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Evaluation of a Process Change Using an Updated Sedation Protocol

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Abstract

Problem: Pediatric delirium is continuing to increase intensive care environments and for patients who require mechanical ventilation and continuous sedative medications. Delirium is harmful to the patient creating lasting neurologic and mental health issues along with prolonged hospitalization and increased healthcare cost

Method: For this quality improvement (QI) project, a descriptive observational study was used to evaluate the implementation of a sedation protocol for patients who are mechanically ventilated and on continuous sedative medications. This was completed with the use of retrospective chart reviews three months prior to implementation and three months after the new protocol was implemented. Nurses were given education prior to implementation and well versed on the protocol. This project evaluated patient's Cornell Assessment of Pediatric Delirium (CAPD) scores, days of mechanical ventilation (MV), and length of stay (LOS) in the ICU.

Results: Sixty patients met eligibility criteria and participated in this project, thirty were before the implementation of protocol, Group A and thirty after Group B. After the implementation of the new sedation protocol the percent positive CAPD scores increased from 67% to 78%. The average LOS for Group B was 10.6 down from Group A at 10.9. The average days of MV decreased from seven in Group A to 6.4 in Group B.

Implications for Practice: After evaluating the implementation of new sedation protocol in a PICU, the CAPD scores did not decrease but the LOS and MV did. Due to many factors including developmental delay, CAPD scores are subjective and can range by scorer. More research must be necessary to evaluate if these changes are decreasing pediatric delirium.

Pediatric patients needing ICU level care are admitted to a pediatric ICU (PICU) and nearly half, require mechanical ventilation (MV) and continuous sedative medications (Gaillard et al, 2016). Each patient admitted on continuous sedative infusions is at increased risk for pediatric delirium. Delirium is a neurocognitive disorder due to an illness or treatment which can present in many different forms, including disturbances in attention or awareness, hyper or hypo active activity, and confusion (American Psychiatric Association, 2013). It is reported 20- 29% of PICU patients are delirious during their admission, and months after discharge report delusions, disturbing hallucinations, and post-traumatic stress (Harris et al, 2016). The Cornell Assessment of Pediatric Delirium (CAPD) is a screening tool created to help clinicians assess for the diagnosis of delirium. Pediatric delirium is often underdiagnosed and missed due to the cognitive abilities of children, especially those under two who cannot communicate verbally.

Delirium is not only harmful to the patient, but it also increases length of stay (LOS) and hospital costs. A diagnosis of delirium is associated with an 85% increase in total PICU costs (Traube et al, 2016). One of the largest risk factors contributing to pediatric delirium is the use of sedative agents during admission. To ventilate a pediatric patient safely mechanically, the use of continuous sedation and analgesia are essential. However, they are also associated with acquired neuromuscular disorders, delirium, and post-traumatic stress disorder (Deeter et al., 2011). These medications are essential to care for the patients to reduce anxiety, physiologic stress, and pain from mechanical

ventilation (MV) (Kongkiattikul et al, 2019). Specifically, opioids are a first line choice for analgesia because benzodiazepines increase hallucinations and delirium.

Hence, implementation of a sedation protocol may decrease LOS, days of MV, and pediatric delirium (Deeter et al., 2011). Sedation protocols are safe and easy to use on units where specific sedation protocols have been implemented and decrease daily doses of medications that increase delirium (Deeter, et al., 2011)

The purpose of this QI project is to evaluate the implementation of a sedation protocol for patients who are mechanically ventilated and on continuous sedative medications. A study question was created to guide this literature review: What is the effect of implementing a new sedation protocol on decreasing pediatric delirium and length of stay in a PICU?

Literature Review

A literature search was completed to examine how continuous sedation for mechanically ventilated PICU patients affects pediatric delirium, along with other adverse outcomes. Databases used in this search include The Cumulative Index of Nursing and Allied Health Literature (CINAHL), EBSCO, PubMed databases, and critical care medicine journals. The search was conducted with key terms such as *pediatric delirium*, which yielded 1261 results, *pediatric sedation protocol*, 141 results and *CAPD AND delirium*, yielding 31 results. Additional searches included retrospective studies, peer reviewed articles, multidisciplinary meta- analysis, and research articles in English. Studies before 2011 were excluded. Inclusion criteria included pediatric patients 0 to 21 years old, excluding patients not mechanically ventilated with continuous sedation. Articles in the review were published between 2015 to 2020. Ultimately, after

further review of abstracts and terminology, eight studies were included in this review. Although pediatric delirium is a relatively new concept, the literature review shows delirium is present in the pediatric population and further research should be directed at prevention. This review includes two articles which describe and define pediatric delirium and the use of CAPD, three articles that explore negative outcomes from pediatric delirium, and the final studies compare data on implemented sedation protocols.

