# ANESTHESIA PROVIDERS' PERCEIVED DISTRACTIONS IN THE OPERATING ROOM DURING INDUCTION AT A LARGE URBAN HOSPITAL

by

#### Elisa Hillman

A doctoral scholarly project submitted to the faculty of The University of North Carolina at Charlotte in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

Charlotte

2023

Approved by:
Dr. David Langford
Dr. Dianne Earnhardt
Dr. Danielle Brown
Dr. Susan Lynch
Dr. Zhou Job Chen
Dr. Elena Platanova
Dr. Katie Shue-McGuffin

© 2023 Elisa Hillman ALL RIGHTS RESERVED

#### ABSTRACT

ELISA HILLMAN. Anesthesia Providers' Perceived Distractions in the Operating Room During

Induction at a Large Urban Hospital

(Under the direction of DR. DAVID LANGFORD)

Induction of anesthesia is a critical part of the anesthesia process where the anesthesia provider begins putting the patient to sleep and secures the airway. The purpose of this group project is to investigate anesthesia providers' opinions on the severity of distractions occurring during induction at three different sites: a level one trauma center, a suburban hospital, and an ambulatory surgery center. The focus of this paper will be on the analysis of the results from the level one trauma center, and its comparison to the results from the other two sites. An anonymous, electronic survey was distributed to physician anesthesiologists, certified registered nurse anesthetists (CRNAs), and student registered nurse anesthetists (SRNAs), at these three different clinical sites. The survey asked providers rate the severity of each potential distraction on a modified Likert scale from "not distracting" to "highly distracting". The results were then compared to see how perceptions varied between site and provider demographics. The results revealed the distraction most frequently ranked as "highly distracting" by providers at all three sites was conversation during induction of anesthesia.

#### **ACKNOWLEDGMENTS**

I would like to express my special thanks to my committee chair, Dr. David Langford, for supporting me through this challenging work. His edits and feedback guided me through both the creation and the final writing of this project. I would like to thank Dr. Dianne Earnhardt for her continuous encouragement and valuable clinical input throughout every stage of this project. Her confidence in me and my team was greatly appreciated. I also want to express sincere appreciation to Dr. Job Chen for assisting with the statistical analysis and taking the extra time to teach me the best ways to convey the results of my project.

Lastly, I would like to extend immense gratitude towards my project group members,
Chantel Glasser and Bailey Coggins. I could not have asked for a better team, and I never could
have completed this project without them.

# TABLE OF CONTENTS

LIST OF TABLES	vi
LIST OF FIGURES	vii
LIST OF ABBREVIATIONS	viii
BACKGROUND	1
PROBLEM STATEMENT	1
PICO QUESTION	2
Conceptual Framework	3
LITERATURE REVIEW	4
Project Thesis	4
Key Topics in Literature Review	4
PROJECT DESIGN	13
Methodology	13
Settings	14
Sample	14
Tools, Measures, and Methods	15
Data Collection and Timeline	16
RESULTS	17
DISCUSSION	23
RECOMMENDATIONS	25
REFERENCES	27
APPENDIX A: Survey	31

	vi
APPENDIX B: IRB Approval	33
APPENDIX C: Wordle	34

# LIST OF TABLES

TABLE 1: Perceptions of distractions across gender, age, and site

22

# LIST OF FIGURES

FIGURE 1: Age Distribution of Participants	18
FIGURE 2: Distribution of Distractions at Level I Trauma Center	19

# LIST OF ABBREVIATIONS

OR Operating Room

CRNA Certified Registered Nurse Anesthetist

SRNA Student Registered Nurse Anesthetist

#### **Background**

The American Society of Anesthesiologists' seal depicts a lighthouse shining brightly over a ship at sea. The ship sailing in rocky seas represents the patient, and the captain of the ship is the anesthesia provider guiding the patient through their journey of fear and uncertainty. The lighthouse portrays the firm foundation of safety and provider knowledge of the science and art of anesthesia (American Society of Anesthesiologists, 2021).

Anesthesia providers hold the responsibility of safely guiding patients through their anesthetic during surgery. Two of the most sensitive times during anesthesia care are the induction and emergence of anesthesia. It is imperative that distractions in the operating room (OR) during the induction of anesthesia be mitigated to facilitate focus for the anesthesia provider as they safely secure the airway and get the patient off to sleep. This project addresses a clinical issue identified by an anesthesia group within an urban health care system in identifying the types of distractions anesthesia providers indicate are the most severe during induction.

#### **Problem Statement**

ORs are notoriously loud work environments. Studies have found that before and after surgery, during critical moments for anesthesia, the noise levels are consistently even *higher* (Ginsberg et al., 2013, p.528). Not only are ORs noisy, but they're also extremely busy. Harten et al. (2020) performed an observational study over a span of 148 hours in three ORs at a large teaching hospital and found a total of 4,594 distracting events occurred during the induction of anesthesia. A systematic review of 38 articles found the two most common distractions to anesthesia providers to be small talk and staff entering and exiting the room. Additional significant distractions included music and faulty equipment alarms (Gui et al., 2021).

These distractions create barriers for the anesthesia provider in delivering safe anesthetic care and can cause serious safety issues. Five percent of human errors in the operating room have been attributed to distracting events (Riutort, 2020). Studies have found that distractions decrease anesthesia providers' clinical reasoning, performance, and lead to poorer patient outcomes (Gui et al., 2021; Enser et al., 2017, p. 466). Evidence has clearly shown that distractions during induction of anesthesia may yield serious consequences and should be addressed.

The stakeholders affected by this issue include the nurse anesthetist and anesthesiologist, the surgical team, hospital administrators, the patient's family, and the patient. Distractions that impair the focus of the anesthesia provider during induction places patient safety at risk. The surgical team has many tasks to accomplish during the induction period as well, and their collaboration is necessary to decrease distractors. Hospital administrators are also stakeholders, as they are interested in decreasing adverse events and increasing cost efficiency. Additionally, they can implement policies to help decrease the distractions. Lastly, and most importantly, the potential adverse effects from distractions can have lifelong impacts on patients and their family members. The top priority of each stakeholder and goal of distraction reduction is to provide the safest patient care.

#### **PICO Question**

A survey was used to assess the severity of potential distractions while investigating the PICO question: How do anesthesia staff members (P) perceptions of distractions during induction (I) at three different clinical sites (C) vary (O)? The three sites are a level one trauma center, an ambulatory surgery center, and a mid-sized local hospital. These three locations have very different environments within their ORs and can yield insight to location-based problems

and ultimately improve the quality of care our patients receive in different perioperative environments.

