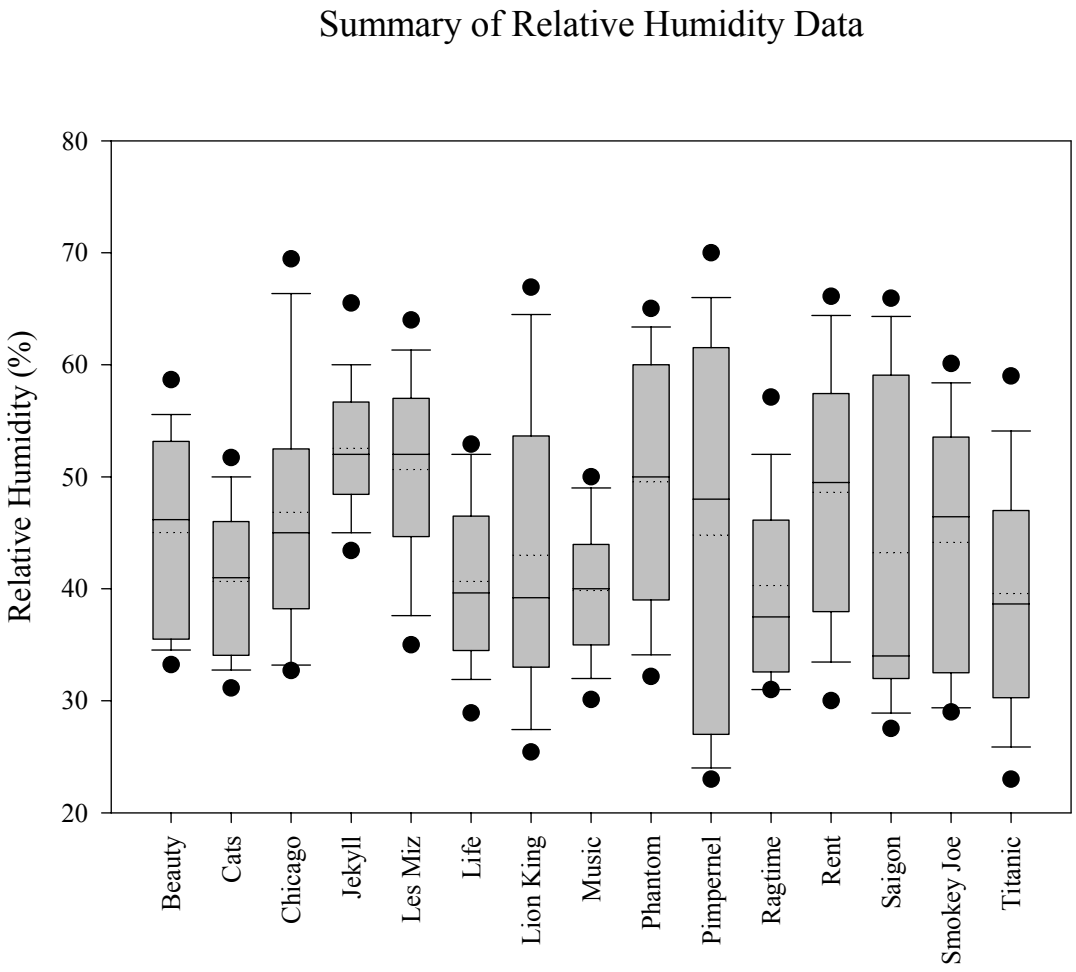
Figures IV-4. Mineral oil concentrations measured from three on-stage locations during a performance of Rent. Mineral oil is released from stage left for a 20-minute period prior to the beginning of the first act (ending at time=0 min). After oil release is discontinued, concentrations decrease exponentially with time. Mineral oil is released again from stage left for a 20-minute period between the first and second acts (approximately time=80 to 100 min). Oil concentrations are similar at all three sampling locations across the stage.



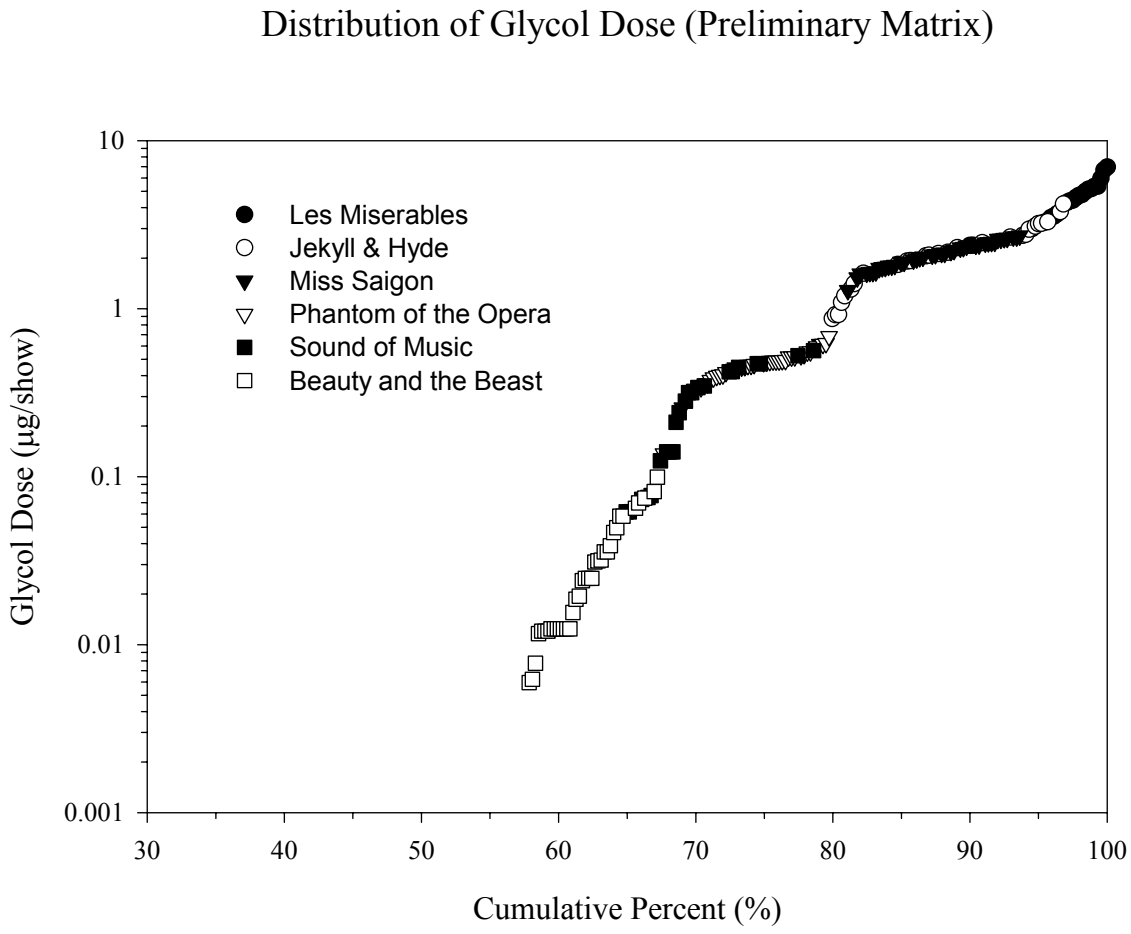
Figures IV-5. Mineral oil concentrations measured from four on-stage locations during the Journey/Addressing The Cats scene from Cats. Two minutes into this scene, mineral oil released for a one-minute period from beneath a giant tire, with Actors located beneath, above, and away from the tire. Oil concentrations during the one-minute cue release period are highest beneath the tire. After cue release is discontinued, oil concentrations approach similar levels across the stage (approximately 5 to 10 mg/m^3).



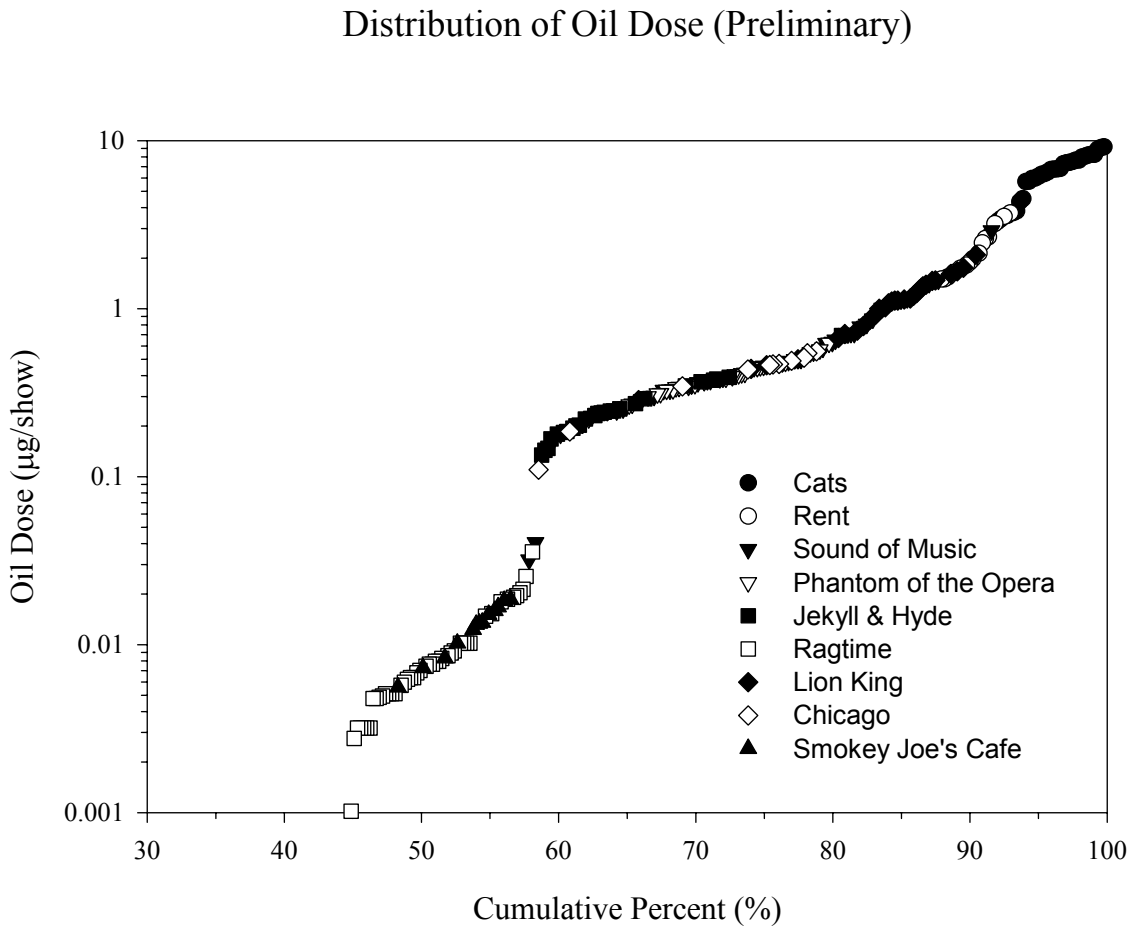
Figures IV-6. Summary of on-stage temperature data collected between January 1998 and May 1999. Box represents the 25th, 50th, and 75th percentile values; dashed line represents the mean value; error bars represent the 10th and 90th percentile values; and circles represent the 5th and 95th percentile values.



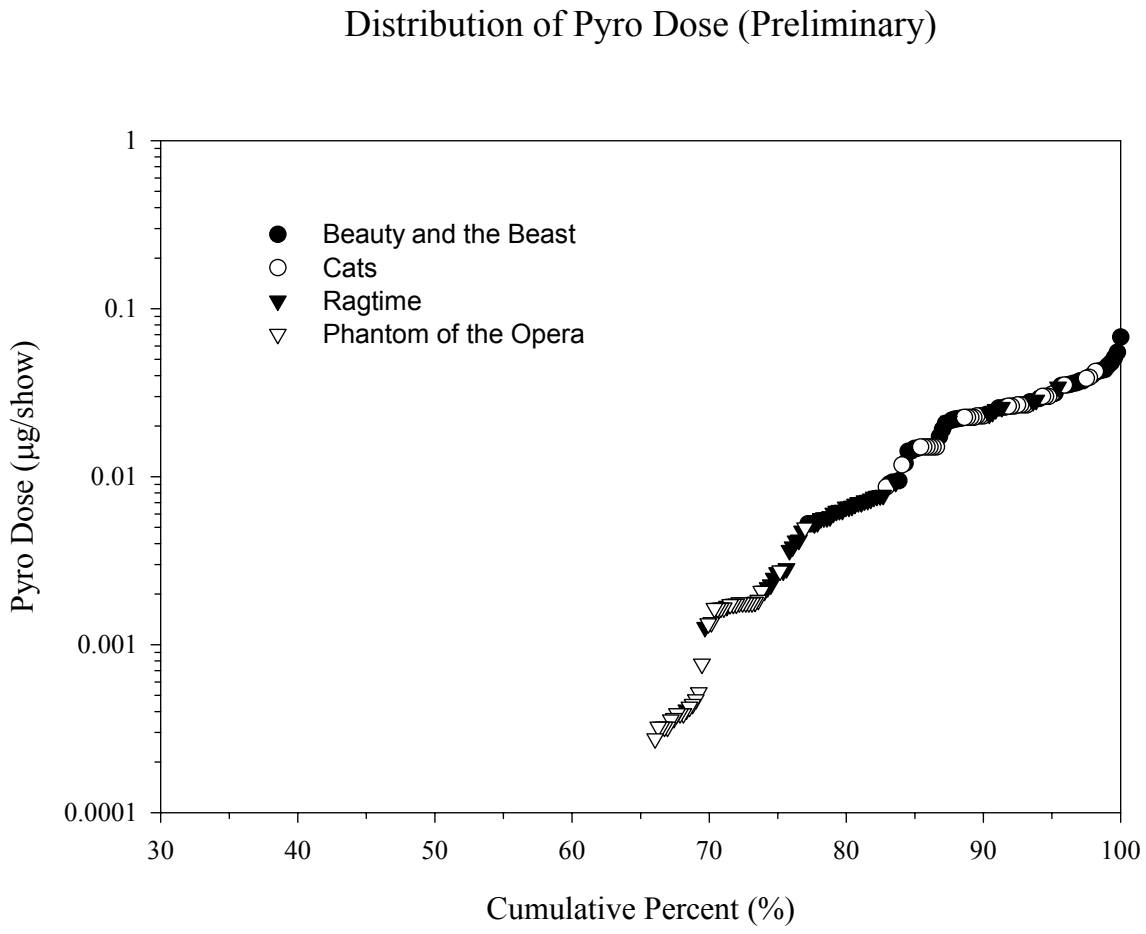
Figures IV-7. Summary of on-stage relative humidity data collected between January 1998 and May 1999. Box represents the 25th, 50th, and 75th percentile values; dashed line represents the mean value; error bars represent the 10th and 90th percentile values; and circles represent the 5th and 95th percentile values.



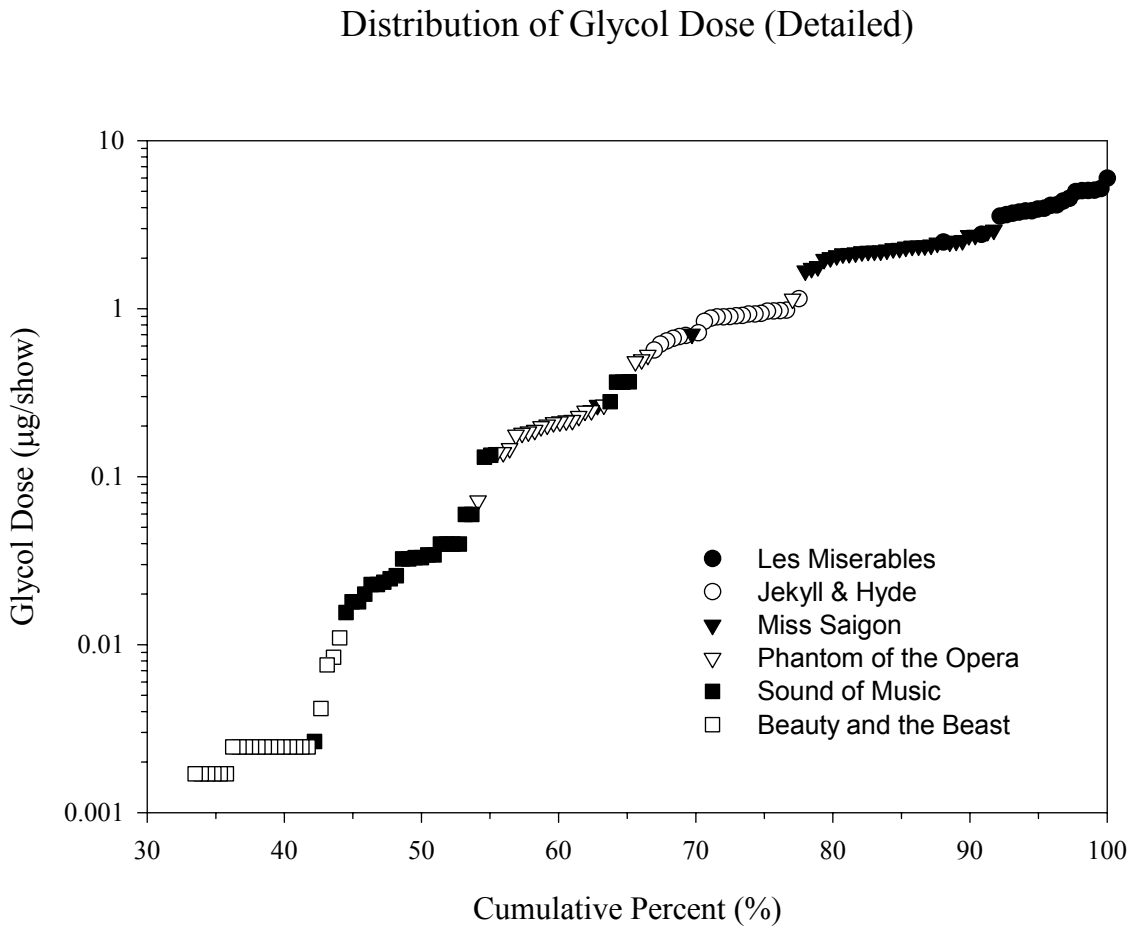
Figures IV-8. Cumulative distribution plot of potential Actor exposures to glycols, based on preliminary exposure matrix.



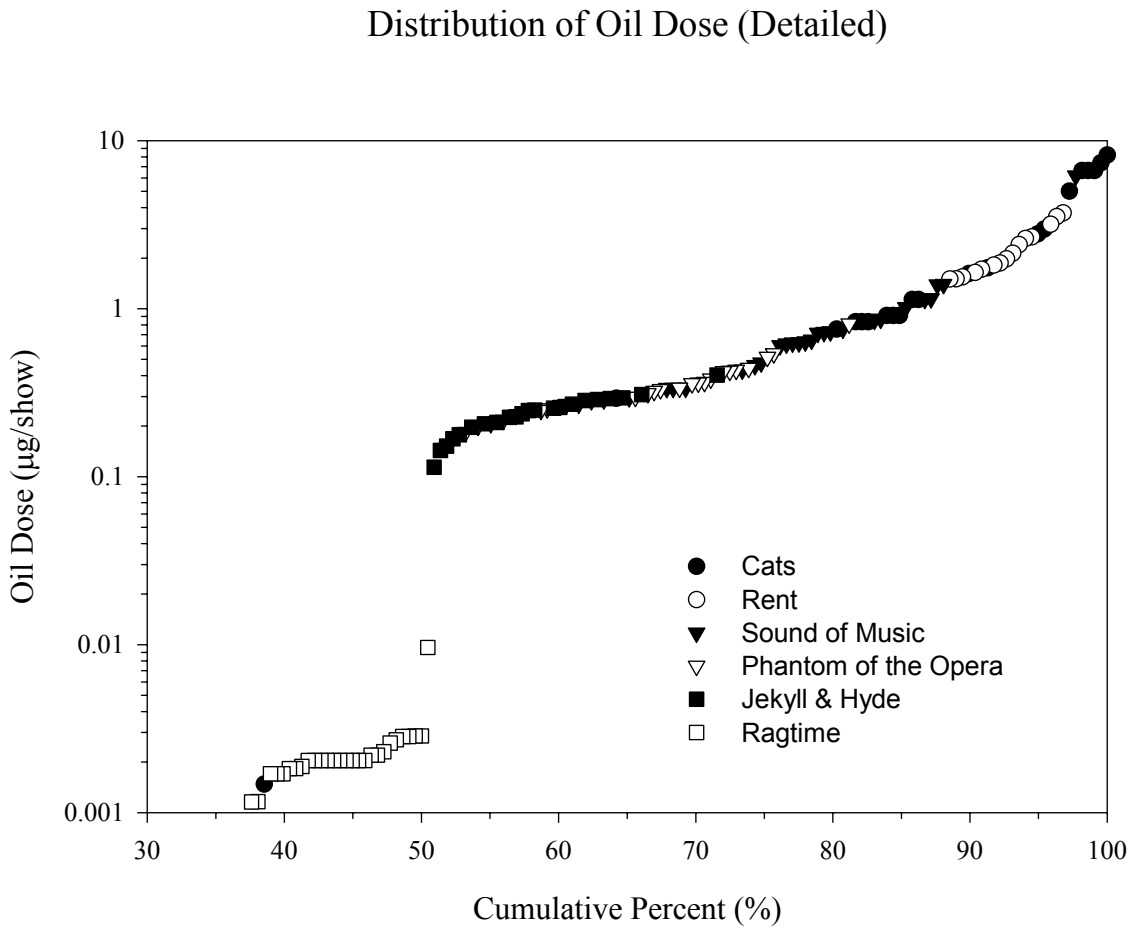
Figures IV-9. Cumulative distribution plot of potential Actor exposures to mineral oil, based on preliminary exposure matrix.



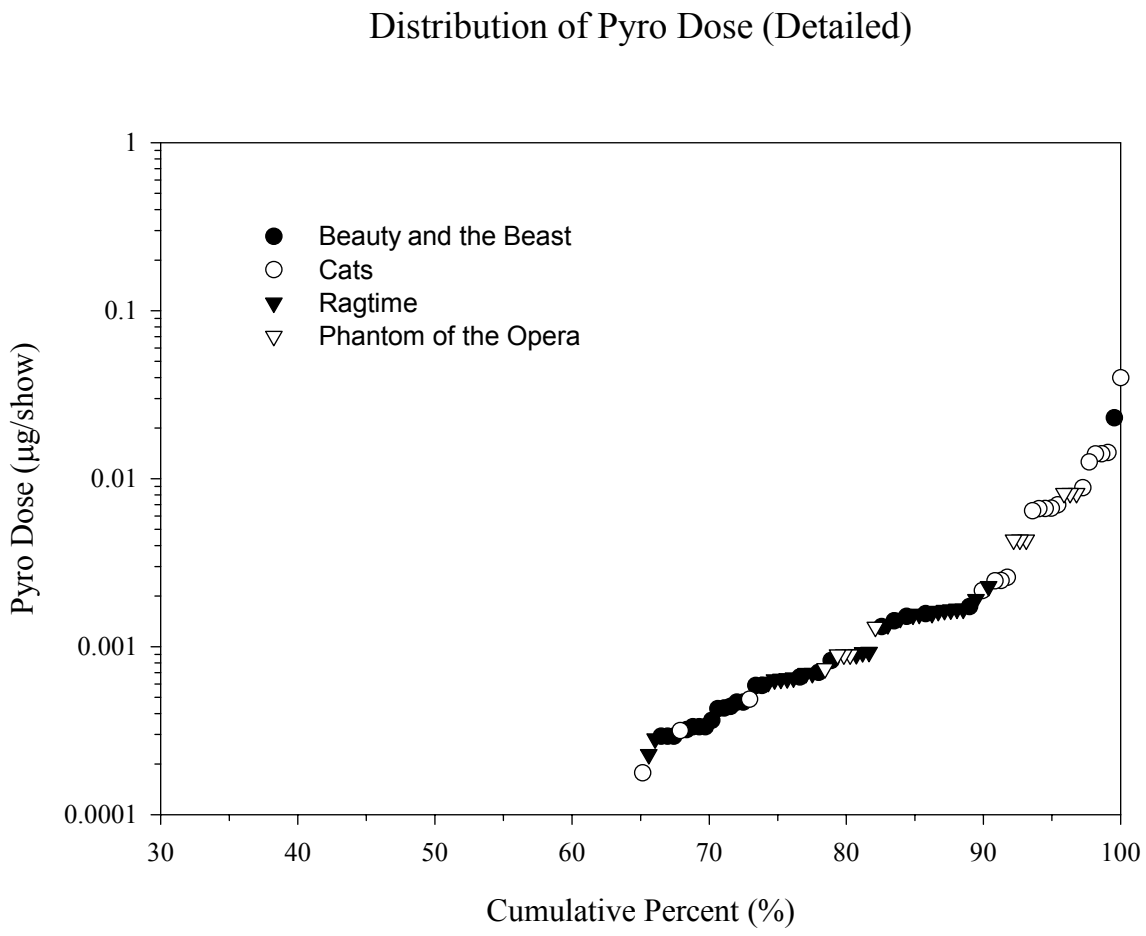
Figures IV-10. Cumulative distribution plot of potential Actor exposures to pyrotechnics, based on preliminary exposure matrix.



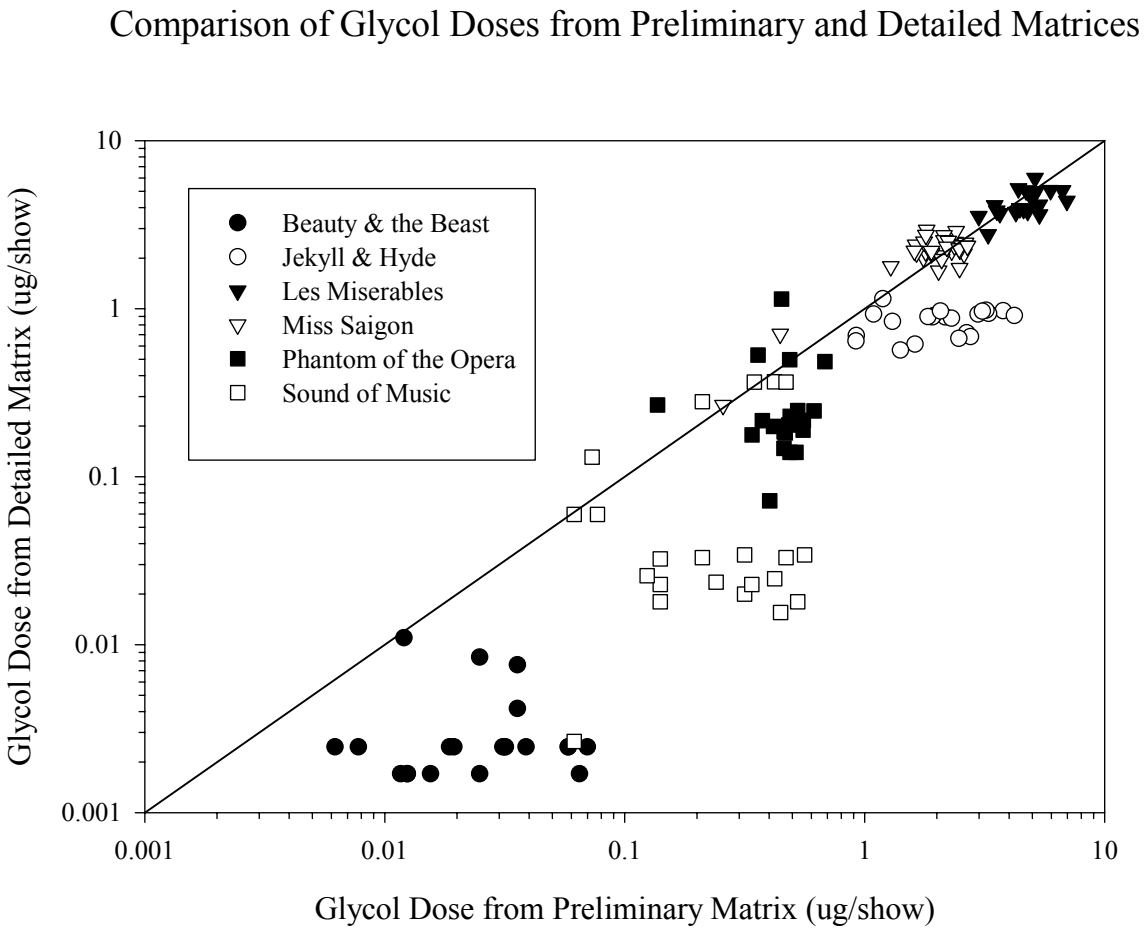
Figures IV-11. Cumulative distribution plot of potential Actor exposures to glycols, based on detailed exposure matrix.



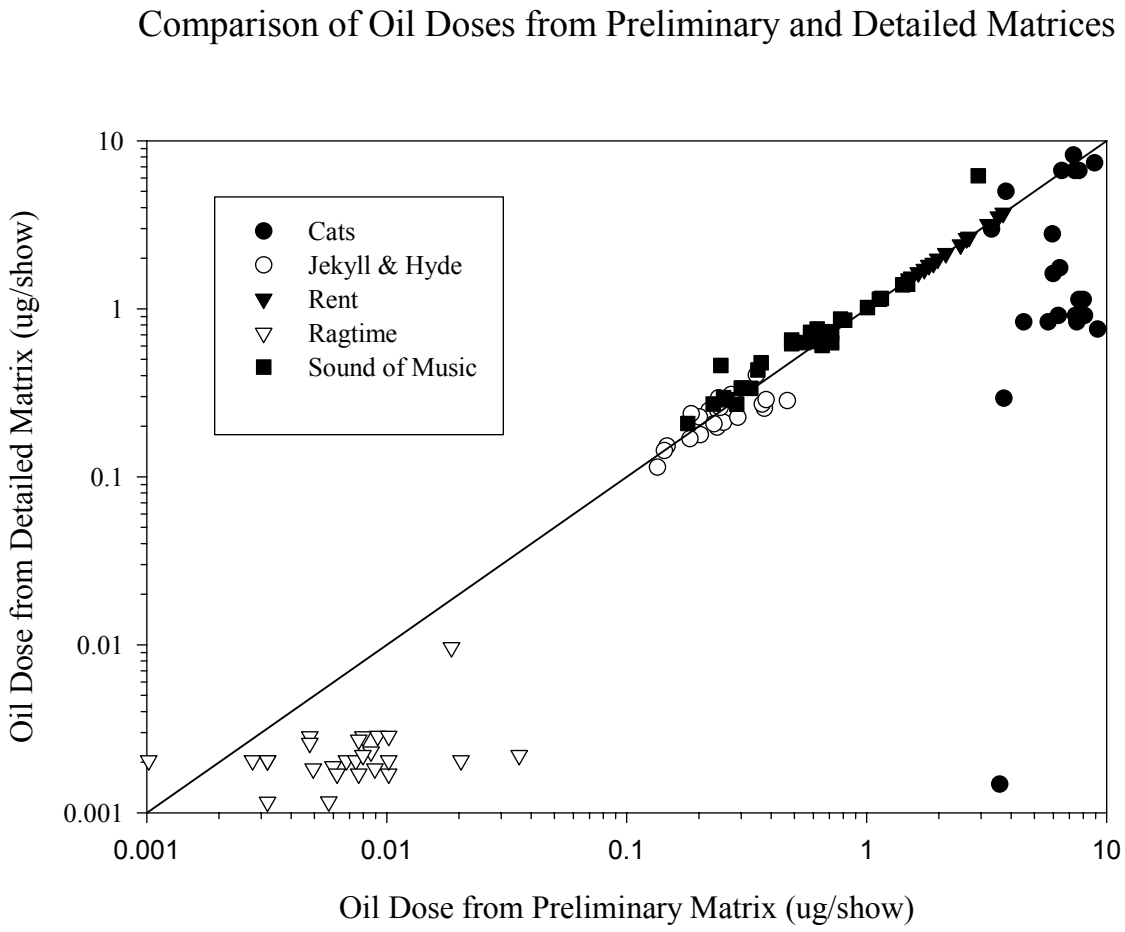
Figures IV-12. Cumulative distribution plot of potential Actor exposures to mineral oil, based on detailed exposure matrix.



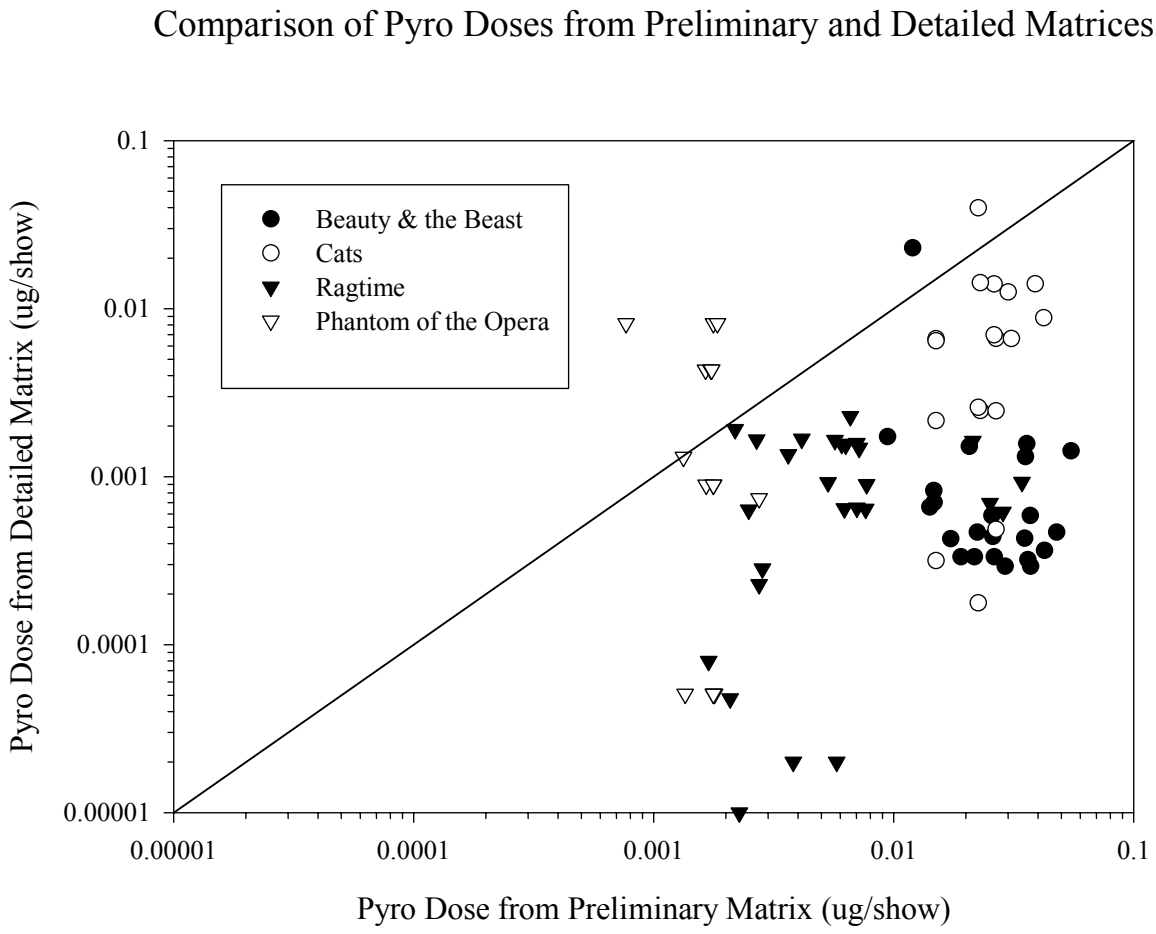
Figures IV-13. Cumulative distribution plot of potential Actor exposures to pyrotechnics, based on detailed exposure matrix.



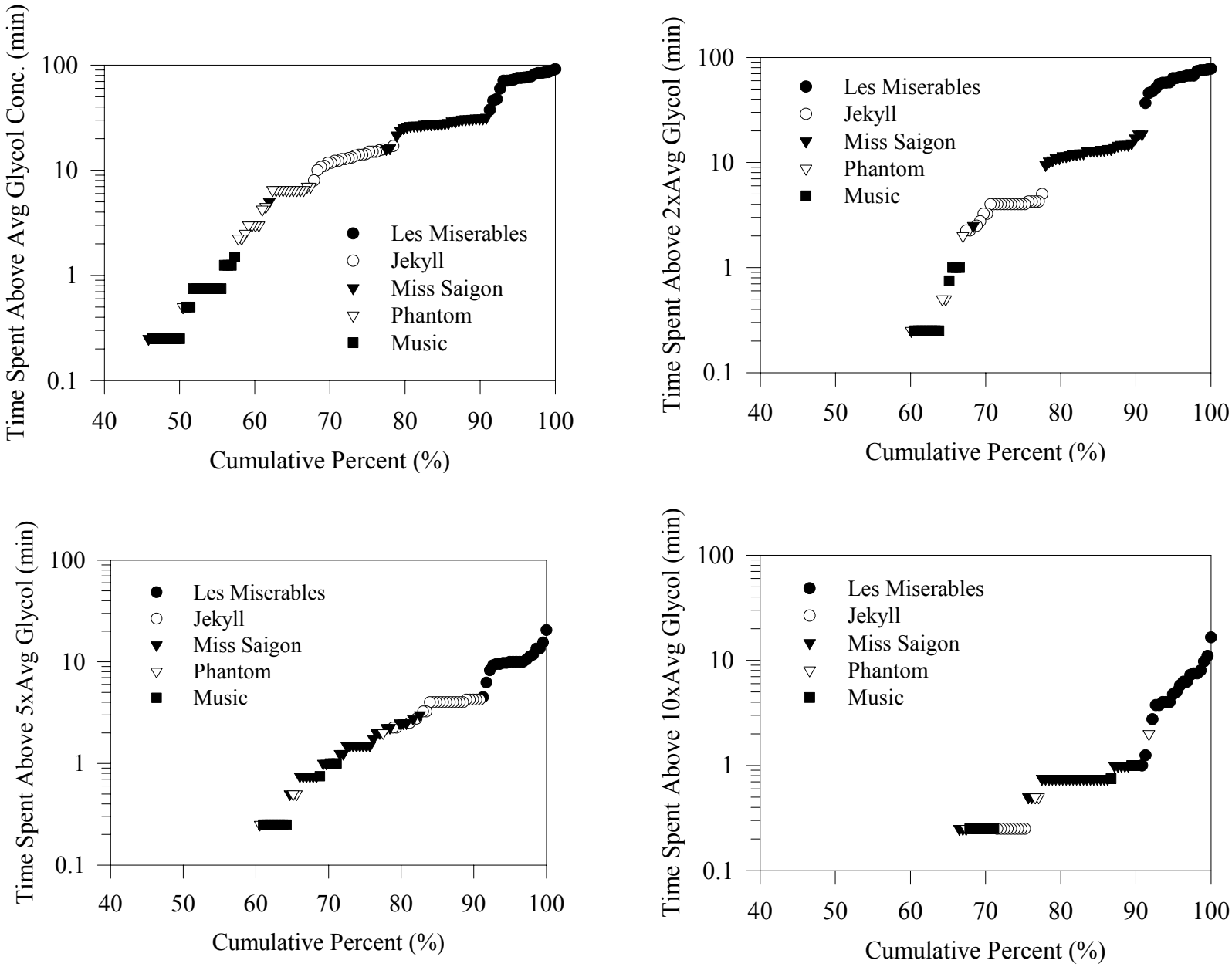
Figures IV-14. Comparison of potential Actor exposures to glycols from preliminary and detailed exposure matrices.



