

A SIMULATION STUDY OF THE EFFECTS OF OPERATING ROOM NOISE ON  
THE PERFORMANCE OF ANESTHESIA PROVIDERS

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## **ABSTRACT**

The purpose of this study was to add to the current research on the effects of noise and environmental stimuli on provider performance. The secondary purpose of the study was to determine whether using an anesthesia simulator is effective for studying the effects of environmental stimuli, such as noise, on performance. The study was designed using a test- retest format. The subjects were thirteen senior nurse anesthesia residents. Each student was given a scenario and asked to perform a standard induction sequence on the anesthesia simulator. The subjects performed an induction sequence in a quiet, controlled environment and were then asked to return to the simulator a week later to perform a similar scenario in a noisy environment. The average noise levels in the control scenario were 24.8db(A) and the average for the noisy scenario was 50.5 db(A). All scenarios were recorded and analyzed using Chi-Square statistical testing, with a significance level of  $p < .05$ . After all scenarios had been completed, the subjects subjectively evaluated the degree of realism that the simulator provided as well as their perceptions of noise in the operating room. Based on the data collected in this study, it could not be concluded that noise had either a positive or negative impact on the performance of anesthesia providers. This study did, however, demonstrate that the use of anesthesia patient simulators is a practical, educational method as performance was improved by repeat training on the simulator.

**KEY WORDS:** Noise, Performance, Anesthesia, Simulation

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THE PERFORMANCE OF ANESTHESIA PROVIDERS

by

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## TABLE OF CONTENTS

ACKNOWLEDGEMENT.....	vii
LIST OF FIGURES.....	x
LIST OF TABLES.....	xi
CHAPTER I: INTRODUCTION .....	1
Background.....	1
Purpose .....	3
Research Questions .....	4
Conceptual Framework .....	4
Conceptual and Operational Definition.....	5
Assumptions .....	9
Limitations.....	9
Summary.....	10
CHAPTER II: REVIEW OF THE LITERATURE.....	11
Introduction .....	11
Noise Measurement.....	11
The Effects of Noise.....	13
OSHA S Permissible Noise exposures .....	14
The Use of Anesthesia Simulators in Research.....	18
Summary.....	20
CHAPTER III: METHODOLOGY.....	21
Research Design and Procedures .....	21

Sample .....	24
Measurement.....	24
Protection of Human Rights .....	25
Plan for Data Analysis.....	25
CHAPTER IV: ANALYSIS.....	27
Results.....	27
CHAPTER V: SUMMARY.....	34
Suggestions for Further Research.....	36
REFERENCES.....	38
BIBLIOGRAPHY .....	41
APPENDICES.....	43
APPENDIX A:Anesthesia Simulator Pretest and Post-test Scenarios.....	
APPENDIX B:Data Collection Instrument.....	
APPENDIX C:Subject Simulator Evaluation Form .....	
APPENDIX D:Informed Consent Form .....	

## LIST OF FIGURES

Figure 1: The Person as an Adaptive System. ....	5
Figure 2: OSHA s Permissible Noise Exposures .....	14

## LIST OF TABLES

Table 1: Pretest Scenario: The Frequency of Correct Responses to Outcome Criteria in a Quiet Environment.....	29
Table 2: Post-test Scenario: The Frequency of Correct Responses to Outcome Criteria in a Noisy Environment.....	30
Table 3: Comparison of Pre- and Post-Test Scenarios Using Chi Square Tests of Significance.....	31
Table 4: Subject Responses to Subjective Questions on Simulator Realism.....	32
Table 5: Subject Responses to Subjective Questions on Noise Distraction.....	33

## **CHAPTER I: INTRODUCTION**

### **Background**

Noise is defined as any unwanted or undesirable sound which is annoying or disruptive (Kam, P., Kam A. & Thompson, 1994; Seidlitz, 1981). Defining noise is quite often subjective and is influenced by many factors such as cultural issues, individual sensitivities and how appropriate the noise is to the situation (Gloag, 1980). Because noise can be so variable, research that has been done on the subject is often varied and broad in nature.

Several studies have documented the detrimental effects of noise on humans. Classical research evaluating the physiologic effects of noise suggests that noise can result in alterations in endocrine, cardiovascular and auditory systems (Falk & Woods, 1973). Noise induced hearing loss has been studied extensively as an occupational hazard (Monsell, Teixido, Wilson, & Hughes, 1997). Documented psychological responses include increased irritability, disrupted person-to-person communication, and reduced ability to work (Seidlitz, 1981). Complications in problem solving and performance requiring alertness have also been discussed (Falk & Woods, 1973). Other studies on the effects of noise in the operating room looked at the impact of hearing and memory on anesthetized patients (Jones & Konieczko, 1986).

In response to research indicating that noise can have detrimental effects, the Occupational Safety and Health Administration (OSHA) created Standard 1910.95 to protect workers from extensive noise exposure ([http://www.osha-slc.gov/OshStd\\_data/1910\\_0095.html](http://www.osha-slc.gov/OshStd_data/1910_0095.html)). OSHA requires that noise entering the ear be less than 90 decibels averaged over eight hours. If noise levels exceed 85 decibels, employers

are required to provide hearing protection programs for their employees. The National Institute of Environmental Health Sciences (NIOSH) reports adverse effects with noise levels as low as 70 decibels (Seidlitz, 1981).

Numerous studies conducted in the past 25 years have consistently reported that hospitals, especially operating rooms, have significantly high noise levels (Falk & Woods, 1973; Hodge & Thompson, 1990; Kamal, 1982; Murthy et al., 1995; Shapiro & Berland, 1972). Noise levels ranging from 60 to 90 decibels have been reported. Some studies compare noise levels in the operating room to those found on a freeway, near a train, and in a kitchen where a blender/mixer is in use (Shapiro & Berland, 1972). Some sources of such noise that have been reported in the operating room include opening packages of gloves (86 dbA), tracheal suctioning (78 dbA), and use of surgical tools (80 dbA). Shapiro and Berland go on to suggest that a quieter environment would benefit the physiologic and psychological well being of both the operating room staff and the patients.

The administration of anesthesia requires both vigilance and the ability of the provider to handle problems that can be life threatening for the patient (Gaba & DeAnda, 1988). The act of vigilance has been described as requiring a state of maximal physiologic and psychological readiness to react (Weinger & Englund, 1990). Loud noise can be disruptive and may impair the ability of the provider to maintain vigilance. Further studies are needed regarding the effects of noise on anesthesia vigilance and performance.

A recent study by Murthy et al.(1995) attempts to address the need to correlate noise with impaired performance by anesthesia providers. This study concluded that

noise has a significantly detrimental effect on cognitive skills such as memory and mental efficiency in anesthesia residents. Cognitive functioning plays an important role in anesthetic practice. Murthy, et al. indicate that their study was limited by an unrealistic setting.