The objective of this portion of the group project is to investigate the PICO question: At a level one trauma center (P) how do perceptions of distractions during induction (I) among anesthesia providers (C) vary (O)? Therefore, this paper will assess distractions at the level one trauma center. This facility has a unique set of needs because it is a level one trauma center and manages 33 operating rooms. This hospital is inherently fast paced, treats the highest acuity patients, and carries a heavy caseload, making it prone to a time-strained workflow. Therefore, it was predicted that the level one trauma center would experience a lot of challenges with distractions during induction compared with the other sites. It also has the largest number of staff members which poses unique issues as well. It can be extremely difficult to communicate with so many employees and involve everyone in creating a workflow change.

#### **Conceptual Framework**

The Plan-Do-Study-Act (PDSA) model is a four-step tool used to improve a process or to carry out a change (Agency for Healthcare Research and Quality, 2020). For this project, the "plan" component of the model began with identifying known distractions in the literature, followed by the development of a survey to elicit anesthesia providers' opinions on the most severe distractions during induction. Secondly, the "do" component encompassed the distribution of the survey. After the results were collected, the "study" phase required thorough review of data and analysis. Lastly, to "act", each group member drew conclusions and made recommendations for distraction mitigation based on the survey results that were shared with the healthcare system's Director of Anesthesia Quality and Safety.

A strength of the PDSA model is that it was formulated to be cyclical in nature, promoting the idea of continual reassessments and improvements. Future implications beyond this project may include educational tools, creation of policy, and further evaluation of outcomes.

#### **Literature Review**

#### **Project Thesis**

It is imperative that distractions in the OR be mitigated to allow the anesthesia provider to focus during the induction of anesthesia. The first step in mitigating distractions is to determine which distractions are causing the most problems so that the appropriate solution can be implemented. This scholarly improvement project aims to achieve this by distributing a survey asking anesthesia providers to rank the severity of different distractions they experience during induction. This will identify which are the worst distractions.

#### **Key Topics in Literature Review**

This review of the literature identified five types of distractions commonly occurring in the OR during the induction of anesthesia. These distractions can be divided into the following major categories: noise, music, cell phones/pagers, production pressure and conversations/movement.

#### Noise

Operating rooms are notoriously loud work environments during surgery, and noise of any kind can be detrimental to the anesthesia provider. A prospective study found that during critical moments for anesthesia, including induction, the noise levels are consistently at their *highest* (Ginsberg et al., 2013, p.528). Shapiro & Berland (1972) found that noise in the OR can be as loud as highway traffic. This is significant because noise can cause serious negative consequences that include communication breakdown, decreased mental effectiveness and short-

term memory abilities, inability to hear important monitors such as the pulse oximeter, and creates physiologic stress in the anesthesia provider (Hodge & Thompson, 1990; Murthy et al., 1995; Stevenson et al., 2013; Kam et al., 1994).

Broom et al. (2011) likens the distractions that occur in the operating room to those that occur in aviation. The authors refer to the sterile cockpit rule that prohibits non-essential conversation during crucial time periods of the flight to prevent any distraction that could lead to a potential accident. The take-off and landing of a flight mirror the induction and emergence phases of anesthesia. Their study recorded noise decibels in the OR every 30 seconds for 30 anesthetic inductions, anesthetic maintenance phases, and anesthetic emergences respectively. This study found the anesthetic emergence phase, the period when the patient gradually regains consciousness after anesthesia, to be noisier than the induction and maintenance phases of anesthesia (Broom et al., 2011). A limitation to this study was the inconsistent placement of the recorder in the OR in proximity to the anesthetist, which could have contributed to variability in decibel recordings.

While the Broom et al. (2011) study found anesthetic emergence to be the noisiest, Hodge & Thompson (1990) found the anesthetic induction to be the noisiest. However, both studies found increased noise to caused decreased effectiveness in communication (Broom et al., 2011; Hodge & Thompson, 1990). When the anesthetist cannot communicate effectively during the induction of anesthesia, this creates the potential for errors.

In a case-control study by Murthy et al. (1995), the impact of noise on the mental effectiveness and short-term memory capabilities of the anesthesia provider was examined.

Anesthesia providers were taken to an audiology lab and listened to previously recorded OR noise with an average of 77 dB(A) while three tests were administered to measure the effects of

noise levels on their mental ability and short-term memory retention. The results demonstrated a statistically significant reduction in mental efficiency and short-term memory abilities when exposed to the OR noise recordings compared to no noise at all (Murthy et al., 1995). Like the Hodge and Thompson (1990) study, the OR recordings done for Murthy's study also found the highest decibel readings occurred during the anesthetic induction phase of surgery. The limitation of Murthy's study is that it measured mental and short-term memory effectiveness in an audiology lab (Murthy et al., 1995). If these tests had been performed in the OR, they may have shown an even greater reduction in mental and short-term memory effectiveness related to completing anesthesia tasks because of the added visual distractions. The delivery of anesthetic care requires extreme vigilance and high levels of critical thinking. These studies support that high levels of noise can impede the mental functioning of the anesthesia provider.

A review article by Kam et al. (1994) examined multiple articles assessing noise levels in OR and its negative consequences. The US Occupational Safety and Health (OSHA) regulations recommended that hospitals not exceed 40 dB(A) during the day. However, the average noise in the OR was found to be 90 dB(A); the maximum decibel level allowed by OSHA (Kam et al., 1994). High noise levels above 90 dB(A) were shown to cause increased release of stress hormones (epinephrine and norepinephrine) in humans and an increase in cardiovascular stress from elevated blood pressure and heart rate. The physiologic effects caused by noise can cause the anesthesia provider to feel irritable, unwell and can cause side effects like fatigue and headache.

Similarly, a more recent observational study by Arabaci & Onler (2021) recorded decibel levels during 403 general surgeries and found noise in the OR to be consistently higher than the World Health Organization's recommended 35 dB(A). During induction specifically, noise in the

OR averaged even higher at 63 dB(A) (Arabaci & Onler, 2021). Anesthesia providers' anxiety levels were assessed using a Likert type anxiety scale but did not reveal statistically significant results. However, in this study, the anesthesia staff was incredibly experienced, with a minimum of eight years previous experience, which could suggest that they have adapted to the noise levels.