Prior to use of the CAPD, pediatric delirium research was limited due to lack of a universal tool to for definition and diagnosis.. Adult population studies in critical care found delirium was exacerbated by use of various sedative medications (Traube et al, 2014). The Diagnostic and Statistics Manual 5th edition published by the American Psychological Association (2011) (DSM 5) includes the diagnosis of delirium in children older than 12 months old, yet many pediatric patients in PICUs, less than 12 months old experience signs and symptoms of pediatric delirium (Traube et al, 2014). Children less than 12 months were not studied prior to creation of the CAPD; however, this represents a substantial group of pediatric patients receiving MV and sedation, thus increasing risk of delirium. The CAPD tool consists of questions in which the bedside RN assesses the patient parameters of consciousness, cognition, orientation, and or psychomotor activity. Any score above nine is indicative of delirium. Traube et al (2014) performed a double-blind study to determine the validity and reliability of the CAPD assessment tool. The nurses followed the prompts to create a score, while an independent psychiatrist conducted their own study to test for delirium. This study was conducted in a twenty-bed PICU in an academic hospital setting measuring outcomes of diagnostic and statistical manual domains. Patients in this study were 0-21 years old with a wide range of

developmental levels. Results showed the prevalence of delirium was 20.6% from both nurse and psychiatrist scoring. The CAPD found delirium in children with an overall sensitivity score of 94.1%.

According to Harris et al (2016), the gold standard of assessing pain is self-report. Children and infants are typically unable to verbalize pain, therefore specialized pediatric pain scales were created to accurately score pediatric pain. When this population is MV and on continuous sedative medications, it is more difficult to interpret pain scores. This is problematic for a young, non-verbal patient who may be over or under sedated. As a result, this is a risk factor for delirium. Because of limited literature regarding PICU pain assessments, Harris et al (2016) performed a systematic review from the PubMed and CINAHL databases. This review formulated clinical questions regarding pain and non-pain related distress assessments in critically ill and nonverbal children. The search included 32 articles written between August 2005 and August 2015 with patients ages ranging from birth to 18 years old. Harris et al (2016) describes optimal sedation as a state in which the patient is somnolent, yet responsive to the environment without excessive movements. Over-sedation can lead to withdrawal or tolerance also contributing to delirium, especially after five or more days of continuous infusions. The results of the systematic review showed critically ill younger children are underdiagnosed with delirium due to the difficulties in assessing symptoms such as pain and agitation (Harris et al, 2016). The sedation protocol used at the proposed project site included integrated treatment plans and recommended doses based on studies done in a randomized control trial.

Delirium can result in negative outcomes during hospitalization including longer LOS, risk of withdrawal, increased days of MV, increased cost, reduced quality of life and mortality. Siegel et al (2020) conducted a retrospective study to review recent data outcomes related to pediatric delirium and discuss prevention strategies. With rates of delirium exceeding 25% in the pediatric population, it is possible that delirium also affects the patient's quality of life post discharge. Siegel et al., (2020) suggested widespread screening of critically ill children is necessary through longitudinal studies to investigate these patients' long term sequelae. Silver et al., (2020) performed a prospective observational cohort study to investigate the residual effect on quality of life at one- and three-months post discharge. The outcome measures were the delirium tool CAPD and quality of life after discharge. Two hundred and seven children less than five years of age were studied and screened for delirium with 117 completing surveys three months later post discharge. Like the findings in Siegel et al., (2020) 27% (56 children) of PICU patients were affected by delirium during their stay. Patients experienced disturbing images and hallucination events continuing post discharge with an independent association between delirium and decreased QOL after leaving the hospital. Children with delirium had an average of 11 points lower general health score than non-delirious patients. This study is unique as it was the first study to research how delirium impacted patients QOL post discharge.