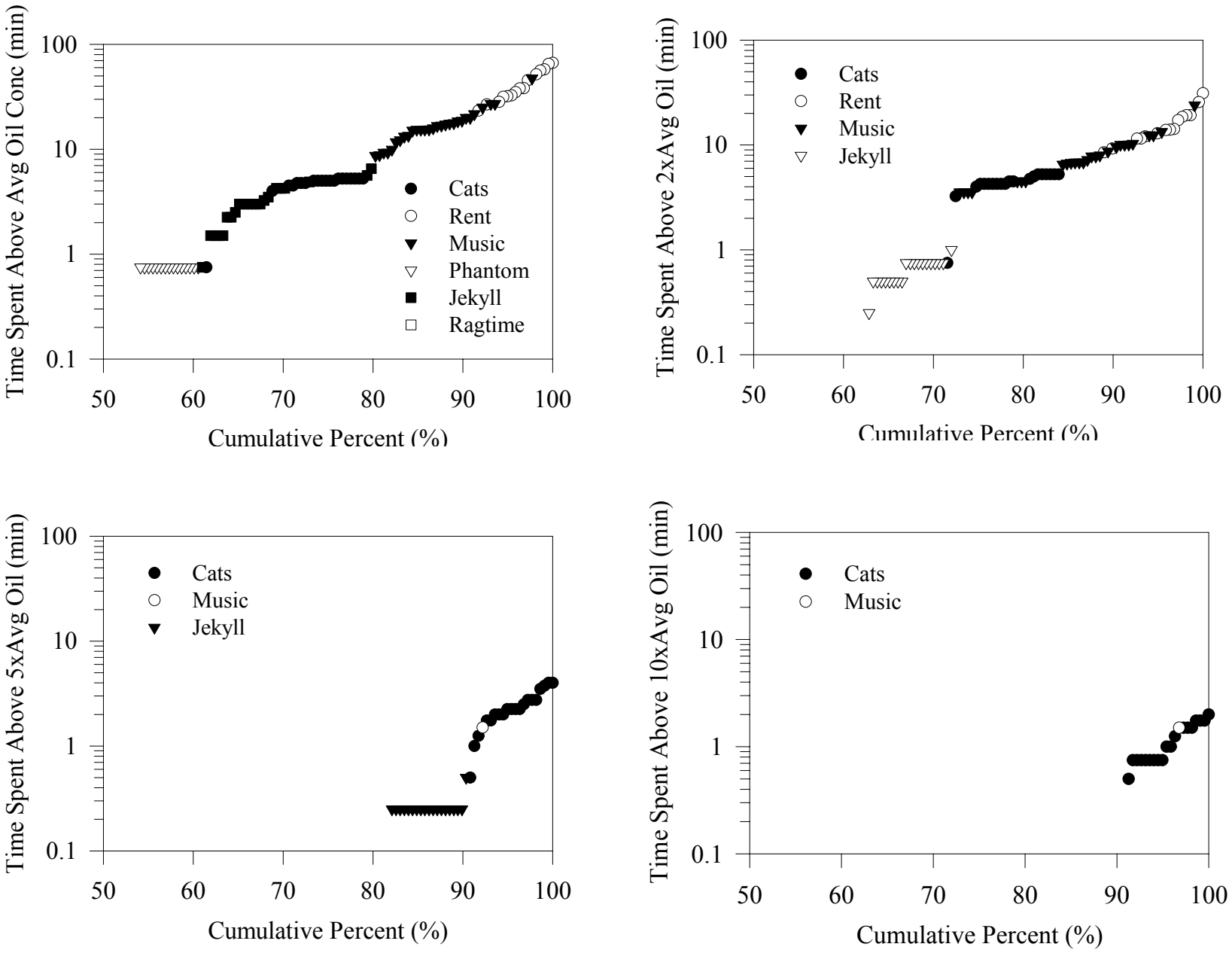
Figures IV-15. Comparison of potential Actor exposures to mineral oil from preliminary and detailed exposure matrices.



Figures IV-16. Comparison of potential Actor exposures to pyrotechnics from preliminary and detailed exposure matrices.



Figures IV-17. Cumulative distribution plot of amount of time (min) spent by Actors exposed to glycol concentrations that exceed the average, two times the average, five times the average, and ten times the average Broadway-wide glycol concentration (0.73 mg/m^3). Cumulative percent based on exposures estimated for 218 Actors included in detailed exposure matrix.



Figures IV-18. Cumulative distribution plot of amount of time (min) spent by Actors exposed to mineral oil concentrations that exceed the average, two times the average, five times the average, and ten times the average Broadway-wide mineral oil concentration (0.74 mg/m^3). Cumulative percent based on exposures estimated for 218 Actors included in detailed exposure matrix

V. RESULTS OF HEALTH EFFECTS EVALUATION

A. Phase 1 – The Baseline Questionnaire

1. Characteristics of the Phase 1 Study Population

a) Demographic Characteristics and Professional Experience

A total of 439 adult Actors comprise the study population for the Phase 1 statistical analyses. Descriptive characteristics of the overall study population are presented in Tables V-1 and V-2, showing their range of demographic characteristics and professional experience. The average age of the Actors was 36 years, with a range from 18 to 81 years. Two-thirds of the Actors were in the ensemble. All vocal categories were represented in the study. The study participants were, on average, very experienced; the average time as a professional Actor was 14.6 years. Most Actors had been in their current production for at least a year, with an average time in the show of 18.4 months. Many Actors had been exposed to theatrical smoke, haze or pyrotechnics in previous productions. They spent time in vocal training for over two hours per week, on average, and had participated in vocal training for over nine years on average. They spent less than two hours per week singing outside the production. Work outside of the theater, aside from other performances, was uncommon and did not contribute to symptoms. Similarly, previous work history did not relate to current symptoms. The predominant type of pre-theater work was clerical, food service or teaching.

b) Other Personal, Environmental and Performance Characteristics

The baseline questionnaire also collected information on factors that might confound an observed association between exposure to theatrical effects and symptoms. These included ***personal factors*** (such as cigarette smoking, and medical history), ***environmental factors*** (such as type of home, type of home heating, use of air conditioners and humidifiers, and prevalent water damage, mildew or cockroach infestation), and ***performance factors*** (such as the objective measures of vocal demand or physical demand of the role(s) performed). Each of these variables was evaluated as a potential confounder of the associations between theatrical exposures and symptoms or clinical findings.

Table V-3 presents the distributions of environmental factors and Table V-4 shows the prevalence of chronic medical conditions that could increase the risk of the symptoms of interest in this study. The most common chronic medical condition reported was seasonal allergies, which affected nearly half of the Actors. A slightly higher proportion of Actors reported worsening of their allergies since starting work in theatrical productions compared to those who felt there was no change. Ten percent of Actors developed adult-onset asthma since starting work in theatrical productions, but there was no reported worsening of symptoms from working in musical productions. The percentage of all Actors requiring asthma medication was 5.2%, a number consistent with national averages for adults. Less than five percent of Actors reported chronic medical conditions affecting their voice. While five percent stated that they had a

history of vocal cord lesions, only 3.2% reported chronic hoarseness and 4.6% reported chronic laryngitis. Less than 12% of Actors were currently smoking cigarettes.

c) Missed Performances Due to Illness or Injury

The proportion of cast members in each show that reported missing performances during the past year due to illness or injury is shown in Table V-6. For several shows, musculoskeletal injury was by far the most common reason for missing work, particularly for Rent (60% of the cast) and Cats (58.8% of the cast). The number of performances missed due to an illness or injury in the past year, which ranged from zero to 82 performances, was highest on average for Rent (13.9), Chicago (12.8), Miss Saigon (7.5), Les Miserables (7.4), and Smokey Joe's Cafe (7.4). When four extremely high values for missed performances (one Actor each from Rent, Chicago, Ragtime, and Miss Saigon with greater than 60 absences) were excluded from the analysis, the ranking by show did not change.

d) Exposure to Theatrical Effects

Among the 439 adult Actors who comprise the Phase 1 study population, 57% work in shows that use glycols, 57% work in shows that use mineral oil, 35% work in shows that use pyrotechnics, and 8% work in shows that do not use any of these three theatrical effects. However, there is variability in level of exposure among the individual Actors in a show that uses effects, with some Actors actually receiving no measurable exposure and some much more than the average level. For this reason, the majority of statistical analyses are based on the individual Actors' exposure measurements. However, as the table below shows, even with a study population of this size, the number of exposed Actors available for analyses decreases with increasing specificity of the exposure. Our ability to analyze some of the outcomes in relation to individual exposure measurements was hampered by small numbers of observations, very limited range of some of the exposure variables, and nonparticipation by some Actors with the highest exposures.

Exposed to:	**Preliminary Measurement (N=439)**		**Detailed Integrated Dose (N=218)**		**Greater than 2x Average (N=218)**		**Greater than 5x Average (N=218)**	
	Any	***None***	***Any***	***None***	***Any***	***None***	***Any***	***None***
Glycol	183	256	145	73	88	130	87	131
Mineral Oil	244	195	136	82	81	137	40	178
Pyrotechnics	147	292	82	136	69	149	54	164

2. Symptom Prevalence Rates in the Phase 1 Study Population

Participants were asked to report whether they experienced symptoms in five categories that may be associated with exposure to irritants. Symptoms affecting the pulmonary or upper respiratory tract (the chest, throat, nose and sinuses), the eyes, and other related symptoms during the month prior to the questionnaire administration were reported as "None =0," "Occasionally =1," or "Frequently =2." The prevalence rates for each of the symptoms included in the questionnaire are shown in Table V-7.

The prevalence of every one of the throat symptoms was particularly high, ranging from 39.7% (coated cords) to 55.8% (excess phlegm). Dry throat, irritated throat and sore throat were reported by 54.7%, 48.8% and 39.9% of Actors, respectively. Forty-six percent of Actors reported a change in voice maneuverability, and 42.8% had complaints of a hoarse voice.

The prevalence of nasal symptoms was also high, with over 53% of Actors reporting nasal congestion. Post-nasal drip, sneezing, congested sinuses and sinus headaches were also reported frequently. Chest symptoms, predominantly cough and phlegm production, were reported by the majority of Actors (50.4% and 65.4%). Almost 31% of Actors complained of shortness of breath; all other chest symptoms were reported in less than 25% of Actors. Approximately 30% of Actors complained of dry (31.2%) or itchy (29.2%) eyes.

Several health-related conditions with no relevance to irritant exposure were included in the questionnaire to assess potential over-reporting of symptoms; they were reported by fewer than 10% of the participants and were not associated with exposure. "Other symptoms" not listed in the questionnaire were written in by less than 1% of the participants.

3. Average Phase 1 Symptom Scores by Show

Because of differences in the time spent and location on-stage among any show's cast, levels of exposure within a show are not uniform for all Actors. Therefore, the majority of our statistical analyses are based on the individual Actors' exposure estimates. However, it was of interest to see if differences in the occurrence of symptoms were evident across shows. Average Phase 1 symptom scores were compared among the 16 shows, grouped by glycol/oil/pyrotechnics exposure category (None, Low, High), as determined by the preliminary average exposure measurement for the shows. These Phase 1 results are presented in Figures V-1 to V-7 for the seven general symptom scores that were collected in both Phases 1 and 2. (Comparable graphs for the Phase 2 results are presented in Figures V-8 to V-14.)

The values for all Phase 1 symptom scores were, on average, lowest in the two "control" shows (High Society and The Scarlet Pimpernel) that used no theatrical effects. Scores for any symptoms, for throat symptoms, and for chest symptoms were higher for shows with high glycol exposure (especially Les Miserables) and shows with high mineral oil exposure (especially Rent). The lack of clear dose-response trends may be due to the variation in exposure within shows, as described above. No interaction between the types of exposures was evident, but the majority of shows used either glycol or mineral oil but not both, and only four shows used any pyrotechnics.

4. Associations between Phase 1 Symptom Scores and Individual Exposure Levels

For each exposure (glycols, mineral oil, and pyrotechnics), two types of statistical analysis were conducted and the results are summarized in sections 4.a-c below. In the first analysis, Phase 1 symptom scores for individual Actors were compared with their exposure values from the "preliminary" and "detailed" exposure matrices. This analysis of symptom scores in relation to preliminary exposure values for all 439 Actors was conducted to determine whether any broad associations were apparent across the entire study population. The

comparison of symptom scores with the exposure values for the subset of 218 Actors was conducted to evaluate the nature of any associations identified from the preliminary comparison (e.g., peak exposures versus integrated dose).

Figures V-15 to V-56 present graphs relating the individual Actors Phase 1 symptom scores to their exposure values. These graphs present the results for any symptom (Figures V-15 to V-17) and symptoms associated with the chest (Figures V-18 to V-20), throat (Figures V-21 to V-38), nose (Figures V-39 to V-47) and eyes (Figures V-48 to V-56). Each set of graphs shows the association between one symptom score and four exposure estimates for each theatrical effect: a) the "preliminary exposure" values (μg/show) for all 439 Actors; b) the "preliminary exposure" values (μg/show) for the subset of 218 Actors for whom detailed sampling was also done; c) the "detailed peak exposure" (number of minutes spent at more than two times the Broadway average) for the subset of 218 Actors; and d) the "detailed integrated dose" measurements (μg/show) for the subset of 218 Actors. Data points were plotted using a numerical code to indicate an Actor's show (see Table III-1 for the shows' numerical codes).

The associations shown in these graphs are not adjusted for potentially confounding factors. In order to take these factors into account, and adjust for the impact of exposure to the other two types of theatrical effects, multivariable regression modeling was conducted. The regression models provide a numerical estimate, called the β coefficient, of the magnitude of the increase or decrease in a symptom score associated with an increase in an exposure variable. The strength of this association is tested for its statistical significance. A β coefficient is deemed "statistically significant" if the likelihood is less than 5% that the observed association occurred by chance; by statistical convention, this result is said to have "a p-value less than 0.05". (The β coefficients for the associations between glycol exposure and Phase 1 symptoms are shown in Table V-8.)

a) Glycol Exposure

In the graphical analyses, associations between Phase 1 symptom reporting and increasing glycol exposure level were observed for all Actors (n=439) and for those with detailed peak glycol exposure measurements (subset of n=218). Throat symptoms, in particular, were consistently associated with all the glycol exposure variables with similar findings for any throat symptoms or when restricted to symptoms of an irritated throat. The combination scores for vocal changes, hoarseness, excess mucus in the throat, and the feeling of "coated cords" were also associated with glycol exposure. Nasal symptoms also increased with increasing glycol exposure in both groups. However, for eye symptoms, only a weak association was seen between glycol exposure and dry or burning eyes.

The multivariable regression models that determined the impact of increasing glycol exposure level on symptoms were adjusted for levels of mineral oil and pyrotechnics exposure and the confounding effects of age, gender, months performing in the show, and seasonal allergies. Several other factors were considered as potential confounders, but none were found to contribute significantly to the model.

As seen in Table V-8, with the exception of eye symptoms, there was a statistically significant increase in symptoms with increasing preliminary glycol exposure level for all

Actors. Considering the detailed analysis of the subset of 218 Actors, it appears that increased symptoms are associated with peak exposures rather than integrated doses. For the variable that measured time spent at greater than two times the Broadway average for glycol exposure, all symptoms were increased with the exception of chest symptoms and eye symptoms. Throat symptoms in particular, considering either the score for any throat symptoms or the score for symptoms of an irritated throat, were statistically significantly associated with the preliminary and peak glycol exposure variables. In the total Actor population, the combination scores for vocal changes, hoarseness, excess phlegm in the throat, and the feeling of "coated cords" were significantly associated with glycol exposure. The association between peak glycol exposure and phlegm, coated cords and voice change was also evident for those Actors with a glycol exposure to greater than five times the Broadway average. Because of the diminished sample size for the subgroup with peak exposure measurements, it was not possible to perform several of the analyses of specific throat symptoms. In the total Actor population, there was a significant association between any chest symptoms and glycol exposure. However, this association was not significant in the subgroup of Actors with detailed peak exposure measurements.

There were no statistically significant associations between the integrated exposure measurement for glycol and increasing symptom scores among the 218 Actors included in the detailed analyses.

b) Mineral Oil Exposure

The graphical analyses show no strong or consistent associations between Phase 1 symptoms and mineral oil exposure. Irritated throat symptoms, in particular coated cords, vocal changes and hoarse voice, did appear to increase above 10 minutes at peak mineral oil exposure in the subset of 218 Actors with detailed exposure measurements. The increase in irritated throat symptoms with peak exposure was also statistically significant in the multivariable analyses (data not shown).

c) Pyrotechnics Exposure

The graphical analyses show no strong or consistent associations between exposure to pyrotechnics and Phase 1 symptoms. All the nose and sinus symptoms increased with the preliminary, but not the detailed, measurements. Irritated throat symptoms and itchy or watery eyes increased with the preliminary measurement, but only in the subset of 218 Actors. No statistically significant or consistent associations were observed for the multivariable analyses between exposure to pyrotechnics and symptoms using the preliminary, peak, or integrated exposure variables (data not shown).

B. Phase 2 – The Daily Checklists

1. Characteristics of the Phase 2 Study Population

All Actors who participated in Phase 1 were automatically enrolled in Phase 2, and they were given the first of the three Checklists on the day they completed the Questionnaire. Checklist 1 was returned by 301 of the 439 Actors (69%), Checklist 2 was completed by 153 Actors (35%), and Checklist 3 was completed by 100 Actors (23%).

Following consultation with our biostatistician, the statistical analyses were conducted on the largest subset of the Phase 2 data – over 50% of the Phase 2 data came from Checklist 1 only – that is most representative of all the study participants and least susceptible to selection factors. Comparison of the demographic and professional characteristics of the Actors who completed the first Phase 2 Checklist with the overall Phase 1 population (Table III-2) shows that they are similar in every respect. For example, those who completed Checklist 1 have comparable distributions for gender (53% male: 47% female), age (mean 37 years), experience as an Actor (mean 15.2 years), time in the current show (mean 18.2 months) and exposure to theatrical effects. The occurrence of symptoms during Phase 2 was examined according to Checklist number, season, and month of Checklist completion, and there was no significant variation in the rates of symptoms by any of these factors. Consequently, the Phase 2 analyses were performed using the 7,616 person-days of follow-up from Checklist 1.

2. Average Daily Symptom Scores during Phase 2 by Show.

Average daily symptom scores from Checklist 1 were compared among the 16 shows. The average Phase 2 symptom scores among Actors in each of the shows are presented as bar charts in Figures V-8 to V-14, grouped by glycol/oil/pyrotechnics exposure category (None, Low, High), based on the preliminary exposure measurement.

As in Phase 1, average scores for Phase 2 daily symptom scores are invariably very low in the two "control" shows (High Society and The Scarlet Pimpernel). Scores for any symptoms and for throat symptoms are higher for shows with glycol exposure and for shows with mineral oil exposure (especially Rent). Interaction between the types of exposures is difficult to evaluate with these crude groupings, but The Phantom of the Opera, which has short but measurable peak bursts of glycols and pyrotechnics, had elevated scores for throat, chest and eye symptoms.

3. Associations between Phase 2 Symptom Scores and Individual Exposure Level

Longitudinal trends in symptoms occurring over the Phase 2 study period were evaluated graphically by plotting the symptom scores among Actors by season, month, day of the week, weekend versus weekday, and number of performances. Furthermore, differences in the average symptom scores according to these "temporal" factors within categories of glycol, mineral oil and pyrotechnics exposure were evaluated. While there was no monthly or seasonal variation, increased symptoms occurred on weekends and on days with more than one performance (data not shown). This pattern was observed in all exposure categories. However, Actors in the high glycol exposure category, whether classified by the preliminary or the detailed measurement, showed highest levels of any symptoms, any throat symptoms, hoarse voice or voice change, and chest symptoms on days with more that one performance. No other interaction between exposure and temporal factors was evident.

Multivariable statistical analyses relating Phase 2 daily symptom scores to individual exposure levels were conducted, using the same exposure variables as the Phase 1 analyses (preliminary measurement for all Actors and the subset; detailed peak and integrated measurements for the subset). Potential confounding of the exposure-symptom relationships was assessed by adjusting for the effects of the personal and environmental factors considered for the

Phase 1 data, as well as the additional factors unique to the longitudinal Phase 2 data. These Phase 2 factors included the date of checklist completion (the month and season) as well as daily performance data, for example, number of performances and day of performance, i.e., weekday (Monday to Thursday) versus weekend (Friday to Sunday). Other covariates considered for inclusion in the models were daily physical or vocal conditioning activities, cigarette smoking, stress level at work and away from work, and concurrent illnesses and medication use. Insufficient data were available to analyze the role(s) played or the Actor's perception of the amount of theatrical effects.

No statistically significant associations were found between any of the theatrical effects exposure variables and the average daily symptom scores from Phase 2 (Table V-9). However, the preliminary glycol exposure variable did show consistent positive associations with incidence of symptoms, which approached statistical significance for any symptoms, any throat symptoms, any nose symptoms, and any eye symptoms. Mineral oil and pyrotechnics exposures showed no consistent associations.

In every regression model for Phase 2, the most consistent and significant predictors of the daily symptom score were the Actor's reported stress level at work and away from work; if the day was on the weekend; the number of performances; and the objective measure calculated for physical demand of the role(s) performed. (Data not shown in tables; available upon request.) For every type of symptom, these factors were overwhelmingly associated with the symptom scores for individual days or averaged over the whole checklist. The reason that these factors might have taken precedence over the theatrical exposure variables in the Phase 2 longitudinal analyses may reflect a limitation of the overall study design and consequent data collection. Actors' exposures were estimated by the one-time environmental measurements taken for each show, therefore, the values are invariant over the daily symptom score analysis. On the other hand, stress level and the number of performances were collected daily and thus could change over the course of the analysis. From both a statistical and an intuitive perspective, this variability would be important in estimating a meaningful change in symptom score associated with the predictor variables. Physical demand, which was also invariant over the daily symptom score analysis, also showed a stronger association with symptoms than exposure to theatrical effects. While it would be ideal to measure actual exposures at the same time the Actors were recording symptoms for a true longitudinal assessment of on-going exposure, this would have been exceedingly time-consuming and prohibitively expensive.

C. Phase 3 – The Medical Evaluations

1. Characteristics of the Phase 3 Study Population

Comparison of the demographic and professional characteristics of the Actors who participated in Phase 3 with the overall study population show that they are similar in most respects. For example, the 95 Actors enrolled in Phase 3 are comparable in their distribution by gender (48 men and 47 women), age (mean 36 years), experience as an Actor (mean 14.2 years), time in the current show (mean 19.9 months), and vocal and physical demand of their roles. They have a slightly longer history of working in shows with smoke or fog effects (22.9 months

versus 17.2 months), and a somewhat smaller proportion of current smokers (8.4% versus 11.8% overall).

2. Associations between Phase 3 Clinical Evaluations and Exposure Level

For Phase 3, data from the clinical evaluations were assessed to determine whether the exposures were associated with abnormalities evident at the pre-performance evaluation, as well as with acute changes in clinical measurements detected following a performance. Factors that were potential confounders of these associations were controlled for in the multivariable regression models; confounders were considered important to keep in the statistical model if they had a p-value of 0.30 or less.

For clinical variables measured on a continuous scale (i.e., the results of the pulmonary function tests and computerized acoustic analysis), the regression coefficient ***(β)*** measures the strength and the direction of the association between increasing exposure level and the measured outcome. A harmful effect of exposure on pulmonary function is evidenced by a *decrease* in a measurement (a negative sign on β), while a harmful impact on the voice is evidenced by an *increase* in an acoustical measurement (a positive β). Statistically significant regression coefficients have p-values less than 0.05. The multivariable linear regression models were adjusted for the three theatrical exposures plus, in some models, for covariates including show, months in the show, gender, age, cigarette smoking, months in shows with pyrotechnics exposure, vocal demand and physical demand.

The remaining Phase 3 analyses involved multivariable logistic regression analysis of categorical clinical variables (i.e., videoendoscopy/videostroboscopy of the vocal cords and perceptual rating of speech sample). The Relative Risk *(RR)* measures whether the probability of having an abnormal finding for a categorical variable is associated with increasing exposure level.[1] A RR=1.0 (the "null" value) indicates no increase in risk; RR=2.00 indicates a doubling of risk (a 100% increase in risk); RR=0.50 indicates a 50% reduction in risk. The statistical significance of a RR is expressed by the 95% Confidence Interval (CI). A statistically significant RR has a 95% CI that does not include the null value of RR=1.00. The multivariable logistic regression models were adjusted for the three theatrical exposures plus cigarette smoking.

a) Pulmonary function tests

Pulmonary function, as assessed by spirometry, included measurements of forced vital capacity (FVC), forced expiratory volume in the first second (FEV_1), the ratio of FEV_1/FVC as an indicator of airway obstruction, peak expiratory flow rate (PEFR), and peak expiratory flow in the mid-portion of the airways (PEF_{25-75}). Overall, the Actors in the study have normal pulmonary function for all these parameters, and have greater lung capacity than would be predicted based on their gender, age, height, weight, and ethnicity.

[1] For the preliminary and detailed integrated dose measurements, the RR and β correspond to increases of 1 μg of glycols and mineral oil, and for pyrotechnics 0.001 μg for the preliminary and 0.0005 μg for the detailed measurements. For time exposed to more than 2x or 5x the Broadway average, the RR and β correspond to increases of 1 minute of exposure for all the theatrical effects.

For Actors exposed to mineral oil, there was a consistent finding of lower forced vital capacity (FVC) and lower forced expiratory volume in the first second (FEV_1) at the pre-show measurement associated with peak exposures (see Table V-10). For Actors with the greatest exposure to mineral oil (those with exposure to greater than five times the Broadway average), there is a statistically significant decrease in FVC and FEV_1. For Actors with exposure at greater than two times the Broadway average, the finding was statistically significant only for FVC. The decreases in FEV_1 and FVC are more pronounced in those Actors with the highest exposure, especially with respect to the FVC. The decrease is potentially clinically significant; that is, the decrease in FVC with increasing time and peak mineral oil exposure may cause Actors to become symptomatic. The decreases in FVC and FEV_1 were concordant, therefore, there was no statistically significant decrease in the ratio of FEV_1/FVC. Cigarette smoking was related to a decrease in lung capacity, but this was not statistically significant. These results were controlled for other confounding factors, as described above.

There were no clinically significant abnormalities in pulmonary function tests associated with exposure to glycols or pyrotechnics. Furthermore, for most Actors there was a very mild, but not clinically or statistically significant, decrement in pulmonary function from before to after a performance associated with exposure to any type of theatrical effect. A small number of Actors in the shows utilizing bursts of mineral oil had substantial decreases in both FEV_1 and FVC in the post-performance measurement.

b) Computerized acoustic analysis

The quality of the acoustic signal produced when an Actor vocalizes, as measured objectively by computerized algorithms, is not negatively impacted by mineral oil exposure. Based on a comparison of pre- and post-performance analyses, a negative change in one of four voice quality parameters (jitter) following a performance was associated with increased time spent above two times and five times the Broadway average glycol concentration. At the pre-show evaluation, glycol exposure at greater than two times the Broadway average was associated with a statistically significant increase in shimmer (see Table V-11). Worsening from the pre- to the post-performance evaluation was found for the preliminary pyrotechnics exposure measurement, with significant increases in all the acoustic parameters (data not shown). Other significant predictors that remained in the models were cigarette smoking, age, female gender, months in the show, vocal demands and prior history of work in shows with smoke or fog exposure.

c) Videoendoscopy/videostroboscopy of the vocal cords

As seen in Table V-12, signs of inflammation (pharyngitis, laryngitis, and tracheitis) were increased at the pre-show evaluation in those Actors with increased glycol exposure over two times or five times the Broadway average exposure level. There was no evidence of acute increases in inflammation from before to after a performance. There were no statistically significant associations between any of the exposures and chronic (pre-show) or acute (pre- to post-show change) effects on vibratory functioning of the vocal cords. Fiberoptic findings such as increased edema and redness of the structures of the throat at the pre-show evaluation were not associated with any of the theatrical exposures; in fact, cigarette smoking was the strongest predictor. However, the acute change model showed an increase in fiberoptic findings was

significantly associated with the preliminary and the detailed integrated glycol exposure variables (data not shown). Increased pathologic findings were not associated with any of the exposures; in fact, Actors with mineral oil or pyrotechnics exposure had significantly fewer findings.

d) Perceptual rating of speech sample

The Actor's voice was recorded before and after a performance, and was rated by Dr. Woo for perceptible hoarseness, roughness (irregularity of vibration), asthenia (weakness), breathiness (turbulence), or strain (hyperfunction). On a scale of normal (0) to extreme (3), very few of the Actors had more than a slight (1) degree of abnormality. There were no significant associations between glycol, mineral oil or pyrotechnics exposure and pre-show abnormalities or changes following a performance.

Table V-1. **Phase 1: Demographic and Professional Characteristics of Actors (N=439)**

Characteristic	**% (n)**
Age at baseline questionnaire:	
18-25 years	10.9 (45)
26-30 years	21.2 (88)
31-35 years	23.2 (96)
36-40 years	20.5 (85)
41-45 years	10.4 (43)
46+ years	13.8 (57)
Missing	--- (25)
Gender: Male	53.3 (234)
Female	46.7 (205)
"What race do you consider yourself to be?":	
White, non-Hispanic	71.1 (312)
Black, non-Hispanic	14.6 (64)
Multiracial	5.9 (26)
Asian	5.7 (25)
Hispanic	1.8 (8)
Other	1.0 (4)
Highest level of education:	
High School/GED	9.8 (42)
Some College	27.2 (116)
College Grad	47.5 (203)
Graduate School	15.5 (66)
Missing	--- (12)
Current role type:	
Principal	34.6 (152)
Ensemble	65.4 (287)
Major vocal category:	
Soprano	26.9 (118)
Mezzo soprano	14.6 (64)
Contralto	3.4 (15)
Tenor	29.1 (128)
Baritone	22.1 (97)
Bass	0.7 (3)
Other	2.7 (12)
Non-singer	0.5 (2)

Table V-2. **Phase 1: Professional and Training Characteristics of Actors (N=439)**			
Characteristic		**Mean**	**Range**
Experience as professional actor		14.5 years	0-44
Time in current show		18.4 months	0-186
Smoke, fog or haze exposure in prior shows		6.6 months	0-260
Pyrotechnics exposure in prior shows		17.2 months	0-139
Training for singing:	Current time spent	2.2 hrs/wk	0-35
	Years of training	9.4 years	0-45
Training for speaking:	Current time spent	0.4 hrs/wk	0-20
	Years of training	2.6 years	0-30
Other singing (e.g., other performances)		1.7 hrs/wk	0-36
Other dancing (e.g., class or other performances)		1.4 hrs/wk	0-25
Physical exercise or conditioning		5.1 hrs/wk	0-21

Table V-3. **Phase 1: Environmental Factors Reported by Actors (N=439)**		
Characteristic		**%**
Cigarette smoking status:	Current	11.8
	Ex-smoker	21.0
	Never	64.9
	Missing	2.3
Type of home:	Apartment	81.5
		15.8
	House	0.7
	Other	
Home heating:	Forced air	9.1
	Hot water steam	51.7
	Other/unspecified	39.2
Air conditioning:	Central	11.6
	Room	67.4
	None	17.8
Conditions in the home (% saying "Yes"):	Water damage	32.6
		32.8
	Mildew	45.1
	Pet animals	34.0
	Cockroaches	53.3
	Humidifier used:	

Table V-4. **Phase 1: Prevalence of Chronic Medical Conditions Diagnosed by a Physician Reported by Actors (N=439)**	
Medical Condition	**%**
Seasonal allergies	48.5
Other allergies	25.7
Among those with allergies: Did allergies worsen since started performing? Yes No	 36.7 31.2
Asthma: As an adult Only as a child	10.0 5.0
Among those with adult asthma: Did asthma develop or worsen since started performing? Yes No	 7.1 2.5
Asthma currently treated with prescription medication	5.2
Chronic laryngitis	4.6
Chronic hoarseness	3.2
Vocal cord lesions	5.0

Table V-5. **Phase 1: Vocal Demand and Physical Demand of Participants' Role(s), by Show**

Show Name	Vocal Demand		Physical Demand	
	Mean	**Range**	**Mean**	**Range**
1. High Society	20.33	1 – 35	1.47	0.51 – 2.40
3. Cats	36.03	15 - 57	**2.34**	**0.73 – 3.56**
4. Chicago	23.77	7 – 37	1.79	0.63 – 2.46
5. Beauty and the Beast	14.32	0 - 49	1.64	0.45 – 2.95
6. Jekyll and Hyde	61.07	29 - 97	1.48	0.86 – 1.98
7. Les Miserables	43.76	7 – 87	1.87	0.83 – 2.77
8. Miss Saigon	47.33	11 - 89	1.51	0.51 – 2.19
9. Rent	**85.80**	**41 - 121**	**2.04**	**1.27 – 3.19**
10. The Scarlet Pimpernel	22.36	5 - 55	1.37	0.49 – 3.31
11. Smokey Joe's Cafe	**106.08**	**61 - 197**	1.54	0.89 – 2.19
12. Ragtime	34.67	5 - 67	1.39	0.45 – 2.69
13. The Life	25.88	0 - 55	1.40	0.18 – 2.30
14. The Phantom of the Opera	15.69	3 - 31	1.20	0.54 – 2.76
15. Titanic	29.69	9 -71	1.34	0.84 – 2.19
16. The Sound of Music	8.76	0 - 25	0.71	0.01 – 2.65
17. The Lion King	36.76	5 - 90	1.83	0.55 – 3.40
TOTAL	**34.7**	**0 – 197**	**1.52**	**0.01 – 3.56**

Vocal Demand = Calculation by vocal coach of the demand on the Actor's voice, incorporating role type and tessitura; the Actor's training and style; and the number of scenes in which the Actor sang.
Physical Demand = Calculation of cumulative physical demand exerted on the Actor per show, incorporating time and inhalation rate for all reported activities per scene.
Note: The shows with the two highest values are highlighted.

Table V-6. **Phase 1: Proportion of Cast who Missed Performances in the Past Year Due to Illness or Injury**

Show Name	Musculoskeletal Injury %	Head Cold %	Throat or Voice Problem %	Gastrointestinal Disorder %	Chest Cold %	Influenza %	Average # of Missed Performances
1. High Society	0	0	11.1	**22.2**	0	0	0.7
3. Cats	**58.8**	11.7	23.9	5.9	29.3	8.9	5.1
4. Chicago	5.0	21.4	21.4	7.1	42.8	14.2	12.8
5. Beauty and the Beast	**37.4**	15.6	18.7	9.4	21.4	18.8	5.8
6. Jekyll and Hyde	19.0	11.5	26.3	15.1	15.4	19.1	4.3
7. Les Miserables	25.0	25.8	**52.1**	0	10.0	25.8	7.4
8. Miss Saigon	**43.9**	12.1	31.7	9.7	26.8	29.3	7.5
9. Rent	**60.0**	33.4	**53.3**	33.4	13.4	0	13.9
10. The Scarlet Pimpernel	10.7	10.7	**35.7**	10.7	14.3	17.9	4.0
11. Smokey Joe's Cafe	**38.5**	0	**38.5**	7.7	15.4	7.7	7.4
12. Ragtime	**22.6**	15.2	15.1	12.6	12.6	10.1	4.5
13. The Life	18.9	6.3	12.6	**25.0**	18.8	**25.1**	6.3
14. The Phantom of the Opera	**37.5**	9.3	21.9	3.1	**34.3**	21.8	6.8
15. Titanic	5.8	8.6	**20.0**	8.6	**22.9**	14.3	3.4
16. The Sound of Music	8.8	5.9	8.8	2.9	**11.8**	5.9	1.5
17. The Lion King	**32.2**	0	7.2	10.7	7.2	10.7	1.6
ALL SHOWS COMBINED	**29.7**	**29.3**	**23.5**	**15.2**	**11.4**	**10.1**	**5.4 (Range 0 - 82)**

Note: For each show, the most common reason for missed performances is highlighted.

Table V-7. **Phase 1: Prevalence of Symptoms in the Previous Month Reported by Actors (N=439)**	
Chest Symptoms	**%**
Tight chest	24.2
Heavy chest	14.8
Short of breath	30.8
Cough	**50.3**
Excess phlegm in chest	**65.4**
Wheezing or whistling in chest	19.8
Respiratory tract infections	20.7
Chest pain	8.0
Throat and Mouth Symptoms	**%**
Dry throat	**54.7**
Irritated throat	48.8
Sore throat	39.9
Excess mucus or phlegm in throat	**55.8**
"Coated" vocal cords	39.7
Hoarse voice	42.8
Change in voice maneuverability	46.5
Mouth ulcers	13.9
Bleeding gums	7.7
Nose or Sinus Symptoms	**%**
Stuffy or congested nose	**53.5**
Runny nose	41.2
Post-nasal drip	44.2
Sneezing	46.0
Congested sinuses	**46.2**
Infected sinuses	21.7
Sinus headaches	31.0
Nosebleeds	7.7
Eye Symptoms	**%**
Dry eyes	**31.2**
Burning eyes	17.3
Itchy eyes	**29.2**
Watery eyes	23.2
Contact lens problems	18.0
Blurred vision	10.5

Note: The two symptoms with the highest prevalence in each category are highlighted.

Table V-7 (continued). **Phase 1: Prevalence of Symptoms in the Previous Month Reported by Actors (N=439)**	
Other Miscellaneous Symptoms	**%**
Dermatitis	5.0
Eczema	6.8
Psoriasis	2.9
Other skin rash	9.1
Headaches (not sinus)	**25.0**
Nausea	9.6
Vomiting	1.3
Fever	5.3

Table V-8. **Phase 1: Associations between Symptom Scores and Glycol Exposure Level**				
Symptom Score	**Preliminary Measurement (N=439)**	**Time at Greater than 2x Average (N=218)**	**Time at Greater than 5x Average (N=218)**	**Detailed Integrated Dose (N=218)**
	β	β	β	β
1. Any symptoms	**0.060***	**0.004***	0.005	0.017
2. Any chest	**0.050***	0.002	0.008	0.011
3. Any throat	**0.090***	**0.007***	0.014	0.021
4. Irritated throat	**0.080***	**0.006***	0.008	0.023
5. Phlegm + coated cords	**0.110***	**--**	**--**	0.032
6. Coated cords + voice change	**0.110***	**--**	**--**	0.058
7. Hoarse + voice change	**0.070***	**--**	0.015	0.046
8. Phlegm + coated cords + voice change	**0.110***	**--**	**0.025***	0.035
9. Any nose	**0.060***	**0.006***	0.009	0.051
10. Stuffy or congested nose	0.060	0.006	0.005	0.044
11. Any eyes	0.010	-0.001	-0.008	-0.028

The regression coefficient ***(β)*** measures the strength and the direction (increasing score or decreasing score) of the association between glycol exposure level and a symptom score. ***Statistically significant associations had p-values less than 0.05.** These multivariable linear regression models were adjusted for mineral oil and pyrotechnics exposure levels plus age, gender, months in the show, and seasonal allergies. (-- Indicates that a model could not be fit due to small number of observations.)

Table V-9. **Phase 2: Associations between Daily Symptom Scores and Glycol Exposure Level**				
Daily Symptom Score	**Preliminary Measurement**	**Time at Greater than 2x Average**	**Time at Greater than 5x Average**	**Detailed Integrated Dose**
	β	β	β	β
1. Any symptoms	0.010	--	0.003	0.008
2. Any chest	--	--	--	--
3. Any throat	0.013	0.001	0.002	0.006
4. Hoarse + voice change	0.006	0.0004	0.003	0.006
5. Phlegm + coated cords + voice change	0.011	-0.0002	-0.002	-0.002
6. Any nose	0.010	0.001	0.004	0.013
7. Any eyes	0.009	--	0.003	--

The regression coefficient ***(β)*** measures the strength and the direction (increasing score or decreasing score) of the association between glycol exposure level and a daily symptom score. **None of these results were statistically significant (no p-values were less than 0.05).** These multivariable linear regression models were adjusted for mineral oil and pyrotechnics exposure levels, whether Actor performed that day, weekend vs. weekday, stress at work, and stress away from work. (-- Indicates that a model could not be fit due to small number of observations.)

Table V-10. **Phase 3: Associations between Pre-Performance Pulmonary Function and Exposure**					
Function	**Exposure**	**Preliminary Measurement** β	**Time at Greater than 2x Average** β	**Time at Greater than 5x Average** β	**Detailed Integrated Dose** β
• FEV_1	Glycol	0.006	0.003	0.083	0.316
	Mineral Oil	-0.043	0.010	**-0.3681***	-0.073
	Pyrotechnics	-7.893	-0.056	0.047	5.535
• FVC	Glycol	-0.009	-0.016	0.071	-0.028
	Mineral Oil	-0.049	**-0.098***	**-0.596***	-0.025
	Pyrotechnics	-8.599	0.051	0.043	-19.815
• PEF_{25-75}	Glycol	-0.044	-0.020	0.026	0.267
	Mineral Oil	-0.101	0.008	-0.276	-0.154
	Pyrotechnics	-7.953	-0.062	-0.036	71.694
• FEV_1/FVC	Glycol	0.001	0.001	0.002	0.002
	Mineral Oil	0.001	0.003	0.003	-0.004
	Pyrotechnics	0.089	0.002	-0.007	3.345

FEV_1 = Forced expiratory volume in 1 second
FVC = Forced vital capacity
PEF_{25-75} = Peak expiratory flow in 25-75% range
FEV_1/FVC = Ratio of FEV_1/FVC (obstruction)
***Statistically significant associations had p-values less than 0.05.** These multivariable linear regression models were adjusted for the three theatrical exposures plus show, gender, cigarette smoking, months in shows with pyrotechnics exposure, vocal demand and physical demand.