The ability to monitor patient vital signs and cardiopulmonary status in the OR is a critical component of safe anesthetic care. A group of researchers studied anesthesia providers in a lab setting and measured their ability to hear pulse oximeter changes when significant background noise (previously recorded OR sounds) was applied. The anesthesia providers had to complete certain tasks with the background noise on and were asked to press a button once they recognized a change in pulse oximeter tone. The study found that the background OR noise significantly decreased providers' response times in noticing the oxygen saturation monitor's auditory drop (Stevenson et al., 2013).

#### Music

Music, like noise, is an audible factor that can divert the attention of anesthesia providers. Weldon et al. 2015 suggests that music is played in 53-72% of surgeries. This high frequency and lack of clinical policies related to music have raised questions about the impact of music has on provider performance and focus. An ethnographic observational study done at a London teaching hospital observed 33 hours of surgery with 5,303 conversational request/response interactions between staff. Results showed that when music was played, requests had to be repeated five times more than when no music was played. Moreover, tensions between staff heightened after these repeated requests, surgical task times increased, and there were difficulties turning down the music volume at crucial times (Weldon et al., 2015).

In contrast to the previous study, Faraj et al. (2014) sought to understand the opinions on music from staff in the OR. A sample of 52 respondents was taken from a hospital with five ORs. Overall, the majority (66%) of staff responded that they enjoyed their workday more when music was playing. Some survey responses did indicate that music should be regulated, as it becomes distracting during times like instrument counting or critical surgical moments (Faraj et al., 2014). It is interesting that while anesthesia professionals were included in the study, no comments were published about the impacts of music on critical moments in anesthesia care—instead focusing concerns on surgical maneuvers. This suggests that anesthesia tasks like anesthetic induction and airway management, are often overlooked by the surgical team.

Research should continue to highlight music's potential impact on the anesthesia providers' focus and patient safety.

A survey in 1997 by Hawksworth et al. assessed music prevalence in the OR and anesthesia providers' opinions on the playing music. The study of 104 anesthesia providers revealed that music was played 72% of the time. The issue of safety was apparent as, "26% of the sample felt that music reduced their vigilance and impaired their communication with other staff while 11.5% felt that music might distract their attention from alarms" (Hawksworth et al., 1997, p. 80). Many of today's ORs are equipped with upgraded stereo systems compared to what was present in 1997. This upgraded technology likely has louder audio capabilities, access to a larger variety of music genres, and complex control consoles which could increase the distraction or inability to quickly reduce the volume/stop the music.

A final study published in 2021 by Fu et al. studied medical students performing simulated laparoscopy. Two groups were compared, one listened to the music of their choice, while the other listened to standard pre-recorded O.R. noise. The group listening to music scored

lower on a standardized mental workload questionnaire after the experience (SURG-TLX), but their heart rate variability was statistically significantly lower. Surgical task performance showed no differences between the two groups. While this suggests that music in the OR can have some positive effects, there are shortcomings in the experiment. No interruptions were levied on the medical students, which would likely be present in a non-simulated situation. Again, anesthesia providers were not included in this study. While the applicability of these findings to anesthesia tasks is small, the results suggest that more work is needed on the impacts of music.

#### Cell Phones and Pagers

With cell phones becoming a necessity for everyday life, it is no surprise that they have found their way into the workplace. When working in the OR, a communication tool is needed to call for help or update others on the progress of the procedure. These tasks can be done with a hospital-issued device or personal cell phone, with the latter creating a special opportunity for distraction. Observations of 52 surgeries recorded 205 phone calls; anesthetists were responsible for 11.7% of the incoming calls and 50% of the outgoing calls (Avidan et al., 2019). While most of these conversations were work-related, none of the conversations were related to the patient in the room. Unfortunately, some of the incoming calls adversely diverted the attention of staff in the room. These findings were limited in that they were subjectively measured by an observer in the room. Overall, the study suggested turning phones off or leaving them outside of the OR. This may not be feasible in cases where the hospital has no policy or requires OR staff to use phones as a work-related communication tool with other staff or with families in waiting areas.

An alternative suggestion has been made to activate the "do not disturb mode" on cellphones in the operating room (Gui et al., 2021). This intervention offers a layer of safety, as vital notifications can be seen at appropriate times and quick communication can be made during

emergencies. However, some facilities use radios or pagers, which may not come with a silencing feature. An observational study by Savoldelli et al. (2010) videotaped 37 anesthesia inductions and found that the unexpected or repeated beep of a pager during critical moments like intubation was distracting and could jeopardize patient safety (Savoldelli et al., p. 686). Further research needs to look at newer technologies such as smart watches, text messaging and social media application use by anesthesia providers.

#### **Production Pressure**

The Agency for Healthcare Research and Quality (AHRQ) defines production pressure as the obvious or unspoken pressure placed on healthcare workers by their organization to prioritize the volume of work they complete over safety and quality (Carayon, 2007). Production pressure is certainly prevalent in the OR to keep surgery schedules on time. In a survey completed by 279 anesthesiologists, 49% reported witnessing production pressure causing an unsafe action by the anesthesia provider (Gaba et al., 1994). By focusing the attention of the anesthesia provider on keeping a schedule, production pressure can potentially be a serious distraction.

Another similar study surveyed 422 hospital employees, the majority being nurses, to investigate whether production pressure decreased safety behaviors. The survey included five questions eliciting opinions on how production pressure distracted providers from their work. The survey results concluded that production pressure had statistically significant negative effect on safe behavior (Amponsah-Tawaih & Adu, 2016). Therefore, it is likely that production pressure can be a distraction to anesthesia providers.

#### **Conversations and Movement**

Communication among healthcare staff is crucial for safe patient care, but conversations can be distracting during the induction of anesthesia. In Broom et al.'s (2011) observational

study, researchers observed 30 inductions and found that side conversations occurred during 40% of anesthetic inductions. Another 3% of inductions had more than two simultaneous conversations. In a systematic review by Gui et al. (2021), conversation was found to be the most frequently reported distracting event, with irrelevant small talk spanning over 70.3% of the induction period. These conversations during induction could create delays in care or misunderstandings— each dangerous to patient safety.

Even relevant conversations about the patient in the room can reduce provider attentiveness, especially if they are teaching or guiding a student anesthetist. Gui et al. (2021) included a study where vigilance was measured by a provider's response time to a flashing light. Talking with a student and providing intraoperative teaching significantly reduced the provider's responsiveness, especially during the phases of induction and emergence (Gui et al., 2021). Teaching students is a common practice but can be highly distracting for the anesthesia provider.