Due to the need to protect the safety of patients, the study by Murthy, et al. (1995) could not have been carried out in the operating room. The recent development of anesthesia simulators could be used to address this limitation. Anesthesia simulators are realistic training devices designed to duplicate many conditions likely to be encountered during the administration of anesthesia in an operating room (Gaba, 1992). Simulators re-create the anesthesia provider's physical and mental task environment (Gaba & DeAnda, 1988). They are designed to be useful for both training and research purposes.

The lack of comprehensive research correlating noise and performance as well as the introduction of the anesthesia simulator, led to the development of this current study which will expand on the work done by Murthy, et al. (1995). It is a simulation study that attempts to create a more realistic setting to evaluate the effects of operating room noise on anesthesia residents performing clinical scenarios on an anesthesia simulator.

### **Purpose**

The primary purpose of this study is to determine whether the noise levels found in operating rooms have an effect on the performance of anesthesia providers. The secondary purpose of this study is to determine whether using an anesthesia simulator is a valid method for studying the effects of environmental factors, such as noise, on performance.

### **Research Questions**

The major research questions for this study are:

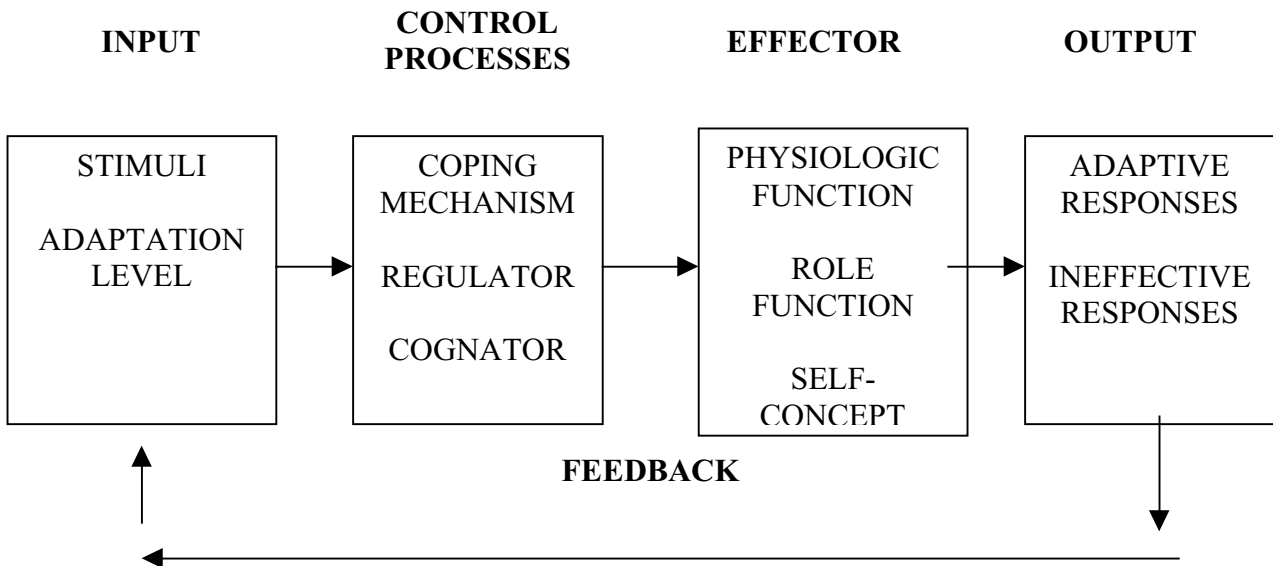
1. Do noise level consistent with those found in the operating room have an effect on the performance of anesthesia providers?
2. Do anesthesia providers feel that noise levels in the operating room have a negative effect on their ability to care for their patients?
3. Does the anesthesia simulator provide a realistic setting for evaluating the performance of anesthesia providers?

### **Conceptual Framework**

The conceptual framework for this study originates in the theoretical world of Sister Callista Roy. In the 1970's, Roy developed the Adaptation Model to guide nursing practice and research. Roy's Adaptation Model evolved from Helson's adaptation theory and Rapaport's systems theory. In general, Roy's Adaptation Model focuses on man's part of a system and on the ability of man to adapt to alterations in the system (Blue et al., 1994).

Sister Roy identifies four main concepts that pertain to the Adaptation Model (Blue et al., 1994). Nursing, person, health, and environment are all influences on man's ability to adapt as a system. According to Roy, the environment is "all the conditions, circumstances and influences surrounding and affecting the development and behavior of persons or groups" (Blue, et. al., 1994, p. 250). By evaluating the effects of noise on anesthesia providers, this study focuses on the influence of the environment on an individual's performance and more precisely, on that individual's ability to adapt to the environment.

The relationships among variables in Roy's Adaptation Model are shown in Figure 1.



**Figure 1.**

**The Person as an Adaptive System, Adapted from Blue, et al., 1994).**

Roy's Adaptation Model begins with a person who receives inputs or stimuli from the environment (Blue, et. al., 1994). The person's level of adaptation is determined by the stimuli to which he or she is exposed. As a result of inputs, the person must use primary control processes, or mechanisms of coping, such as regulator and cognator mechanisms, to adapt. Secondary response mechanisms, or effectors, are manifestations of the control processes. The end results, or outputs, may be either adaptive or ineffective responses. Outputs provide feedback into the system in the form of new inputs. The ultimate goal of the person is to respond and adapt to changes in the environment. In this study, the ability of the anesthesia provider to respond and adapt to noise levels in the

operating room will be evaluated.

### **Conceptual and Operational Definition**

Using Roy's Adaptation Model, terms central to this study were conceptually and operationally defined. Some terms used in Roy's theory were defined, but not specifically measured in this study.

#### System

Conceptual definition. a set of units that are connected to form a whole and are characterized by inputs, control processes, feedback processes and outputs.

Operational definition. the anesthesia provider-patient relationship is the system. The provider and the patient are in constant contact as the provider continuously monitors and responds to the patient. The provider-patient system is subject to inputs, control and feedback processes and outputs. For the purposes of this study, anesthesia providers were senior nurse anesthesia residents.

#### Inputs:

Conceptual definition. referred to by Roy as information (Blue, et. al., 1994).

Operational definition. the environmental conditions in the operating room and the clinical status of the patient are the inputs into the provider-patient system.

#### Focal stimuli

Conceptual definition. the stimulus most immediately confronting the person and the one to which the person must make the adaptive response (Blue et al., 1994).

Operational definition. noise levels in the operating room during induction and maintenance of anesthesia and during emergence from anesthesia are the focal stimuli. Noise levels were measured in decibels (dbA).

### Contextual stimuli

Conceptual definition. all other stimuli that contribute to the response generated by the focal stimuli (Blue et al., 1994).

Operational definition. distractions in the operating room, other than noise, that could affect the performance of the anesthesia provider. Contextual stimuli were not measured in this study.

### Adaptation level

Conceptual definition. the person's individual range of stimuli to which he or she can respond with ordinary responses (Blue et al., 1994).

Operational definition. the extent to which the provider is able to maintain focus on the patient despite increasing noise levels. This level may vary among providers.