Table V-11. **Phase 3: Associations between Pre-Performance Vocal Analysis and Exposure**					
Acoustical Parameter	**Exposure**	**Preliminary Measurement**	**Time at Greater than 2x Average**	**Time at Greater than 5x Average**	**Detailed Integrated Dose**
		β	β	β	β
• Fundamental Frequency	Glycol	-3.315	-1.300	-8.660	-26.564
	Mineral Oil	-3.243	1.423	0.261	-4.335
	Pyrotechnics	67.480	-18.023	-13.387	-3302.451
• Jitter (%)	Glycol	0.025	0.004	0.024	0.053
	Mineral Oil	0.005	0.001	-0.021	0.004
	Pyrotechnics	-1.668	0.025	0.100	11.723
• Shimmer (%)	Glycol	0.129	**0.018***	0.050	0.139
	Mineral Oil	0.083	0.024	-0.010	0.099
	Pyrotechnics	3.713	0.473	0.517	59.198
• Noise to Harmonic Ratio	Glycol	-0.001	-0.0001	0.009	-0.005
	Mineral Oil	0.002	-0.001	0.004	0.002
	Pyrotechnics	1.088	0.010	0.0004	3.592

***Statistically significant associations had p-values less than 0.05.** These multivariable linear regression models were adjusted for the three theatrical exposures plus age and gender of Actor, show, months in the show, and vocal demand.

Table V-12. **Phase 3: Associations between Pre-Performance Stroboscopic and Perceptual Findings and Exposure**									
		Preliminary Measurement		**Time at Greater than 2x Average**		**Time at Greater than 5x Average**		**Detailed Integrated Dose**	
Acoustical Parameter	**Exposure**	***RR***	***95% CI***	***RR***	***95% CI***	***RR***	***95% CI***	***RR***	***95% CI***
• Vibratory abnormality	Glycol	1.32	0.50-3.49	1.00	0.33-2.99	1.08	0.36-3.25	1.28	0.48–3.38
	Mineral Oil	0.71	0.26-1.90	1.33	0.47-3.78	0.56	0.11-2.78	0.81	0.29-2.26
	Pyrotechnics	0.62	0.23-1.69	0.54	0.18-1.68	0.54	0.16-1.84	0.51	0.18-1.46
• Fiberoptic observation	Glycol	0.60	0.25-1.47	1.37	0.51-3.68	1.16	0.42-3.18	0.58	0.24-1.41
	Mineral Oil	0.59	0.24-1.49	0.69	0.26-1.88	0.65	0.16-2.63	0.65	0.26-1.67
	Pyrotechnics	0.69	0.28-1.71	0.75	0.28-2.02	0.88	0.31-2.48	0.66	0.25-1.68
• Pathologic finding	Glycol	0.96	0.41-2.26	0.76	0.29-1.98	0.68	0.26-1.79	0.83	0.35-1.97
	Mineral Oil	**0.32***	**0.13-0.83**	0.63	0.25-1.58	**0.19***	**0.05-0.78**	0.42	0.16-1.06
	Pyrotechnics	0.70	0.29-1.98	**0.37***	**0.14-0.95**	**0.32***	**0.11-0.87**	0.52	0.21-1.26
• Inflammatory finding	Glycol	1.17	0.38-3.59	**3.17***	**0.97-10.31**	**3.43***	**1.05-11.23**	1.14	0.37-3.49
	Mineral Oil	1.39	0.42-4.59	2.56	0.76-8.54	1.04	0.20-5.39	1.72	0.48-6.13
	Pyrotechnics	0.41	0.12-1.41	0.29	0.06-1.40	0.17	0.02-1.40	**0.21***	**0.04-0.99**
• Grade	Glycol	0.37	0.10-1.33	0.48	0.10-2.38	0.22	0.03-1.77	0.34	0.09-1.25
	Mineral Oil	1.05	0.29-3.79	1.42	0.37-5.49	0.65	0.07-5.62	1.24	0.32-4.77
	Pyrotechnics	0.76	0.21-2.78	1.38	0.37-5.17	1.16	0.28-4.81	0.99	0.27-3.61

The Relative Risk ***(RR)*** measures the increase (*RR* > 1.0) or decrease (*RR* < 1.0) in risk of a clinical finding associated with an increase in exposure level. ***A statistically significant *RR* has a 95% Confidence Interval that does not include the null value of *RR*=1.00.**

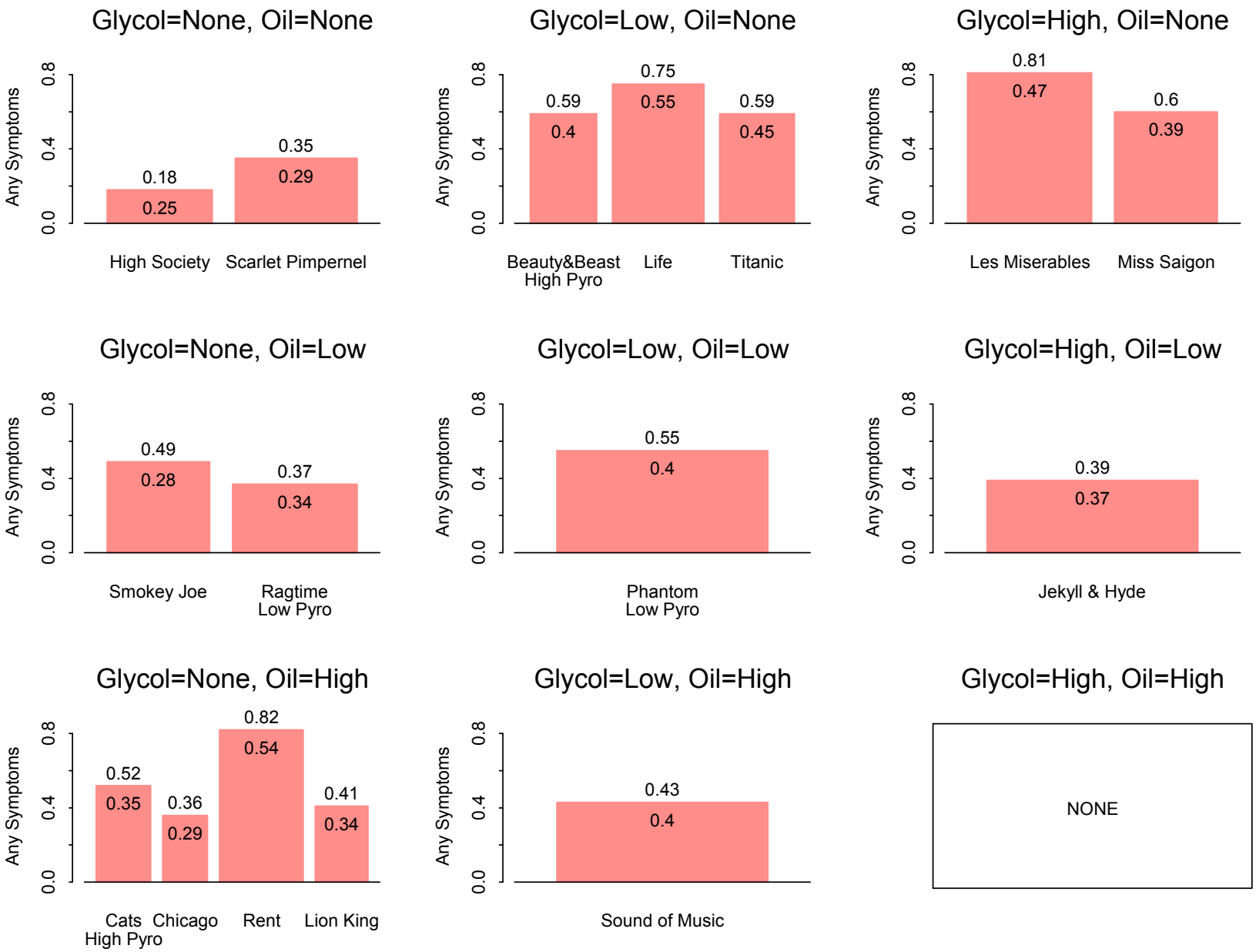


Figure V-1. **Phase 1: Any Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

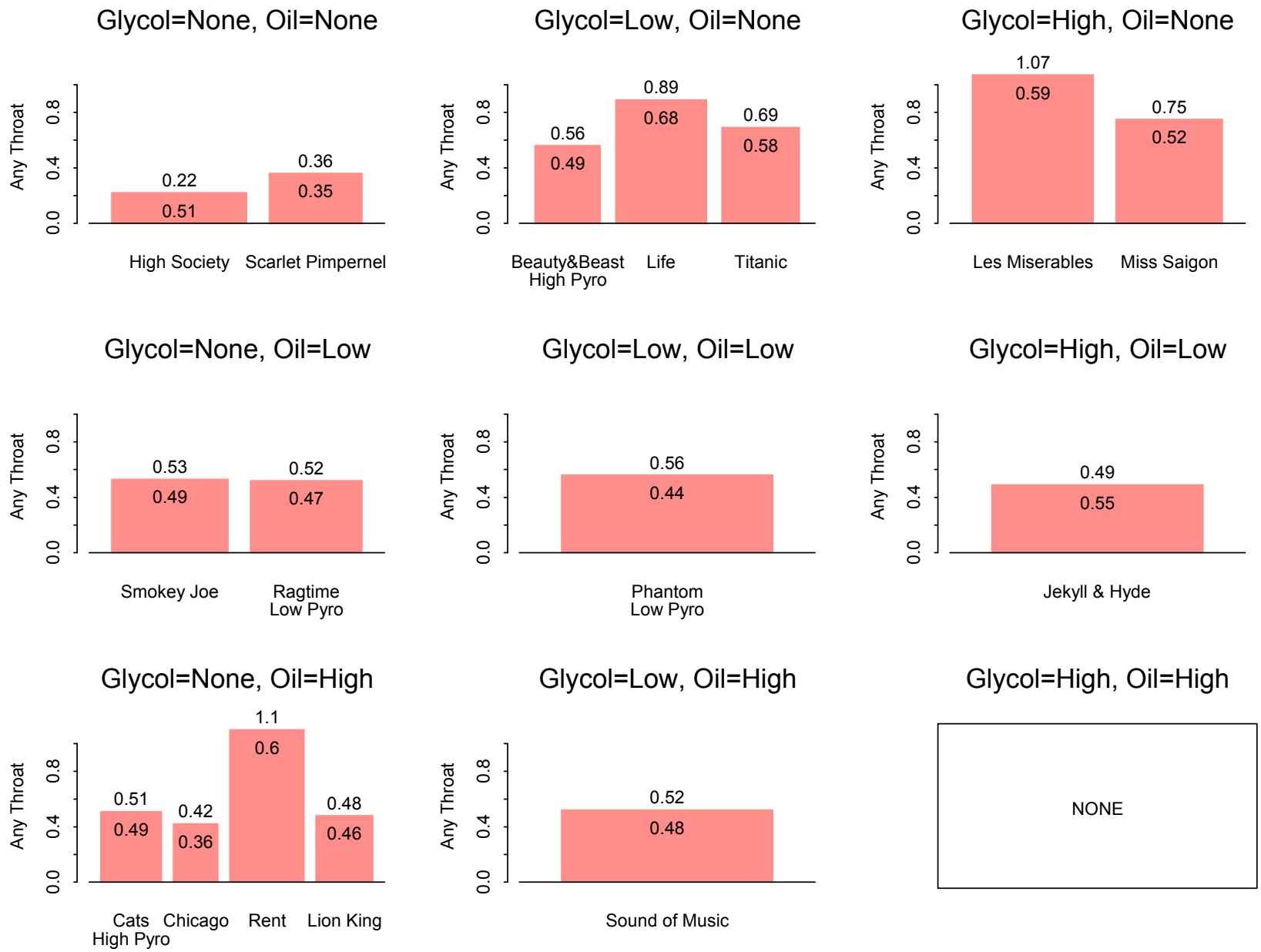


Figure V-2. **Phase 1: Throat Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

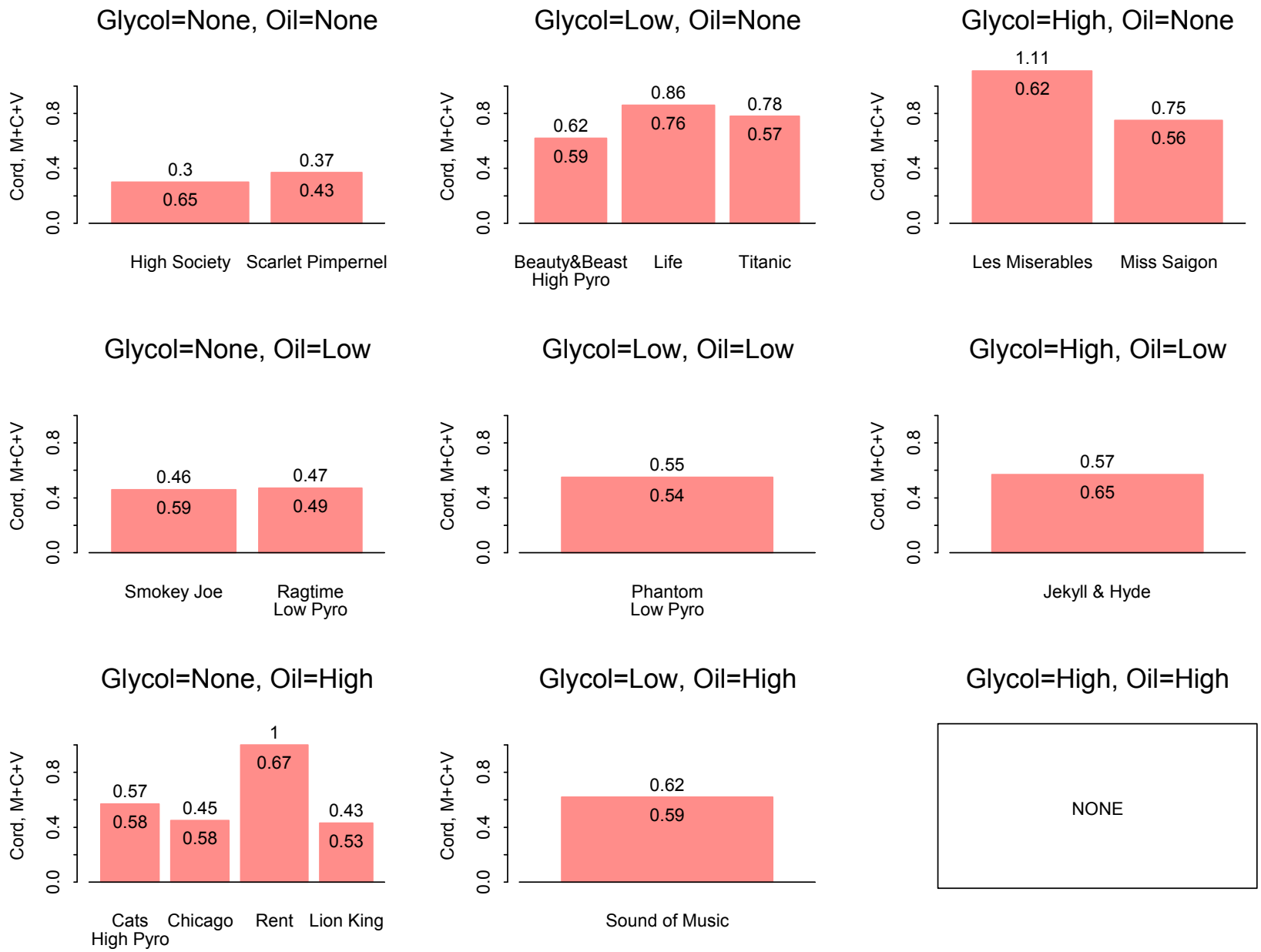


Figure V-3. **Phase 1: Phlegm & Voice Change Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

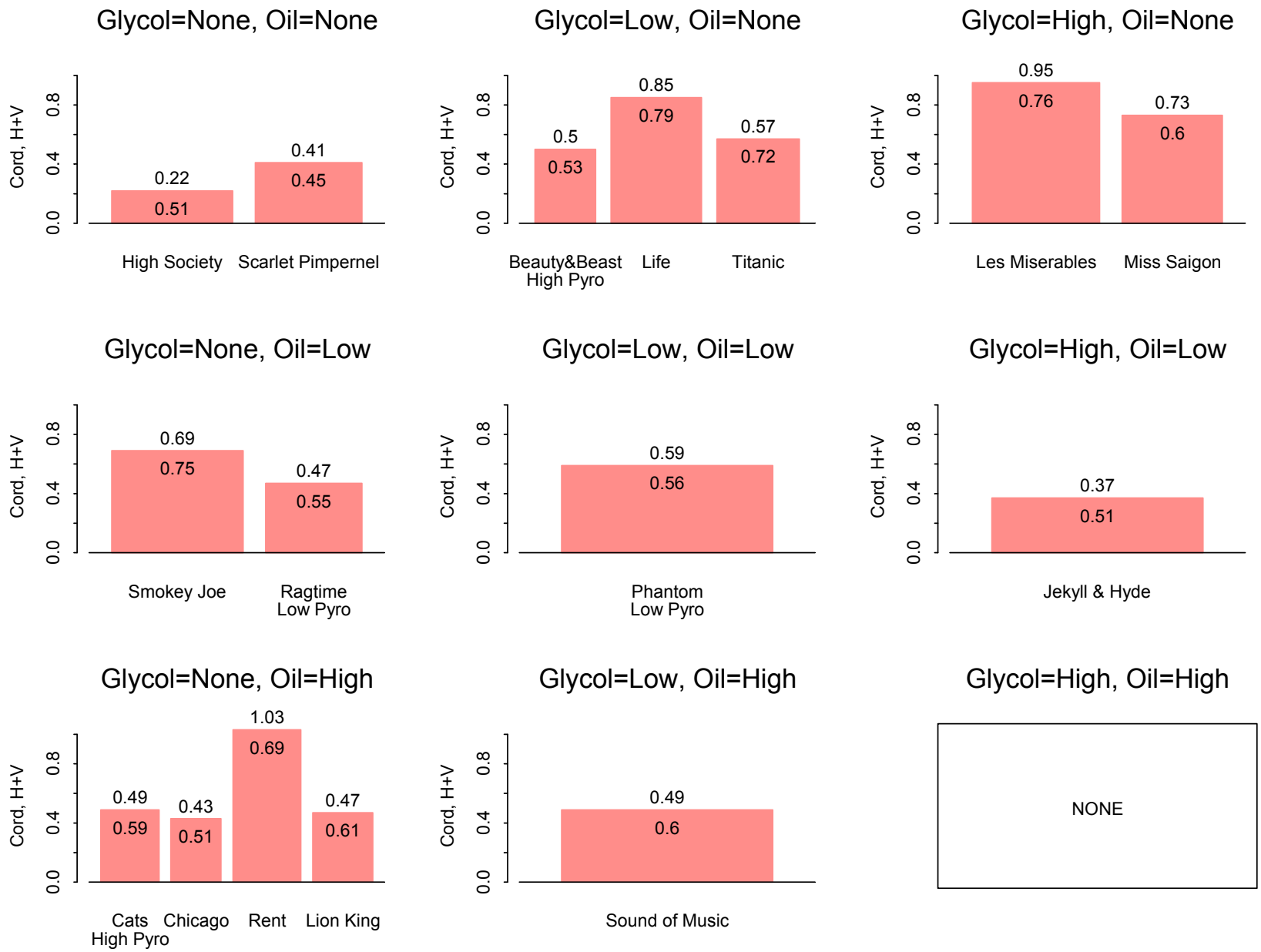


Figure V-4. **Phase 1: Hoarseness & Voice Change Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

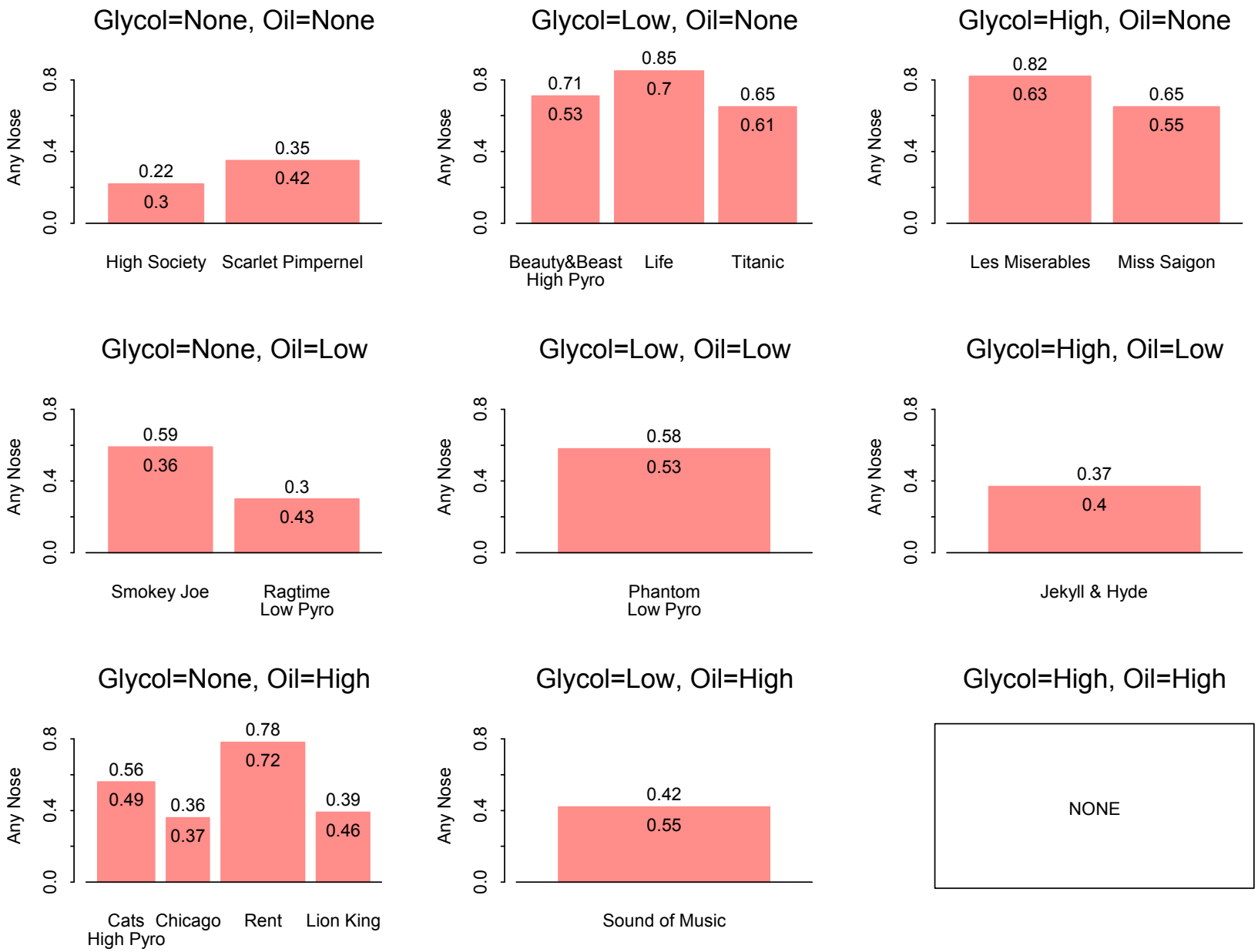


Figure V-5. **Phase 1: Nose Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

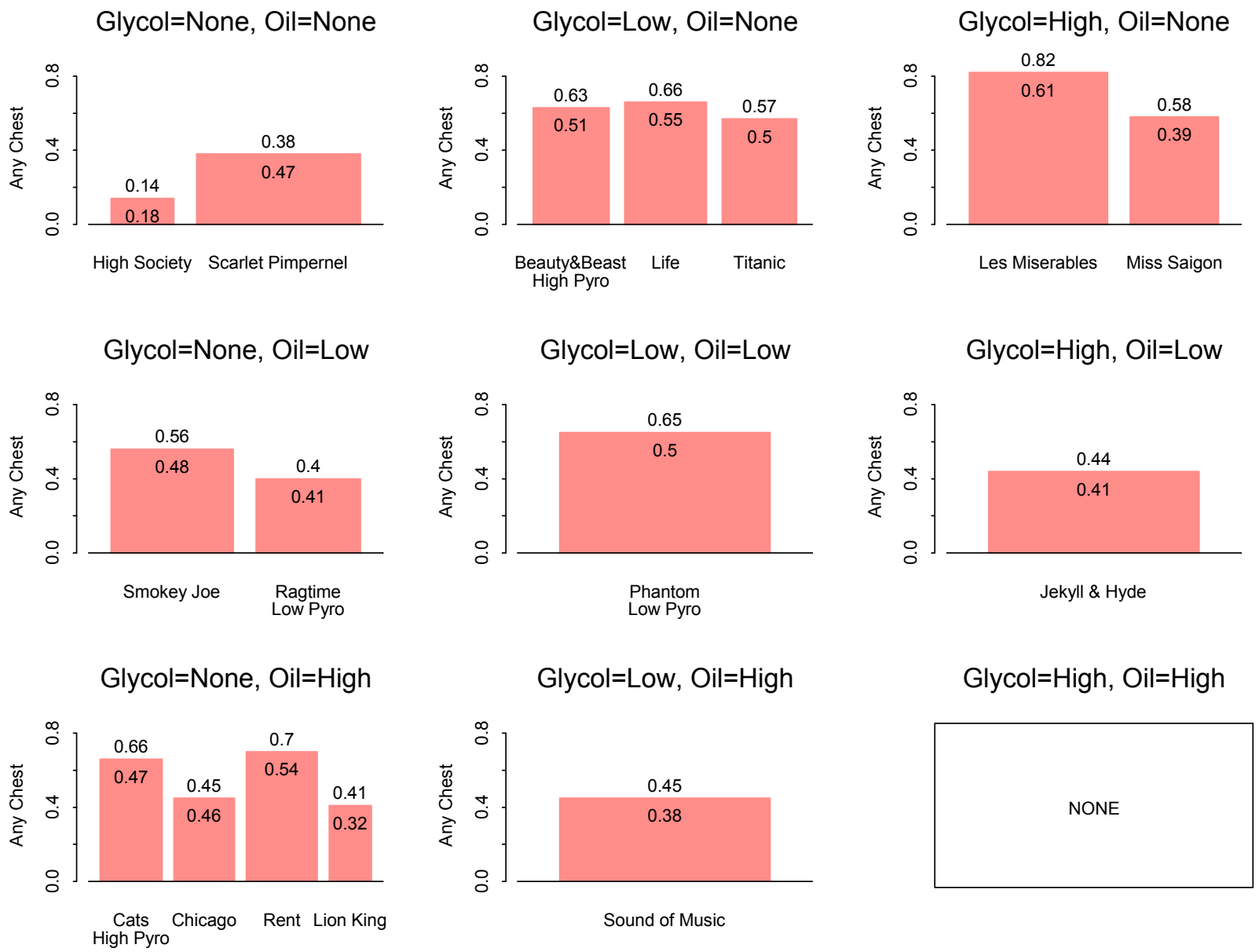


Figure V-6. **Phase 1: Chest Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

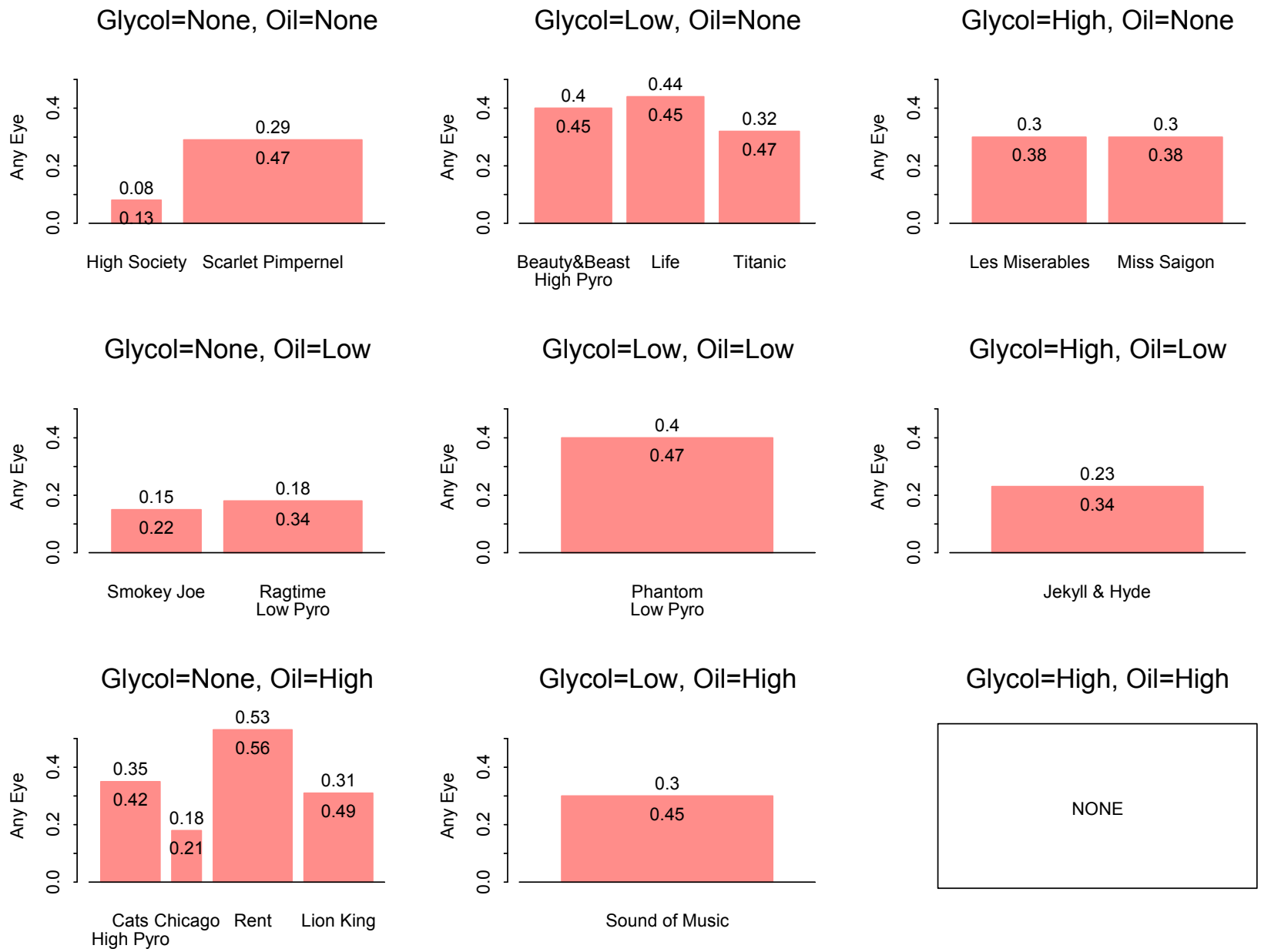


Figure V-7. **Phase 1: Eye Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

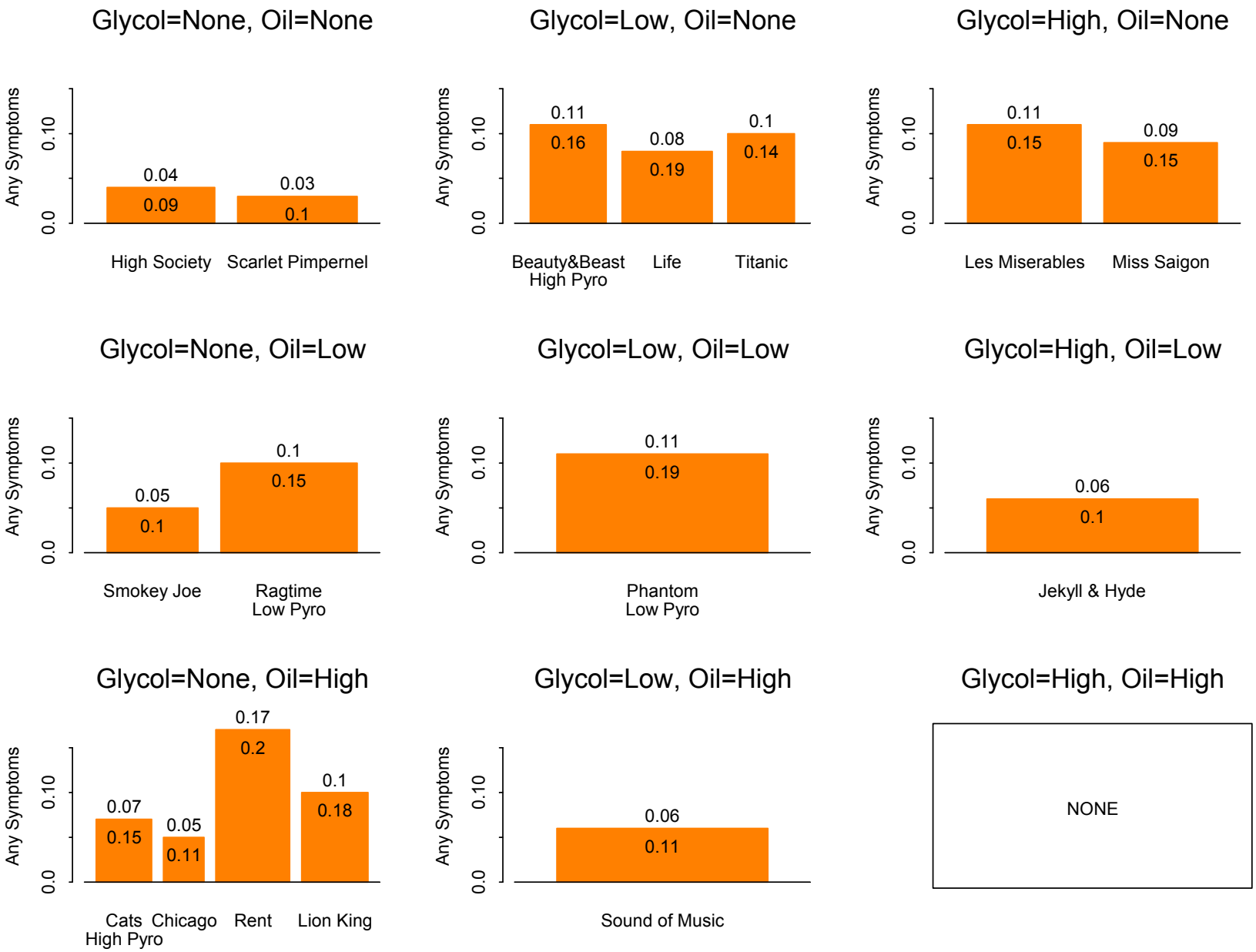


Figure V-8. **Phase 2: Any Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

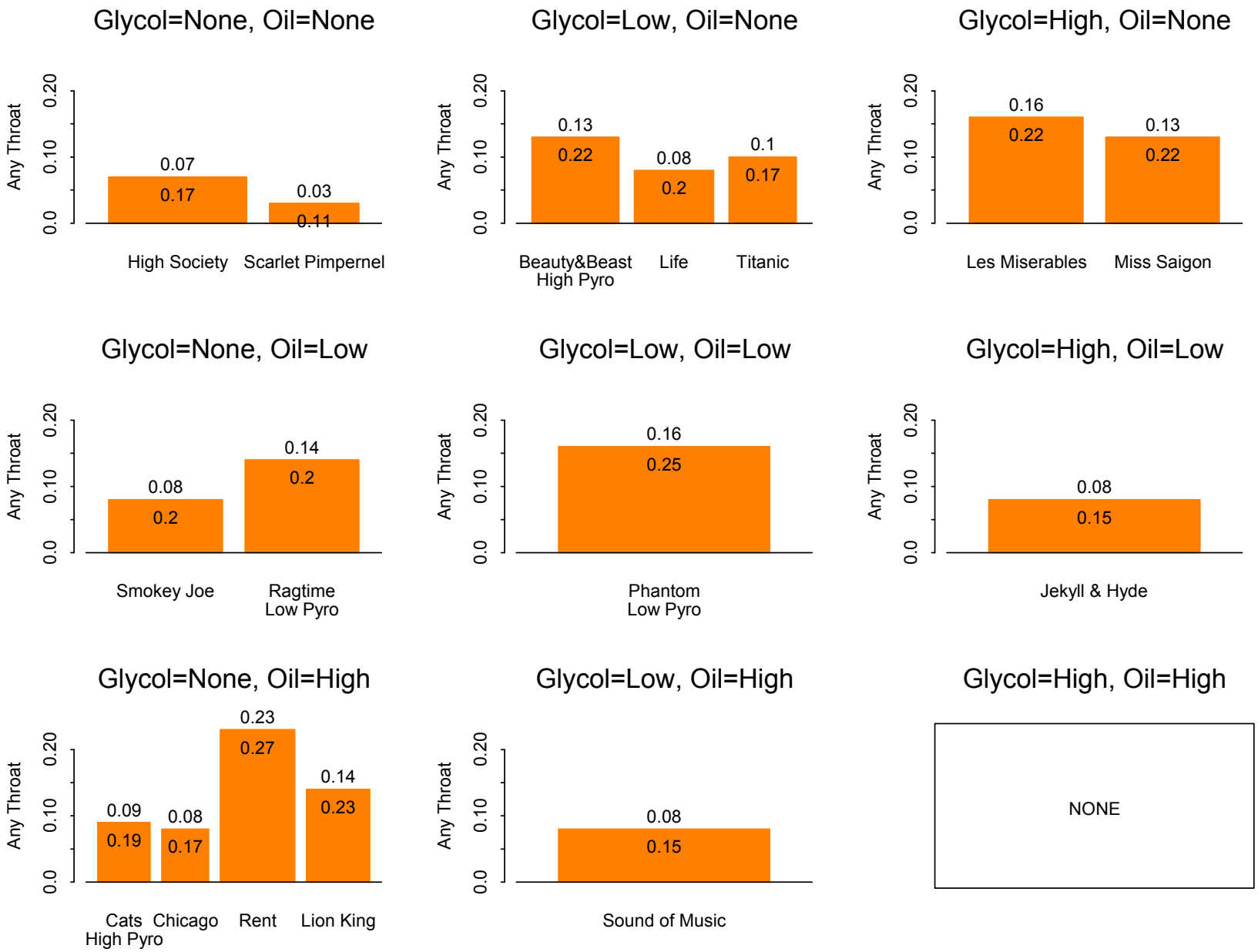


Figure V-9. **Phase 2: Throat Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