Staff frequently enter and exit the room during anesthetic inductions and can be highly distracting to the anesthesia provider. In an observation of 30 anesthetic inductions, staff movement in and out of the O.R. was reported during 37% of inductions (Broom et al, 2011). Harten et al. (2020) observed 148 hours in the OR and found that door movements were the most frequent distraction during the induction phase of anesthesia, with staff entering or exiting the OR an average of 28 times per hour. Conversation and movement of staff in the OR have been shown in the literature to be very frequent distractions during the anesthetic induction phase. Although these studies observed the frequency of the distractions, they did not assess whether the providers found the interruptions to be a barrier to safe patient care.

#### Multifactorial Issues

While isolated distractors have been investigated and studied, these distractions frequently happen in combination with each other, creating a unique challenge for the anesthesia provider. An observational study of 37 anesthesia inductions found the median number of distractions during a single induction to be five- and 39.5% of the time, at least one distracting event spanned the entire duration of induction (Savoldelli et al., 2009). These distractions had a negative impact on the patient 21.5% of the time, including poor preoxygenation, accidental administration of anesthesia gases, and increased duration of tourniquet placement for peripheral IV placement (Savoldelli et al., 2009).

A study by Slagle et al. (2018) observed 319 nurse anesthetists and anesthesiology residents during all phases of anesthesia. They concluded that self-initiated distractions, such as social conversations, reading, and personal email occurred during anesthetic periods of patient stability. This suggests that anesthesia providers distract themselves during the maintenance phase of anesthesia. The researchers recommend that distraction management should be included in anesthesia provider training.

Using a quasi-experimental design, Crockett et al. (2019) implemented a distraction reduction tool during the induction phase of anesthesia in a pediatric otolaryngology OR. The team investigated the impact of noise, conversation, and music on increasing levels of distraction to the anesthesia provider during induction and found a correlation between increased noise levels and decreased patient safety. A quality improvement project was then created to mitigate distractions during induction using three specific interventions. First, education was provided to the entire perioperative staff on the negative impact of distractions on patient safety during anesthetic induction. Second, the circulating nurse was given the responsibility of turning any music off just before the patient entered the OR. And lastly, the anesthesiologist took on the role

of announcing the beginning of anesthetic induction and addressing the room if any disrupting noise occurred during the induction phase. Over a span of nine weeks implementing this quality improvement measure, the team decreased induction distractions down to a mere ten percent of the previous levels (Crockett et al., 2019). This quality improvement project demonstrated that reducing distractions in the OR during induction can be done with the collaboration and dedication of the entire perioperative team.

#### Conclusion

A review of the literature demonstrates that distractions are a significant problem for anesthesia providers. The literature reveals how common distractions can impede the provider's focus, potentially making induction of anesthesia more dangerous for patients. There is usually not just one single distraction for anesthetists to deal with; there are a multitude of noises, alarms, and even other clinicians, that compete for the anesthesia provider's attention.

This project seeks to answer a question posed by a specific healthcare system related to perceived distractions within its system. This larger project aims to investigate the perceptions of anesthesia providers toward distractions across three different settings. This paper reports one aspect of that larger project; the perceived distractions at a level one trauma center in relation to two other sites.

#### **Project Design**

#### Methodology

This is a quality improvement project using a descriptive survey to examine distractions in the ORs of a large busy medical center as perceived by different anesthesia staff. The surveys were administered to CRNAs, SRNAs, and physician anesthesiologists over a three-week period. The survey was developed to elicit what anesthesia providers find to be the most severe

distractions during induction of anesthesia at a level one trauma center. Additionally, results were compared to similar projects conducted at two other clinical sites: an ambulatory surgery center and a suburban hospital.

#### **Settings**

The setting for this quality improvement project is a busy level one trauma center in a large urban North Carolina city. It serves the surrounding areas of North and South Carolina. This hospital provides care for patients across all socioeconomic and racial/ethnic groups. With 874 beds and 33 operating rooms (excluding obstetrics and out of department areas) approximately 150 surgical cases are completed per day across every medical specialty. As a level one trauma center, they provide surgical care for both healthy and complex patients. This high volume of surgeries requires significant staffing, including many anesthesia providers. There has also been high turnover among anesthesia providers in the past year, similar to other healthcare facilities. Currently there is a mix of both new and veteran anesthesia providers. With hundreds of perioperative employees, this site poses unique challenges in teamwork, timing, and communication.

#### Sample

The sample for this project consists of CRNAs, SRNAs, and physician anesthesiologists. The CRNA population has either a doctoral degree, master's degree, or in some cases a certificate. The SRNA population for this project is currently enrolled as nurse anesthesia students in a Doctor of Nursing Practice (DNP) program. Anesthesiologists have completed four years of medical school, four years of anesthesia residency, and may have completed a fellowship in an anesthesia specialty.

The clinical site operates under the anesthesia care team (ACT) model which consists of one physician anesthesiologist supervising usually three ORs, each with a CRNA providing anesthesia for that OR. The physician anesthesiologist performs a documented preoperative interview for each patient, is typically responsible for procedures such as peripheral nerve blocks, central line insertions, transesophageal echocardiograms etc., and is present on induction and emergence of anesthesia. The CRNA stays in one OR and provides the anesthetic for the entirety of the surgical case. The SRNA is assigned and directly supervised by a CRNA.

Inclusion criteria for the survey required that the participant be either a CRNA, SRNA, or anesthesiologist. Anesthesia providers received the survey through their Atrium email or via QR code on posted fliers. Those excluded from participating were SRNAs who were not currently active at this Level I trauma center during the three-week survey period.

### **Tools, Measures, and Methods**

This project used a survey developed by the larger project team. The information collected in the literature guided what questions were put on the survey. The survey used a modified Likert scale; a validated method for data collection with ordinal measurement (Davino & Fabbris, 2013). The five-point scale provided a range from 'not distracting' to 'highly distracting' as the extreme anchor points on each end of the scale. The survey was created in the health system's Microsoft Forms program. This survey software did not allow users to skip sections of the survey.

The electronic survey was securely distributed to CRNAs, SRNAs, and anesthesiologists at each of the three hospital sites using health system's Microsoft Outlook email system and on a QR code in breakrooms. The introduction page stated the survey inclusion criteria, consent, and a statement ensuring confidentiality and anonymity before providers began.

The first portion of the survey asked participants for demographic information: job title, age, gender, and clinical site. Anonymity was maintained by having the participant select within a numerical range instead of providing a specific number for age.