### Control processes

Conceptual definition. functional coping mechanisms, including regulator and cognator mechanisms, used by the person (Blue et al., 1994).

Operational definition. coping mechanisms, such as focused attention, used by the provider to maintain optimal performance and to protect the wellbeing of the patient.

### Regulator

Conceptual definition. an automatic coping mechanism involving a neural-chemical-endocrine response (Blue et al., 1994).

Operational definition. increased level of arousal, increased sympathetic nervous system output and other physiologic responses of the provider when exposed to noise.

Regulator responses were not measured in this study.

### Cognator:

Conceptual definition. a coping mechanism that responds through complex processes of perception and information processing, learning, judgement, and emotion (Blue et al., 1994).

Operational definition. a coping mechanism used by the provider based on the provider's perception of the noise. This mechanism is affected by the provider's prior experience as well as his or her current emotional state. This variable may vary among providers and was not measured in this study.

#### Effector modes

Conceptual definition. secondary mechanisms of coping that manifest regulator and cognator activity. Effector modes involve the physiologic functioning, role functioning and self-concept of the person (Blue et al., 1994).

#### Adaptive responses

Conceptual definition. responses that promote the integrity of the person and his or her goals (Blue et al., 1994).

Operational definition. performance levels of anesthesia providers using clinical scenarios implemented by an anesthesia simulator. The ability of the anesthesia provider to provide safe anesthetic care in a simulated environment despite increased noise levels reflects the provider's performance. This variable is specifically measured by evaluating the provider's ability to respond accurately and quickly to simulated changes in the patient's condition.

#### Ineffective responses

Conceptual definition. responses that do not contribute to the adaptive goals of the person (Blue et al., 1994).

Operational definition. The inability of the anesthesia provider to maintain safe levels of patient care and to respond to changes in the patient's condition in an accurate and timely manner. This variable was measured using clinical scenarios implemented with an anesthesia simulator.

The Adaptation Model developed by Roy effectively defines the relationships between the environment and the person as a system as they pertain to this study (Blue et al, 1994). Roy's Adaptation Model guided this study by defining the relationship between noise levels in the operating room and the performance of anesthesia providers.

### **Assumptions**

The following assumptions were made for the purposes of this study:

1. Noise levels in the operating room vary with different health care facilities and different types of surgical procedures.
2. Perception of noise levels vary among anesthesia providers.
3. Subjects were familiar with the use of the anesthesia simulator for performing clinical scenarios.
4. Subjects had the knowledge level and clinical experience required to respond accurately to clinical scenarios using the anesthesia simulator.

### **Limitations**

The following were limitations for this study:

1. The Hawthorne effect may have limited this study because subjects were aware that they were in a study environment when performing clinical scenarios using the anesthesia simulator.
2. Subjects were placed in a test-retest situation using simulator scenarios.

3. Subject selection and sample size were based on convenience.
4. Subjects were senior nurse anesthesia residents with varying levels of clinical skill and knowledge.
5. Lack of realistic environment. Patient safety precludes conducting this study in an actual operating room. Use of an anesthesia simulator provides a more realistic testing environment than those used in previous studies.

### **Summary**

Noise levels in operating rooms have previously been found to be significantly high compared to OSHA standards. Noise has been implicated in the impairment of cognitive functioning. Murthy et al. (1995) evaluated the effects of noise on the cognitive skills of anesthesia residents, but measured variables that were not specific to anesthesia practice, nor were they measured in a realistic environment. This study attempted to further the work of Murthy et al. by evaluating the effects of noise on anesthesia providers as they perform anesthesia-specific tasks in a simulated operating room environment.

## **CHAPTER II: REVIEW OF THE LITERATURE**

### **Introduction**

In the past few decades a variety of studies have been published on the subject of noise exposure in the hospital environment. Noise levels have been measured and documented for a variety of hospital settings with special emphasis placed on the operating room environment. Many studies also have examined the variety of effects noise exposure has on humans. Physiologic as well as psychological effects have been examined. Anesthesia providers are exposed to operating room noise daily and should be considered at high risk for the effects of noise exposure. It is difficult, however, to quantify the impact noise has on the ability of providers to perform patient care. Recent research using anesthesia simulators has helped to address issues related to performance evaluation.

### **Noise Measurement**

One of the first major studies to evaluate the significance of noise levels in the operating room was a 1973 study by Shapiro and Berland. This study first defined noise as an unwanted, noxious, or harmful sound (p. 236) and then set out to survey noise levels in the operating room. After determining that noise levels often approximated the maximum noise exposure levels set by the United States Federal Occupational Safety and Health Act, the study proposed that noise should be considered a potential hazard for operating room personnel as well as the patients. The authors suggested that physiologic effects and impaired communication could have detrimental effects on the staff. Shapiro and Berland concluded that a quieter working environment would have fewer psychological and physiologic effects and would provide a safer environment for the

patients.

Another early study measured hospital noise and detailed the physiologic effects it had on staff and patients (Falk & Woods, 1973). Noise levels were measured in several areas of the hospital including, a neonatal unit, two acute care units, and the recovery room. Measured noise levels ranged from 55 to 75 dB(A) and were thought to be responsible for a variety of physiologic effects including stimulation of the hypophyseal — adrenocortical axis, as well as stimulation of the cardiovascular system with resulting peripheral vasoconstriction and tachycardia. Other noticeable effects were hearing damage and sleep disruption. Sources of noise that contributed to the measured levels were identified in the study. Common sources of noise were patient suctioning, communication between staff, moving the bed, etc. These noises are also commonly found in operating rooms.

Modern Healthcare (1974) reported several sources of noise found in operating rooms and measured their levels. Noise levels ranged from 70 to 86 dB(A). Opening packages of gloves, surgical instruments hitting each other or being dropped, suctioning patients, and staff conversations contributed significantly to noise levels. Difficulty in inducing anesthesia and impaired speech communication between staff members were also mentioned as possible detrimental effects of noise.

More recent studies continue to support the work of earlier research. Operating room noise was measured during a variety of procedures and at various times throughout the procedures (Hodge & Thompson, 1990; Kam P., Kam A. & Thompson, 1994; Kamal, 1982). Noise levels were consistently measured and reported using the dB(A) scale which most closely follows the subjective impressions of loudness and intensity of acoustic

noise (Kam, P. et al., 1994). Hodge & Thompson (1990) found that although overall noise level fell within acceptable OSHA standards, loud intermittent noises were frequently emitted from a variety of sources. They found that the noisiest time was during the preparation period of the operation and that verbal communication was difficult due to prevailing noises. Orthopedic procedures were found to have noise levels exceeding 100 dB(A) (Kamal, 1982). It was suggested by the authors that tasks requiring increased vigilance of the anesthesia provider may be affected most by high noise levels (Kam, P. et al., 1994; Hodge & Thompson, 1990). Also consistent with earlier studies, recommendations were made to reduce noise levels.