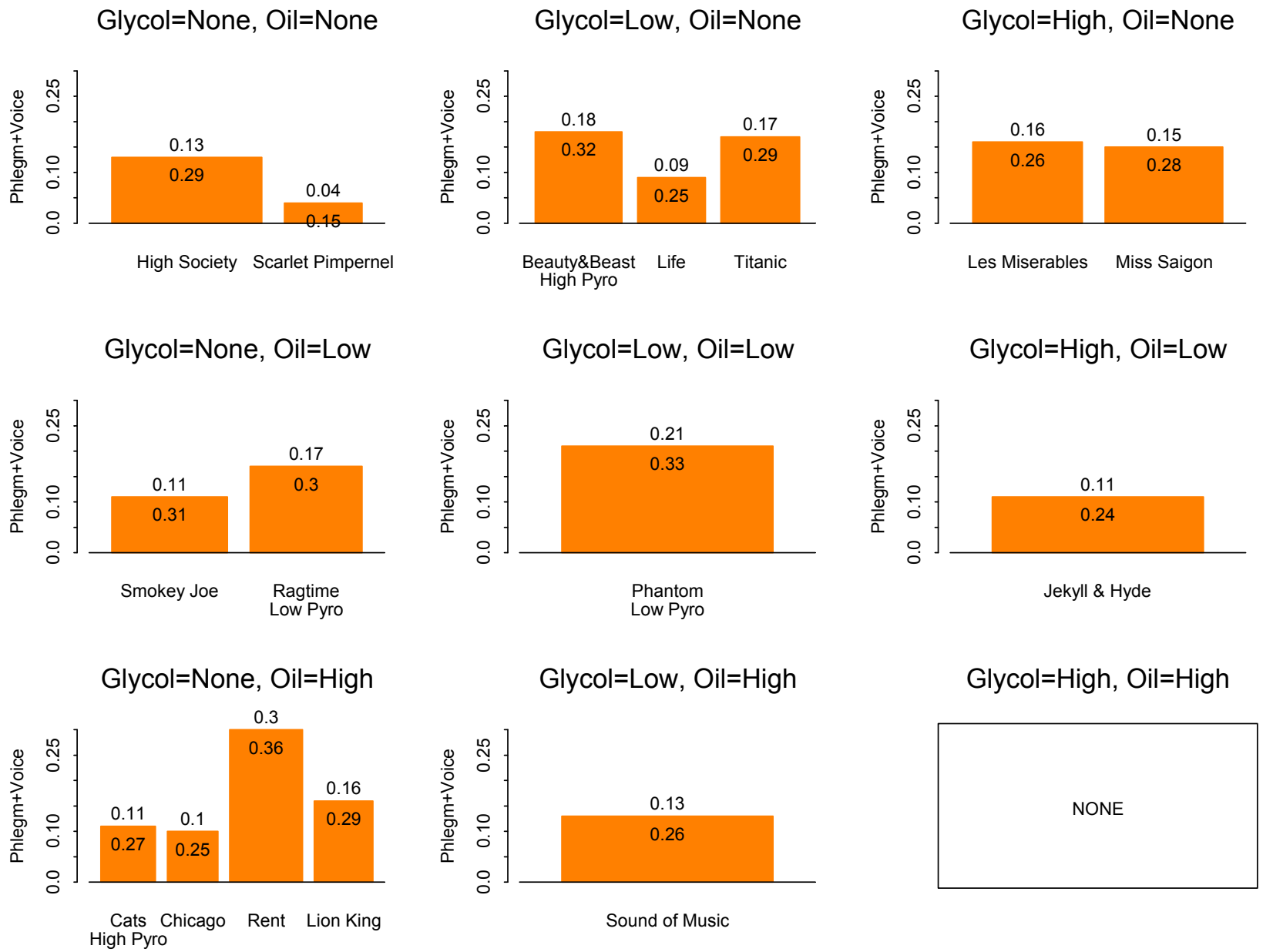


Figure V-10. **Phase 2: Phlegm & Voice Change Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

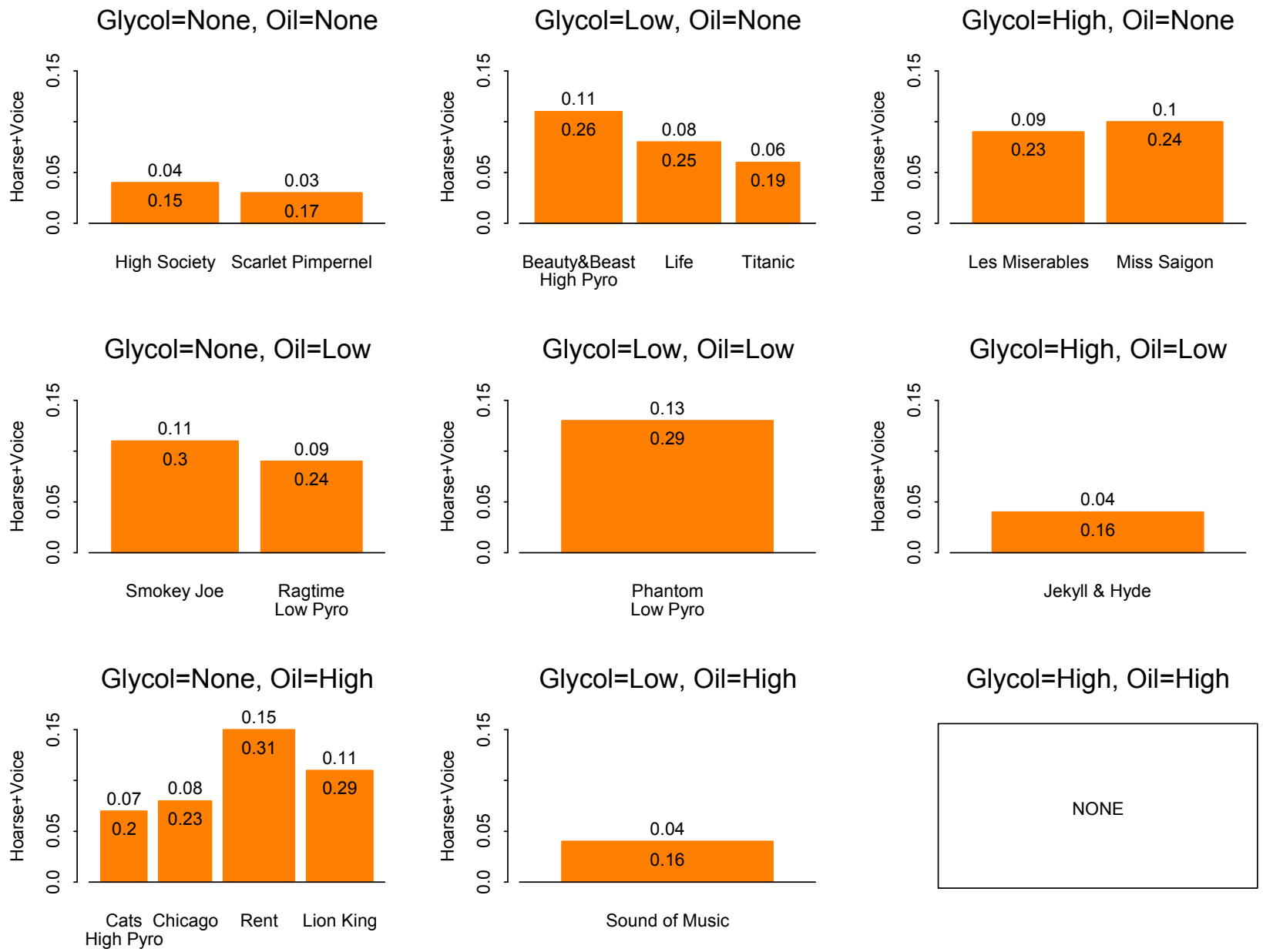


Figure V-11. **Phase 2: Hoarseness & Voice Change Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

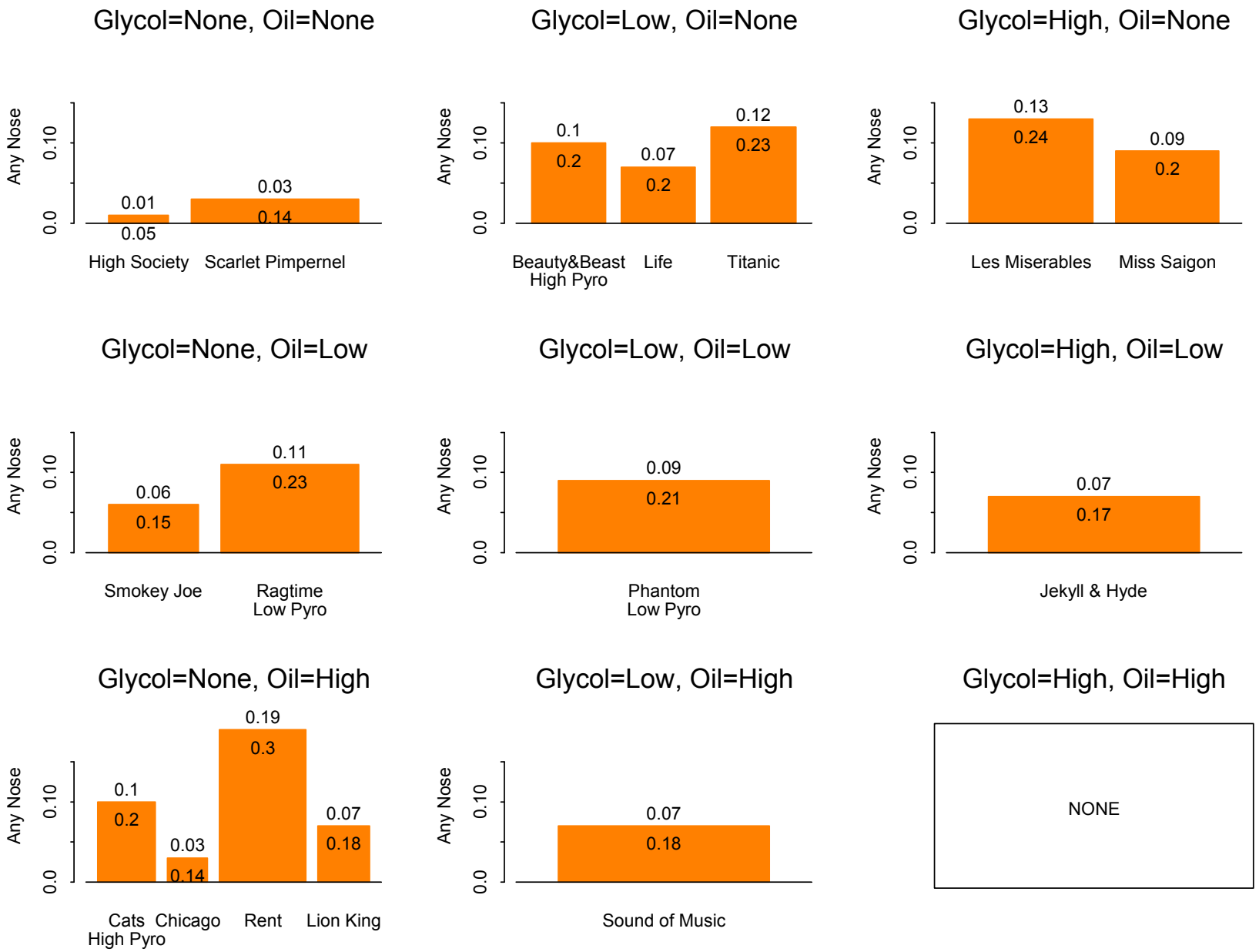


Figure V-12. **Phase 2: Nose Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

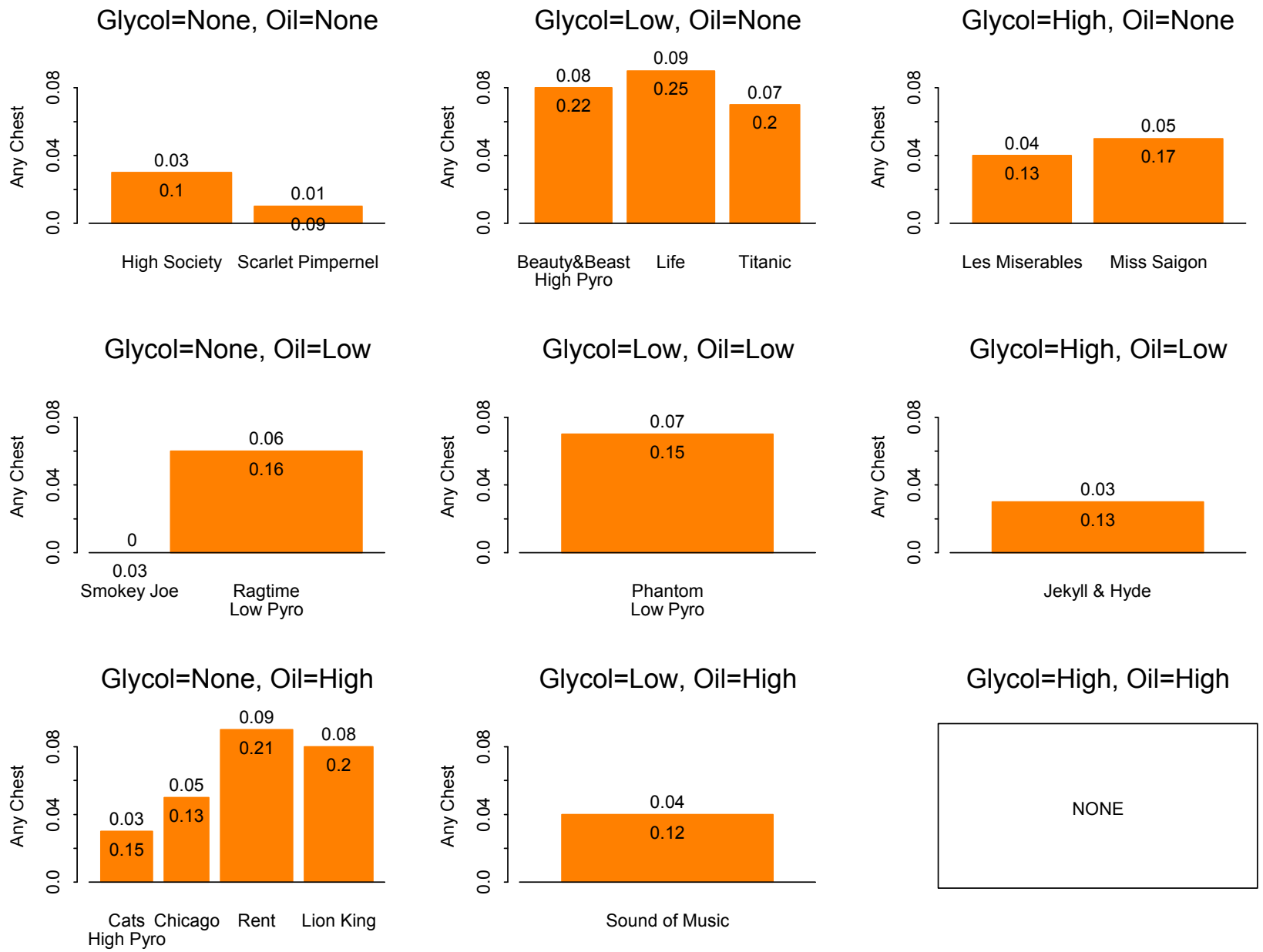


Figure V-13. **Phase 2: Chest Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

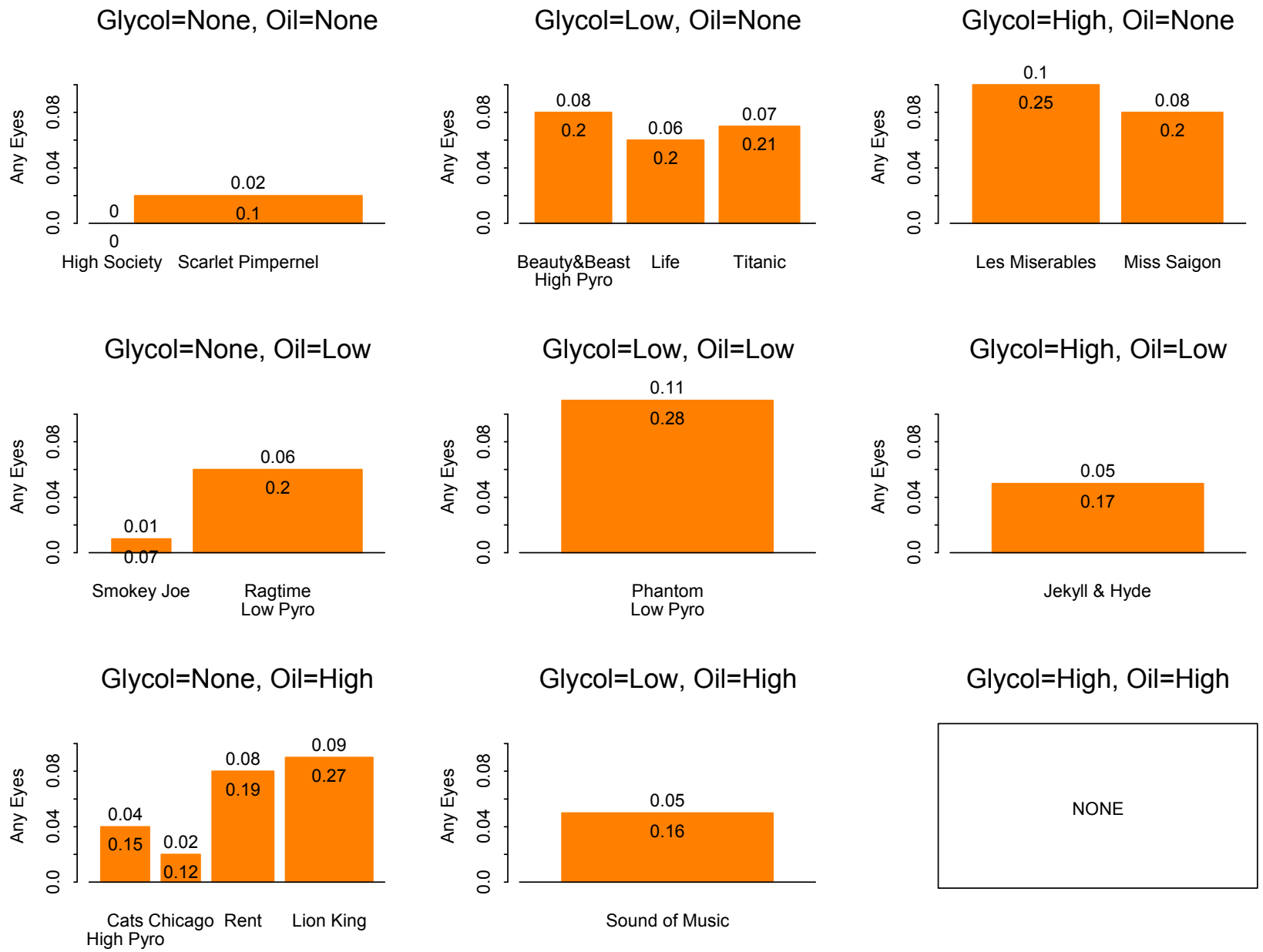
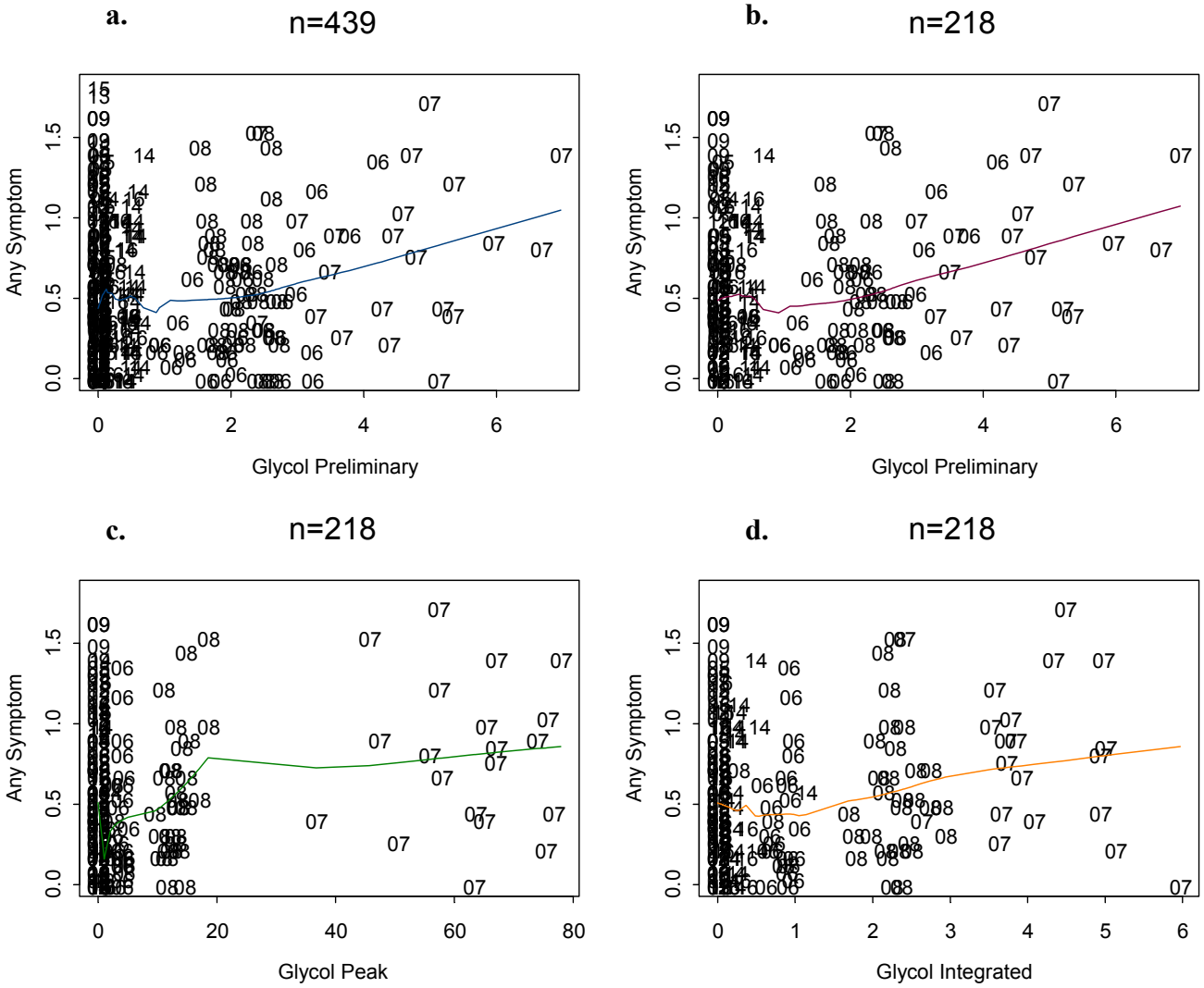


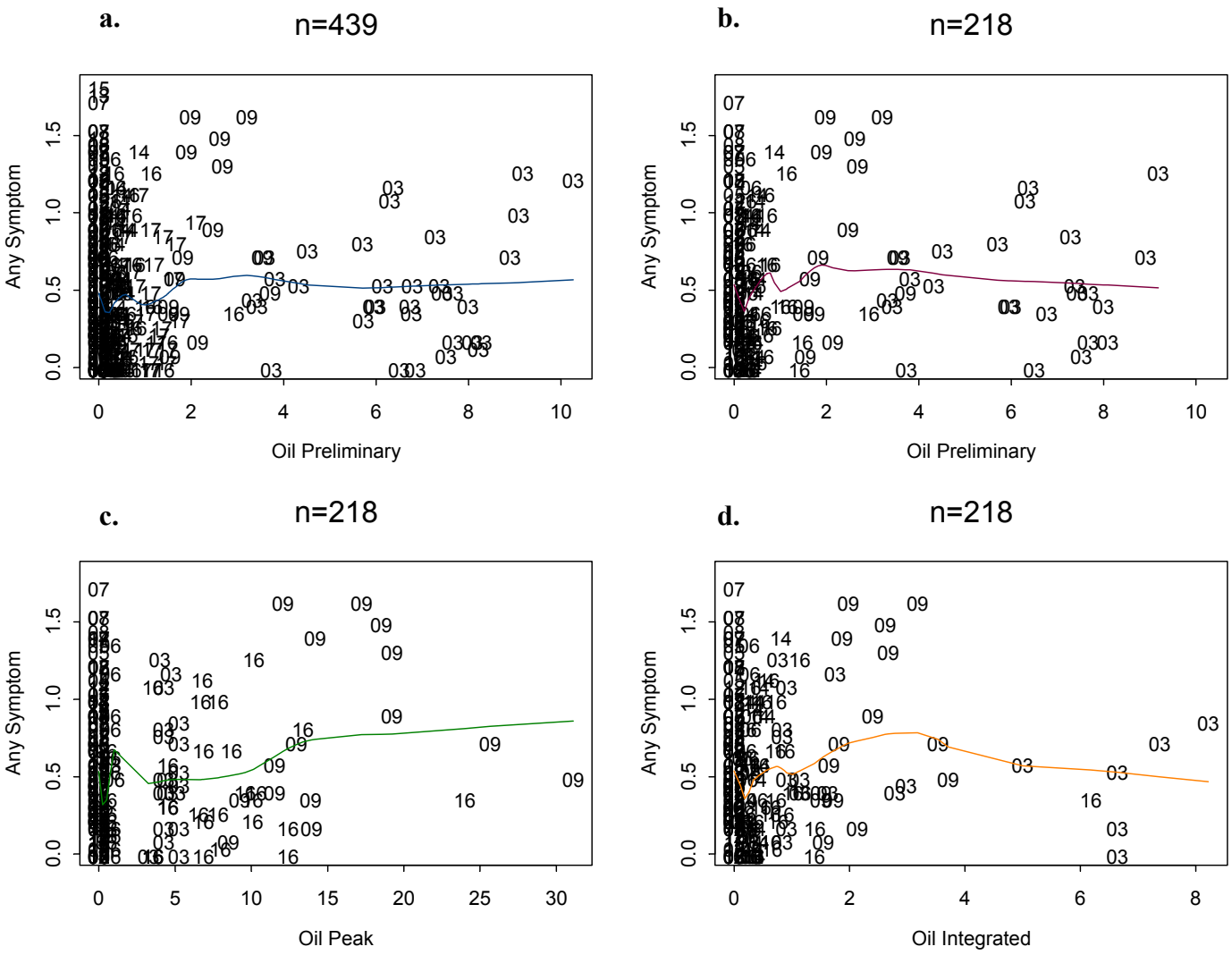
Figure V-14. **Phase 2: Eye Symptom Score by Show and Glycol/Mineral Oil Exposure Category**
(means above bar, standard deviations within bar)

Figure V-15. **Any Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



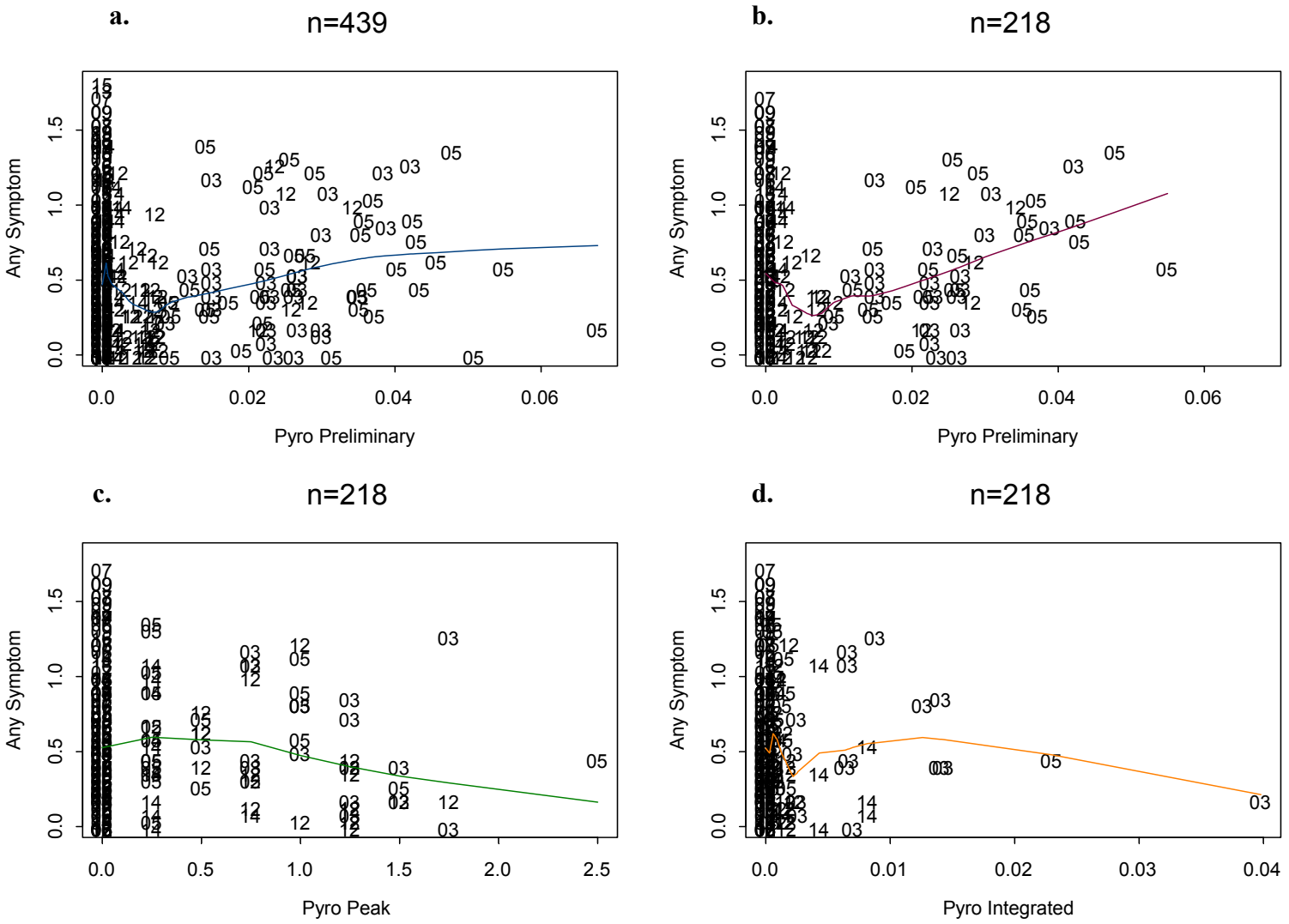
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-16. **Any Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



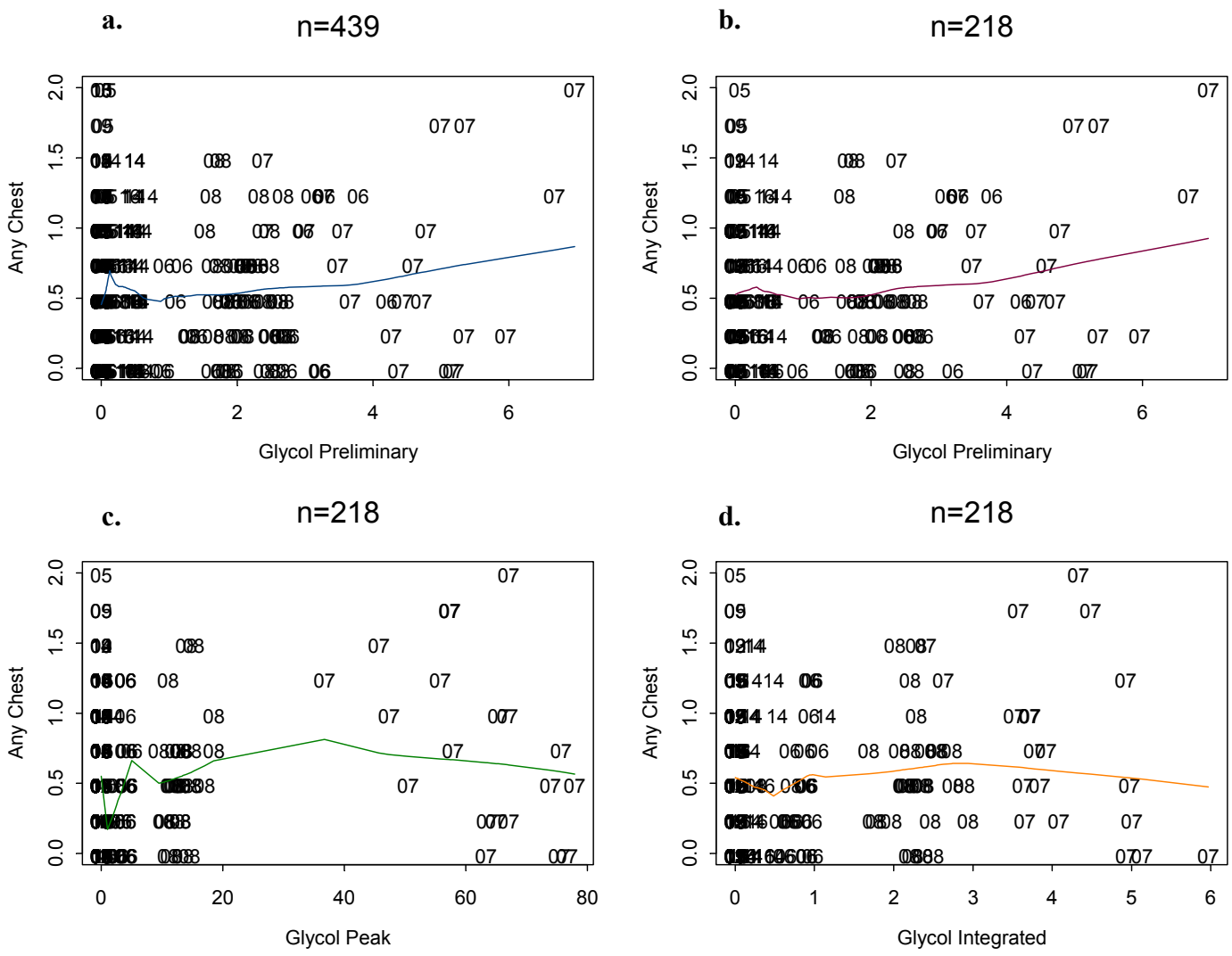
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-17. **Any Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



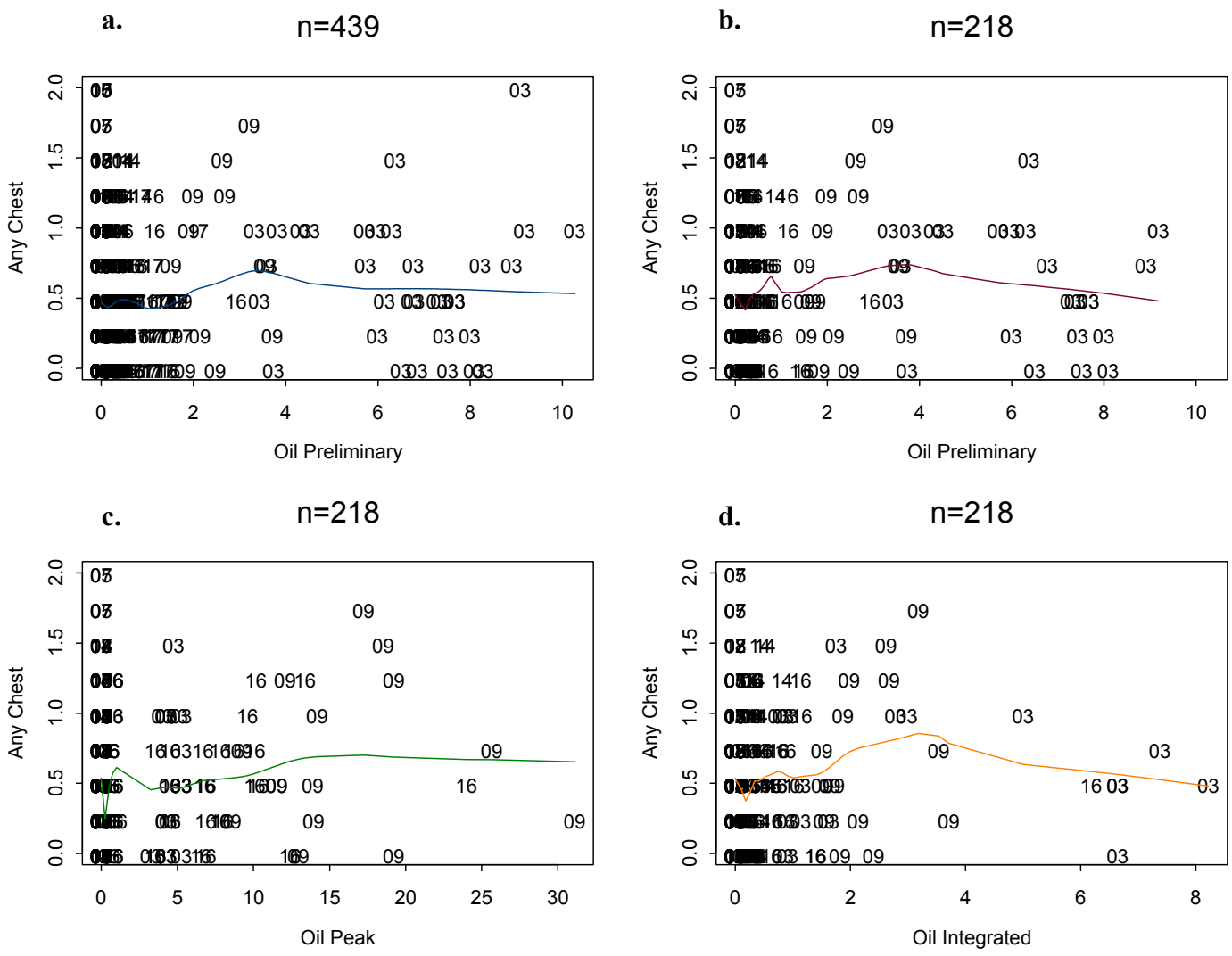
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-18. **Chest Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



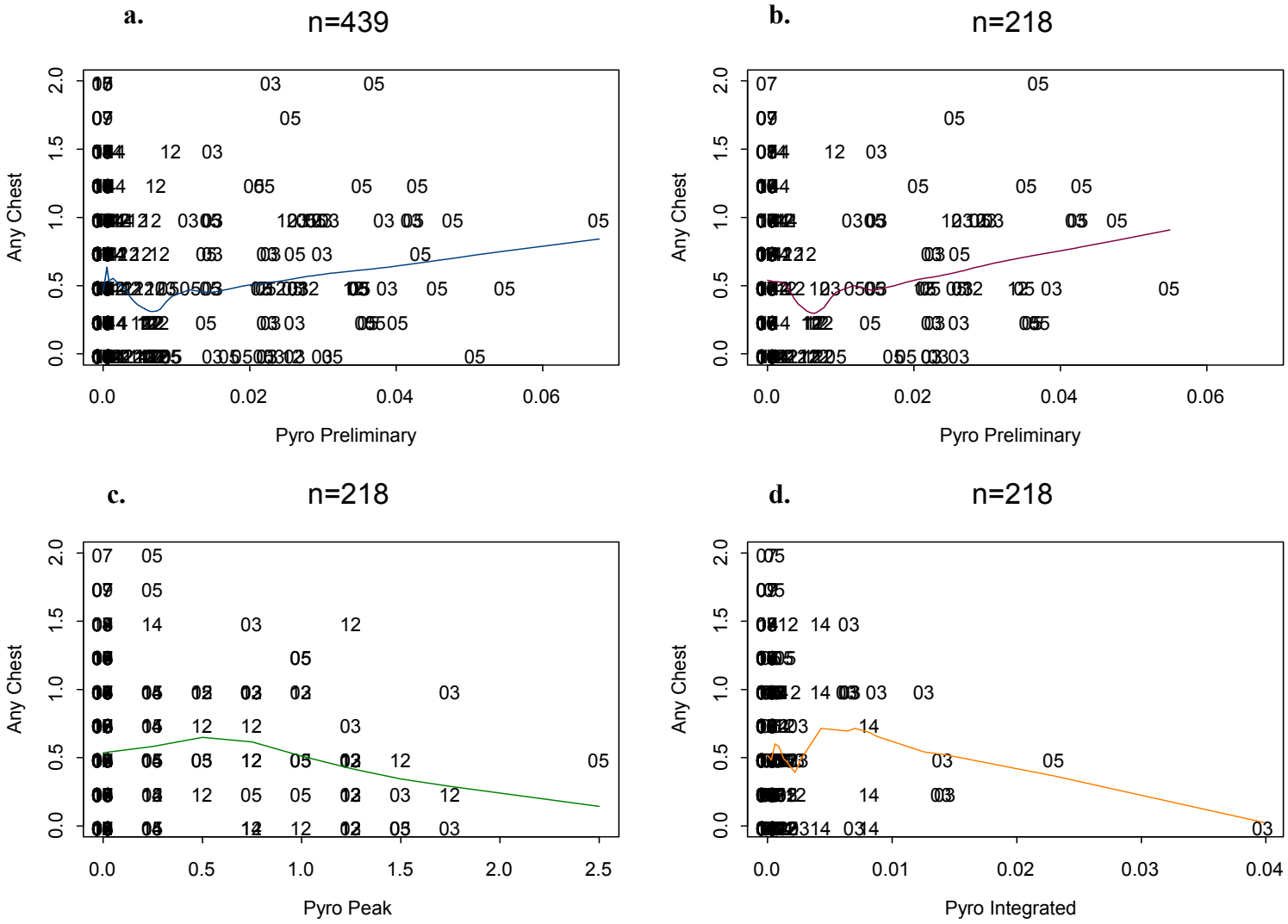
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-19. **Chest Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