The second portion of the survey was designed to present providers with a list of potential distractions. The survey included the following events: music, conversations, equipment alarms, Vocera/work phone, staff entering/exiting the OR, and personal cell phone use. The participant was asked to rank each event on the modified Likert scale based on their last administered general anesthetic. The question read 'Please rate each event based on the last general anesthetic you provided at your primary work site'. The provider then selected whether the event was not distracting, somewhat distracting, undecided, distracting, or highly distracting. The survey concluded with a text box where the participant could list any distracting events they experience that were not listed. A copy of the survey is available in Appendix A.

#### **Data Collection and Timeline**

The survey was created and distributed through an emailed link to Microsoft Forms and fliers were placed in lounges and breakrooms advertising the survey and providing a QR code for quick access. The project team also advertised the survey dates using word of mouth. These steps aimed to encourage potential participants and hopefully yielded higher participation rates. The survey could only be completed one time per provider. Contact information for the project directors was included in the email so participants could reach out with concerns.

The survey response data was collected in Microsoft forms. No patient information or unique provider identifiers were collected. The survey results are password protected and access is restricted to the project team.

Data collection was obtained over a three-week period in September 2022. Reminders were emailed to providers supplying the link midway through the survey period. Statistical analysis, conclusions, and recommendations based on the final results were completed in November 2022. Hospital system and University IRBs reviewed the proposal and determined it to be quality improvement project that did not require further action. A copy of the IRB assessment is available in Appendix B.

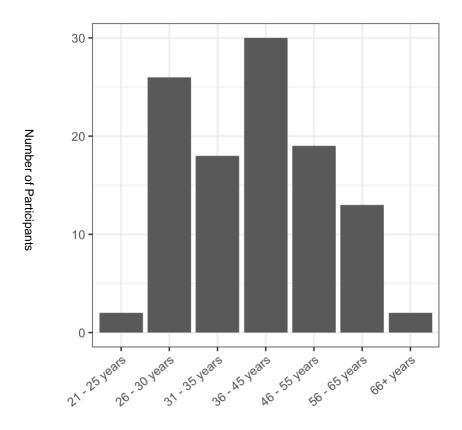
#### Results

The data was exported to an Excel spreadsheet for statistical analysis. The total sample across all three sites contained 110 participants, 30 male and 80 female. There were 90 responses from CRNAs, 15 from SRNAs, and 5 from physician anesthesiologists.

Broken down by site, there were 75 responses from the Level I trauma center, 13 responses from the ambulatory surgery center, and 22 responses from the suburban hospital. The two age groups most represented amongst the participants across all three sites were 26 - 30 years old and 36 - 45 years old (Figure 1).

At the Level I trauma center, the survey was distributed to a total of 214 anesthesia providers: 159 CRNAs, 47 physician anesthesiologists, and eight SRNAs. The total number of survey responses received was 75, yielding a survey response rate of about 35%. There were 62 responses from CRNAs, five responses from physician anesthesiologists, and eight responses from SRNAs. Most participants were female, with 56 female participants and 19 male participants. Out of this sample, the participants ages ranged from 21 to 66+ years.

**Figure 1**Age Distribution of Participants



Age of Participant in Years

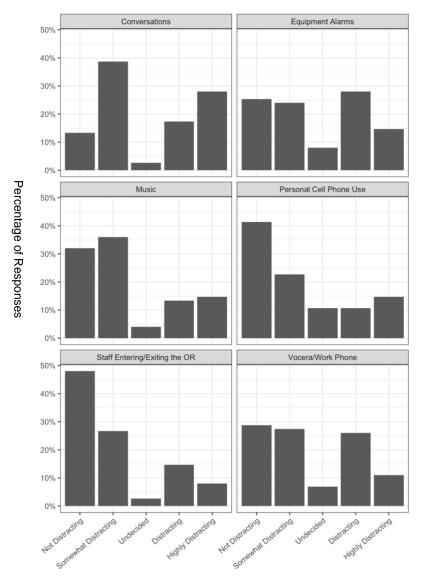
The results for the level one trauma center showed that during induction of anesthesia, providers felt "conversations" were the most highly distracting. Conversations were ranked as "highly distracting" by over 25% of the participants. The next three most highly distracting events were "equipment alarms", "music", and "personal cell phone use". These were each reported to be highly distracting by 15% of anesthesia providers.

The event rated as the least distracting was "staff entering and exiting the OR" during induction, which was reported as "not distracting" by 50% of providers. Similarly, 40% of providers reported that "personal cell phone use" was not distracting.

An interesting note is that although conversations were rated highly distracting by more participants than any other distractor, almost 40% of participants reported that conversations were only somewhat distracting to them. These results are shown in Figure 2.

Figure 2

Distribution of Distractions at the Level I Trauma Center



Least to Most Distracting

Table 1 shows the perception of distraction in relation to demographic factors such as: gender, age, and work site. Additionally, at the bottom it compares the perception of distraction across the three sites. The p-value is the top number listed, appearing in line with the title of the demographic group. For statistical analysis, the Likert scale was assigned numbers one through five; with one being "not distracting" and five being "highly distracting". In the table, the demographic groups are listed down the left column. How each demographic group ranked the distractions is listed beneath each type of distraction. The first number shows the mean response (with one being not distracting and five being highly distracting) and the second number provides the standard deviation. Differences between demographic groups or sites that were statistically significant have a p-value <0.05.

There was no statistical difference in what anesthesia providers found to be distracting at the three different sites. All three sites found "conversations" to be ranked "highly distracting" by the most providers. The level one trauma center had a mean rating of 3.08 for conversation, the ambulatory surgery center had a mean rating of 3.46, and the suburban hospital had a mean rating of 2.77. Of note, the suburban hospital did have lower scores for each distraction compared to the level one trauma center and ambulatory surgery center.

Across all three sites, there were statistically significant findings between the demographic groups. There was a significant difference between female and male anesthesia providers in how they ranked the following distractions during induction: conversations, music, and personal cell phone use. Females reported conversation to be more distracting during the induction of anesthesia, with a mean rating of 3.31. In comparison, males reported conversation to be less distracting with a mean rating of 2.40. Female providers also reported music to be more distracting, rating it a mean score of 2.46 while males gave it a mean score of 1.67. Lastly,

females rate personal cell phone use to be more distracting with a mean score of 2.56 while male providers gave it a mean rating of only 1.73.

There is a statistical difference between three age groups for equipment alarms. Providers aged 21 - 30 years old rated equipment alarms to be much more distracting with a mean score of 3.57 compared with age groups 31 - 45 years (mean rating of 2.38) and 46+ years (mean rating of 2.21).