A study by Meyer-Falke, Rack, Eichwede, and Jansing (1994) also added to existing research by evaluating perioperative noise levels and the effects they had on patients. Meyer, et al. conducted their research in the surgical intensive care unit, the operating room and the recovery room. Similar to other research, the authors found levels that consistently exceeded 60 dB(A) with maximum levels greater than 100 dB(A). These noise levels are significant when one considers that the normal wake up threshold in healthy patients is 60 dB(A) and in unhealthy patients is at least 50 dB(A) lower. Unlike other studies, however, this one looked at the relationship between noise levels and type of surgery and found no relationship. They also found that noise levels were lowest in dangerous situations and highest during routine work.

### **The Effects of Noise**

The initial studies (Falk & Woods, 1973; Hodge & Thompson, 1990; Kam, P. et al., 1994; Kamal, 1982; Shapiro & Berland, 1973) on noise levels in and around operating rooms suggested that noise levels may be excessive and may have deleterious

effects on patients and staff. In recent years, additional studies have emerged in order to expand the work done by early researchers and to determine more precisely the effects of noise. The impact noise has on hearing, psychological well-being, and stress response was examined. Research has also been done on how these effects can impact a person's ability to perform certain tasks. It is important to consider this research when evaluating the role noise plays in the performance of anesthesia providers.

Many sources indicate that noise can be a significant source of hearing loss (Dobie, 1995; Gloag, 1980; Monsell et al., 1997). Van Wagoner and Maguire published a study as early as 1977 indicating that hospital noise causes hearing loss. The Occupational Safety and Health Act (OSHA) has responded to the growing problem of occupational noise exposure by publishing the following guidelines for maximum levels of noise exposure (Figure 2). In addition to establishing maximum noise standards, OSHA Standard 1910.95 also generated a hearing conservation program to prevent hearing loss due to occupational exposure (<http://www.osha-slc.gov/>).

<b>OSHA S Permissible Noise exposures</b>	
<b>Duration per Day in hours</b>	<b><u>Maximum permissible noise level in dB(A)</u></b>
8	90
6	92
4	95
3	97
2	100
1.5	102
1	105
.5	110
Less than .25	115

**Figure 2.**

**OSHA s Permissible Noise Exposures. Adapted from [http://www.osha-slc.gov/OshStd\\_data/1919\\_0095.html](http://www.osha-slc.gov/OshStd_data/1919_0095.html).**

The National Institutes of Health (NIH) 1990 consensus conference on noise and hearing loss defined noise induced hearing loss as any sound of sufficient intensity that will damage the ear and result in temporary or permanent hearing loss (p. 3185). The conference went on to emphasize that the duration of exposure was critical. It also was noted that noise induced hearing loss is preventable, but not treatable and can have a major impact on one s ability to communicate. These elements are particularly important to the practicing anesthesia provider who is exposed to occupational noise daily.

In addition to hearing loss, the effects of noise on work performance have been the subject of many studies. The results of these studies, however, are inconsistent which suggests the complexity involved in evaluating the effects noise levels have on performance.

In one study, Belojevic, Ohrstrom and Rylander (1992) examined the effects of noise on mental performance with regard to subjective noise sensitivity. The authors referred to the previous work of Hodge and Thompson (1990) as it explored how an environment such as the operating room can be a source of surprisingly high noise levels. In a controlled study, the researchers tested the mental performance of 45 subjects when exposed to quiet and noisy conditions. The subjects performed cognitive tasks involving different psychological functions including: short term memory, search and memory, and mental arithmetic. The subjects were also studied with respect to their subjective noise sensitivity. The study found that there were significant differences in the subjects abilities

to perform short term memory and mental arithmetic tasks when they were exposed to noisy conditions. There was not a significant difference in search and memory skills. There was also a greater difference in performance ability among the subjects who were considered noise sensitive based on a noise sensitivity assessment scale. The subjects, regardless of their score on the noise sensitivity scale, regularly reported feeling annoyed when asked to perform under noisy conditions.

Studies such as this one by Belojevic et al. (1992), however, are important for evaluating the effects of noise on the performance of anesthesia providers. Cognitive skills evaluated in this study such as search and memory skills are particularly valuable in anesthesia because they are a measure of vigilance. Vigilant observation of the patient is necessary for providing safe anesthetic care (Gaba, Fish, & Howard, 1997). Distractions, such as noise, can degrade vigilance and put the patient at risk.

Other studies have examined noise and performance. Broadbent (1979) found that loud noise, over 95dB(A), had minimal effect on sensory and motor functions and simple tasks were unimpaired. Inefficiency or errors, however, may occur with monitoring tasks, continuous tasks, or multiple tasks. Broadbent also found that intermittent noises may impair speed and accuracy of responses.

Smith (1989) reviewed the effects of moderate levels of noise (80 — 85dB(A)) on performance, and determined that they were dependent on the task being performed and on the experimental situation. It was also noted that noise created an impact by affecting the subjects choice of strategies for task performance leading subjects to choose certain strategies in preference to others. Smith also noted that research still needs to be done on the effects of chronic exposure to noise in the workplace.

Smith and Stansfeld (1986) compared self-reports of everyday occupational errors between two groups of subjects. One group was exposed high noise levels and the other was not. The high noise group had a higher number of everyday errors such as failures of attention, memory and action. These were the type of errors that had been observed in laboratory studies on the effects of noise.

As was mentioned previously, the practice of anesthesia involves the performance of many cognitive tasks. A large 1993 study by Baker and Holding specifically evaluated the effects of noise on cognitive task performance. Using 160 subjects, the researchers found that white noise actually improved performance on tasks involving short term memory demands. Simple tasks were more closely correlated with longer response times as a result of noise, but complex tasks were heavily affected by other variables such as time of day and gender. This study also confirmed the need for more research on the effect of noise on cognitive performance.

The job of the anesthesia provider involves obtaining information from various sources, verifying the validity of the information, formulating priorities and taking immediate action based on the information gathered (Weinger & Englund, 1990). In an attempt to specifically assess the impact of noise on anesthesia providers, Murthy et al (1995) conducted a controlled study using anesthesia residents as subjects. In this study, they measured noise levels in a variety of operating rooms to determine the average noise level. After the average noise level was determined, a recording of the actual operating room noise was made. The second phase of the study involved 20 anesthesia residents were asked to perform various cognitive tasks in a sound proof room. The tests measured short term memory and mental efficiency. After two weeks, the subjects were

retested in the same environment with the addition of the pre-recorded operating room noises. Subjects performed significantly poorer on the tests when they were exposed to noise. The major limitation of this study is that it was not performed in the work environment. This, however, is often difficult due to the need to protect patient safety.

Research on the effects of noise is varied and at times contradictory. More research certainly needs to be done to confirm or refute any previous findings. Conclusions need to be more specific in order to be applicable to clinical situations. The use of an anesthesia simulator may help to address this major limitation.