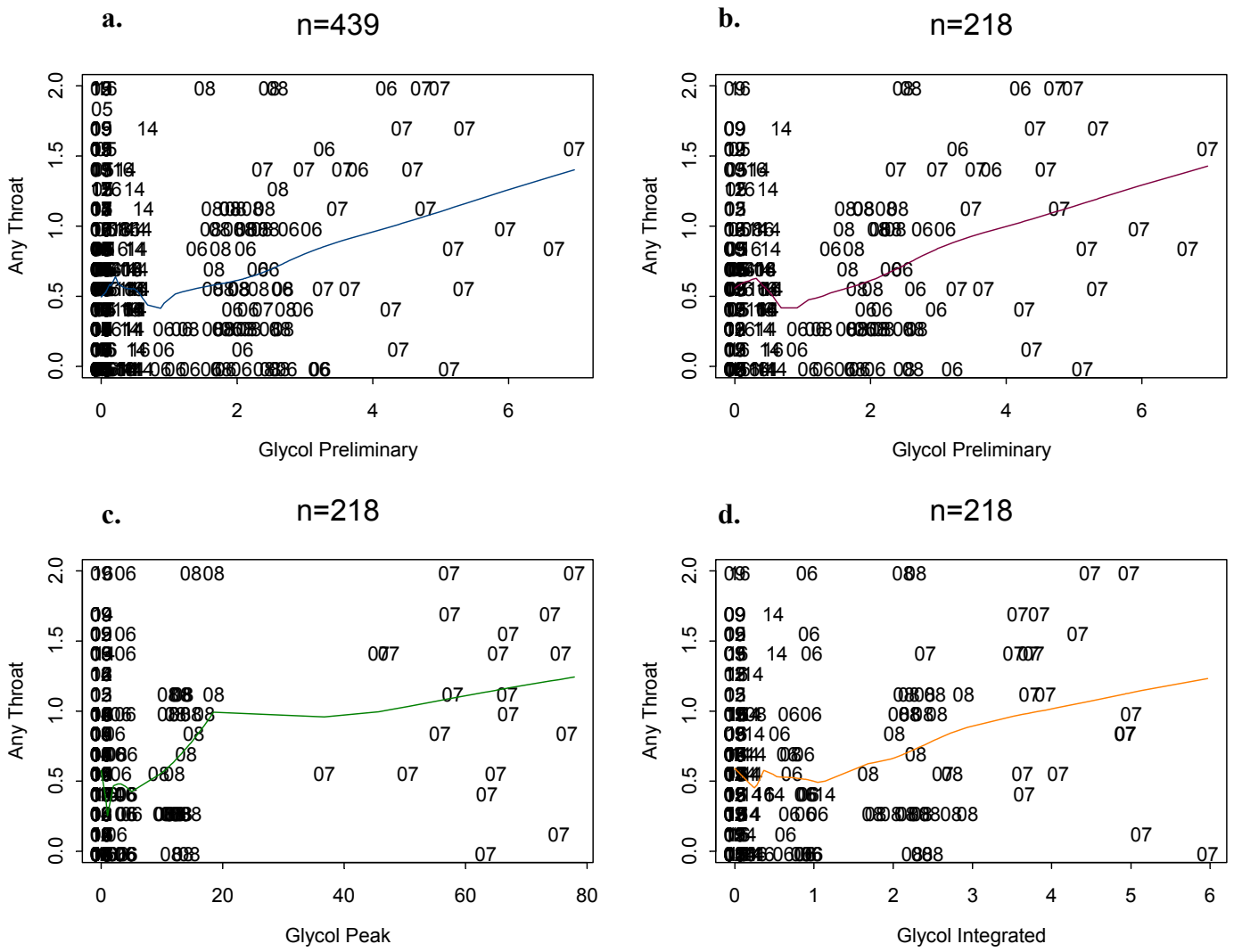
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-20. **Chest Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



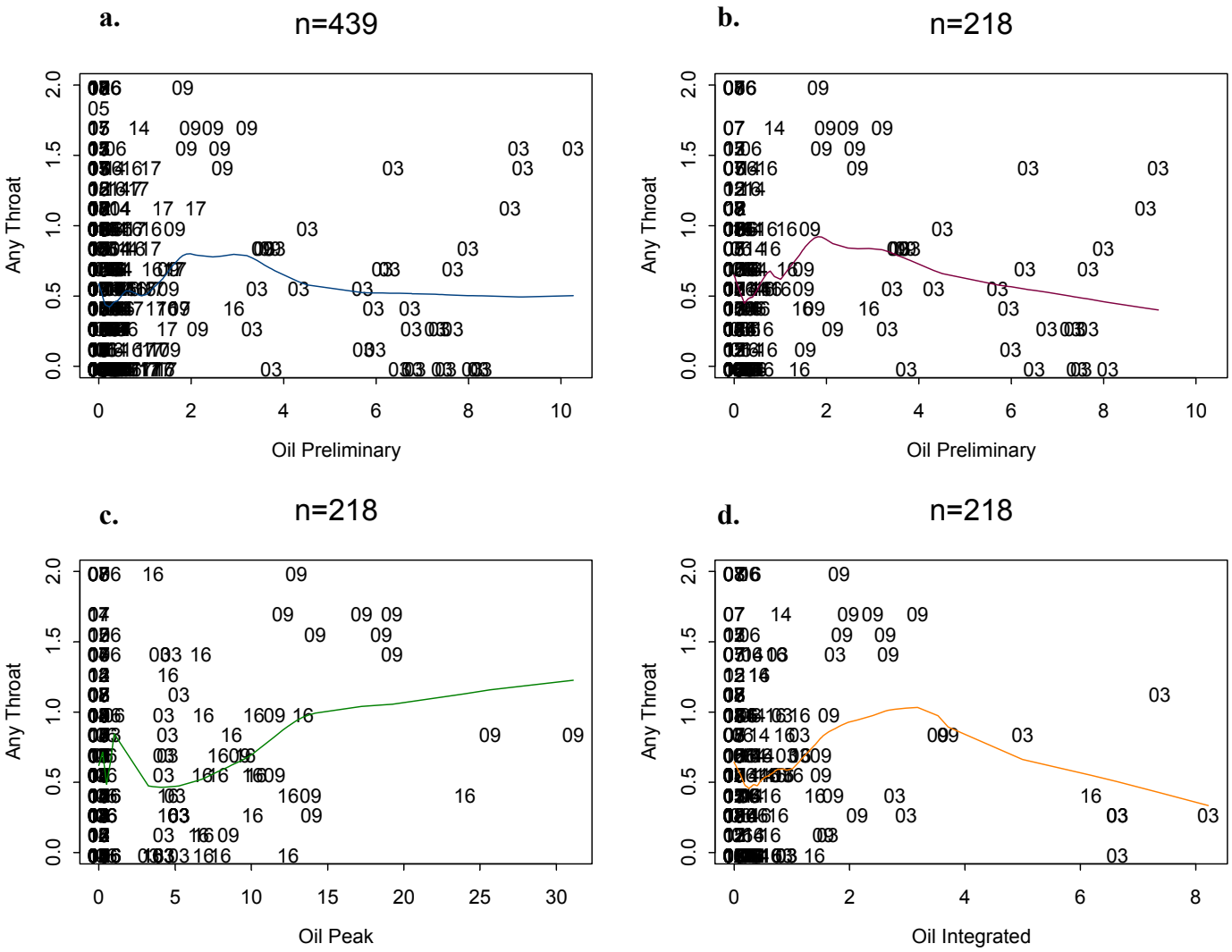
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-21. **Throat Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



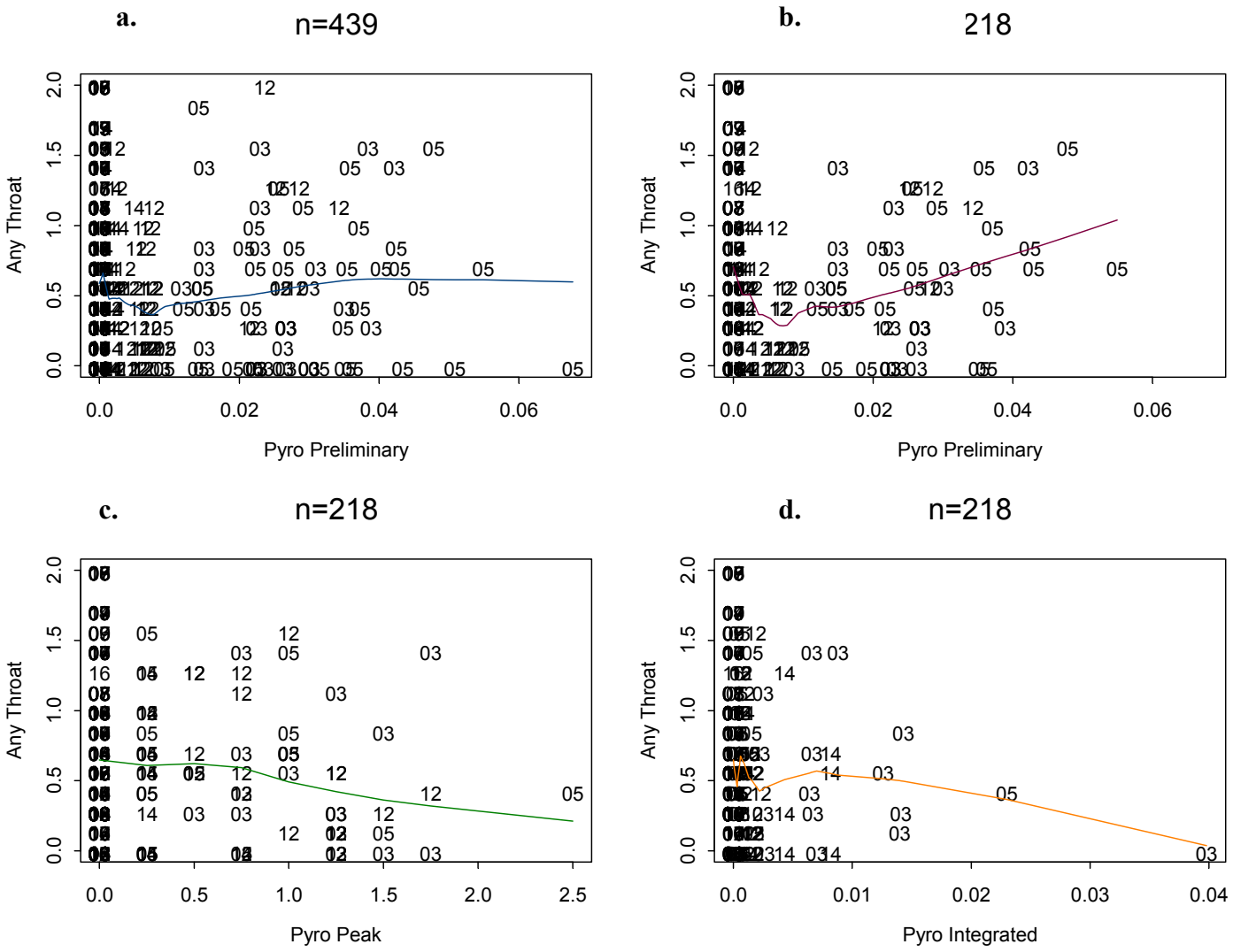
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-22. **Throat Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



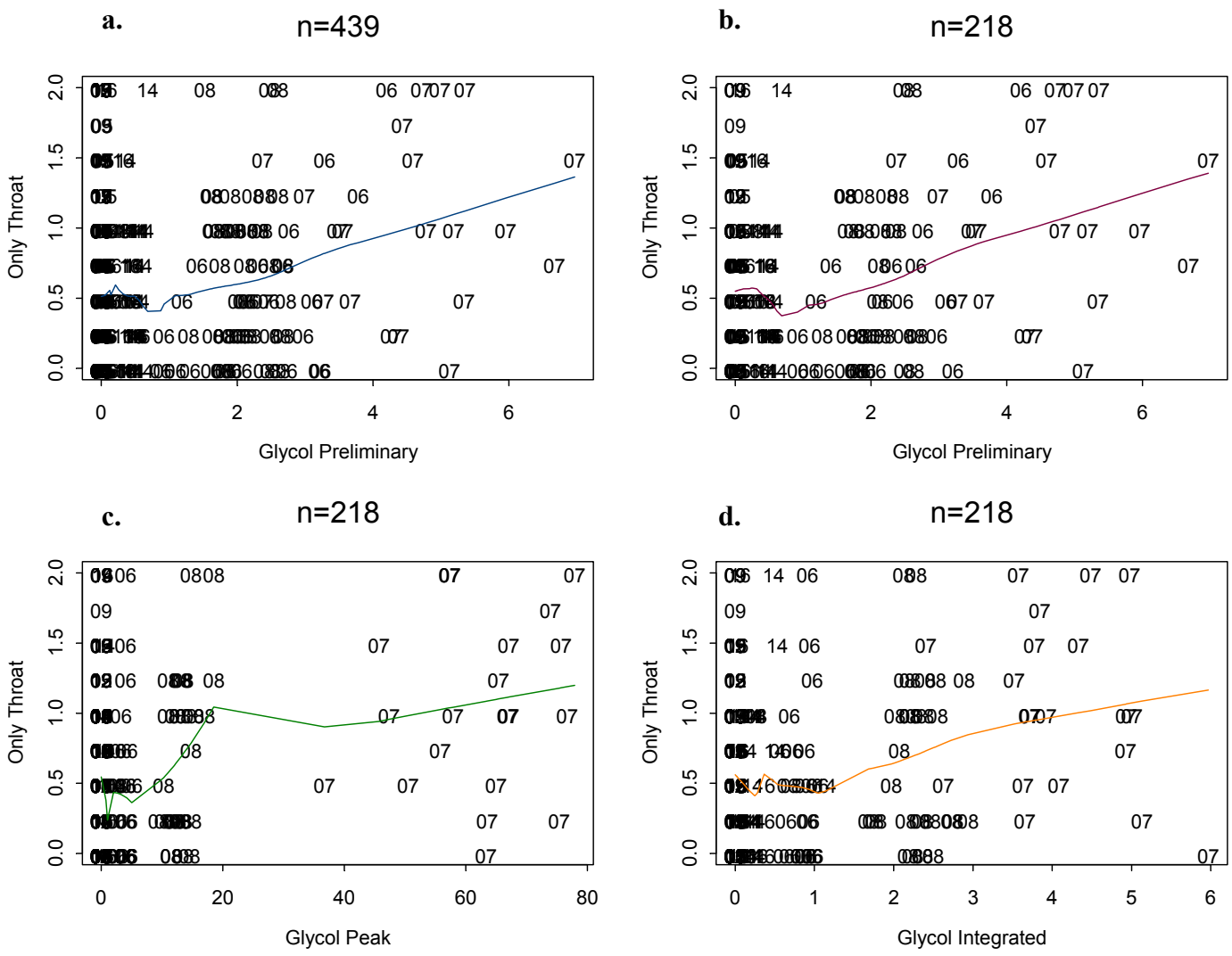
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-23. **Throat Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



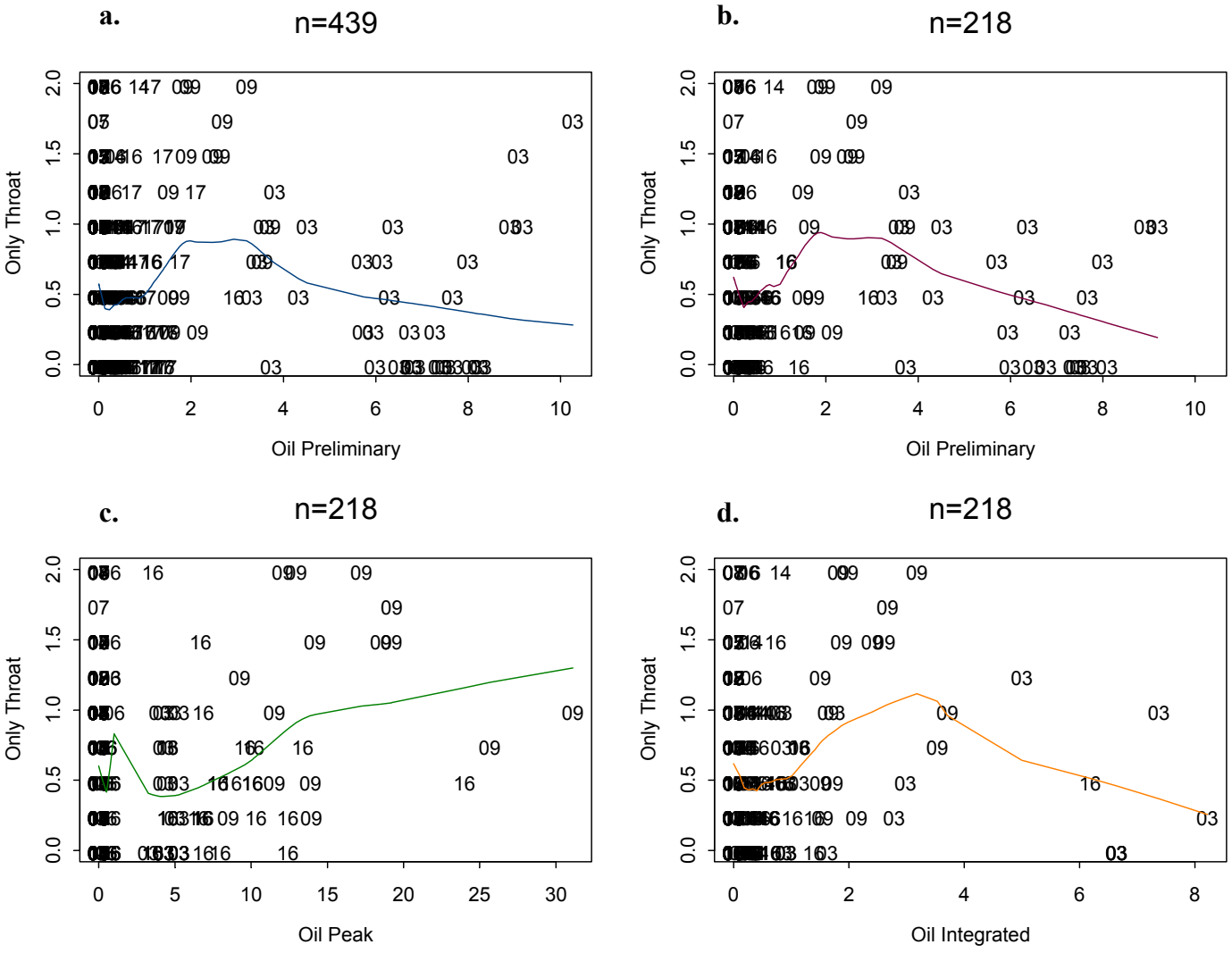
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-24. **Irritated Throat Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



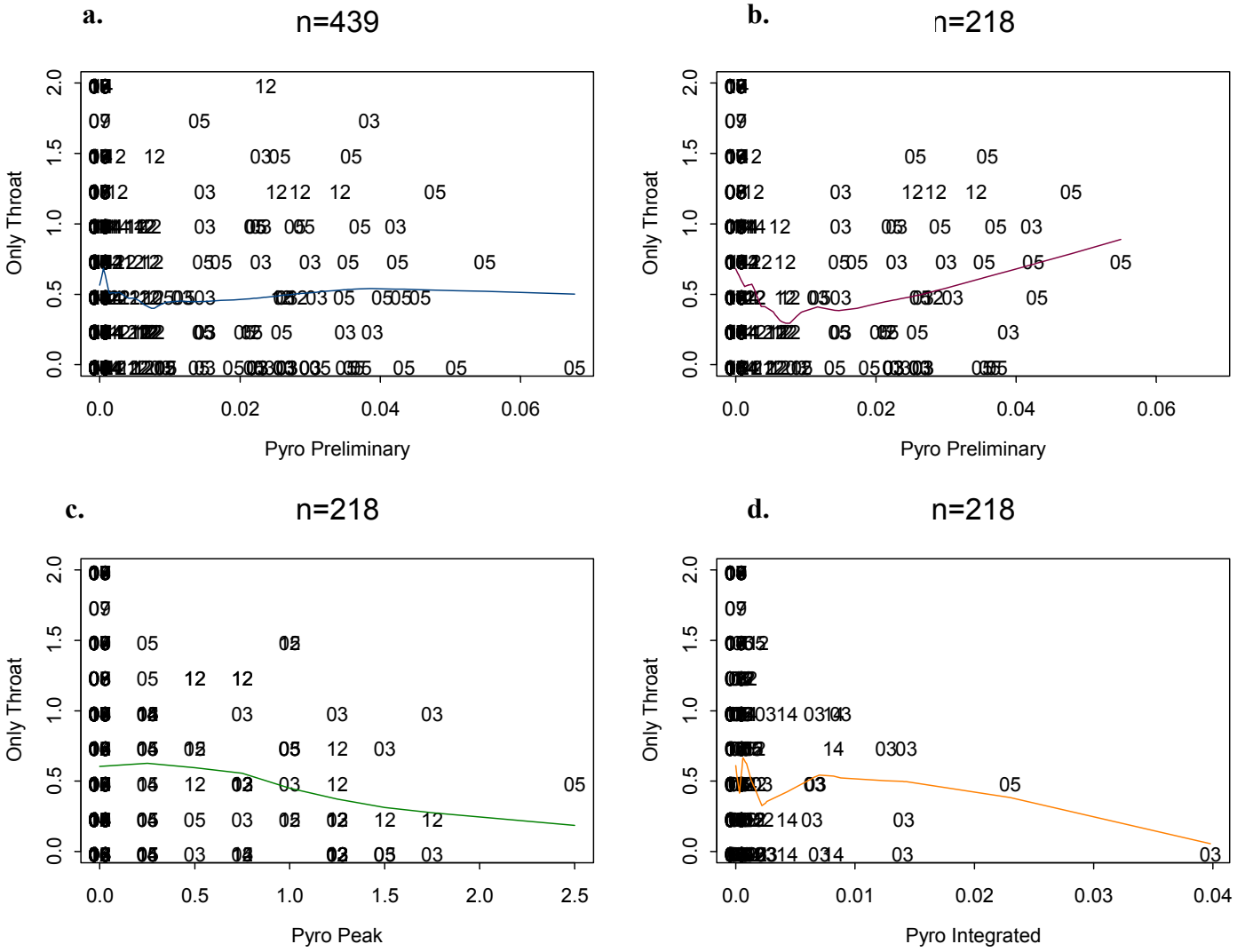
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-25. **Irritated Throat Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors



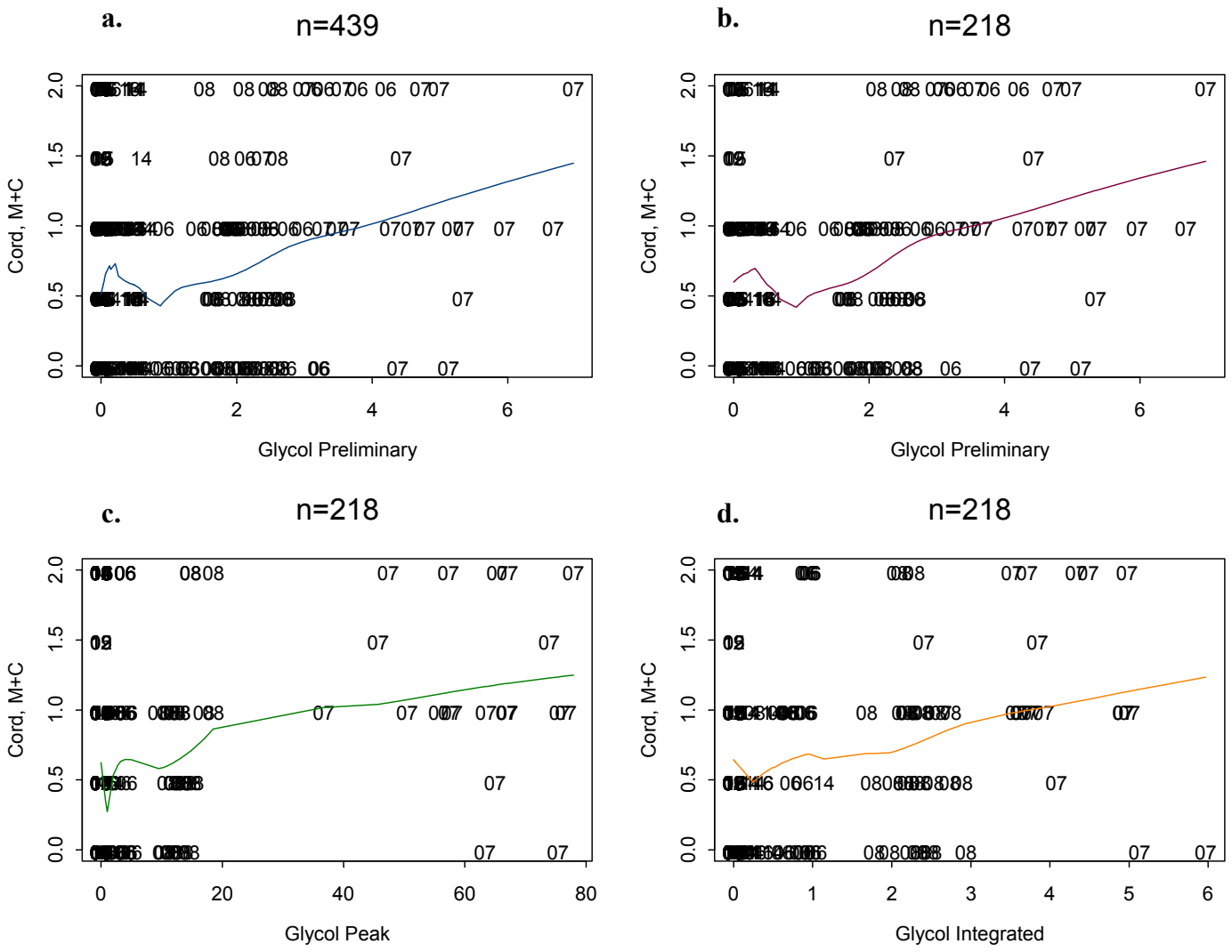
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-26. **Irritated Throat Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



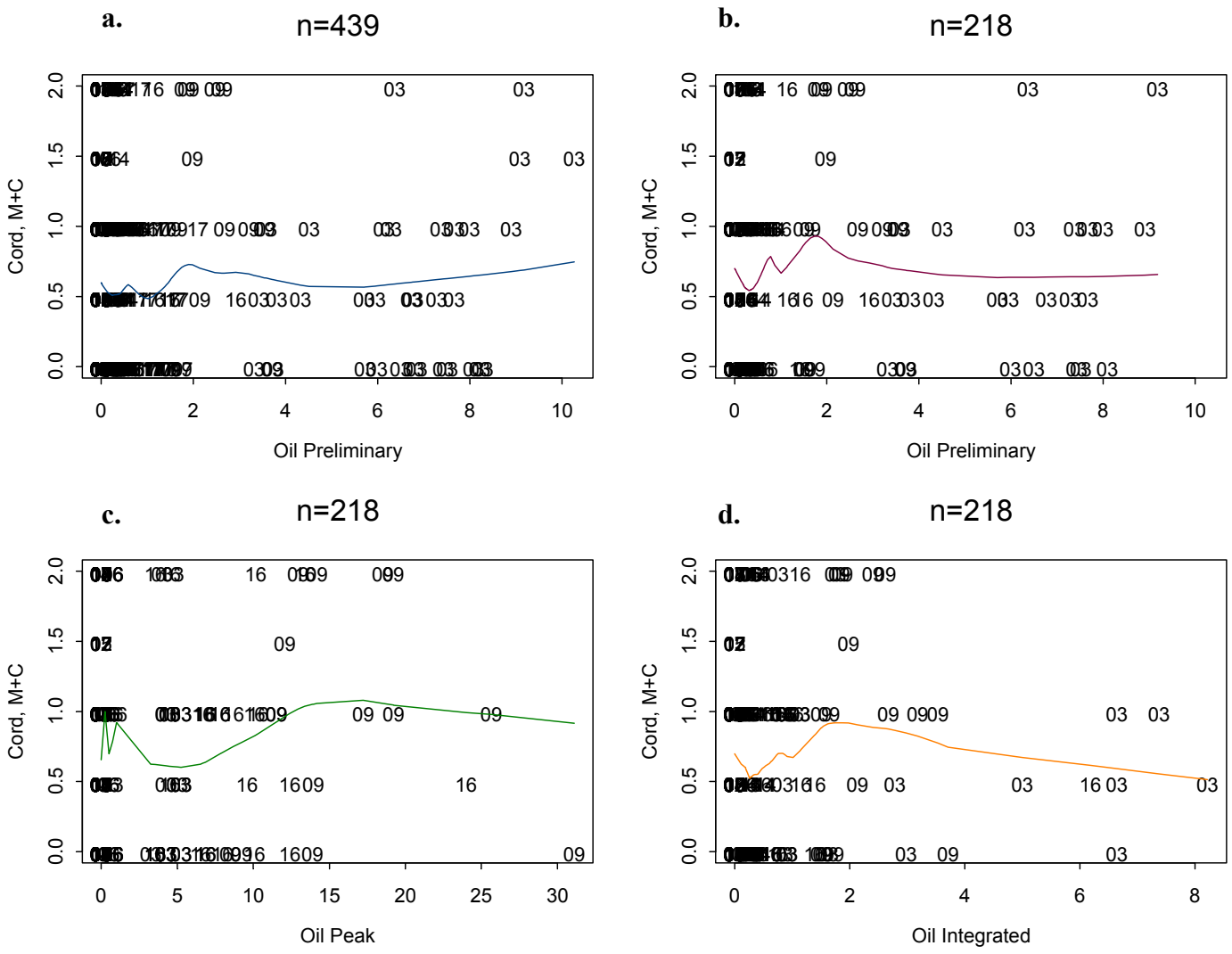
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-27. **Mucus & Coated Cords Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



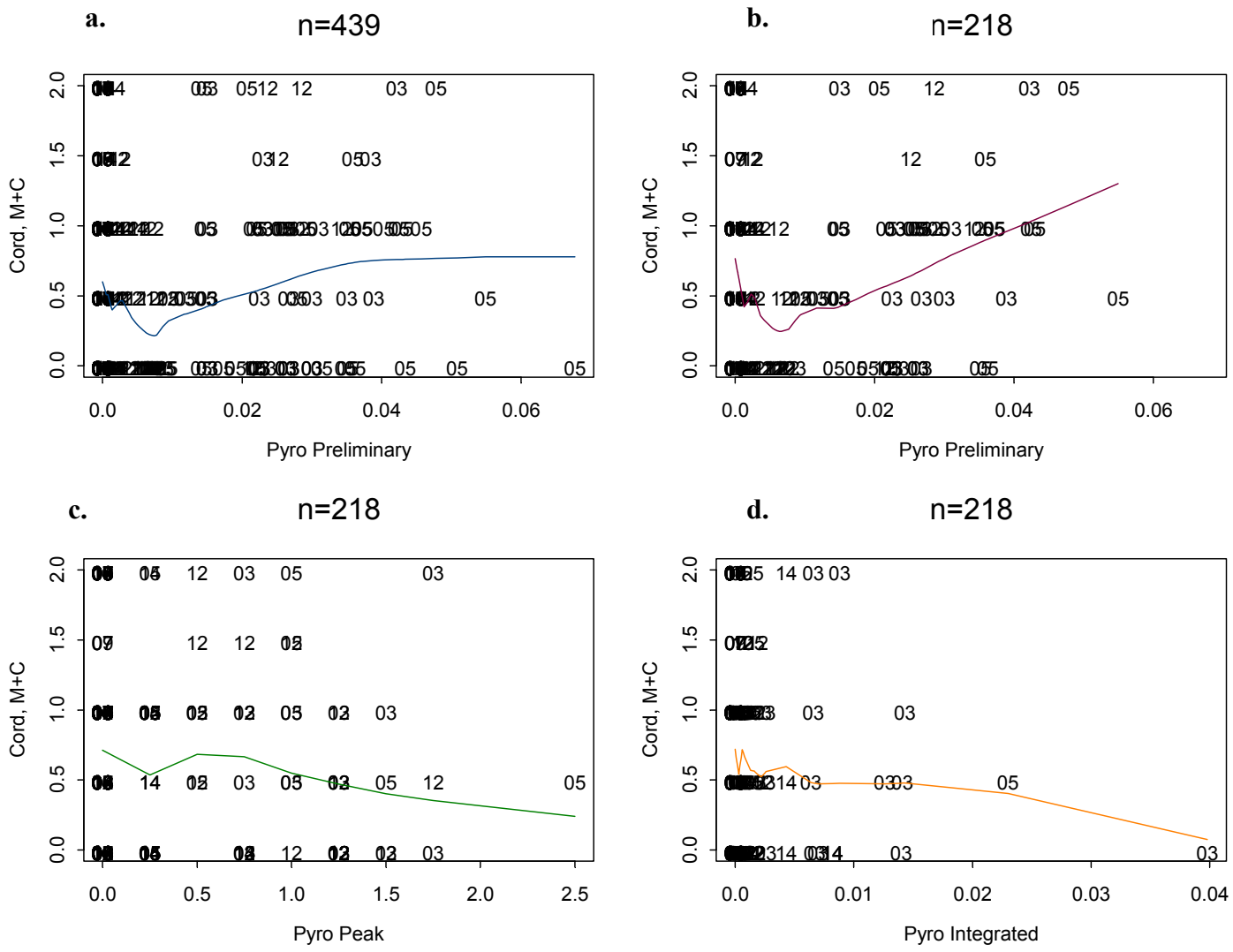
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-28. **Mucus & Coated Cords Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



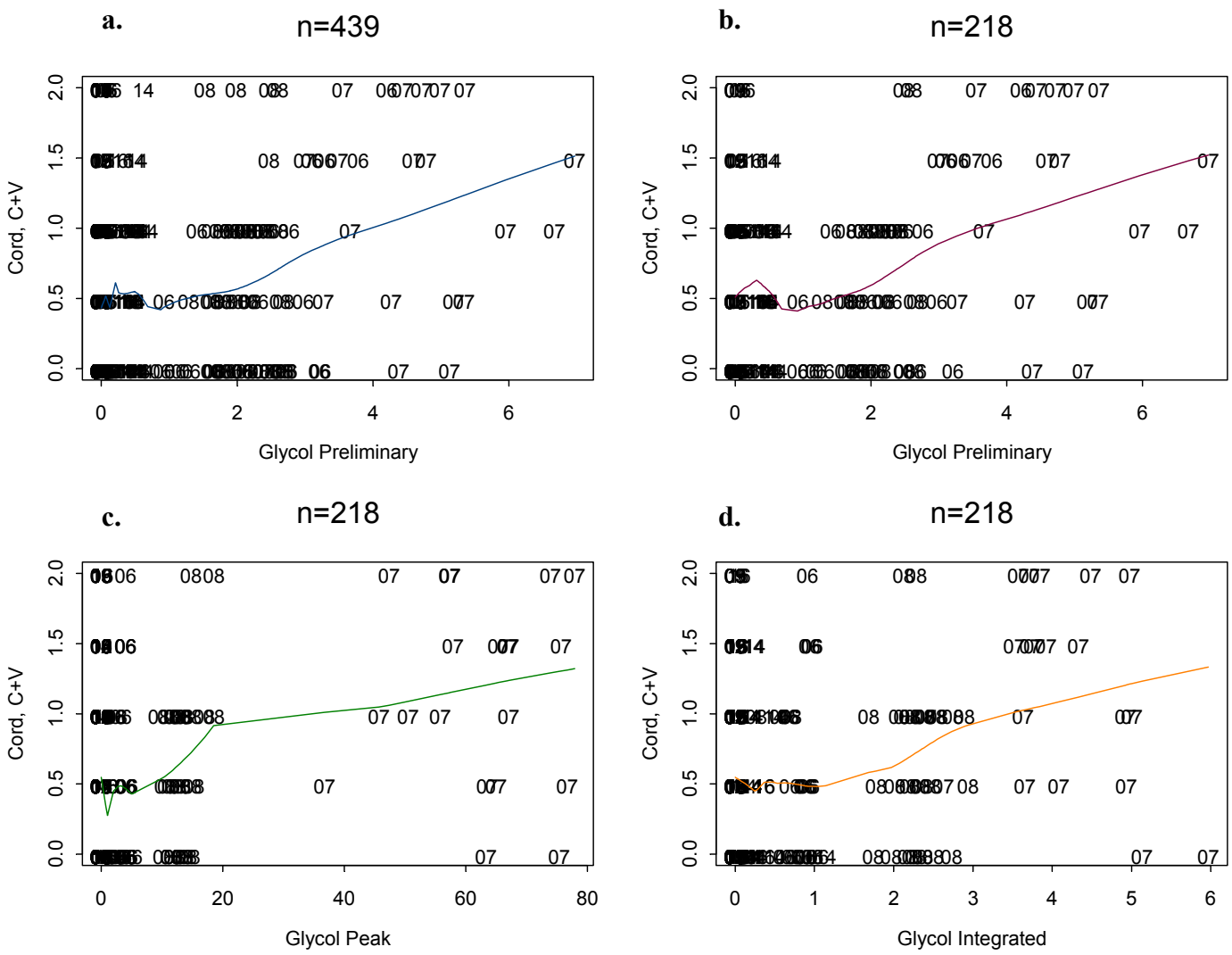
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-29. **Mucus & Coated Cords Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



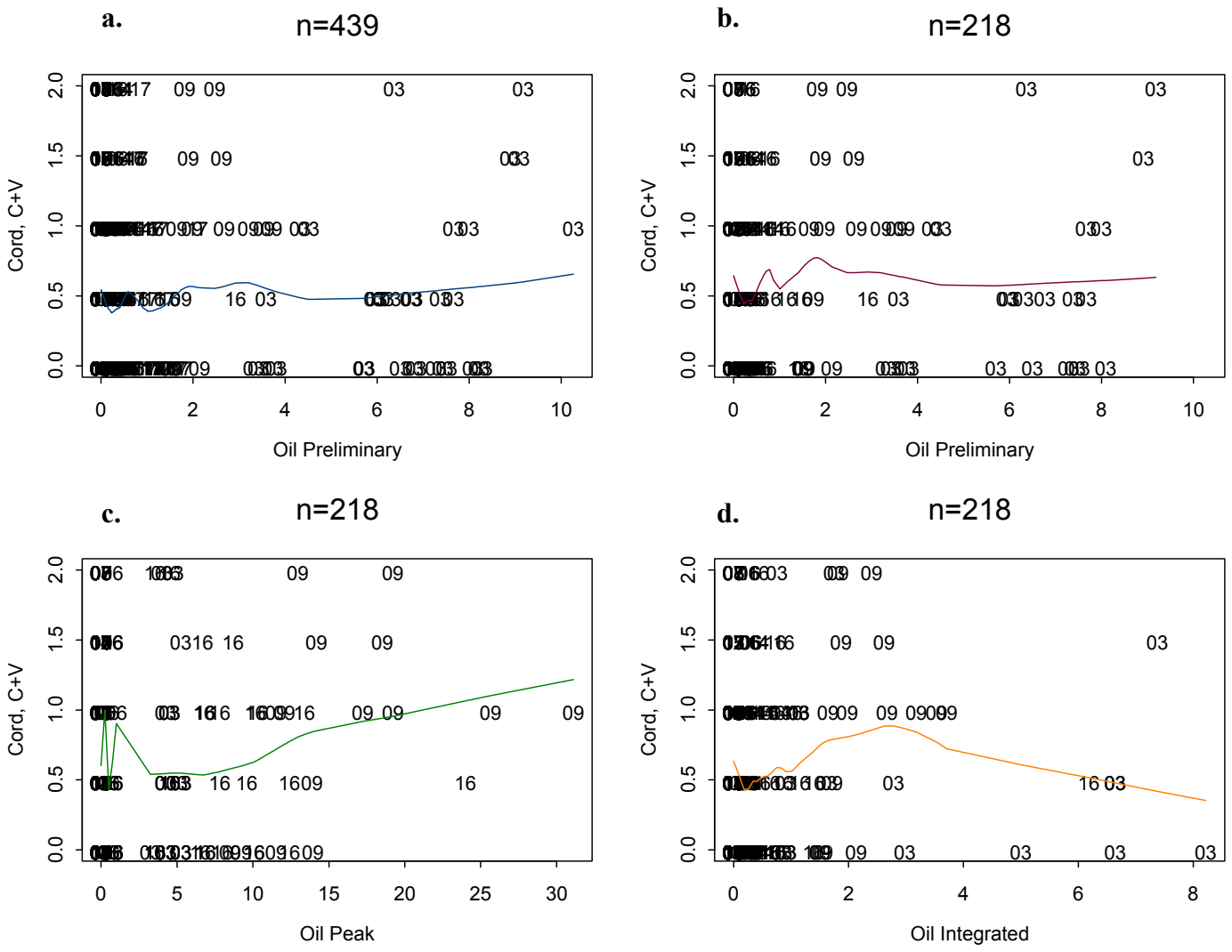
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-30. **Coated Cords & Voice Change Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