Another outcome of pediatric delirium is increased cost. Increased LOS increases overall hospital cost. While studies showed the presence of delirium in pediatric patients, few children's hospitals have implemented screening. A prospective observational study was conducted by Traube et al., (2016) to associate cost and pediatric delirium. Five

hundred PICU admissions in an urban, academic PICU were assessed for delirium was using a CAPD score. Statistical analysis using the Kruskal-Wallis test to compare total PICU costs with costs per day was performed by the researchers. The average LOS was five PICU days and results showed significantly higher costs with groups in which delirium was diagnosed. Results showed a diagnosis of delirium was associated with an 85% increase in PICU costs (Traube et al, 2016). A limitation to this study is physicians' charges were not included in this cost analysis which underestimates the true healthcare cost. Traube et al., (2016) estimated the cost of hospitalizing a patient in the PICU with delirium is approximately \$14,000 more per admission. There are 250,000 children admitted to critical care in the United States annually. The numbers translate to more than \$560 million each year in hospital charges related to pediatric delirium.

There is little data regarding how use of nurse-driven sedation protocols in the pediatric population impacts the use of sedative medication. A nurse driven protocol is one in which the nurses uses assessment and clinical reasoning skills to decide how much sedation or what sedation medication should be used. Gillard et al (2016) researched this topic by conducting a single center prospective before and after study. The before cohort was pre sedation protocol and post cohort was after implementation of the sedation protocol. The purpose of this study was to evaluate the impact of nurse driven sedation protocols with outcome measures of length of ventilation and complications of sedation. Patients studied were twenty-eight days old to eighteen years over a two-year period with inclusion criteria of MV and use of sedatives for more than 24 hours. Criteria excluded: more than 24 hours of sedation before admission, intubated longer than 45 days and death during admission. Secondary outcome measures evaluated mean sedation scores before

and after protocol and length of PICU stay. Statistical analysis found that duration of MV did not differ between groups, but the total use of midazolam decreased in the protocol group (0.56-1.8) vs (0.85-2.4). Implementation of a nurse driven protocol proved beneficial in decreasing exposure to midazolam. Research in adults has shown an association between midazolam and delirium. More studies in children are needed to gain information on pediatric delirium and use of benzodiazepines such as midazolam.

Another study showed similar responses with a nurse driven sedation protocol in Australia. Larson et al (2018) evaluated a nurse led protocol specifically for pediatric cardiology patients. A retrospective chart review was performed on 100 patients, 50 pre protocol and 50 post implementations. Stata12 was used to perform t-test scores between the two groups. This study was limited in its focus on of the cardiology pediatric patient. The study mirrors others in design and data collection methods. This study differed in that patients had longer days of MV in the post protocol group, and no statistical difference was found between the number of morphine infusions between groups. The total dose in mcg/kg/hr was decreased after protocol was implemented. Days of MV are inconsistent across these studies on sedation protocol implementations. It is recommended for PICU units who plan to implement sedation protocols review outcome measures involving duration of MV.

A common theme among published articles evaluating sedation protocols is the study design of retrospective cohorts with historical controls. A 2011 study evaluated the effect of nursing driving protocols and sedative medications (Deeter et al). This study consisted of 153 patients ventilated and sedated excluding patients with heart failure, reintubation, or morphine allergies. Charts were reviewed and statically analyzed using Wilcoxon's

rank sum test. Outcome measures included days of exposure to sedatives, duration of MV, and LOS. Prior to protocol implementation, orders were placed by providers and the post cohort nurses titrated sedation following the nurse driven protocol. This post implementation group showed the opposite of Larson et al., (2018) associating fewer days of MV and decreased LOS stay. This study suggests the need of pediatric assessment tools for delirium and posttraumatic stress disorder.

Outcome measures on sedation protocols remain consistent through various research articles: LOS, days of MV and total dose of sedation. Care bundles are being implemented to integrate these outcomes called ICU bundles on delirium. Simone et al., (2017) conducted a study to examine the impact of ICU bundles on delirium screening and characteristics of delirium cases. Multidisciplinary teams were created to implement bundled care and protocols to decrease delirium, sedation, and promote early mobilization. This QI project was conducted with a prospective observational analysis in which 1875 patients were screened for delirium using the CAPD tool. Statistical process control was used to determine the mean delirium rates decreased from 19.3% to 11.84% after the bundle was implemented. This study summarizes the importance of all the data found in this literature review using a CAPD score to screen for delirium and implementing protocols which aim to increase prevention of it.