### **Use of Anesthesia Simulators in Research**

Extensive research has been done in recent years on the use of anesthesia simulators. In the past, simulators have been used extensively in the fields of aviation and ship handling where potentially risky activities are routine. Most of the work with anesthesia simulators has been done at Stanford University by Gaba and DeAnda(1988, 1989). The simulator was designed to facilitate training for anesthesia residents (Gaba & DeAnda, 1988). Simulation has been used to train personnel for both routine and emergency operations. For anesthesia practice, the simulator provides a re-creation of the anesthesia provider's physical and mental task environment in an operating room setting. It also provides an appropriate laboratory for the study of the human limitations for maintaining patient safety (Gaba & DeAnda, 1989).

As many as 50% of serious anesthetic mishaps are caused by preventable human error (Derrington & Smith, 1987; Gaba, Maxwell, & DeAnda, 1987). Simulation training has been proposed as a means to reduce mishaps (Gaba & DeAnda, 1988). The simulator allows subjects to respond to different problems based on actual cases of anesthesia

mishaps. The simulator successfully reproduces most aspects of a patient undergoing general anesthesia. Some of the most common crisis scenarios that have been used include endobronchial intubation, cardiac arrhythmias, equipment malfunction, and hypotension (Gaba & DeAnda, 1989). In addition to crisis scenarios, the simulator may also be used for routine tasks such as induction and emergence sequences. The advantages to simulation training are that there is no risk to the patient. Scenarios involving uncommon but serious problems can be presented, the simulation can be halted or recorded and replayed for teaching, and error can be allowed that would not be allowed in a clinical setting. The simulator experience was subjectively rated by anesthesia providers as very realistic (Gaba & DeAnda, 1988).

In one of the initial studies evaluating the use of the simulator, nineteen anesthesia trainees were asked to perform crisis management scenarios using the simulator (Gaba & DeAnda, 1989). The performance of each subject was recorded and evaluated. Subjects were evaluated based on detection as well as correction of the problem that was presented. Data that were obtained from the study gives insight into the performance of anesthesia providers in a variety of situations. Specific aspects of performance that were highlighted by the authors include provider vigilance, problem-solving skills and experience.

Studies using the anesthesia simulator are ongoing. One study used the simulator to specifically evaluate the role of provider experience in response to critical incidents (De Anda & Gaba, 1991). Another study used the simulator to track the progress of anesthesia students performance throughout their training (Chopra et al. 1994). Despite current research, the ultimate reliability of the simulator as an educational tool has not been

fully established and more research in this area needs to be done (Gaba & DeAnda, 1989).

Another proposed use of the simulator is for research on the effects of fatigue and other stressors on the performance of anesthesia providers (Gaba & DeAnda, 1988). Studying the effects of noise on anesthesia providers would be an appropriate use of the simulator because it more closely resembles the physical and mental task environments of the anesthesia provider.

### **Summary**

The current body of knowledge on noise and its effects is varied. Substantial evidence exists that noise has many physiologic and psychological effects. Studies are still exploring the effects noise has on cognitive performance. The results of studies on noise and performance are often contradictory suggesting that more research needs to be done in this area to determine what, if any effect noise has on cognitive performance. High levels of cognitive functioning are essential in the practice of anesthesia. The use of an anesthesia simulator is an appropriate way to expand existing research and evaluate the effects of noise on anesthesia providers while assuring patient safety.

## **CHAPTER III: METHODOLOGY**

### **Research Design and Procedures**

This study is a simulation study using a quasi-experimental one group pretest-post-test research design. This design was selected to examine the relationship between noise and the performance of anesthesia providers. Burns and Grove (1997) identify quasi-experimental design as an alternate approach for the assessment of causality in situations where experimental controls are not practical. This design is meant to control as many threats to validity as possible in a situation where not all of the components of a true experimental design such as random sampling, control groups, and manipulation of the treatment, are present. Quasi-experimental one group pretest-post-test design is limited by several uncontrolled threats to validity. Events such as statistical regression, maturation processes and changes in instrumentation may occur between the pretest and post-test and may alter responses to the post-test.

This study was conducted using an anesthesia simulator to evaluate whether operating room noise has an effect on anesthesia provider performance. Each of thirteen senior nurse anesthesia residents was asked to participate in two clinical scenarios using the anesthesia simulator. The scenarios were presented in a pre-test-post-test manner. The scenarios were pre-scripted and based on standard scenarios designed for use with the anesthesia simulators (see Appendix A). The pre-test and post-test scenarios were conducted one week apart and lasted approximately fifteen minutes each.

The anesthesia simulator used for this study was located at a local school of medicine and graduate school of nursing. The simulator environment included a life-sized human mannequin that responds to computer generated input. The computer input is

based on actual physiologic parameters and is scenario specific. The simulator environment also included a standard Ohmeda anesthesia machine and all the monitoring equipment needed to provide anesthetic care based on current practice standards. The simulator was isolated from outside influences and interruptions. All activity that took place within the simulator was video and audio taped for later evaluation and data analysis. Computer reports were also generated by the simulator to reflect all interventions made by the subjects during the scenarios.

The subjects were each brought into the anesthesia simulator environment on one of two days to participate in the pretest scenario. After informed consent was obtained, the subject was introduced to the simulator setup and equipment available for use. The subjects did not have prior knowledge of the scenarios. Each subject was then asked to participate in the pre-test scenario. The pretest scenario involved an uncomplicated rapid sequence induction of general anesthesia. Noise levels were kept to a minimum by actors as they recreated a "quiet" operating room scenario. No additional background noise was added to the scenario. Noise levels were recorded and controlled using a noise level dosimeter. Average noise levels were less than 25 db(A). In the scenario, actors played the role of an anesthesiologist, a surgeon, and an operating room nurse. The actors had prior knowledge of their roles and were only present to provide an element of realism. They were not allowed to assist the subjects in the scenario. Each subject was asked to assume the role of the primary anesthesia provider for the patient and to perform the appropriate care for an induction of general anesthesia. Each subject was given the same pretest scenario and was tested individually. Essential criteria for induction were determined prior to the scenario. After the induction sequence was completed, the

scenario was stopped. The subjects were asked not to discuss their scenario with anyone.

Data obtained from the videotapes and computer printouts was reviewed within one week of collection by the primary investigator. Performance will be measured based on current standards of care for rapid sequence induction protocols. Subjects will be evaluated as to whether each criterion was met or not met. Data was recorded on a data sheet (see Appendix B).

After a period of one week, the same subjects were brought back to the simulator to participate in the post-test scenario. The same rapid sequence induction sequence scenario was used, however, the patient description that the subject received was different to help eliminate some test-retest bias. The change in patient description did not affect the approach for the patient's care during the scenario. The same actors were used and each scenario was recorded using an audio tape, videotape and computer printout. In this scenario, the actors were instructed to make noises consistent with those noises found in an operating room. The actual noise level generated was measured and controlled using the noise logging dosimeter. Average noise levels were maintained at approximately 50db(A) with peak levels reaching over 100db(A). These levels are consistent with those found in operating rooms as determined by previous studies (Kamal, (1985), Hodge & Thompson, (1990), Falk & Woods, 1973)).