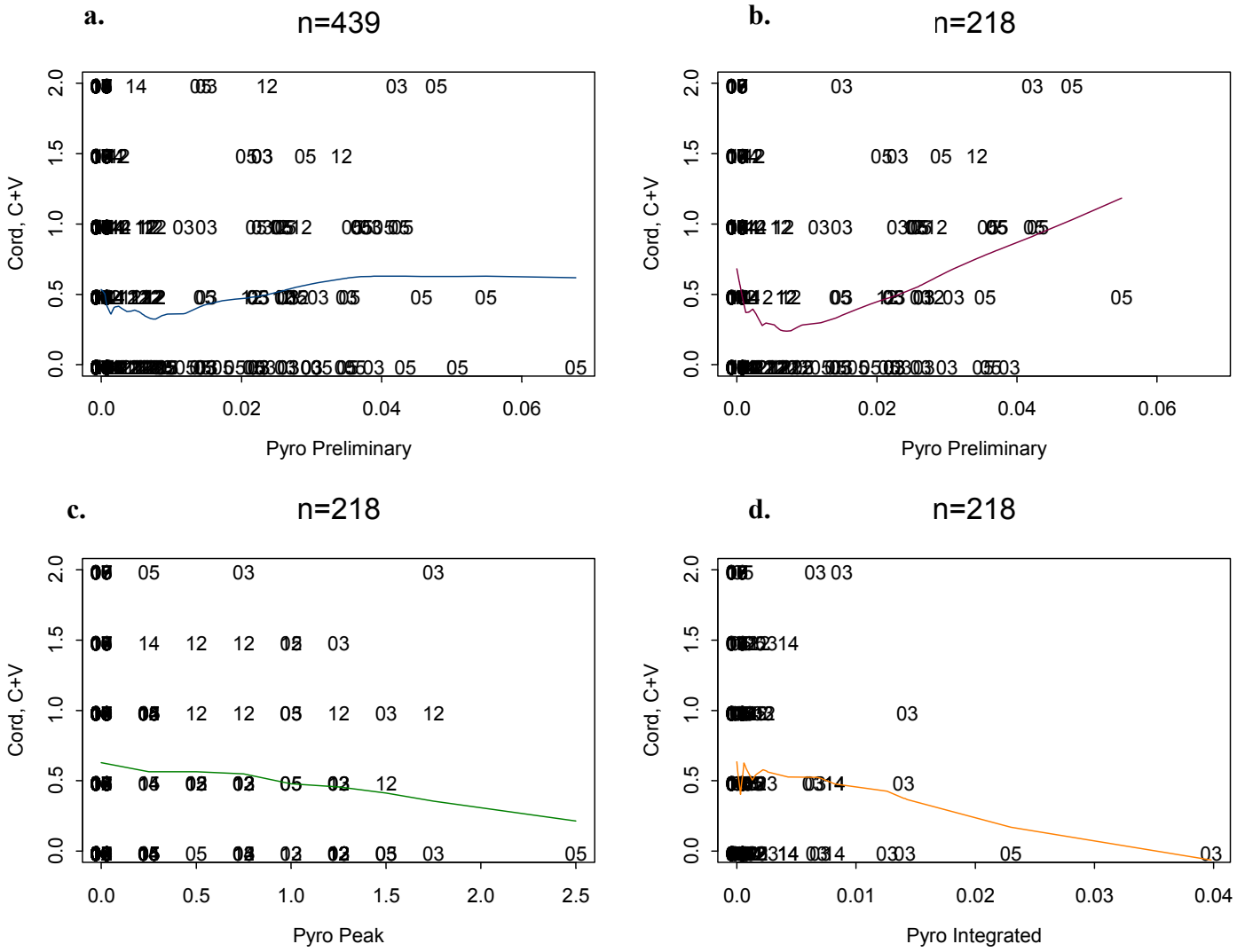
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-31. **Coated Cords & Voice Change Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



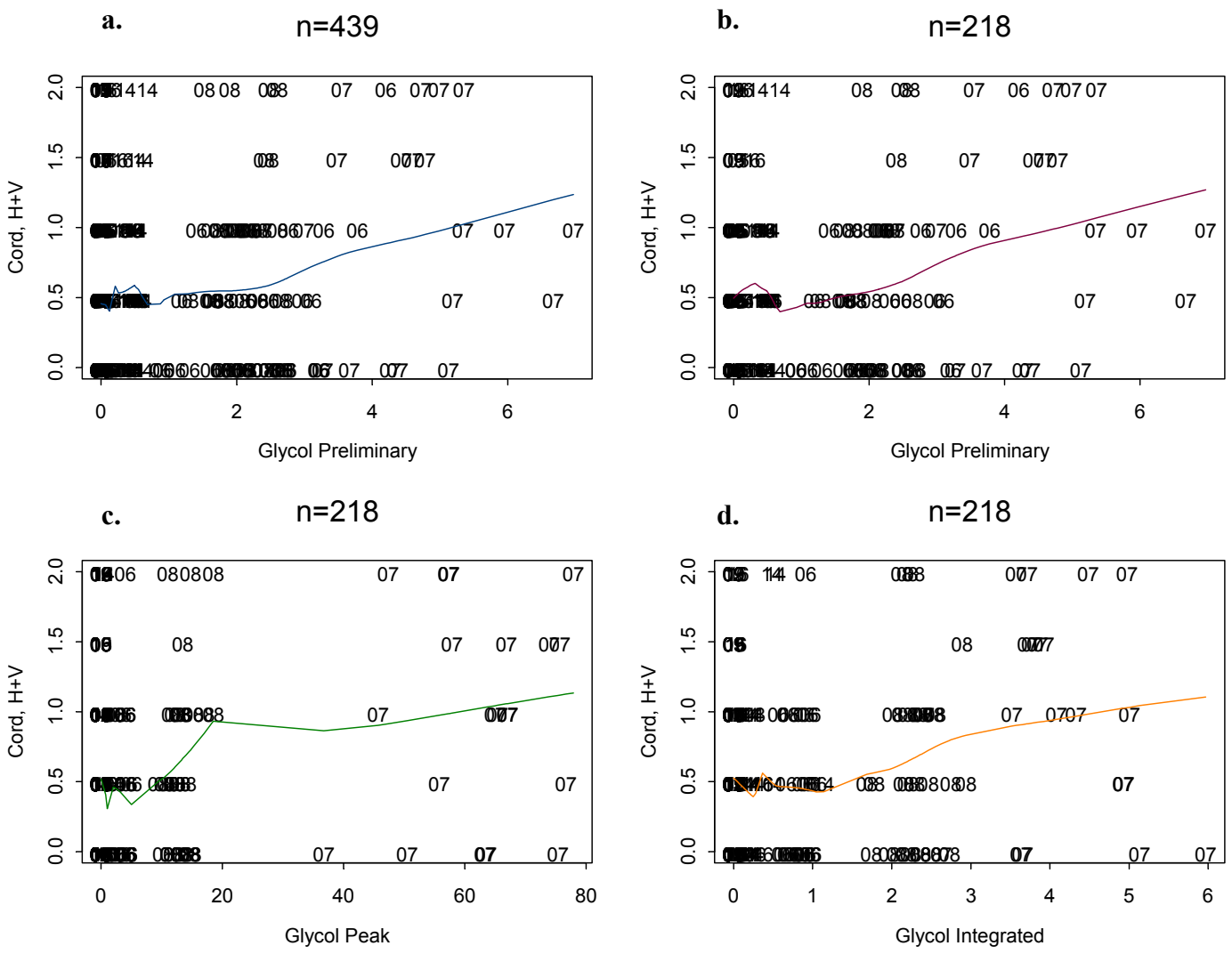
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-32. **Coated Cords & Voice Change Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



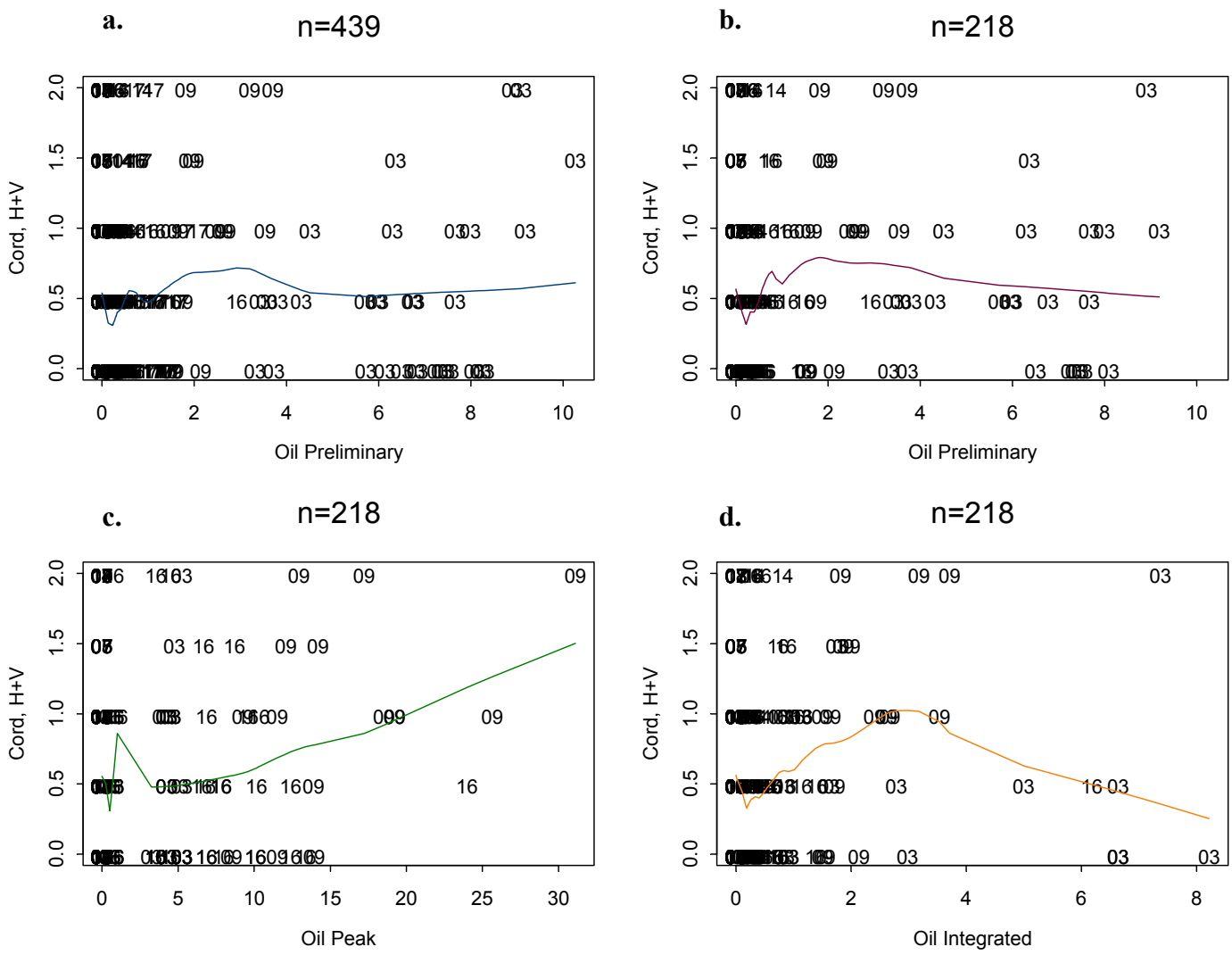
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-33. **Hoarse & Voice Change Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



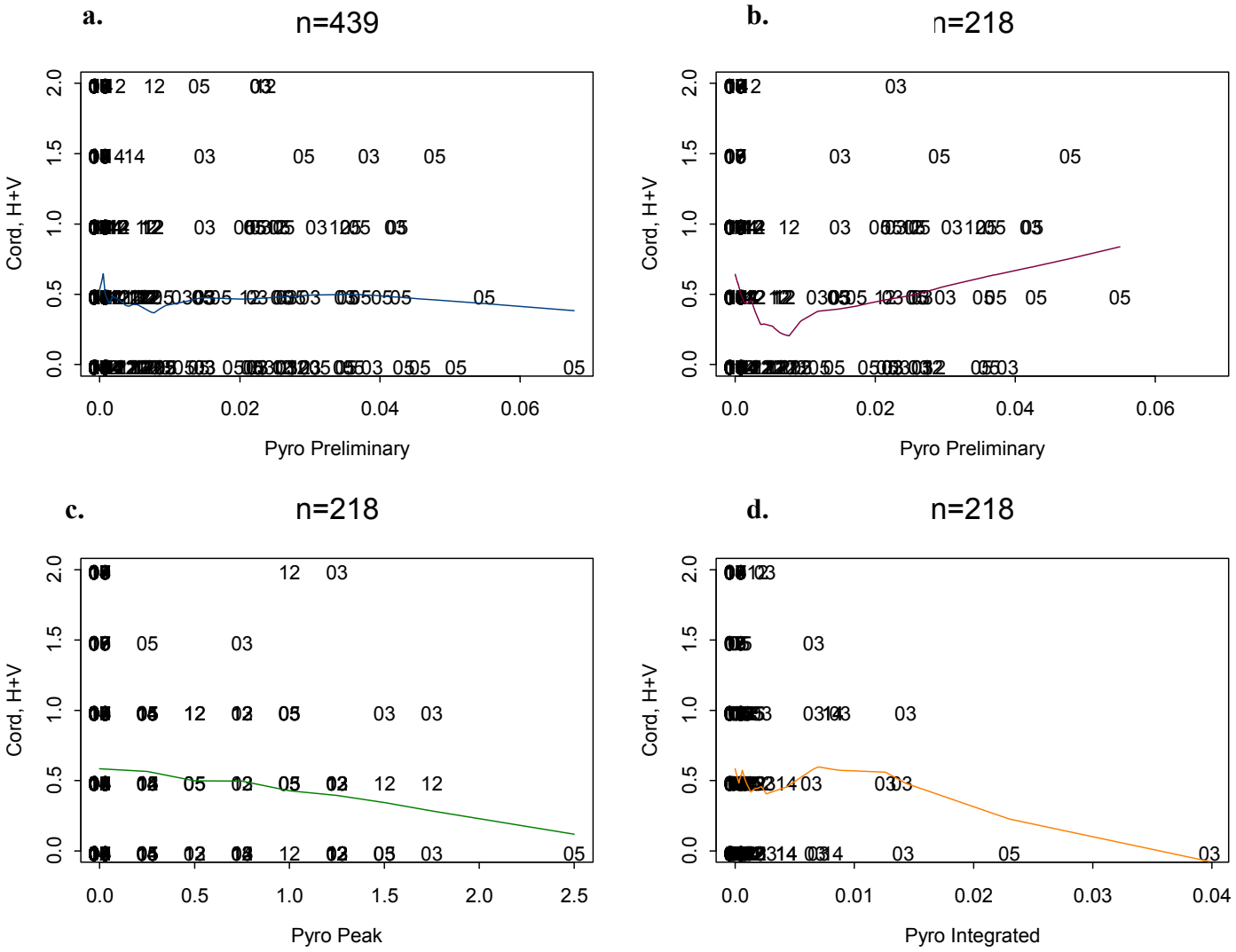
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-34. **Hoarse & Voice Change Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



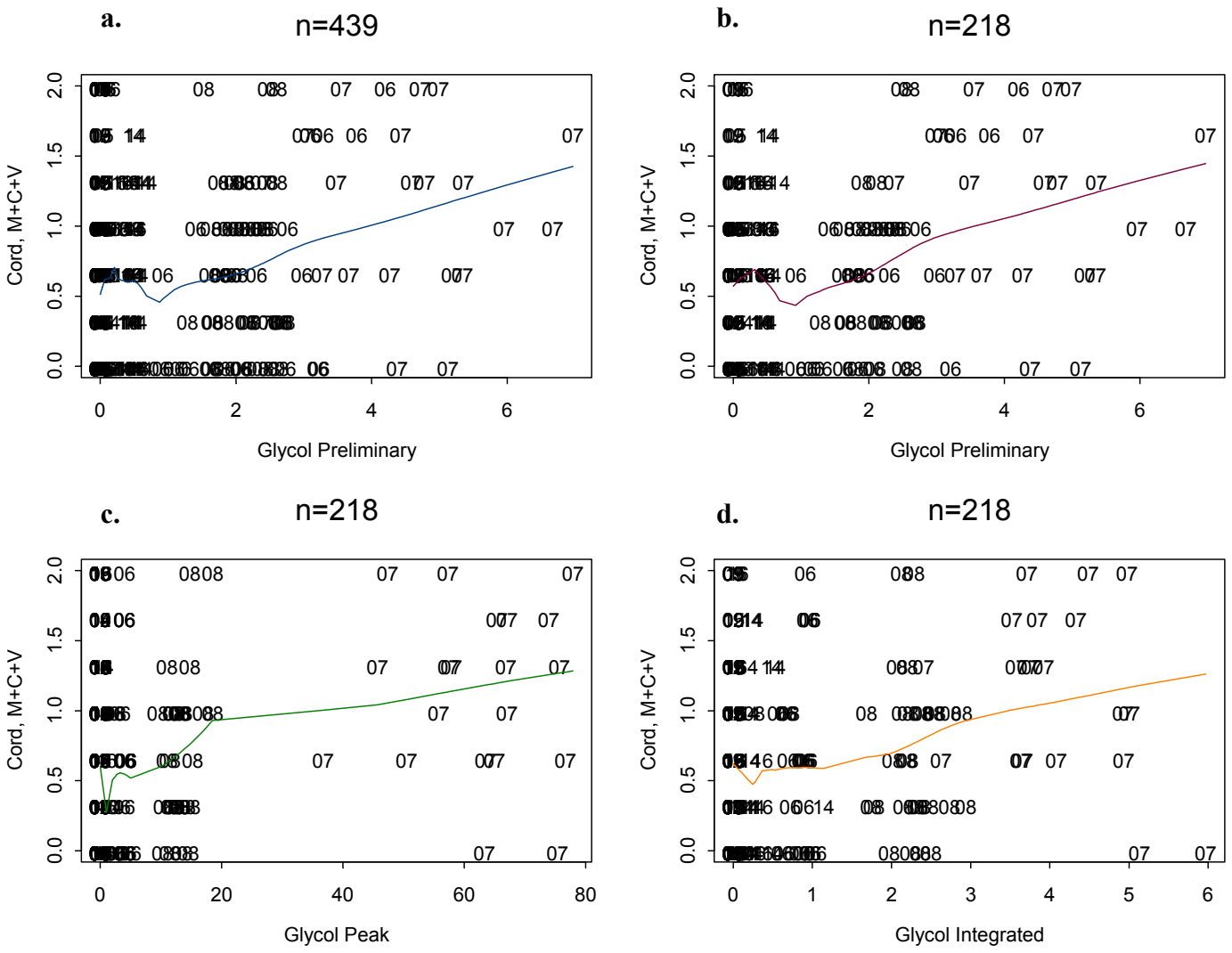
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-35. **Hoarse & Voice Change Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



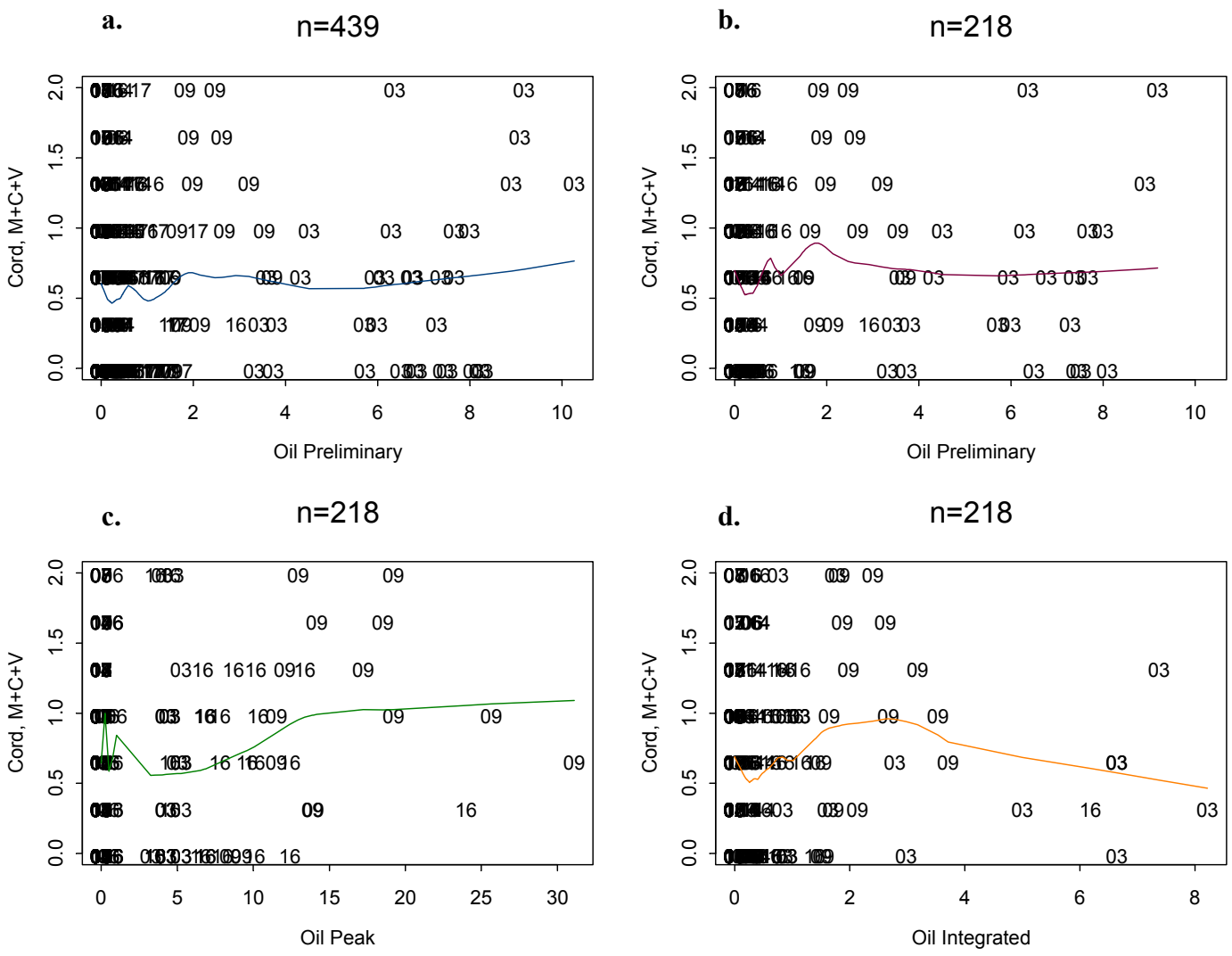
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-36. **Phlegm, Coated Cords & Voice Change Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



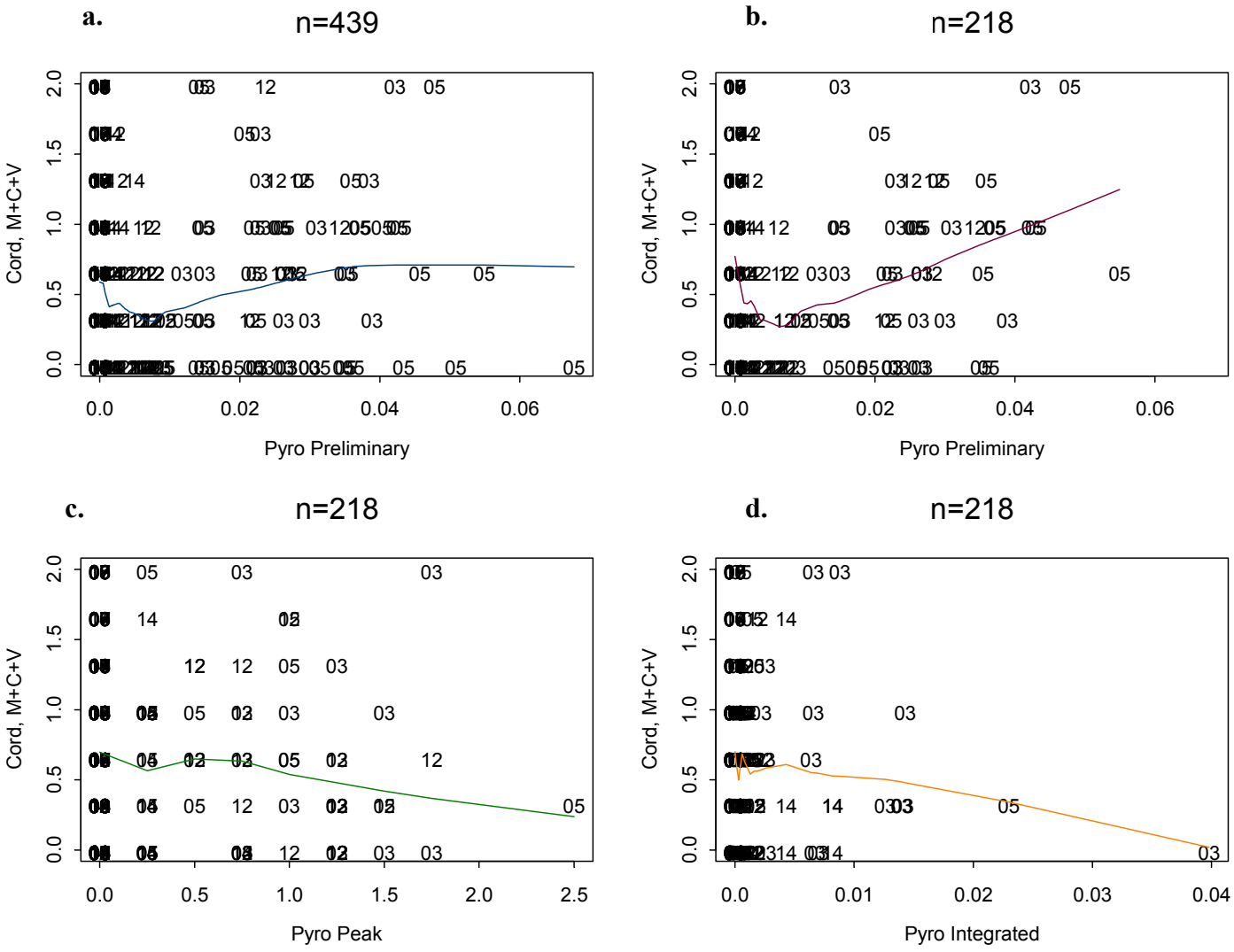
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-37. **Phlegm, Coated Cords & Voice Change Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



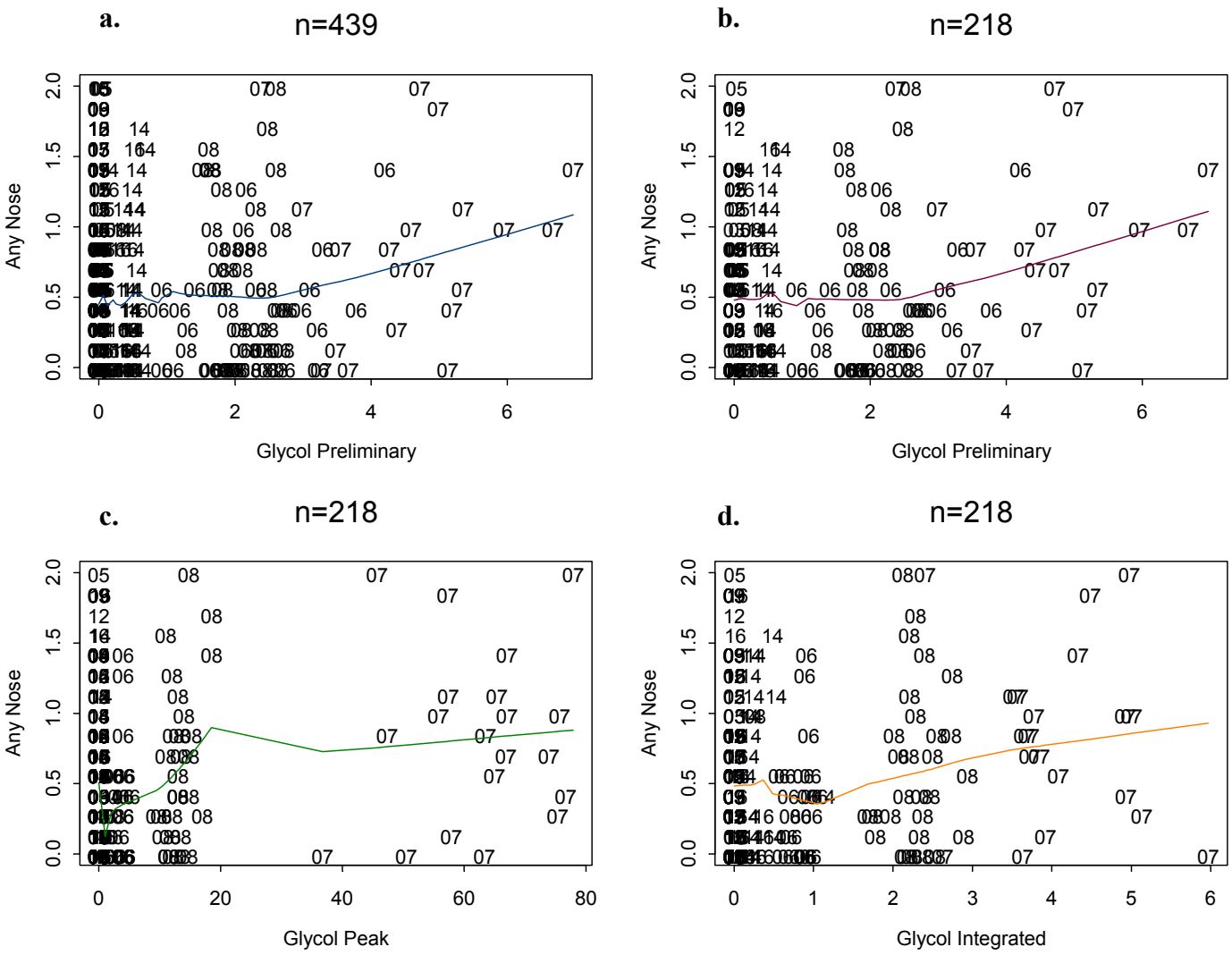
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-38. **Phlegm, Coated Cords & Voice Change Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



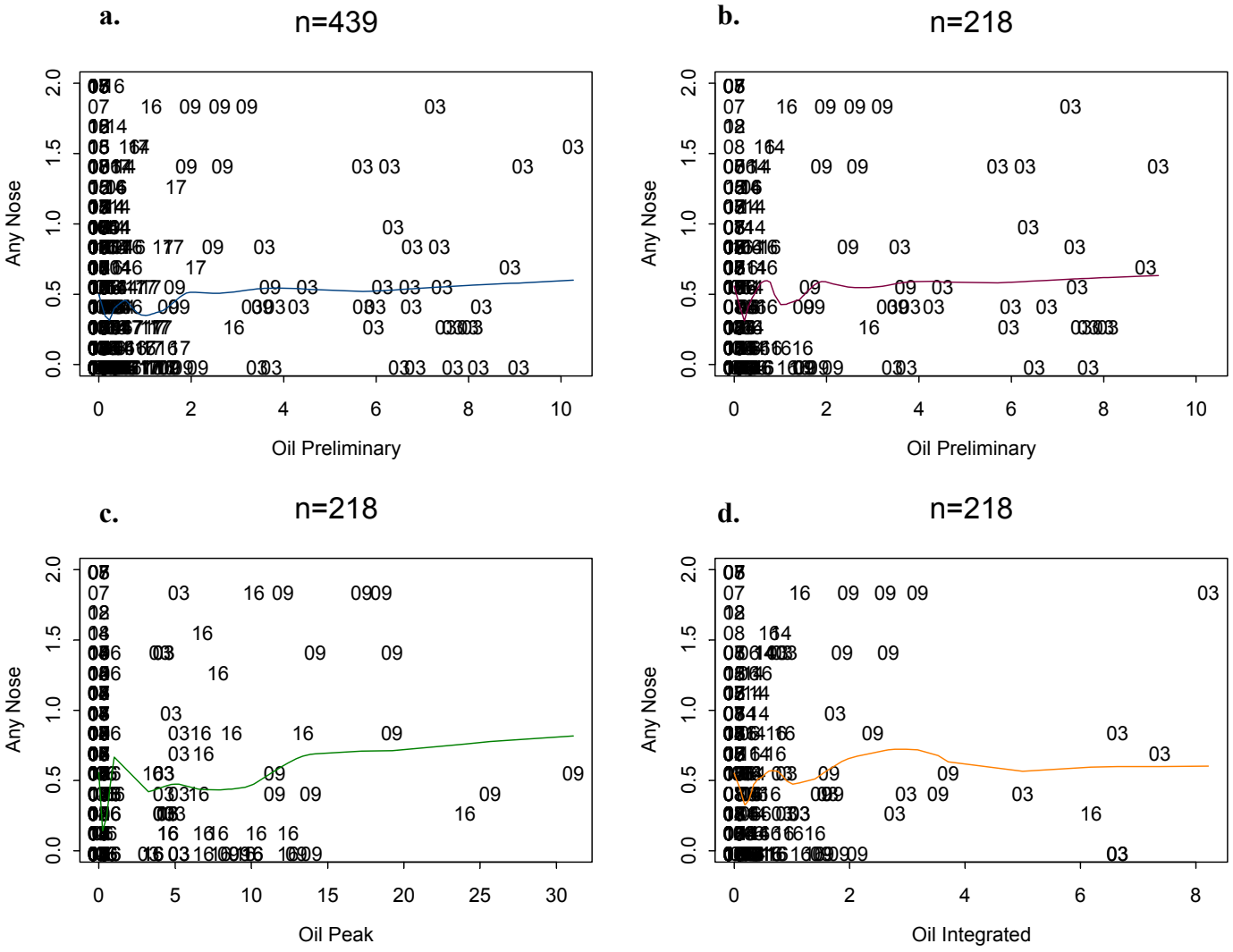
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-39. **Nose Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



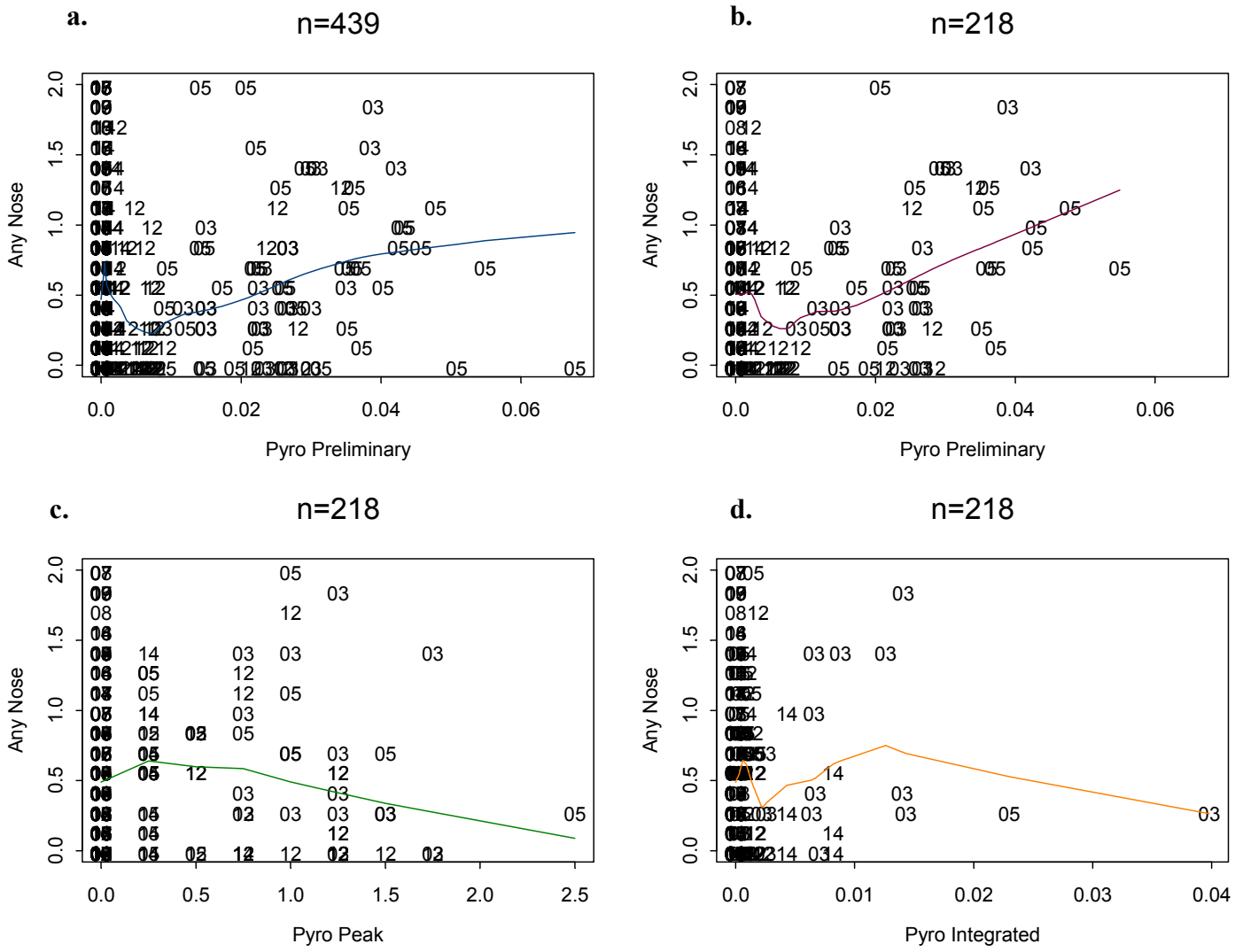
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-40. **Nose Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



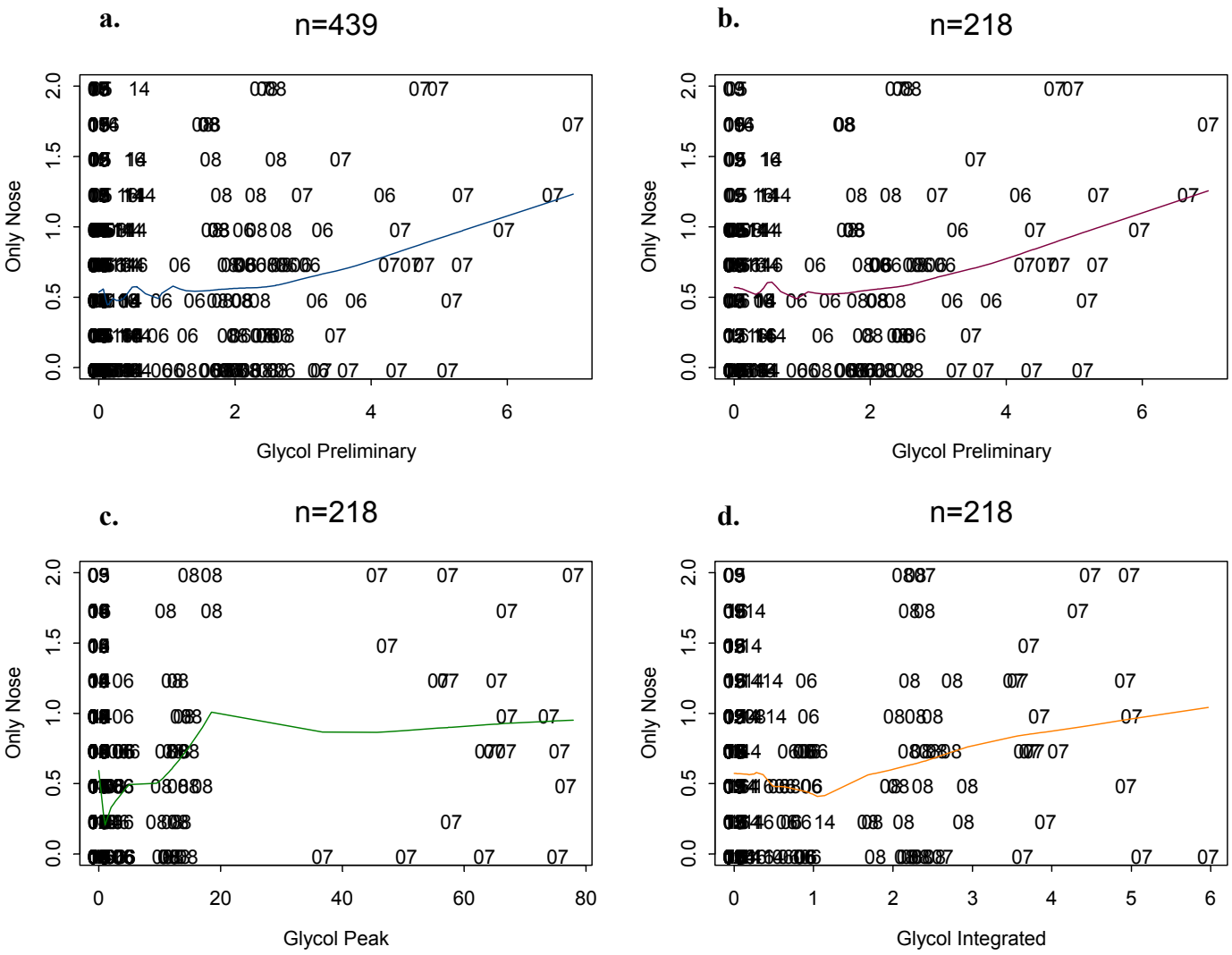
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-41. **Nose Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