The survey had a text box for providers to write-in distractions or comments they felt were not covered in the survey questions. A wordle was generated to show the words most frequently written into the text box and can be viewed in Appendix C. At the level one trauma center, conversations and talking to the anesthesia provider while they were securing the patient's airway were two of the biggest concerns. Other write-ins included distractions like production pressure and banging of sterile surgical equipment by other staff.

Table 1. Perceptions of six sources of distraction across gender, age, and site.

	Perceptions of Distraction M $\pm$ SD, p-values					
	Conversations	Music	Equipment	Vocera/Work	Staff Entering/	Personal Cell
			Alarms	Phone	Exiting the OR	Phone Use
Gender	p = .004*	p = .005*	p = .393	p = .216	p = .080	p = .009*
Male	$2.40 \pm 1.25$	$1.67 \pm 1.09$	$2.43 \pm 1.48$	$2.27 \pm 1.23$	$1.70 \pm 1.06$	$1.73 \pm 1.05$
Female	$3.31 \pm 1.51$	$2.46 \pm 1.38$	$2.70 \pm 1.44$	$2.64 \pm 1.46$	$2.20 \pm 1.41$	$2.56 \pm 1.57$
Age groups	p = .891	p = .371	p < .001*	p = .307	p = .280	p = .610
21-30 years	$2.96 \pm 1.35$	$1.96 \pm 1.04$	$3.57 \pm 1.26$	$2.68 \pm 1.42$	$2.29 \pm 1.30$	$2.25 \pm 1.43$
31-45 years	$3.15 \pm 1.54$	$2.38 \pm 1.41$	$2.38 \pm 1.39$	$2.60 \pm 1.45$	$2.04 \pm 1.35$	$2.56 \pm 1.57$
46 or above	$3.03 \pm 1.57$	$2.29 \pm 1.49$	$2.21 \pm 1.37$	$2.31 \pm 1.33$	$1.91 \pm 1.36$	$2.09 \pm 1.42$
Site	p = .416	p = .116	p = .107	p = .324	p = .219	p = .790
Level I Trauma Center	$3.08 \pm 1.50$	$2.43 \pm 1.43$	$2.83 \pm 1.46$	$2.63 \pm 1.42$	$2.08 \pm 1.35$	$2.35 \pm 1.47$
Ambulatory Surg Ctr	$3.46 \pm 1.45$	$1.92 \pm 1.26$	$2.23 \pm 1.48$	$2.69 \pm 1.55$	$2.54 \pm 1.56$	$2.54 \pm 1.45$
Suburban Hospital	$2.77 \pm 1.51$	$1.82 \pm 0.96$	$2.18 \pm 1.33$	$2.14 \pm 1.25$	$1.73 \pm 1.08$	$2.18 \pm 1.62$

<sup>\*</sup>Significant p < .05

*Note.* Perception of distractions were measured on a 1 thru 5 scale with higher values indicating the source as more distracting. In the cells are mean  $\pm$  standard deviations. Analysis of variance (ANOVA) compared group differences across gender, age, and site for the six distractions, respectively. The p-values based on the ANOVA are included in the entry for gender, age groups, and site. A p-value < .05 would indicate a statistically significant difference across the groups being compared. Significant difference existed between female and male for conversations, music, and personal cell phone use; and between three age groups for equipment alarms.

#### **Discussion**

It was expected that the three different types of clinical sites would show a difference in what anesthesia providers found to be distracting. However, there was no statistically significant difference in how the distractions were ranked by providers at each site. This finding came as a surprise because the project team thought different types of clinical settings would each have unique challenges due to their different workflows, patient populations, and surgical cases. However, these results imply that regardless of the type of clinical facility, whether it's an urban trauma center, a suburban hospital, or an ambulatory surgery center- they all struggle with the same distractions during induction of anesthesia.

The statistical significance across all three sites between what males and females find to be distracting is also of interest. Overall, female providers reported being more distracted during the induction of anesthesia than male providers. It is possible that gender norms and masculine expectations like stoicism, toughness, and self-sufficiency- could have influenced male providers' responses. Male participants may not want to admit that things can distract them at work. Similarly, women are expected to be considerate and focused on peoples' needs other than their own. This may have led female participants to feel more distracted by events because they are compelled to pay attention to things outside their workflow. Further research is warranted to investigate why female and male providers experience distractions differently.

The statistical significance between older age groups finding equipment alarms to be less distracting than younger age groups is also an interesting finding. Compared to the older age groups, the youngest group, 21 - 30 years old, reported the equipment alarms to be the most distracting with a mean score of 3.57. The 31 - 45-year-olds reported equipment alarms to be less distracting with a mean score of 2.38. Providers aged 46 years and older ranked equipment

alarms even less distracting with a mean score of 2.21. As anesthesia providers get older and have more years of work experience in the OR, perhaps they become more desensitized to the alarms and find them less distracting. As the younger providers gain more experience, it would be interesting to see if they begin to find equipment alarms less distracting. The younger age group may also represent many of the SRNAs who are still in training and may be more susceptible to the distractions of alarms.

A limitation to this project was low participation of physician anesthesia providers. Most participants were either CRNAs or SRNAs. Because only three physician anesthesiologists participated at the level one trauma center and five anesthesiologists participated in total, a meaningful analysis of their perceptions was not possible. The low participation may have been caused by issues with the survey being sent to an email less frequently used by the physicians or they did not value the topic or have time to complete the survey within their workday. If more physicians had participated, it would have been interesting to see if there was a statistically significant difference in what they found to be distracting. All three providers, CRNAs, SRNAs, and physicians, have a different training background, which could potentially influence what is found to be distracting.

The survey asked the provider to respond to a list of potential distractions based on what the provider remembered during a case that may have been hours earlier. It is possible that types of distractions did not get reported because they were not in the list or had been forgotten.

Another limitation to this project was reported discussion at the level one trauma center among providers that they did not want to take the survey because they did not want to admit to being distracted at work and feared punitive action. Despite clearly labeling the survey as anonymous on both fliers and the survey itself- providers were still wary which may have discouraged some

from participating. This may reflect an institutional culture at this facility where providers don't feel comfortable participating in quality improvement projects and could limit any future quality improvement initiatives to correct or decrease distractions in the OR.