After the induction sequence was completed, the scenario was stopped and the subject was asked to evaluate the simulator experience. The subjects were asked to rate both the pretest and post-test simulator scenarios for realism (see Appendix C). The subjects also will be asked if a change in noise level was distracting and if so to rate how distracting they felt the noise was to their performance. The videotapes, audio tapes and

computer reports were then analyzed using the same criteria as in the pretest scenario.

All data from the pre- and post-test scenarios were then analyzed using the Statistical Package for the Social Sciences (SPSS) software version 9.0, 1999.

### **Sample**

The sample for this simulation study was a convenience sample. The subjects were thirteen second-year nurse anesthesia students with fifteen months of clinical anesthesia experience. The subjects attended the graduate school of nursing where the simulator is located and is used as a part of nurse anesthesia education. Subjects were approached in person by the primary investigator and asked to participate in a study using the anesthesia simulator. None of the subjects had prior experience with using an anesthesia simulator. The subjects served as their own controls in this quasi-experimental research design. Sample size for this pilot study was determined based on a power analysis of .80, a significance level of .05 and a medium to large effect size. Even though the power of the study in terms of establishing causality may be low, the study will provide useful information on which to design future studies.

### **Measurement**

As was previously stated, the dependent variable, performance, was measured based on whether essential tasks for rapid sequence induction of general anesthesia were completed or not completed. In order to assure validity of these measures, experts in the fields of anesthesia and anesthesia simulator training evaluated the pretest and post-test scenarios as well as the proposed data collection instruments. Written standards of care for anesthesia practice were also used to determine the essential tasks to be evaluated. Subjective evaluations of the study by the subjects will be measured using a Likert scale.

### **Protection of Human Rights**

The rights of the subjects were protected based on the guidelines set forth by the Institutional Review Board (IRB) at the Uniformed Services University of the Health Sciences. All subjects were asked to sign an informed consent form prior to the conduction of the experiments (see Appendix D). Subjects were able to withdraw from the study at any time without any risk of retribution. There was no risk to the subject of physical or mental harm. All data collected including the audio and videotapes was kept confidential and was maintained in a locked cabinet at the Patient Simulation Laboratory at the Uniformed Services University of the Health Sciences. This cabinet was only accessible to the researcher. After the study was completed the video tapes were returned to the participants for their own use or erased and discarded. The questionnaires completed by the participants were destroyed by the researcher after the study was completed.

Due to the element of deception involved in conducting the data collection using the simulator, participants were fully debriefed in regards to the purpose and methodology of the study. Participants were also allowed to view the videotapes. The debriefing occurred the day following the last data collection simulation and were performed by the researcher and committee members.

### **Data Analysis**

Correlational data for the pretest and post-test related to noise and performance was analyzed by the researchers after all the scenarios were completed and evaluated using appropriate statistical methods. Subjective responses of the subjects also will be analyzed. The Statistical Package for the Social Sciences (SPSS) was used for data

analysis

### **Summary**

A quasi-experimental design was the most appropriate method to conduct a pilot study on the relationship between operating room noise and anesthesia provider performance. This design has limitations, however, they do not undermine the value this study has for future research.

## CHAPTER IV: ANALYSIS

### Results

A total of 26 scenarios were conducted using the anesthesia simulator. Thirteen senior nurse anesthesia residents each completed a scenario in a controlled, quiet environment and then returned a week later to complete a scenario in a noisy environment. The average noise level in the control scenarios was 24.8db(A) with a maximum noise level of 81.8 db(A). The average noise levels for the experimental (noisy) scenarios was 50.5 db(A) with a maximum noise level of 108.8 db(A).

Audio tapes, videotapes and computer printouts of each scenario were reviewed and the performance of each subject was recorded on a data collection sheet (see Appendix B). Nine different outcome variables were measured and the frequency and percentage of correct responses was calculated for each of the two scenarios. The outcome variables that were measured during the scenario are the elements of a rapid sequence induction that are considered essential. Participants were evaluated on their accuracy of performing an equipment check and pre-oxygenating the patient prior to induction of anesthesia. Other measured variables include the application of cricoid pressure and appropriate dosing of induction agents and muscle relaxant. The number of attempts required for intubation and assessment of proper endotracheal tube placement via ETCO<sub>2</sub> assessment and presence of bilateral breath sounds were also outcome variables. These results are presented in Table 1 and Table 2. The percent correct indicates the percentage of subjects with a positive response to each variable. The data collected from the control and experimental scenarios were then correlated using Chi-Square statistical testing. The only outcome variable that was found to be statistically

significant ( $p < .05$ ) was the assessment of the equipment. This result is contrary to the predicted hypothesis that subjects would perform less accurately in a noisy environment. In the first scenario 30.8% of subjects performed an equipment check and in the second scenario the number of subjects who performed an equipment check increased to 53.8%. Table 3 presents the results of the statistical tests of significance.

**Table 1.****Pretest Scenario: The Frequency of Correct Responses to Outcome Criteria in a Quiet Environment.**

<b>Outcome variable</b>	<b>Number of subjects</b>	<b>Percent correct</b>
1. Equipment Check	13	30.8
2. Pre-Oxygenate	13	100
3. Cricoid pressure/RSI	13	92.3
4. Induction drug	13	92.3
5. Muscle relaxant	13	84.6
6. Intubation(1 attempt)	13	92.3
Intubation(>1 attempt)	13	7.7
7. Assess Breath Sounds	13	100
8. Assess ETCO <sub>2</sub>	13	100
9. Assess vital signs	13	
0 times		7.7
1-2 times		30.8
3 or more times		61.6

**Table 2.****Post-test Scenario: The Frequency of Correct Responses to Outcome Criteria in a Noisy Environment.**

<b>Outcome variable</b>	<b>Number of subjects</b>	<b>Percent correct</b>
1. Equipment Check	13	53.8
2. Pre-Oxygenate	13	100
3. Cricoid pressure/RSI	13	100
4. Induction drug	13	92.3
5. Muscle relaxant	13	69.2
6. Intubation(1 attempt)	13	92.3
Intubation(>1 attempt)	13	7.7
7. Assess Breath Sounds	13	92.3
8. Assess ETCO <sub>2</sub>	13	92.3
10. Assess vital signs	13	
0 times		7.7
1-2 times		38.5
3 or more times		53.9

**Table 3.****Comparison of Pretest and Post-Test Scenarios using Chi-Square Tests of****Significance.**

<b>Outcome Variable</b>	<b>Level of Significance (2-sided)</b>
1. Assess Equipment	.026
2. Pre-oxygenate	No association
3. Cricoid Pressure/RSI	No association
4. Induction drug	No Association
5. Muscle relaxant	.522
6. Intubation attempts	.764
7. Assess breath sounds	No association
8. Assess ETCO <sub>2</sub>	No association
9. Assess vital signs	.609

After all the subjects had completed both scenarios, they were each asked to complete a brief questionnaire related to the simulator as well as their subjective perception of the impact of operating room noise. In the first two questions, the subjects were asked to rate how realistic the scenarios were. Overall, subjects found the noisy scenario more realistic than the quiet scenario. Sixty-one percent of subjects found the noisy scenario realistic or very realistic as compared to 46% for the quiet scenario.