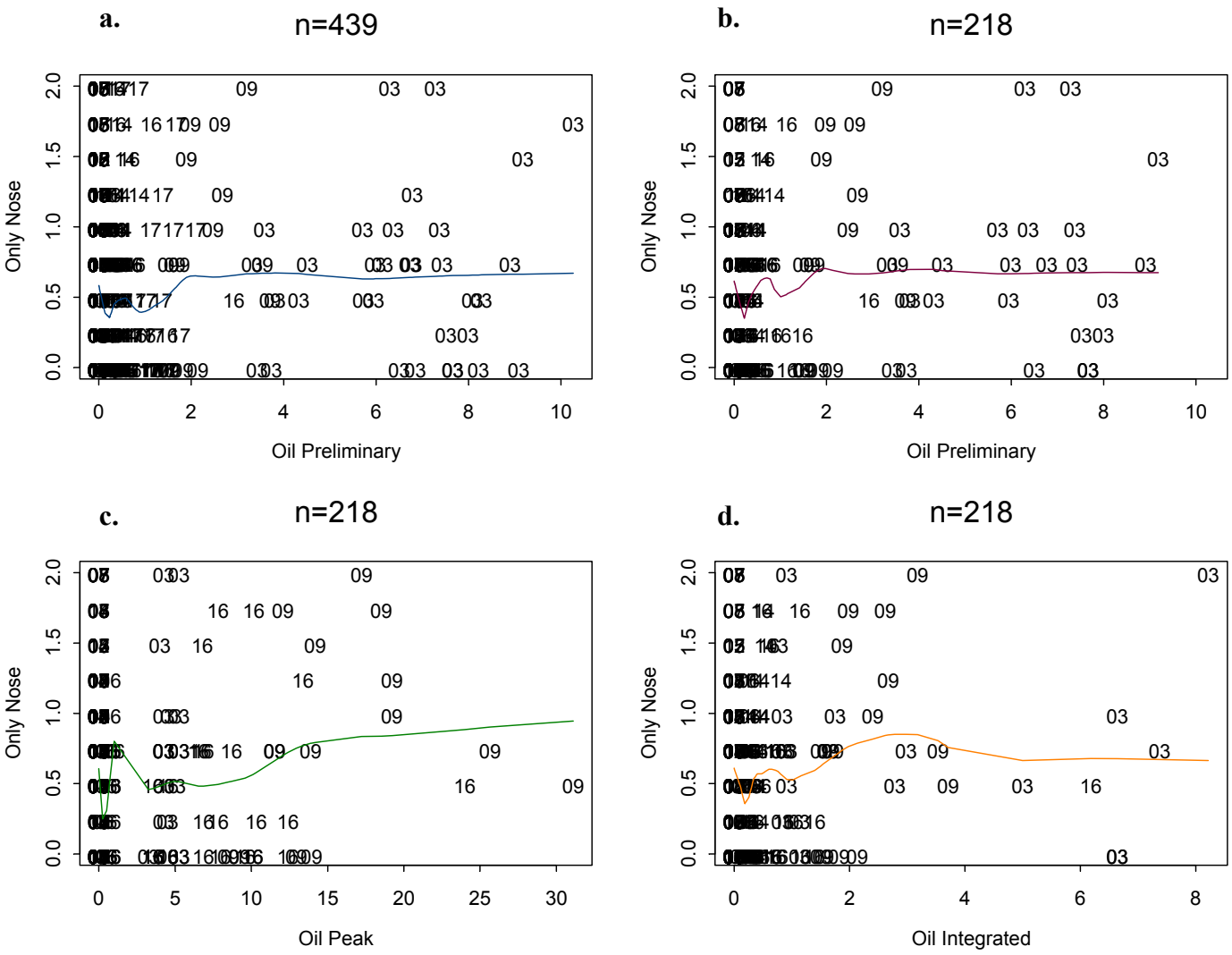
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-42. **Stuffy or Congested Nose Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



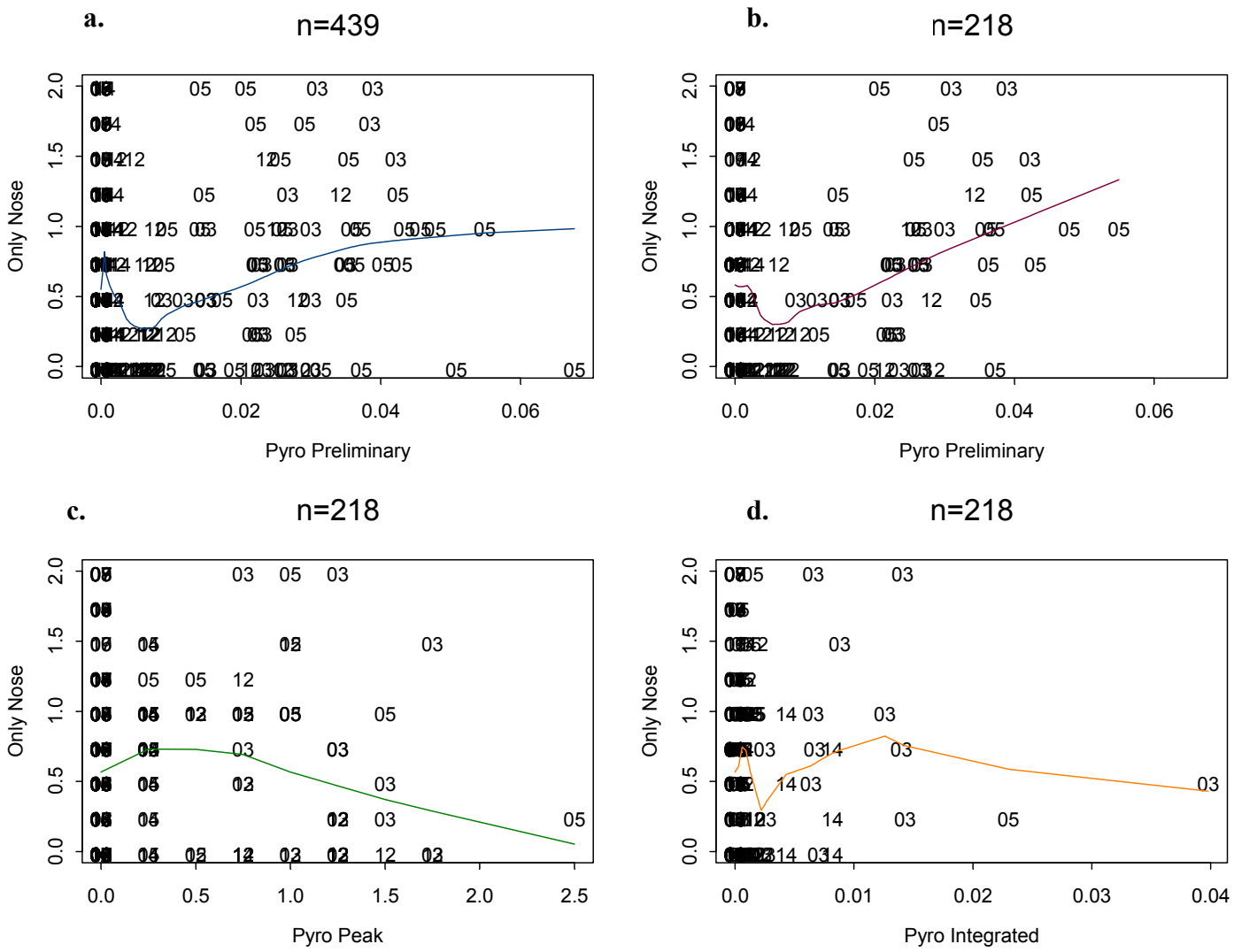
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-43. **Stuffy or Congested Nose Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



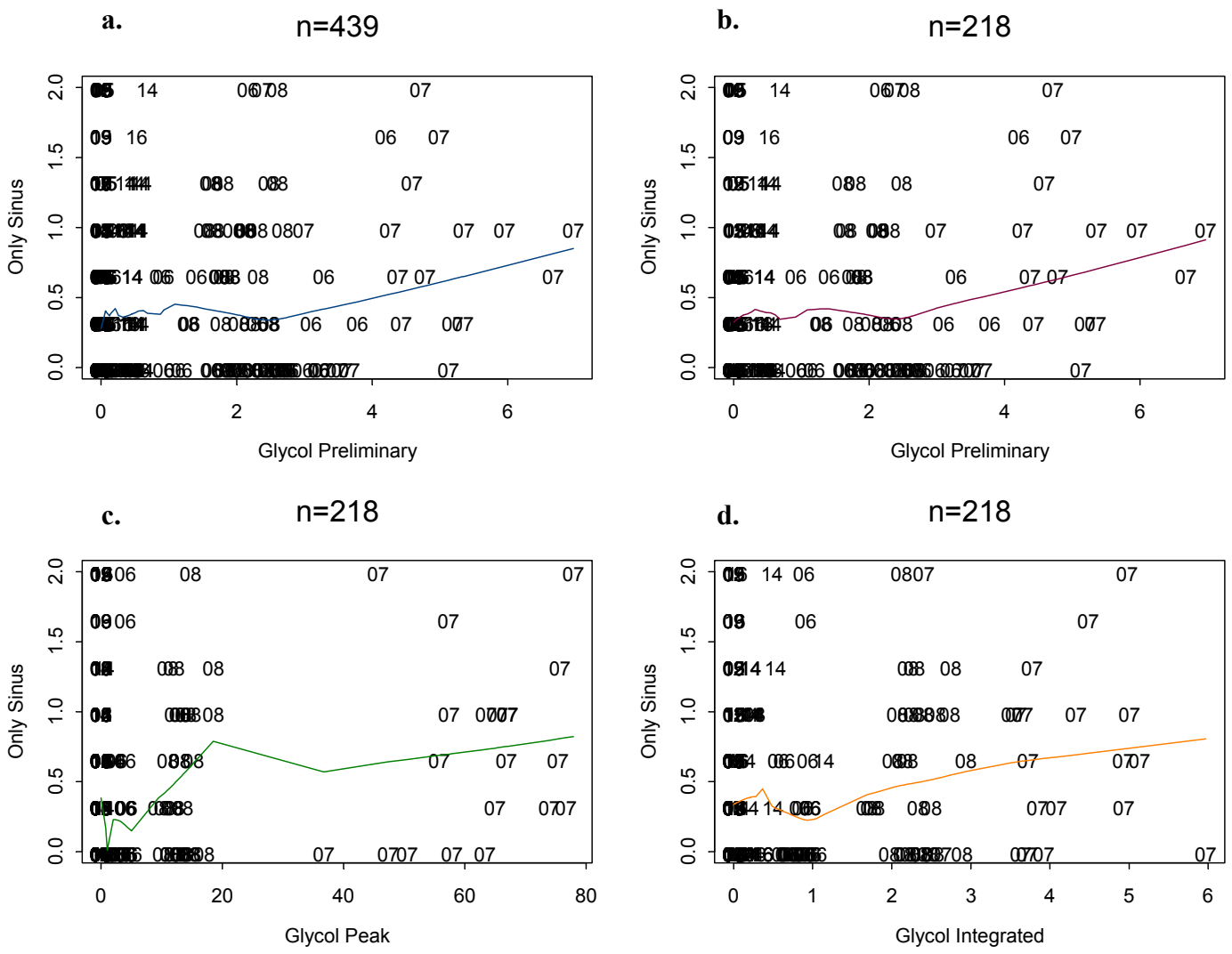
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-44. **Stuffy or Congested Nose Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



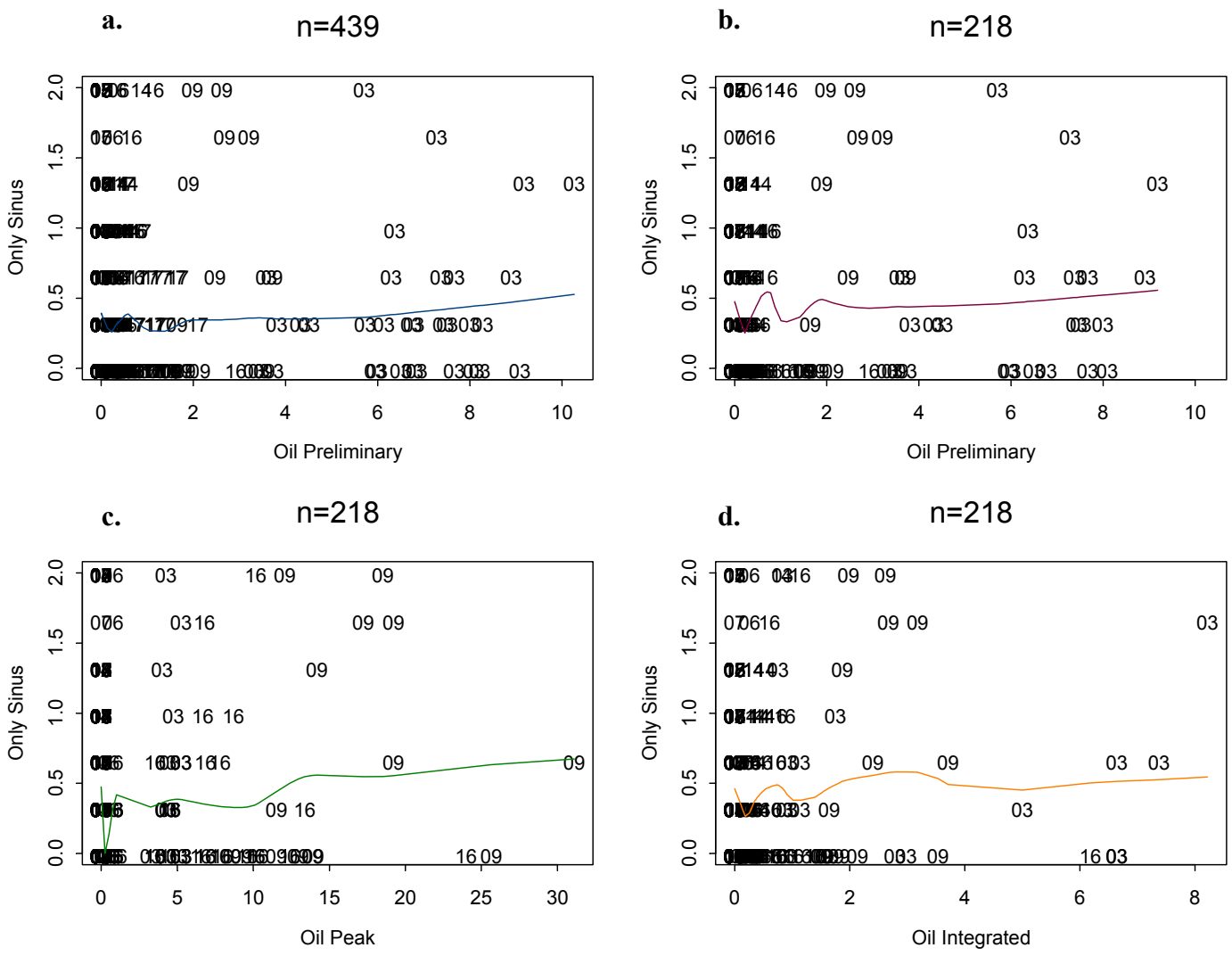
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-45. **Congested Sinus Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



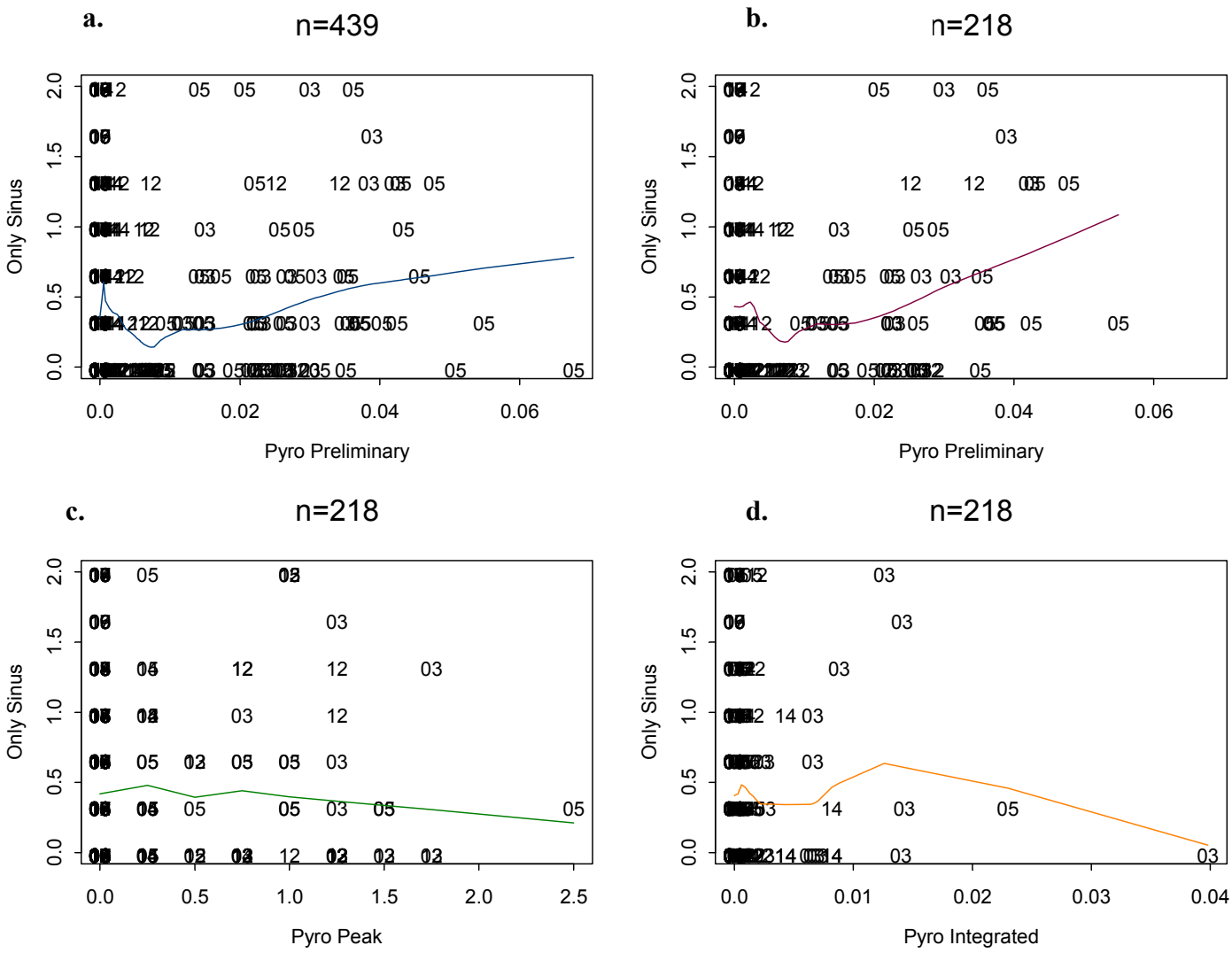
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-46. **Congested Sinus Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



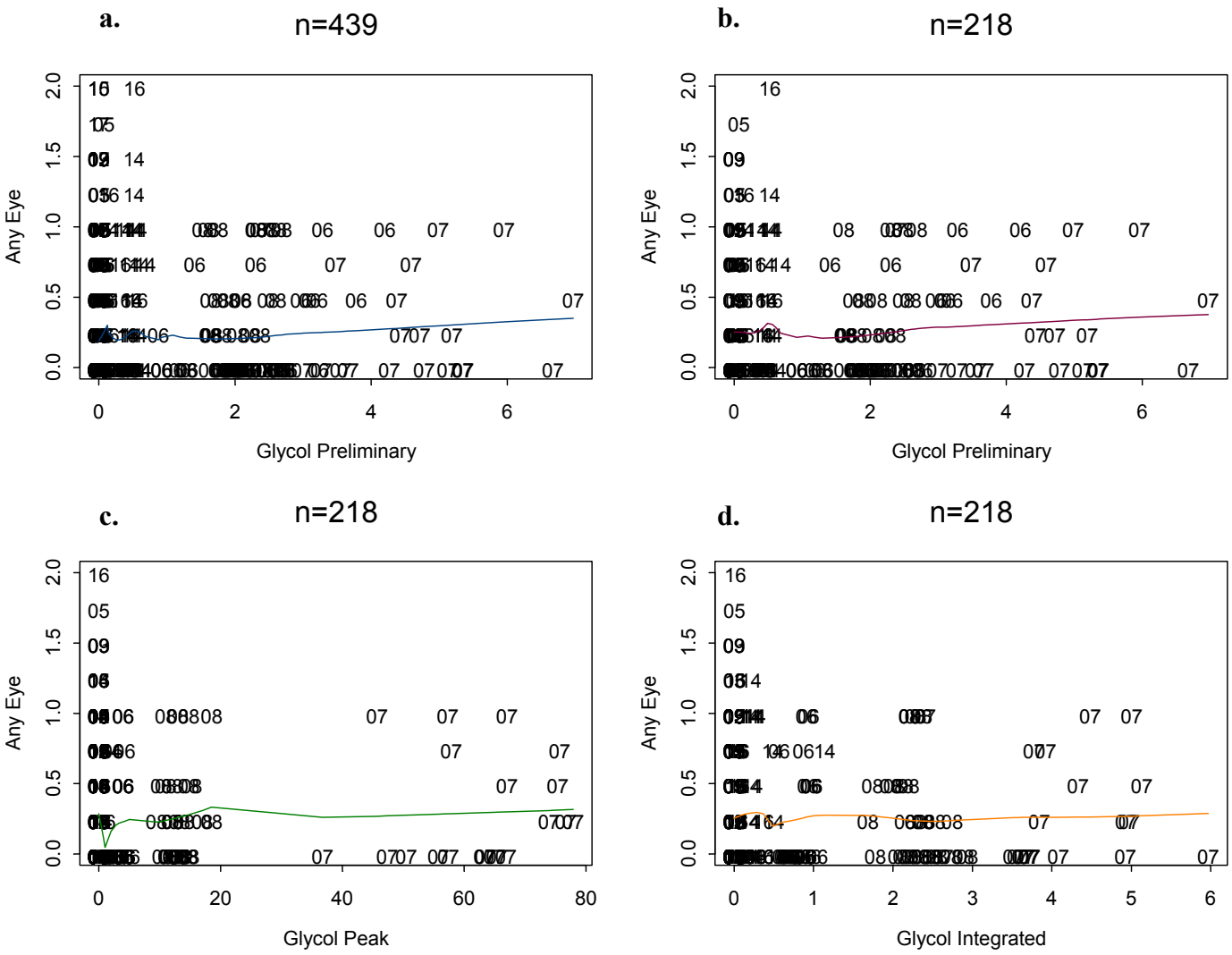
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-47. **Congested Sinus Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



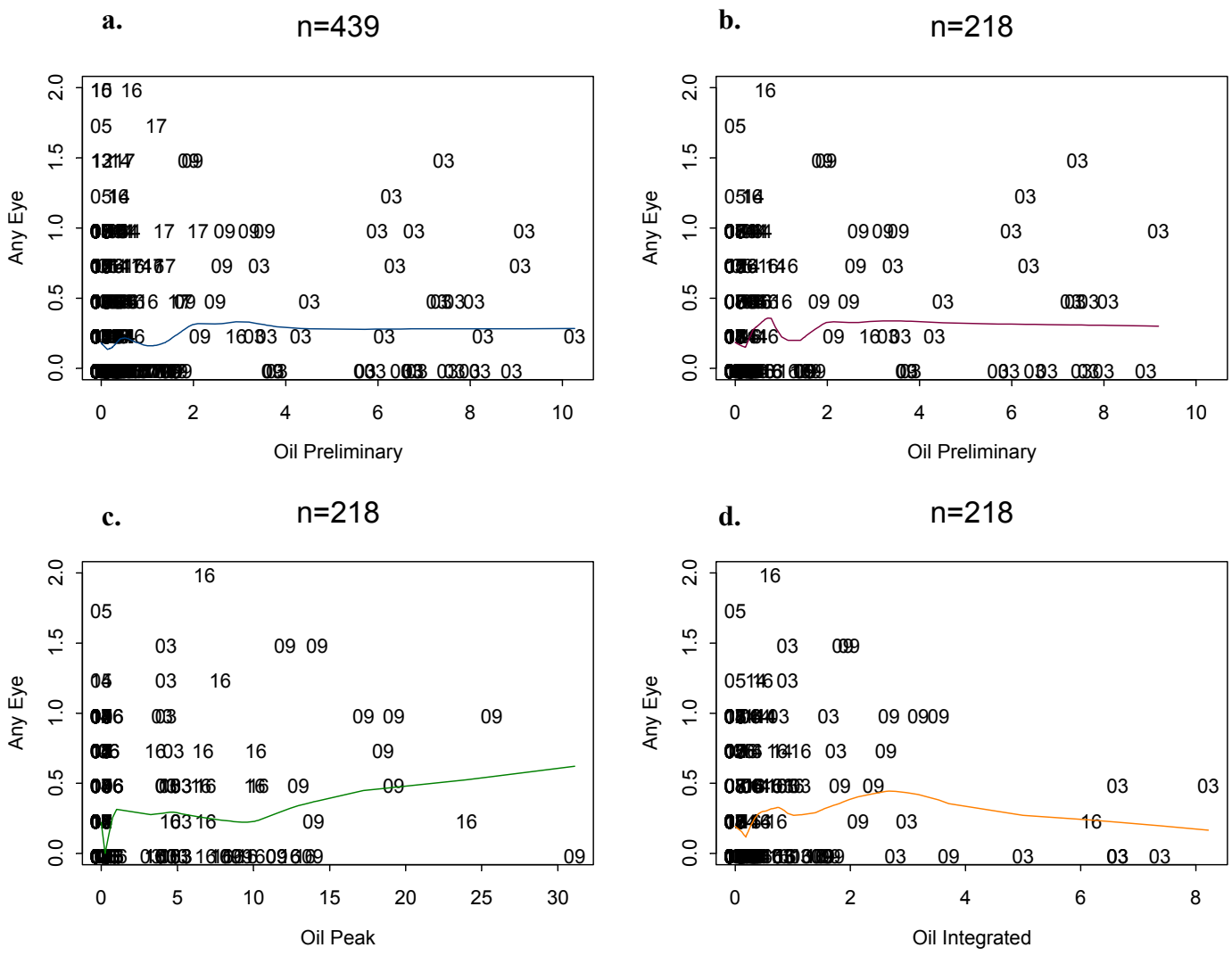
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-48. **Eyes Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



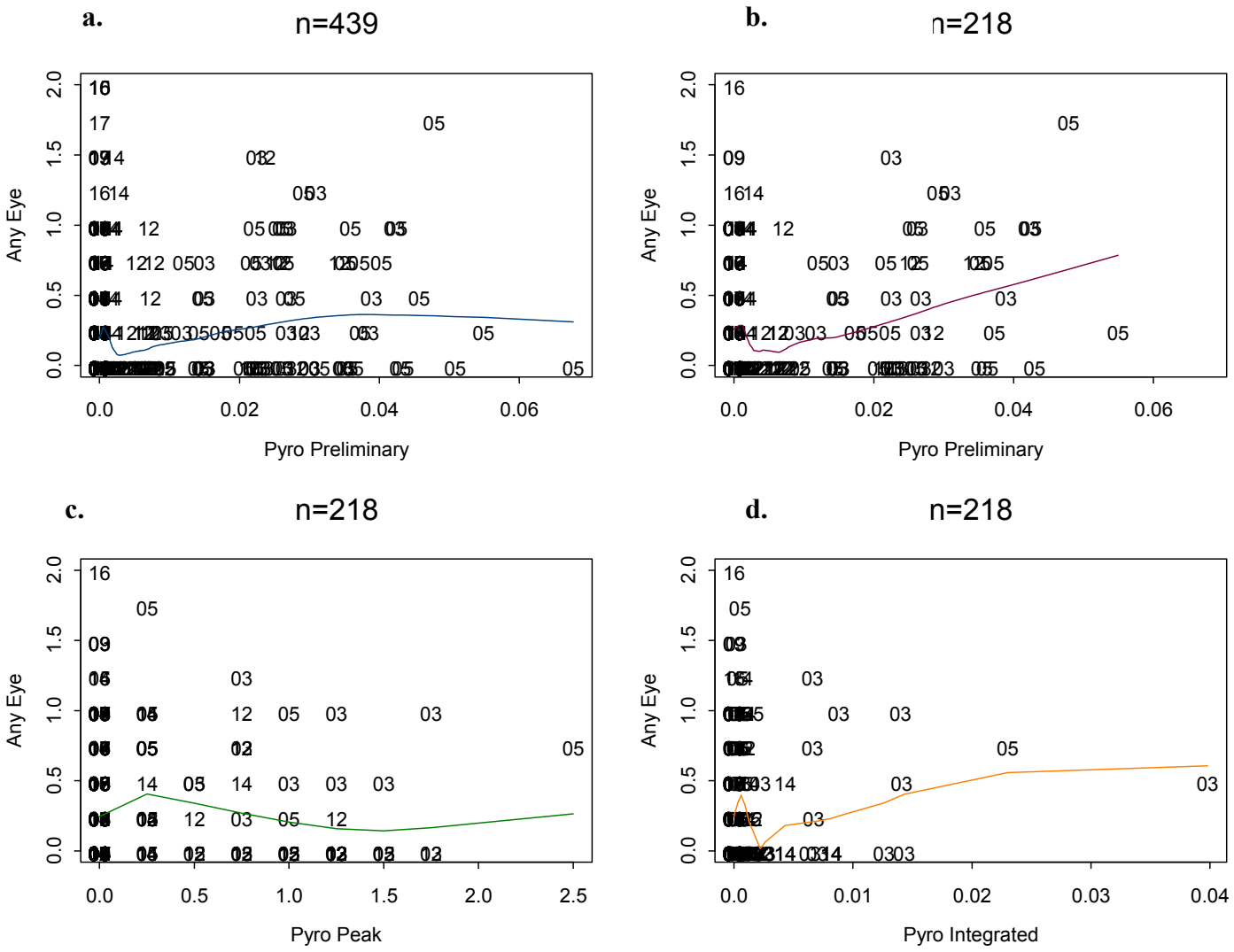
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-49. **Eyes Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



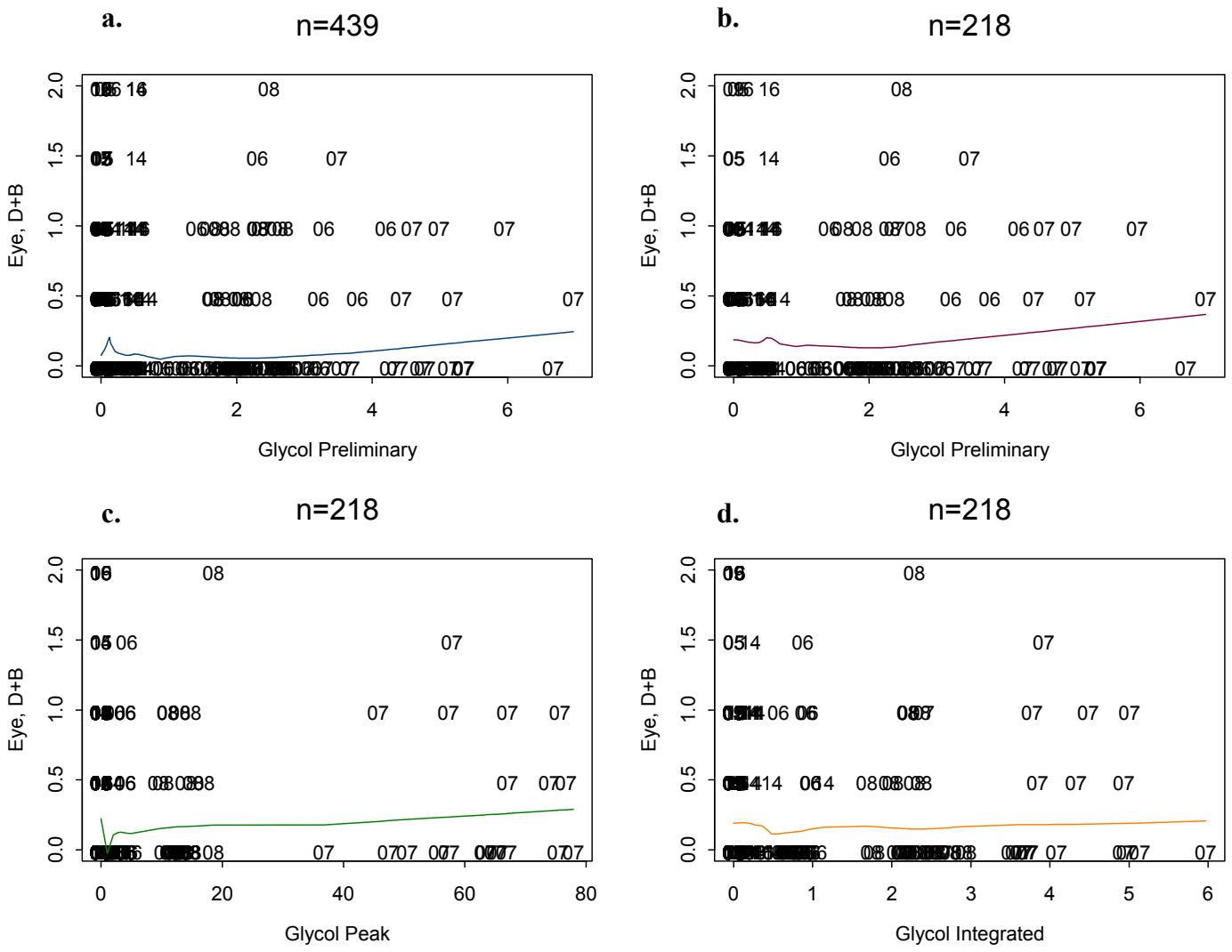
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-50. **Eyes Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



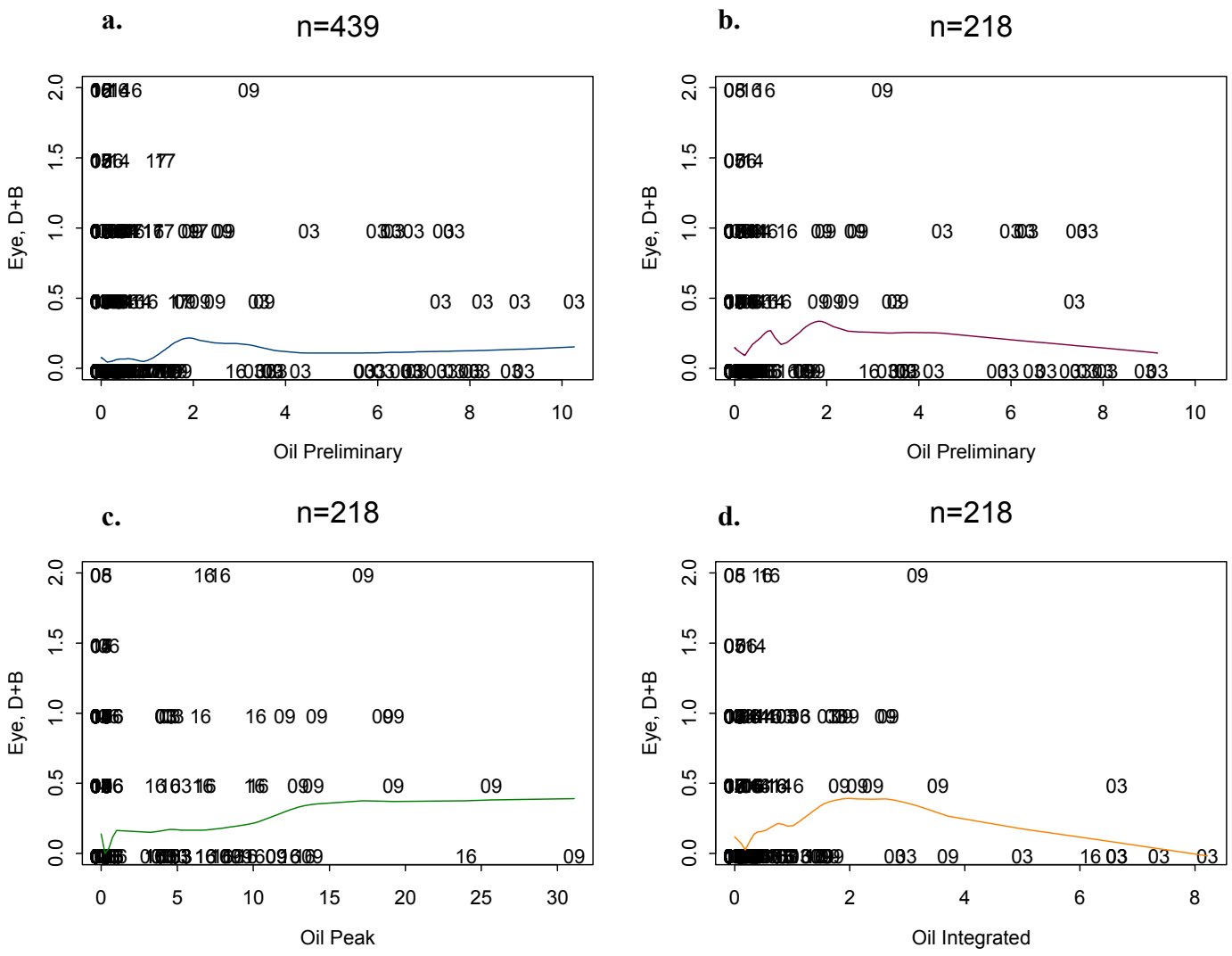
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-51. **Dry or Burning Eyes Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



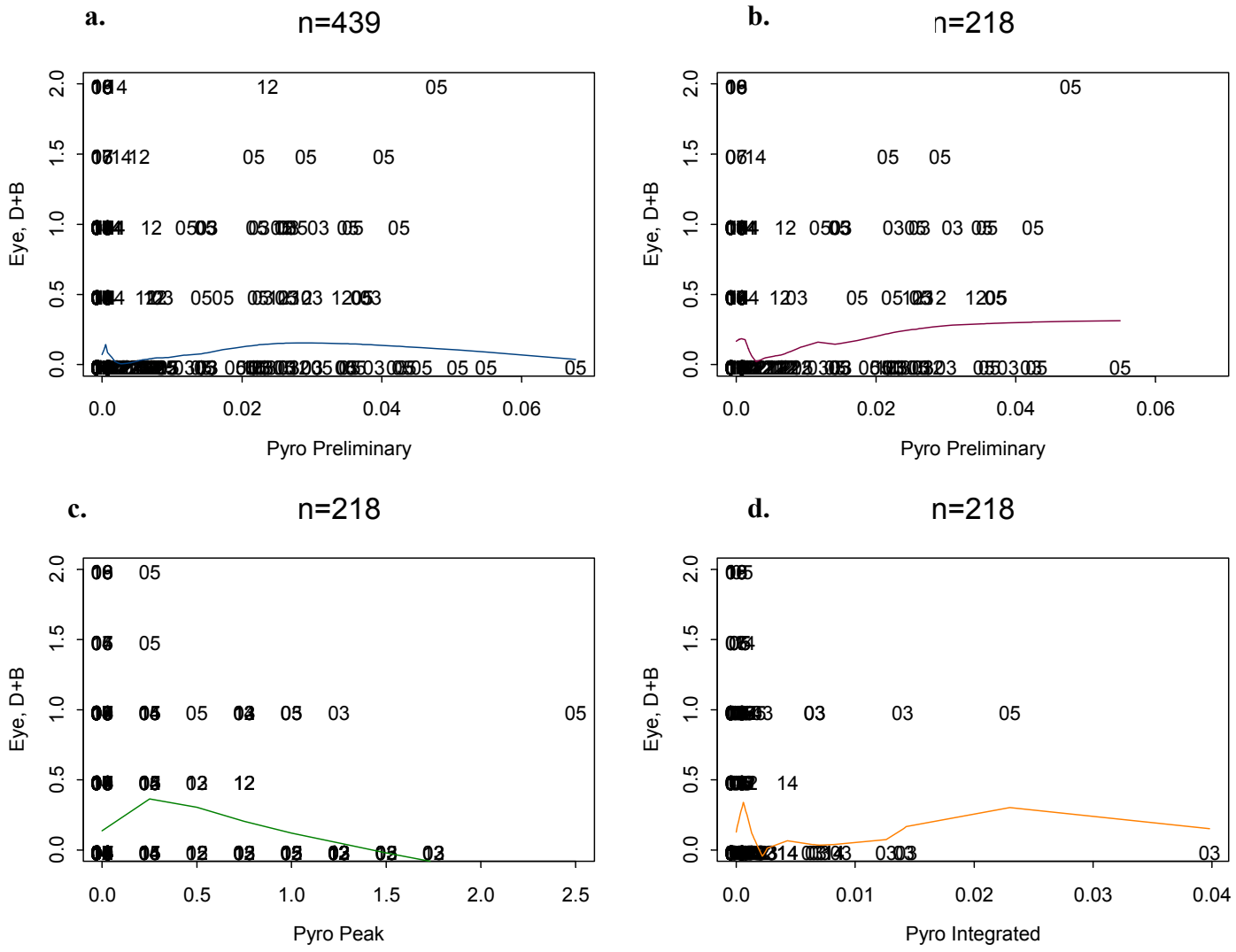
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-52. **Dry or Burning Eyes Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