Of note, as an SRNA currently working in the OR, teaching during the induction phase can be highly distracting to SRNAs. It is very common to have preceptors (both CRNAs and physician anesthesiologists) ask the SRNA questions, "quiz" them, or teach complex concepts during induction. However, being new to the anesthesia skill set, it is challenging to think and listen to these preceptors while trying to secure an airway and complete the many tasks/skills needed to get the patient ready for surgery to begin. Some preceptors acknowledge this and deliberately wait until after the induction period has passed so there is undivided time to debrief with the student. This can be much more beneficial for the student because they can give their full attention to the preceptor and any question or teaching points they may have. This may be a practice we encourage all anesthesia preceptors to adopt to facilitate patient safety and the SRNA's learning during the induction phase.

#### Recommendations

In the future, it would be useful to compare two additional demographic factors: experience level and role. By asking providers' how many years of experience they have providing anesthesia, it would be interesting to whether it impacts what the provider finds to be distracting. Because this demographic information was not collected in the project survey, an assumption was made with our results that age equates more experience. Similarly, because not enough data was collected from physician anesthesiologists, this project could not compare roles. In the future, it would be worthwhile to investigate whether different roles find different things to be distracting during induction.

At all three sites, conversations were ranked as "highly distracting" more than any other distractor. A future quality improvement project should be conducted to review the literature for successful strategies to reduce conversations in the OR and implement a pilot project to see if improvements can be made at this facility. Now that the biggest distractor to providers has been identified, it is important to mitigate the problem. It is also important to raise awareness among the entire OR staff that conversations during the induction of anesthesia are highly distracting for anesthesia providers. By educating OR staff to avoid conversation during the anesthetic induction period, this alone could significantly cut down on the number of unnecessary conversations.

Anesthesia providers should also be empowered to reduce distracting conversations during the induction of anesthesia by speaking up. It may reduce conversations if anesthesia providers announce to the OR staff that they are starting the induction of anesthesia. This could alert the OR staff to pause their non-emergent conversations. If there are still side conversations happening, the anesthesia provider should be taught a strategy to respectfully ask those talking to stop. This could greatly reduce the amount of distracting conversation during induction.

Another recommendation could be the adoption of a "sterile cockpit rule" in the OR. In aviation, the sterile cockpit rule prohibits any staff on the airplane from doing non-essential activities during critical flight times, like take-off and landing. This is very similar to anesthesia and the phases of induction and emergence (Broom et al., 2011). By creating a new expectation that all OR staff must be quiet during the induction of anesthesia, this could greatly decrease the number of distractions occurring- especially conversations. It may work best if the circulating nurse is tasked with enforcing the "sterile cockpit rule" in the OR. In the study by Crockett et al. (2019), having the circulating nurse turn off music when the patient enters the OR was very

successful in reducing distraction. This study also had a lot of success with educating all the perioperative staff about the importance of remaining quiet during the induction of anesthesia and saw a significant decrease in the number of distractions.

#### Conclusion

This project aimed to quantify distractors during induction of anesthesia in a busy level one trauma center. It found conversations were rated as "highly distracting" by more anesthesia providers than any other distraction during anesthetic induction. Additionally, there was statistical significance between female and male providers, with female providers being more distracted by conversations, music, and personal cell phone use. It also found alarms to be more distracting the younger the age of the provider. This quality improvement project creates the opportunity for policies, education, and changes in practice to be initiated that improve patient safety.

#### References

- American Society of Anesthesiologists. (2021). *About ASA's Lighthouse Logo*. https://www.asahq.org/about-asa
- Amponsah-Tawaih, K., & Adu, M. A. (2016). Work Pressure and Safety Behaviors among

  Health Workers in Ghana: The Moderating Role of Management Commitment to Safety.

  Safety and health at work, 7(4), 340–346. https://doi.org/10.1016/j.shaw.2016.05.001
- Agency for Healthcare Research and Quality. (2020, September) *Plan-Do-Study-Act (PDSA) Directions and Examples*. AHRQ. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html
- Arabaci, A., & Onler, E. (2021). The effect of noise levels in the operating room on the stress levels and workload of the operating room team. *Journal of PeriAnesthesia Nursing*, *36*, 54-58. https://doi.org/10.1016/j.jopan.2020.06.024
- Avidan, A., Yacobi, G., Weissman, C., & Levin, P. D. (2019). Cell phone calls in the operating theater and staff distractions: An observational study. *Journal of Patient Safety*, *15*(4), e52–e55. https://doi.org/10.1097/PTS.00000000000000351
- Broom, M. A., Capek, A. L., Carachi, P., Akeroyd, M. A., & Emp; Hilditch, G. (2011). Critical phase distractions in anaesthesia and the sterile cockpit concept. *Anaesthesia*, 66(3), 175–179. https://doi.org/10.1111/j.1365-2044.2011.06623.x
- Carayon, P. (2007, May 1). *Production pressures*. Agency for Healthcare Research and Quality.
- Crockett, C. J., Donahue, B. S., & Vandivier, D. C. (2019). Distraction-free induction zone: A quality improvement initiative at a large academic children's hospital to improve the quality and safety of anesthetic care for our patients. *Anesthesia and analgesia*, 129(3), 794–803. https://doi.org/10.1213/ANE.0000000000003879

- Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. Psychometrika, 16, 297-334. doi: 10.1007/BF02310555
- Davino, C., & Fabbris, L. (2013). Survey data collection and integration. Springer.
- DeMaria, S., & Neustein, S. M. (2010). Production pressure, medical errors, and the preanesthesia checkout. *M. E. J. Anesthesia*, 20(5), 631-638.
- Enser, M., Moriceau, J., Abily, J., Damm, C., Occhiali, E., Besnier, E., Clavier, T., Lefevre-Scelles, A., Dureuil, B., & Compere, V. (2017). Background noise lowers the performance of anesthesiology residents' clinical reasoning when measured by script concordance. *European Journal of Anesthesiology*, *34*(7), 464-470. https://doi.org/10.1097/EJA.0000000000000000024
- Faraj, A. A., Wright, A. P., Haneef, J. H., & Jones, A. (2014). Listen while you work? The attitude of healthcare professionals to music in the operating theatre. *Journal of perioperative practice*, 24(9), 199–204. https://doi.org/10.1177/175045891402400903
- Fu, V. X., Oomens, P., Kleinrensink, V., Sleurink, K. J., Borst, W. M., Wessels, P. E., Lange, J. F., Kleinrensink, G. J., & Jeekel, J. (2021). The effect of preferred music on mental workload and laparoscopic surgical performance in a simulated setting (OPTIMISE): A randomized controlled crossover study. *Surgical endoscopy*, 35(9), 5051–5061. https://doi.org/10.1007/s00464-020-07987-6
- Gaba, D. M., Howard, S. K., & Jump, B. (1994). Production pressure in the work environment.