In the third question less than 40% of the subjects found the noise level in the noisy scenario to be distracting or very distracting . When asked to rate how distracting noise levels found in the operating room were, only 23% of subjects found levels to be at least distracting. The responses to these questions are presented below in Table 4 and Table 5.

**Table 4.**

**Subject Responses to Subjective Questions on Simulator Realism:**

	QUESTION 1	QUESTION 2
NOT AT ALL REALISTIC	15.4%	0
SOMEWHAT REALISTIC	38.5%	38.5%
REALISTIC	38.5%	38.5%
VERY REALISTIC	7.7%	23.1%

**Table 5.****Subject Responses to Subjective Questions on Noise Distraction.**

	<b>QUESTION 3</b>	<b>QUESTION 4</b>
<b>NOT AT ALL DISTRACTING</b>	<b>7.7%</b>	<b>30.8%</b>
<b>SOMEWHAT DISTRACTING</b>	<b>53.8%</b>	<b>46.2%</b>
<b>DISTRACTING</b>	<b>7.7%</b>	<b>15.4%</b>
<b>VERY DISTRACTING</b>	<b>30.8%</b>	<b>7.7%</b>

## CHAPTER V: SUMMARY

The main purpose of this study was to determine whether noise levels found in operating rooms have an effect on the performance of anesthesia providers. The secondary purpose of this study was to determine whether using an anesthesia simulator is useful for studying the effects of environmental factors, such as noise, on performance. The data presented in this study addresses these issues and adds to the body of existing knowledge on the topics of noise, performance and the use of anesthesia simulators.

The results of this study were inconclusive in determining whether noise affects the performance of anesthesia providers. The data does not indicate that noise has any effect on provider performance. Only one of the nine outcome variables (whether the subject performed an equipment check) demonstrated that noise could have caused a significant change in provider performance. These results do not concur with the projected hypothesis that noise has a detrimental effect on provider performance. There are several limitations to this study that could have influenced these results.

As previously stated some of the limitations to this study include the Hawthorne effect, test-retest situations, and sample size, characteristics and selection. The Hawthorne effect explains that subject responses may be altered by the fact that participants are aware that they are in a research study (Burns & Grove, 1990). The Hawthorne effect also implies that subjects perform better when they know they are being evaluated. This potentially alters the significance of a study's results. In this current study, subjects knew their performance was being videotaped and evaluated, therefore the performance of the subjects could have been impacted.

Another potential limitation to the study that could impact the findings is that the

study design was a test-retest format. The subjects had no prior experience with the anesthesia simulator so the exposure to a new environment could have negatively affected the performance in the control simulation. When the subjects returned for the second scenario, learning had occurred because the simulator environment was no longer an unfamiliar one. The subjects also learned from one scenario to the next by reflecting upon their own performance. This is evidenced by the fact that some errors that were made in the first scenario were corrected in the second scenario by the same subject.

The sample used for this study was one of convenience. The limitation of this type of sampling for this study is that the sample size may have been too small to make any significant correlation between noise and performance. Within the sample itself there was variation in clinical skill level even though all subjects were at the same point in their training. It also must be considered that the response to environmental influences such as noise is very subjective. There was a wide variety of responses of the subjects when they were asked whether noise interfered with their daily clinical practice. It could be assumed that providers who consider noise to be more of a distraction would be more likely to demonstrate an alteration in performance.

Other limitations discovered during the course of this study include creating a realistic environment in which to evaluate provider performance, determining the validity of using a simulator to measure performance and determining the reliability of the use of videotapes for evaluating simulation scenarios.

By attempting to evaluate providers in a realistic simulation environment, it was hoped that an element of realism that was absent in previous studies would be addressed. Over 80 % of the study participants found the simulator environment to be at least

somewhat realistic. When noise was added to the scenario, 100% of the participants felt that the environment was at least somewhat realistic. As the element of realism increases so does the validity of using simulation studies to evaluate different aspects of provider performance. The frequency of using anesthesia simulators to conduct research on such topics as education as well as performance seems to be increasing. In a recent study by Devitt et al. (1997), analyzing videotapes of simulation scenarios was found to be a valid means of scoring provider performance. The article identifies the need, however, for more research to be done to determine valid methods for evaluating provider performance.

Overall, this study could not prove that noise had either a positive or a negative impact on anesthesia provider performance. Despite many limitations, this study did support existing research that noise is a significant element in operating rooms today and that noise may have a subjective impact on anesthesia provider performance. The study also adds to the body of knowledge that studies using the anesthesia simulator can create a more realistic environment in which to study a variety of topics that cannot be conducted in operating rooms. It also demonstrated that the use of patient simulators is a practical, educational training method.

#### Suggestions for Further Research

A variety of research topics could be derived from the ideas set forth in this study. Broad scale surveys could be done on the subjective impact of noise in the operating room environment. Surveys could also be conducted of the usefulness of anesthesia in provider education. A study similar to this one could be designed with a larger sample size and with subjects that were very familiar with the use of the anesthesia simulator.

More research is also needed to determine ways of measuring performance in an objective and valid manner.

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## **APPENDICES**

**APPENDIX A**  
**Anesthesia Simulator Pretest and Post-test Scenarios**

**PRETEST SCENARIO:**

Mr T., Age 22, presents today with acute appendicitis with complaints of lower abdominal pain, nausea and vomiting for 12 hours. Plan for appendectomy.

Physical Exam: Airway is adequate with full range of motion of the neck.

Lungs: CTA Heart RRR without murmur

CXR: WNL HCT 46

He is 5'10", 74kg.

Allergies: Bee stings

He is healthy with no past medical history. He works out daily.

He does not drink or smoke.

BP 127/70 Pulse: 70 Respirations: 18

**POST-TEST SCENARIO:**

Ms P. age 18, presents today for a fixation of a fractured humerus.

Physical Exam: Airway is adequate. Lungs CTA. Heart RRR without murmur.

CXR: WNL HCT 38

Last ate 4 hours ago

She is 5'5", 52kg.