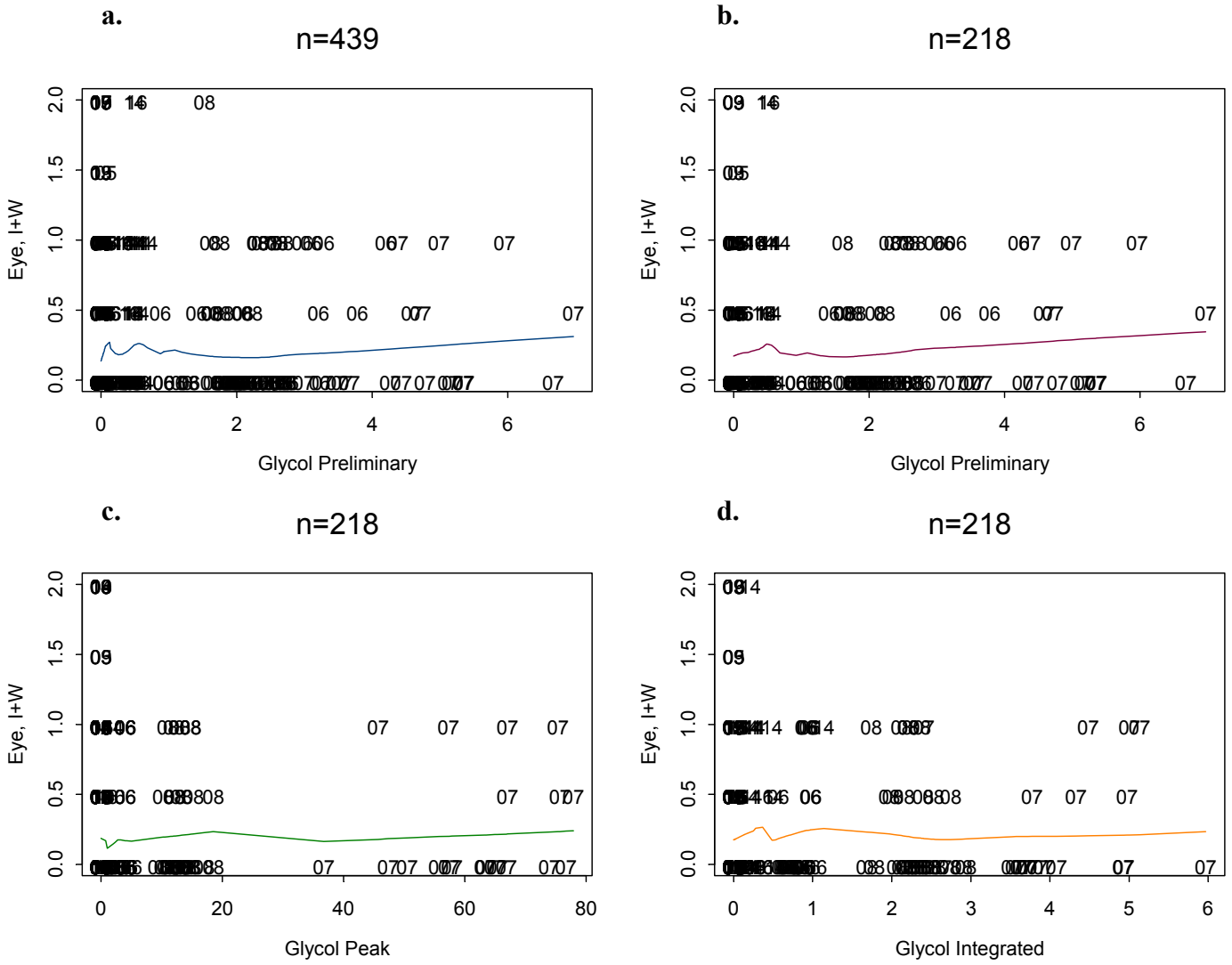
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-53. **Dry or Burning Eyes Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



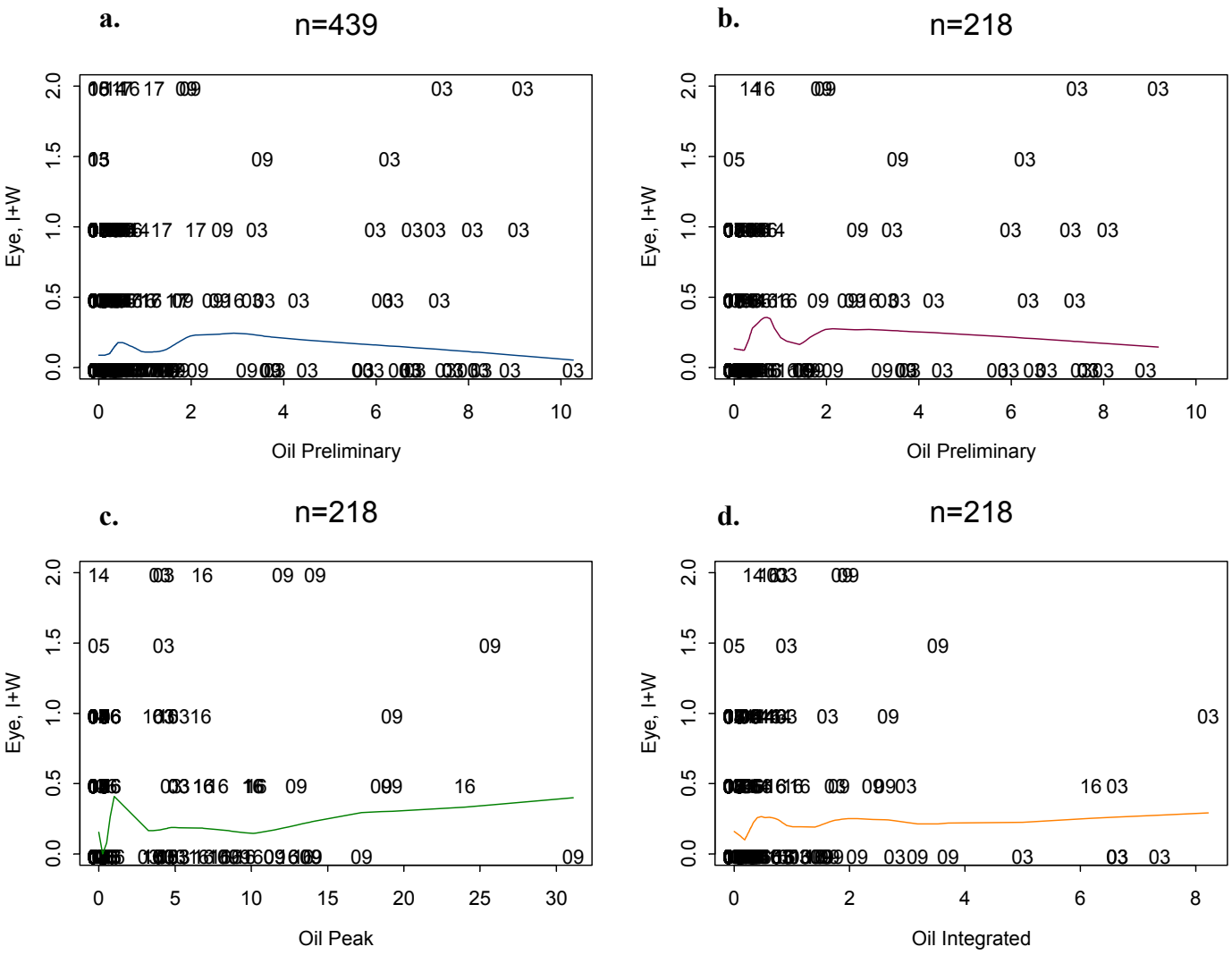
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-54. **Itchy or Watery Eyes Symptom Score by Glycol Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



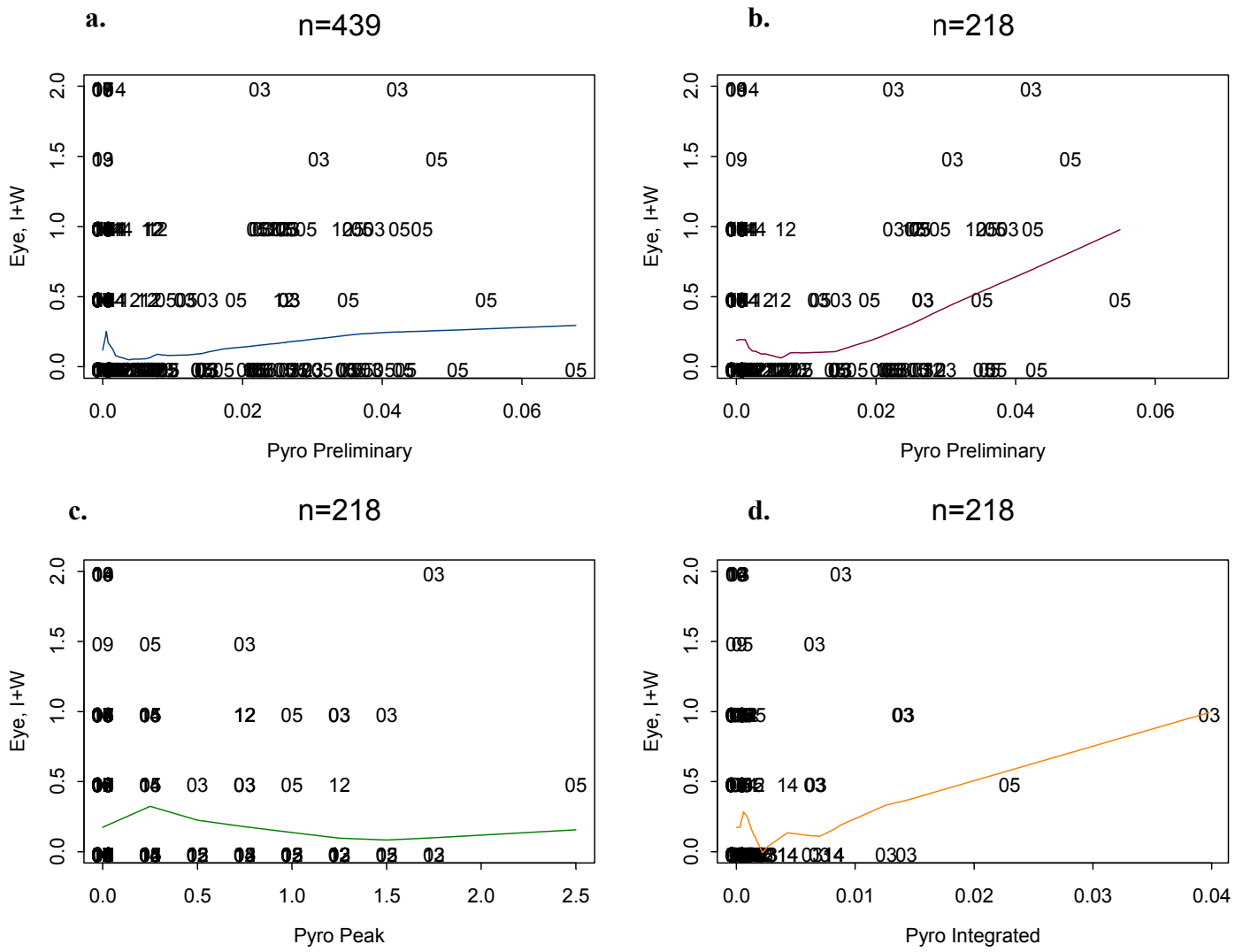
*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-55. **Itchy or Watery Eyes Symptom Score by Mineral Oil Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

Figure V-56. **Itchy or Watery Eyes Symptom Score by Pyrotechnics Exposure:** (a) "preliminary" measurement for 439 Actors, (b) "preliminary" measurement for subset of 218 Actors, (c) "detailed peak time" for subset of 218 Actors, and (d) "detailed integrated dose" measurement for subset of 218 Actors.



*Note: For Graphs **a**, **b**, and **d**, the units of exposure are µg/show. For Graph **c** exposure is expressed in minutes spent exposed above the Broadway average.

VI. DISCUSSION AND CONCLUSIONS

A. Introduction

This study was conducted in 1998-1999 with 439 adult Actors from 16 Broadway musicals. No significant acute change in voice quality, pulmonary function or vocal cord appearance was found among Actors who have greater exposure to theatrical smoke, haze or pyrotechnic agents. However, Actors with exposures to elevated or "peak" levels of glycols and mineral oil, in particular smoke effects from glycols, reported more symptoms than Actors with less exposure. In addition, some mild chronic effects in Actors with greater exposure to glycols and mineral oil were observed.

In comparison to this study, NIOSH studied Actors from four "smoke" musicals and Actors from five non-smoke musicals in the first aspect of their study (1991). In their follow-up study, the three musicals still open from the 1991 study using effects were compared to three dramatic productions. Actors in productions using glycols or mineral oil were more likely to report work-related mucus membrane irritation, upper respiratory symptoms and lower respiratory symptoms. The NIOSH investigators also performed measurements of the constituents of theatrical effects. They found peak exposures to glycol or mineral oil aerosols occurred during the time of cue release in the shows. Overall, the average exposure to glycol or mineral oil, as measured over the course of the entire production, was low. NIOSH investigators concluded that peak exposures may contribute to the high rates of symptoms seen in Actors exposed to theatrical effects. There was no association between asthma and exposure to smoke or haze.

The current study found that overall exposures, as measured by time-weighted integrated averages, were also low. Unlike the NIOSH study, however, physical activity was also factored into the exposures for each Actor, since those with greater activity have increased respiratory rates and thus greater opportunity for inhalation of theatrical effects. Our exposure-activity matrix incorporated information about actual time on stage, breathing rates associated with specific activities and ambient exposure measurements. For a subset of 218 Actors, more detailed measurements of theatrical exposures, activities and time on stage were performed. As described in Chapter IV, this included repeated theatrical measurements using cued releases and quantifying Actors' time on stage using scratch tape reviews. In the subset, there was a strong correlation between self-reported time and activities on stage and time and activities identified in the scratch tape reviews.

B. Phase 1 – The Baseline Questionnaire

The methodologies used to assess levels of exposure to theatrical effects differed between the preliminary (available for all Actors, n=439) and the detailed (available for a subset of Actors, n=218) measurements, as outlined in Chapter IV. The preliminary measurements reflected potential peak exposures for any Actor in a given production. In the detailed

measurements, both an individual Actor's exposure to overall (time-weighted integrated averages) and peak exposures were quantified.

Given the low average overall exposures of Actors in the musical productions, it is not surprising that there was no significant correlation between Phase 1 symptoms and time-weighted integrated exposure to glycol, mineral oil or pyrotechnics among the 218 Actors in the detailed exposure assessment. This was in contrast to the data from the preliminary exposure-activity matrix, where increased Phase 1 symptoms were significantly associated with higher exposure to glycols for most symptom categories. Moreover, when the detailed peak exposures were evaluated, using time exposed to two times and five times the Broadway average exposure level, there were statistically significant associations between exposure to glycol and increased respiratory, throat and nasal symptoms. Thus, increased exposure to "peak" levels of glycol is associated with increased symptoms in Actors.

Peak levels of glycol exposure are associated with symptoms of mucus membrane irritation. This is consistent with the chemical and physical properties of glycols, since they have irritative and drying properties at high doses and chronic (i.e., on a continuing basis) exposure. There are consistent, statistically significant associations between an overall increase in throat symptoms, for both individual throat symptoms and composite throat symptom scores, with increasing glycol exposures. Similarly, symptoms such as coated vocal cords, hoarseness and voice change were associated with increasing glycol exposure, as were symptoms of nasal irritation. While most of the symptoms were increased for Actors with time spent at greater than two times the Broadway average, only the symptom score for phlegm, coated cords and voice change was significant at the five times the Broadway average level. This is supported by the pre-performance fiberoptic findings of inflammation in Actors with the highest glycol exposure; excess phlegm is physically demonstrable on the fiberoptic evaluation and the Actors reported analogous symptoms. All other symptoms related to respiratory tract irritation were positively associated, but did not reach statistical significance. The lack of statistical significance may be related to the small numbers of individuals with time at this level of exposure or may reflect the lack of an effect. We did not find a statistically significant increase in eye symptoms with glycol exposure.

As opposed to glycols, which are generally used to generate localized effects, mineral oil is usually used to produce a uniform, low level haze effect across the stage. Thus, the distribution of oil is similar for all Actors on stage regardless of their locations, with no exposure to short bursts of high concentration. Two shows, however, Cats and Sound of Music, utilized mineral oil in a peak concentration during one scene.

In this study, exposure to mineral oil was not associated with increased respiratory or nasal symptom reporting, as glycol exposure was. There was, however, a statistically significant increase in irritated throat symptoms among those Actors with the highest exposures in the detailed exposure analysis (those with more than 10 minutes at peak mineral oil exposure, principally Actors from Rent).

Overall, there were no significant or consistent associations observed between symptoms and pyrotechnics use. This may reflect the relatively low current use of pyrotechnics on

Broadway, both in numbers of shows utilizing pyrotechnics and the magnitude of the exposure, or that under the conditions of use in participating shows, no adverse effects occur. An increase in nose and sinus symptoms was noted for the preliminary pyrotechnics exposure assessment, which is consistent with irritative effects of particulates. However, there was no association with the detailed measurements.

We also investigated whether Actors exposed to more than one theatrical effect had increased rates of symptoms compared to Actors exposed to a single special effect. There was no evidence of an additive or multiplicative effect from exposure to more than one agent.

One objective measure of the potential impact of theatrical exposures is the number of performances missed due to health problems. For many shows, musculoskeletal injuries caused the greatest proportion of Actors to miss a performance. There were seven shows in which Actors missed performances due to throat problems or voice problems at rates higher than the Broadway average: Rent, Les Miserables, Smokey Joe's Café, The Scarlet Pimpernel, Miss Saigon, Jekyll and Hyde, and Cats. Three of these shows have the highest glycol exposures (Les Miserables, Miss Saigon and Jekyll and Hyde), and two had the highest oil exposure (Rent and Cats). These five shows are also among the seven shows with the highest vocal demands (see Table V-5). Smokey Joe's Café has low oil exposure, but the highest vocal demand of any musical. The Scarlet Pimpernel, a show that does not use any theatrical effects, has an average vocal demand. However, there was a significant correlation between throat symptoms reported in Phase 1 and vocal demand for Actors in this show. These data suggest that multiple factors can be involved when performances are missed due to voice or throat problems.

C. Phase 2 – The Daily Checklists

Symptoms reported frequently in Phase 1 were also commonly reported on the Daily Checklists during Phase 2. Interestingly, there is no variation in symptom frequency by month of the year or season, making heating or air conditioning in the theater less likely determinants of symptoms in this population. This suggests that integrated exposure levels, which are dependent on ventilation in the theater and may vary as the ventilation is changed from month to month, are not associated with symptom frequency (as opposed to peak concentrations, which are generally independent of ventilation). No consistent statistically significant associations are found between occurrence of symptoms and exposure to glycol, mineral oil or pyrotechnics, although a positive association is seen for glycol use and most of the Phase 2 symptom scores. The strongest predictors of daily symptoms in Phase 2 were the number of performances, performances on a weekend, physical demand of the role(s) played, and perceived levels of stress at work and away from work. These associations were much stronger than any contribution to symptom occurrence from theatrical effects.

The finding of a strong association between weekend performances (Friday, Saturday and Sunday were classified as the weekend) and daily symptoms may be due to several factors. Typically, most Actors perform five shows over these three days; thus, the weekend is the most demanding part of their workweek. The occurrence of vocal fatigue is also, by its very nature, multifactorial. For shows using theatrical effects, Actors will have had greater cumulative exposure by the end of the weekend. Increased numbers of performances also places greater

physical and vocal demands on Actors. The stress variables may also be intermediate in the causal pathway between increased exposure from the typical weekend performance schedule and symptoms. For example, Actors in Rent, a show with high vocal and physical demand, have the highest rate of reported symptoms. Stress level, another significant factor in Phase 2 symptom rates, is also very high among Actors in Rent. Conversely, Actors in Smokey Joe's Café, the show with the highest vocal demand, but average physical demand and the lowest stress level at work, report low rates of symptoms for Phase 2. Thus, stress levels at work and performance schedules are associated with increased symptom rates.

D. Phase 3 – The Medical Evaluation

There were four components to Phase 3 evaluations: videoendoscopy/videostroboscopy to evaluate the vocal cord appearance and function, perceptual voice analysis, computerized voice analysis, and pulmonary function tests. Each test was performed before and after a matinee performance. The comparison of each Actor before and after a show was designed to measure acute changes in these measurements due to exposure to theatrical effects. Most Actors were evaluated on Wednesday, after one or two days off from performing on Broadway. Because it is an important irritant in and of itself, all of these analyses were controlled for cigarette smoking.

No statistically significant acute changes after a performance were detected in vocal cord appearance and function, perceptual voice analysis, or pulmonary function. The lack of acute change in vocal cord appearance is consistent with no adverse effect from these exposures or may in part reflect the short-term humectant properties of glycols and mineral oil, which may inhibit acute irritant effects. This humectant property may also account for the high prevalence of the sensation of coated vocal cords noted in the Phase 1 and Phase 2 symptoms analysis. Thus, immediately following exposure, no irritant effects will be apparent but there may be chronic irritation, as suggested by the observed association between glycol exposure and pre-performance findings of throat or laryngeal inflammation, as described below. These findings are consistent with the high prevalence of throat symptoms in Phases 1 and 2 among Actors with exposure to peak levels of glycols.

One surprising finding of the study was the strong effect of warm-up on vocal parameters. In general, Actors had improved vocal cord function and appearance as well as perceptual voice rating in the pre- to post-performance comparison. A limitation of the perceptual voice rating was that it was only performed on the spoken voice, not on the singing voice. Few experts are trained to rate the singing voice, and the findings presented are relevant only for the speaking voice.

For most voice quality parameters measured from the computerized voice analysis, no demonstrable change between the pre- and post-performance evaluations was evident. However, increasing peak glycol exposures were associated with a negative change in one of the four measures of voice quality (jitter). The sustained vowel "ee" used in the computerized voice analysis has limited sensitivity for detecting problems in "supernormal" singers. The parameters produced by the sustained "ee" analysis are crude measures and may not detect subtle

differences. In addition, Actors performing on Broadway, in general, have tremendous vocal capacity and seem to be able to compensate for mild vocal cord irritation and/or inflammation.

To supplement the comparisons of pre- and post-performance examinations for acute changes, data from the pre-performance evaluations were analyzed independently to determine whether exposures were associated with signs of chronic irritation. In the analysis of Phase 3 data from the pre-performance examination, Actors whose performance requires longer exposure to elevated levels of glycols (longer times of exposure above two-times and five-times the Broadway average) had a significantly increased rate of tracheitis, laryngitis or pharyngitis, indicating inflammation of the throat or vocal cords. There was no adverse impact from mineral oil or pyrotechnics use. Rates of other vocal cord abnormalities (such as nodules or polyps) were not increased by exposure to any theatrical effect, or to cigarette smoke. There was no negative impact on vocal cord function (vocal cord movement) from exposure to glycol, mineral oil or pyrotechnics. However, increasing glycol exposure above two times the Broadway average was associated with a negative change in one of the four measures of voice quality (shimmer) from the computerized voice analysis.

As in other studies of performers, we found that Actors have superior pulmonary capacity compared to the general population. There was no clinically significant adverse impact on pulmonary function due to either acute or chronic use of glycol or pyrotechnics. This is consistent with the findings from the second NIOSH study, where there was no increase in rates of asthma or other pulmonary disorders in Actors in smoke shows compared to non-exposed Actors. It is also consistent with the chemical properties of glycol at the concentrations measured in the theaters, where these compounds can exert irritant effects on mucous membranes but not on the lower respiratory tract. While pyrotechnics, and particulates in general, are associated with asthma and other lung disorders, the current exposures in the theaters to these agents for most Actors are low and Actors who participated in the study showed no decrements in respiratory function.

On the other hand, in the pre-performance data, Actors with the highest exposure to mineral oil had a statistically significant decrease in forced vital capacity (FVC) and forced expiratory volume (FEV_1). As with glycol exposure, there was no evidence of airway obstruction as measured by the FEV_1/FVC ratio. This finding was surprising, as decreases in forced vital capacity are usually associated with interstitial lung processes or with interference with taking a deep breath from external pressures, such as pleural thickening or obesity. The decrease in FVC may be related to a response in the smaller airways. In previous studies of workers with extremely high exposure to mineral oil or to other oil mists – levels much greater than those experienced by Actors on Broadway under the worst case scenario – impairments of pulmonary function have been noted. While there are larger decreases at the highest exposures, it is important to note that the Actors still have pulmonary function within the normal range and, therefore, there is likely no clinical decrement in their breathing capacity.

E. Conclusions

The overall results of this study of the effects of theatrical smoke, haze and pyrotechnics indicate that there are health effects associated with Actors exposed to elevated or peak levels of

glycol smoke and mineral oil. However, as long as exposures are kept below the guidelines described below, Actors in general should not suffer adverse impacts to their health or their vocal abilities. Mineral oil, for the most part, does not appear to have as significant an effect on Actors, provided that the exposures are minimized and uniform, rather than in concentrated bursts. Pyrotechnics as currently used on Broadway did not have a significant effect on Actors' health.

Other than irritant effects on the vocal cords, throat and nose, performing in Broadway musicals using theatrical effects at the levels measured in this study does not appear to have impacted the careers of participating Actors. However, this study was unable to determine whether Actors are no longer performing on Broadway as a result of exposure to these agents. This type of selection bias in occupational health studies is known as the "healthy worker effect," as those who are able to perform successfully may be less sensitive to theatrical effects than others who are no longer performing. No conclusions can be drawn regarding Actors who no longer perform on Broadway or did not participate in the study.

The findings of this study are consistent with the NIOSH studies, as well as reports regarding the health effects of glycols and mineral oil in animals and humans. The health effects noted, specifically the clinical signs and symptoms of irritation to the mucous membranes and upper respiratory tract, are those that were anticipated from exposure to glycols by inhalation. However, this study also found associations between health effects and rigors of performing that are not related to theatrical smoke and haze, such as stress, performance schedule and the physical demand of the role.

F. Guidance for the Use of Glycols and Mineral Oil in Theatrical Musical Productions

Based on the results of this study, certain irritant effects were found to be associated with peak exposures to glycols. In addition, some mild chronic effects were found to be associated with peak exposures to glycols and mineral oil. In order to provide guidance for the use of glycols and mineral oil in current and future theatrical musicals, the results of the study were compared with the available toxicological literature and existing occupational exposure limits. While the focus of this study was limited to adult Actors, the same guidelines described below would also be expected to be protective of child Actors.

1. Glycols

As discussed in Chapter II, the possible health effects resulting from exposure to glycols can be categorized as either systemic effects arising from repeated exposures and subsequent absorption of the chemicals into the body, or local irritant effects. Review of the available toxicological literature on glycols indicates that the primary health endpoints of concern following inhalation exposure to aerosols and vapors are irritant effects in the respiratory tract, particularly at the exposure concentrations likely to be encountered in theatrical productions. The lack of systemic effects from these inhalation exposures to glycols is a function of both the high exposures required to induce such effects and the relatively poor absorption of glycols into the body following inhalation exposures (compared to oral exposures), which limits the amount of glycol available to induce systemic toxicity.

With respect to existing occupational exposure limits, there are limited values available for the glycols used in theatrical smoke (i.e., diethylene glycol, triethylene glycol, propylene glycol, and butylene glycol). This is primarily due to the lack of exposure to aerosols or vapors containing these chemicals in large worker populations and, consequently, the lack of data on the health effects of such inhalation exposures. It is therefore useful to examine the occupational exposure limits for related glycols, which have similar biological and chemical properties and for which sufficient data are available to serve as a basis for setting exposure limits. Table VI-1 defines and summarizes the occupational exposure limits established by regulatory bodies (i.e., the Occupational Safety and Health Administration [OSHA] and the United Kingdom Health and Safety Executive [UK HSE]) or professional societies (i.e., the American Conference of Governmental Industrial Hygienists [ACGIH] and American Industrial Hygiene Association [AIHA]) for various glycols (limits have not been established for triethylene glycol and butylene glycol).

TABLE VI-1
Summary of Occupational Exposure Limits for Glycols

Glycol	OSHA PEL	ACGIH TLV	AIHA WEEL	UK HSE OES (mg/m^3)
Ethylene glycol (EG)*	127 mg/m^3 *C* (50 ppm)	100 mg/m^3 *C,* aerosol (40 ppm)	----	10 mg/m^3 *TWA*, particulate (4 ppm) 60 mg/m^3 *TWA*, vapor (24 ppm) 125 *STEL*, vapor (50 ppm)
Diethylene glycol (DEG)	----	----	10 mg/m^3 *TWA* (2.3 ppm)	101 mg/m^3 *TWA* (23 ppm)
Propylene glycol (PG)	----	----	10 mg/m^3 *TWA*, aerosol (3.2 ppm) 156 mg/m^3 *TWA*, total vapor and aerosol (50 ppm)	----
Hexylene glycol (HG)*	121 mg/m^3 *C* (25 ppm)	121 mg/m^3 *C* (25 ppm)	----	123 mg/m^3 *TWA* (25 ppm) 123 mg/m3 *STEL* (25 ppm)

TABLE VI-1
Summary of Occupational Exposure Limits for Glycols

Glycol	OSHA PEL	ACGIH TLV	AIHA WEEL	UK HSE OES (mg/m^3)

Abbreviations:
OSHA PEL – U.S. Occupational Safety and Health Administration Permissible Exposure Level (although these PELs promulgated in 1989 were later vacated in 1992 by the U.S. Court of Appeals, they do serve as a guidance for evaluating occupational exposure limits for these chemicals)
ACGIH TLV – American Conference of Governmental Industrial Hygienists Threshold Limit Value
AIHA WEEL – American Industrial Hygiene Association Workplace Environmental Exposure Level
UK HSE OES – United Kingdom Health and Safety Executive Occupational Exposure Standard
C = Ceiling limit (boundary that concentrations should not be permitted to exceed);
TWA = Time Weighted Average (concentrations averaged over an 8-hour period);
STEL = Short-Term Exposure Limit (concentrations averaged over a 15-minute period).
***** These chemicals are not used in theatrical/musical productions.

In its standard setting procedures, OSHA has determined that "no employee should be subjected to mucous membrane or respiratory irritation caused by exposure to toxic agents and that this effect represents material impairment of health and adversely affects the well-being and functional capacity of employees." Thus, OSHA set the exposure standards for both ethylene glycol and hexylene glycol at levels below those at which clinical symptoms of irritation have been noted in humans, as described below.

For ethylene glycol, throat and upper respiratory irritation was reported in volunteers exposed to 55 ppm (140 mg/m^3); exposures to 74 ppm (188 mg/m^3) were only tolerable for 15 minutes; and exposures to 96 ppm (244 mg/m^3) were sufficiently irritating to only be tolerable for a minute or two (Wills et al. 1974). Based on this study, OSHA set a Permissible Exposure Limit (PEL) at 50 ppm (OSHA 1989). Using the same data, ACGIH established a Threshold Limit Value (TLV) for ethylene glycol at the slightly more protective value of 40 ppm (100 mg/m^3) to minimize the potential for respiratory and ocular irritation (ACGIH 1998).

For hexylene glycol, slight eye irritation was reported in humans following exposures to 50 ppm (240 mg/m^3) for 15 minutes; 100 ppm (480 mg/m^3) exposures resulted in nasal irritation and respiratory discomfort; and 1,000 ppm (4,800 mg/m^3) exposures were associated with irritation of the eyes, nose, and throat and respiratory discomfort (Cavender and Sowinski 1994). Bases on these observations, OSHA set the PEL set at 25 ppm to reduce the risks of eye and respiratory irritation (OSHA 1989). Similarly, ACGIH established a TLV at 25 ppm to prevent eye irritation.

For both chemicals, the PELs and TLVs were established as ceiling limits, i.e., levels that should not be exceeded at any time in the workday. It should also be noted that the UK occupational exposure standards (OES) are generally consistent with those of OSHA and ACGIH, although the UK values were established as short-term exposure levels rather than the ceiling limits set by OSHA.

Due to the lack of data on inhalation exposures in humans or experimental animals, the AIHA Workplace Environmental Exposure Level (WEEL) for diethylene glycol was based on extrapolations from experimental animal studies in which systemic effects were observed following oral administration of diethylene glycol. For propylene glycol, AIHA determined that propylene glycol is of lower acute toxicity than ethylene glycol or diethylene glycol, and set the WEEL based on the diethylene glycol value. For both chemicals, the WEEL was established as an 8-hour time weighted average (as compared to the ceiling limit approach taken by OSHA and ACGIH). However, there is some question as to the relevance of extrapolating from oral to inhalation exposures for these glycols, as there is evidence that these chemicals are relatively poorly absorbed into the body following inhalation exposures and will therefore have much lower bioavailability compared to orally-administered glycols.

One additional report that should be considered is an experimental animal study of propylene glycol that was reported after the AIHA WEEL was established. In this study, rats were exposed by nose-only inhalation to propylene glycol concentrations up to 700 ppm (2,200 mg/m^3) for 6 hours/day, 5 days/week for 90 days (Suber et al. 1989). Nasal hemorrhaging was observed in the rats exposed to 51 ppm (160 mg/m^3), although the authors did not consider this a significant effect and attributed it to a dehydrating effect of propylene glycol on peripheral tissues. Rats exposed to 320 ppm (1,000 mg/m^3) had thickened respiratory epithelium and other histological changes consistent with an irritant effect.

In reviewing the available data set on the irritant effects of the glycols following inhalation exposures, it is striking to note that 50 ppm or slightly higher appears to be a consistent effect level across different glycols, different exposure times, and even across species. This is not inconsistent with the relatively straightforward nature of the effect: a simple chemical reaction between the glycol and the biological target. Thus, 50 ppm is an exposure level that can be considered as a representative effect level for the group of glycols used in theatrical productions.

Of the relevant occupational exposure limits, the most conservative (i.e., health protective) approach applied in establishing a safe exposure level was that used for hexylene glycol, in which the effect level of 50 ppm was divided by 2 to ensure an adequate margin of safety to protect against its irritant effects. The resulting value of 25 ppm therefore represents a level of exposure to glycols that is likely to be without irritant effects.

Given that respiratory and vocal demands put stress on the same biological tissues that are the target of the irritant effects, Actors represent a “sensitive subpopulation,” and an additional factor of 2 may be applied to the 25 ppm level as an extra margin of safety. Therefore, based on the findings of this study, the existing toxicology literature, and previous standard setting exercises, we believe that by limiting maximum exposure concentrations of glycols to 12.5 ppm will protect Actors against the irritant properties of glycols used in theatrical/musical productions.

The exposure concentration of 12.5 ppm is equivalent to 40 mg/m^3 propylene glycol, 54 mg/m^3 diethylene glycol, 77 mg/m^3 triethylene glycol, and 46 mg/m^3 butylene glycol.[2] Consistent with the approaches used by OSHA and ACGIH, and the nature of the irritant effect, this value should be incorporated as a ceiling limit, i.e., exposures should not exceed this level during any part of the workday. It is important to note that 12.5 ppm glycols represents the total exposure concentration to all glycols combined and not the limit for exposures to individual glycols that may comprise the overall exposure. Thus, as an added conservative (health-protective) element, the recommended maximum exposure concentration to total glycols may also be expressed as 40 mg/m^3, which corresponds to the lowest limit among the glycols used in theatrical/musical productions.

2. Mineral Oil

With respect to mineral oil mists, the existing occupational standards (as adopted by ACGIH and proposed by OSHA) recommend exposures be limited to 5 mg/m^3 as an eight-hour time weighted average concentration to protect against eye and respiratory tract irritation. ACGIH also established a STEL of 10 mg/m^3 to minimize any irritant effects workers may experience in differing industrial settings. The basis for these standards is the lack of health effects observed in workers following exposures to 5 mg/m^3 oil mist; i.e., 5 mg/m^3 represents a no observable adverse effect level (NOAEL). Furthermore, only mild respiratory tract effects were observed in workers following exposures to 100 mg/m^3 oil mists (OSHA 1989). As noted by both OSHA and ACGIH, there is concern about possible chemical contaminants (e.g., polycyclic aromatic hydrocarbons) present in crude petroleum oil products that may present more significant toxicological issues than irritation. However, the food or pharmaceutical grade mineral oils used in theatrical productions are not likely to contain such contaminants, thereby limiting the toxicological issues to irritant properties.

Given the relatively mild health effects that serve as their basis, the existing standards established for oil mists (5 mg/m^3 as an eight-hour TWA, and 10 mg/m^3 as a 15-minute STEL) should also be protective for Actors in theatrical productions. In addition, we recommend a maximum exposure (ceiling) limit of 25 mg/m^3 for mineral oil mists that should also protect against irritant effects following very short-term exposures by Actors in theatrical productions. This maximum limit is five times the TWA and 2.5 times the STEL, values that are consistent with approaches used by ACGIH and OSHA for other irritants. Furthermore, the ceiling limit is a factor of four below the 100 mg/m^3 exposure concentration that represents a lowest observable effect level.

3. Pyrotechnics

This study did not find consistent evidence of health effects from exposures to pyrotechnics for either symptom reporting or clinical findings. Thus, the current use patterns of pyrotechnics do not appear to adversely affect the Actors' health.

[2] See Table VI-1 for conversion from ppm to mg/m^3.

4. Implementation of These Guidelines

Based on the guidance provided in this chapter, several shows would need to evaluate their productions to ensure that Actors are not exposed to peak concentrations that exceed the recommended levels. For productions in which the potential peak glycol concentrations exceed 40 mg/m^3 (i.e., Jekyll & Hyde, Les Miserables, Miss Saigon, and Phantom of the Opera – see Table IV-11), a real-time personal aerosol monitor (e.g., the PDR-1000 units used in this study) can be used to measure peak glycol levels during the period immediately following the release of a cue. During this time, the fresh aerosol can be measured using an aerosol monitor before volatilization to the vapor phase occurs (i.e., before the aerosol has aged for over a few minutes). Each production would need to have the aerosol monitor calibrated for its specific glycol mixture/smoke generator combination. Based on these measurements, the production will need to determine whether Actors are likely to be situated in proximity to peak exposure levels and whether these exposures can be reduced through changes in the blocking or choreography. If such changes cannot be made, an adjustment in the discharge of the glycol effect would be necessary (e.g., timing, duration, or location of release; pulsed release; change in direction of release).

Mineral oil concentrations can also be measured using the same type of portable aerosol monitor. A similar evaluation as described above for glycol shows would need to be conducted for productions in which the peak oil concentrations exceed the recommended level of 25 mg/m^3 (i.e., Cats and Sound of Music – see Table IV-9).

G. References

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