  California anesthesiologists' attitudes and experiences. Anesthesiology, 81(2), 488–500.

  https://doi.org/10.1097/00000542-199408000-00028

- Ginsberg, S., Pantin, E., Kraidan, J., Solina, A., Panjwani, S., & Yang, G. (2013). Noise levels in modern operating rooms during surgery. *Journal of Cardiothoracic and Vascular Anesthesia*, 27(3), 528-530. https://doi.org/10.1053/j.jvca.2012.09.001
- Gui, J. L., Nemergut, E. C., & Forkin, K. T. (2021). Distraction in the operating room: A narrative review of environmental and self-initiated distractions and their effect on anesthesia providers. *Journal of Clinical Anesthesia*, 68.
  https://doi.org/10.1016/j.jclinane.2020.110110
- Harten, A. V., Gooszen, H. G., Koksma, J. J., Niessen, T. J., & Abma, T. A. (2020). An observational study of distractions in the operating theatre. *Anaesthesia*, 76(3), 346-356. https://doi:10.1111/anae.15217
- Hawksworth, C., Asbury, A. J., & Millar, K. (1997). Music in theatre: not so harmonious. A survey of attitudes to music played in the operating theatre. *Anaesthesia*, *52*(1), 79–83. https://doi.org/10.1111/j.1365-2044.1997.t01-1-012-az012.x
- Hodge, B., & Thompson, J. F. (1990). Noise pollution in the operating theatre. *The Lancet*, 335(8694), 891–894. https://doi.org/10.1016/0140-6736(90)90486-o
- Kam, P. C., Kam, A. C., & Thompson, J. F. (1994). Noise pollution in the anaesthetic and intensive care environment. *Anaesthesia*, 49(11), 982–986.
  https://doi.org/10.1111/j.1365-2044.1994.tb04319.x
- Lau F. Chapter 13: Methods for Survey Studies. In: Lau F, Kuziemsky C, editors. Handbook of eHealth Evaluation: An Evidence-based Approach [Internet]. Victoria (BC): University of Victoria; 2017 Feb 27. Available from:

  https://www.ncbi.nlm.nih.gov/books/NBK481602/

- Murthy, V. S., Malhotra, S. K., Bala, I., & Raghunathan, M. (1995). Detrimental effects of noise on anaesthetists. *Canadian journal of anaesthesia = Journal canadien d'anesthesie*, 42(7), 608–611. https://doi.org/10.1007/BF03011878
- Riutort, K. T. (2020). Distractions in the operating room. *Current Anesthesiology Reports* (*Philadelphia*), 10(4), 456–462. https://doi.org/10.1007/s40140-020-00409-2
- Savoldelli, G. L., Thieblemont, J., Clergue, F., Waeber, J. L., Forster, A., & Garnerin, P. (2009). Incidence and impact of distracting events during induction of general anaesthesia for urgent surgical cases. *European Journal of Anasethesiology*, 27 (8), 683-689.
- Shapiro, R. A., & Berland, T. (1972). Noise in the operating room. *New England Journal of Medicine*, 287(24), 1236–1238. https://doi.org/10.1056/nejm197212142872407
- Slagle, J. M., Porterfield, E. S., Lorinc, A. N., Afshartous, D., Shotwell, M. S., & Weinger, M. B. (2018). Prevalence of potentially distracting noncare activities and their effects on vigilance, workload, and nonroutine events during anesthesia care. *Anesthesiology*, 128(1), 44–54. https://doi.org/10.1097/ALN.000000000001915
- Stevenson, R. A., Schlesinger, J. J., & Wallace, M. T. (2013). Effects of divided attention and operating room noise on perception of pulse oximeter pitch changes. *Anesthesiology*, 118(2), 376–381. https://doi.org/10.1097/aln.0b013e31827d417b
- Weldon, S. M., Korkiakangas, T., Bezemer, J., & Kneebone, R. (2015). Music and communication in the operating theatre. *Journal of advanced nursing*, 71(12), 2763–2774. https://doi.org/10.1111/jan.12744

# APPENDIX A: SURVEY

# Survey

Select your primary worksite.						
2. Select your role.						
Anesthesiologist						
Certified Registered Nurse Anesthetist (CRNA)						
Student Registered Nurse Anesthetist (SRNA)						
3. Select your age range.						
21 - 25 years						
26 - 30 years						
31 - 35 years						
36 - 45 years						
○ 46 - 55 years						
O 56 - 65 years						
66+ years						

4. 9	Select your gender.					
	Female					
	Male					
	Non-binary					
	Other					
5. The following list includes events that may be distracting during the induction of anesthesia.  Please rate each event based on the last general anesthetic you provided at your primary work site.						
		Not Distracting	Somewhat Distracting	Undecided	Distracting	Highly Distracting
	Music	$\circ$	$\circ$	$\circ$	$\circ$	$\circ$
	Conversation s	0	0	0	0	$\circ$
	Equipment Alarms	0	0	0	0	0
	Vocera/Work Phone	0	0	0	0	0
	Staff Entering/Exiti ng the OR	0	0	0	0	0
	Personal Cell Phone Use	0	0	0	0	0
6. If there is a distraction you find to be significant, but was not listed, please add your thoughts here.  Enter your answer						

#### APPENDIX B: WAKE FOREST IRB APPROVAL

Office of Research

INSTITUTIONAL REVIEW BOARD

# **MEMORANDUM**

To: Exie Earnhardt

Atrium/Carolinas Healthcare System

From: Jeannie Sekits, Senior Protocol Analyst

Institutional Review Board

Date: 7/7/2022

Subject: Not Human Subjects Research: IRB00086377

Surveying Anesthesia Providers on Perceived Distractions in the Operating Room

During Induction of Anesthesia

The Wake Forest University School of Medicine Institutional Review Board has reviewed your protocol and determined that it does not meet the federal definition of research involving human subject research as outlined in the federal regulations 45 CFR 46. 45 CFR 46.102(f) defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The information you are receiving is not individually identifiable. In recent guidance published by the Office of Human Research Protections (OHRP) on the Guidance on Research Involving Coded Private Information or Biological Specimens, OHRP emphasizes the importance on what is being obtained by the investigator and states "if investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects."

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study does not meet the federal definition of human subject research. Investigators do not have the authority to make an independent determination that a study does not meet the federal requirements for human subject research. Each project requires a separate review and determination by the Board. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to not meet the federal requirements for human subject research. If you have any questions or concerns about this information, please feel free to contact our office at 716-4542.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International