Allergies: NKDA

Past medical History: none

Past surgical history: none

Current Medications: none

Vital signs: HR:104 BP 106/60 RR 18

## **APPENDIX B**

### **Data Collection Instrument**

**Pretest/Post-test Scenario Data Collection Instrument**

SUBJECT #: \_\_\_\_\_

MALE/FEMALE: \_\_\_\_\_

AGE: \_\_\_\_\_

NOISE LEVEL: MIN: \_\_\_\_\_

MAX: \_\_\_\_\_

AVG: \_\_\_\_\_

**REQUIRED CRITERIA FOR INDUCTION / MEASURED OUTCOME**

1. Evaluate equipment function (Anesthesia Circuit, Suction)

\_\_\_\_\_ COMPLETED

\_\_\_\_\_ NOT COMPLETED

2. Pre-oxygenate patient with 100% oxygen

\_\_\_\_\_ COMPLETED

\_\_\_\_\_ NOT COMPLETED

3. Assess vital signs on monitor

\_\_\_\_\_ NUMBER OF TIMES ASSESSED

4. Asks an assistant to apply Cricoid pressure and reforms a rapid sequence induction.

\_\_\_\_\_ COMPLETED

\_\_\_\_\_ NOT COMPLETED

5. Administer appropriate dose (1-4mg/kg) of Sodium Thiopental or Propofol(2-2.5mg)

\_\_\_\_\_COMPLETED CORRECTLY

\_\_\_\_\_COMPLETED INCORRECTLY

\_\_\_\_\_NOT COMPLETED

6. Assess ability to ventilate patient after patient is asleep

\_\_\_\_\_COMPLETED

\_\_\_\_\_NOT COMPLETED

7. Administer appropriate dose of succinylcholine(1-1.5 mg/kg)

\_\_\_\_\_COMPLETED CORRECTLY

\_\_\_\_\_COMPLETED INCORRECTLY

\_\_\_\_\_NOT COMPLETED

8. Successfully orally intubates patient using laryngoscopy

\_\_\_\_\_COMPLETED

\_\_\_\_\_NOT COMPLETED

\_\_\_\_\_NUMBER OF ATTEMPTS

9. Assess placement of endotracheal tube

\_\_\_\_\_AUSCULTATES BREATH SOUNDS

\_\_\_\_\_ASSESSSES END-TIDAL CO2 WAVEFORM MONITOR

## **APPENDIX C**

### **Subject Simulator Evaluation Form**

## Phase II: Subject Evaluation of Simulator Experience

MALE \_\_\_\_\_ FEMALE: \_\_\_\_\_

AGE IN YEARS \_\_\_\_\_

1. In the first simulator scenario, how realistic would you rate the simulator environment?

1	2	3	4	5
Not at all Realistic	Not very Realistic	Somewhat Realistic	Realistic	Very Realistic

2. In the second simulator scenario, how realistic would you rate the simulator environment?

1	2	3	4	5
Not at all Realistic	Not very Realistic	Somewhat Realistic	Realistic	Very Realistic

3. How distracting did you find the change in noise level from the first to the second scenario?

1	2	3	4	5
Not at all Distracting	Not very Distracting	Somewhat Distracting	Distracting	Very Distracting

4. In your clinical practice, how distracting do you find the noise levels in the operating room to be?

1	2	3	4	5
Not at all Distracting	Not very Distracting	Somewhat Distracting	Distracting	Very Distracting

## **APPENDIX D**

### **Informed Consent Form**

**INFORMED CONSENT FOR ANESTHESIA SIMULATION STUDY****Principal Investigator: Heather A. Lembo, LT NC USNR**

My name is LT Heather A. Lembo. I am a Nurse Anesthesia graduate student conducting research for my masters thesis. You are being asked to take part in a research study. Before you decide to be a part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent. This consent form provides information about the research study that has been explained to you. Once you understand the study and the tests it requires, you will be asked to sign this form if you desire to participate in the study. Your decision participate is voluntary. This means that you are free to choose if you will take part in the study.

**Purpose and Procedures**

The Department of Nursing Anesthesia of the Uniformed Services University of the Health Sciences is carrying out this research study to find out how anesthesia simulators may be used to evaluate anesthesia provider performance. Thirteen volunteers will be asked to participate in this research study. The procedure for this study involves each volunteer participating in two separate scenarios using the anesthesia simulator. One scenario will be done initially and the other one week later. The details of the simulator setup and equipment will be explained in detail prior to conducting the scenario and any questions that you may have will be answered. Each scenario will be recorded using audio and videotape. The content of these tapes will be reviewed only by myself and my

thesis committee members. After completing the scenarios, you will be asked to evaluate your simulator experience and to make any comments about the study that you may have.

### Benefits

The benefits of this study are that a potential method for evaluating and improving anesthesia provider performance will be tested. You may benefit by getting experience with a new tool used for anesthesia education. Anesthesia simulators are being used in a variety of settings with the aim of improving provider skills and optimizing patient care.

### Time Commitment

The time commitment for this study will consist of two 30 minute sessions.

### Risks, Inconveniences, Discomforts

There are no physical risks involved with this study. Your performance will not be graded nor will they be held against you in any way. Scenario sessions will be scheduled during school hours and can be arranged to accommodate prior commitments.

### Cost of Participation

None to you.

### Research Related Injury

This study should not entail any physical or mental risk. If, for any reason, you feel that continuing this study would constitute a hardship for you, we will end your participation in the study.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project you should contact the Office of Research

Administration at the Uniformed Services University of the Health Sciences, Bethesda, MD 20814 at (301) 295-3303. This office can review the matter with you, can provide you information about your rights as a subject, and may be able to identify resources available to you. Information about judicial avenues of compensation is available from the University's General Counsel (301) 295-3028.

#### Confidentiality of Records

All information that you provide as a part of this study will be confidential and will be protected to the fullest extent of the law. Information that you provide and other records related to this study will be kept private, accessible only to those persons directly involved in conducting this study and members of the Uniformed Services University of the Health Sciences Institutional Review Board, who provide oversight for human use protection. All questionnaires and forms will be kept in a restricted access, locked cabinet while not in use. However, please be advised that under UCMJ, a military member's confidentiality cannot be strictly guaranteed. To enhance the privacy of your responses you will not be identified on any of the data collection tools utilized. Any reports generated from this study will not divulge your name or identity.

#### Withdrawal

I understand that I may at any time during the course of this research study revoke my consent, and withdraw from the study without prejudice. I have been given an opportunity to ask questions concerning this research study, and any such questions have been answered to my complete satisfaction. Call LTJG Heather A. Akins at 301-869-3183, If you have any concerns, questions, or W. Patrick Monaghan Ph.D. at 301-295-6565, chair of my thesis committee. If you have any questions about your rights as a

research subject, you should call the Director of Research Programs in the Office of Research at the Uniformed Services University of the Health Sciences at (301) 295-3303. This person is your representative and has no connection to the researchers conducting this study.

I do hereby volunteer to participate in a research study designed to evaluate the use of anesthesia simulators for assessing anesthesia provider performance. The implications of my voluntary participation: the nature, duration and purpose; the methods and means by which it is to be conducted; and the inconveniences and hazards to be expected have been thoroughly explained to me by LT Heather Akins. By signing this consent form you are agreeing that the study has been explained to you and that you understand this study. You are signing that you agree to take part in this study. You will be given a copy of this consent form.

I have been given the opportunity to ask questions concerning this study, and any such questions have been answered to my full and complete satisfaction.

I willingly give my consent to take part in this study.

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Participant s Signature

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Date and time

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Participant s Social Security Number

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Witness Signature

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Date and time

I Certify that the research study has been explained to the above individual, by me, and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

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Investigator

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Date