This quality improvement project will evaluate the implementation of a new sedation protocol where morphine replaces fentanyl. This QI initiative will determine if this change decreased pediatric delirium measured by CAPD scores in the post implementation cohort. Pediatric delirium increases hospital costs and decreases QOL for PICU patients after discharge. Literature is inconsistent regarding outcome measures of

LOS and days of MV. This literature review details common associations between increased sedative medications and delirium as well as adverse patient outcomes. Nurse driven sedation protocols can reduce utilization of benzodiazepines. There are gaps in literature for delirium as an outcome measure which is the purpose of this project.

The Plan-Do-Study-Act (PDSA) cycle was chosen as the framework for this project. Completed in four segments: Plan, Do, Study, Act; this framework is effective using qualitative and quantitative measures to standardize and implement the change (Laverentz, 2017). The aim of this proposed QI project is to evaluate a sedation protocol to determine if there has been a decrease in pediatric delirium by 10% in the first three months post implementation of the new protocol. Primary outcome measures of this study are CAPD scores. Secondary outcome measures are days of MV and amount of PICU length of stay

Methods

Design

This quality improvement project was completed by a retrospective chart review utilizing an observational descriptive design. It includes data from patients three months prior to new protocol and three months after implementation.

Setting

The project took place in a 40 bed PICU at a pediatric hospital located in a major Midwest urban city. This hospital has a level one trauma center and specializes in high-level care. This unit has patients ranging from two days old up to young adult requiring

different levels of care and mechanical ventilation. This PICU is staffed with 136 nurses along with 50 other collaborating team members. These members include attending, fellow, and resident physicians, APRNs, respiratory therapist, physical and occupational therapists, speech therapists, and patient care technicians.

Sample

A convenience sample was used in this study. Inclusion criteria was patients ages zero days to 21 years old who were intubated and sedated on mechanical ventilation greater than one day. Exclusion criteria included patients with tracheostomies, receiving extracorporeal membrane oxygenation (ECMO), continuous renal replacement therapy (CRRT), visits ending in death, MV longer than 45 days, and patients who did not follow protocol. Medical records for these patients were divided into two cohorts. Data was reviewed from patients in the pre implementation phase from April 16, 2020- July 16, 2021, and post implementation phase from July 17, 2021- October 17, 2021.

Data Collection/Analysis

Data information was collected and deidentified through retrospective chart review. Patient's name, date of birth, sex, race, and address were deidentified and protected. Requested information was gathered by the children's data collector and entered into an excel sheet. Data variables analyzed were CAPD scores per shift, PICU LOS, and days of MV. Data was analyzed using Intellectus Statistics for descriptive statistical analysis.

Approval Processes

Approval for this project was first obtained by the PICU leadership team and clinical staff who created the new sedation protocol at this children's hospital. Approval from the clinical agency was sought and found to be a Qualitative Improvement Project.

International Review Board (IRB) was granted through UMSL IRB before starting this clinical project. Risks for this project were minimal and determined not to be human subject's research. CAPD scores are already a standard evaluation tool in patient care. Benefits of this project included decreasing pediatric delirium post implementation of sedation protocol.

Procedures

Before work on this clinical scholarship project began, a multidisciplinary team consisting of nurse managers, attending and fellow doctors, and APRNs created a new sedation protocol. After discussing with members of this multidisciplinary team, a QI project was created by the Doctor of Nursing Practice (DNP) candidate to assess delirium post implementation. Staff RNs were given education in April of 2021 regarding the new protocol and protocol was displayed at each bedside for reference and education. The protocol was implemented on July 17, 2021. The CAPD score, a validated tool, was used in this PICU prior to implementation. Using new protocol, each staff nurse assessed and scored their patient using the CAPD tool per shift, for a cumulative of two CAPD scores in 24 hours. The data were collected for the pre and post period from patient's charts who meet inclusion criteria.

Results

Sixty patients' charts underwent review who met criteria. Thirty of these charts were patients admitted from April 16, 2021, to July 15, 2021, and thirty of those were from patients admitted July 16, 2021, to October 16, 2021. In pre protocol group (A), 50% of the population were male and female while in the post new protocol group (B), 60% were male and 40% female. Group A's race consisted of 37% black and 63% white, and

zero % Hispanic or Pacific Islander. The race of Group B consisted of 50% black, 43% white, three percent Hispanic and three percent Pacific Islander. The majority of Group A were between one month to one year of age at 33%, similarly Group B had 30% of the population in this age range. The most frequent ages between both studies included patients between one month of age to five years of age 58%. Demographic data is shown in Table 1.

The primary outcome measure of this study was CAPD scores. CAPD scores were compared from the pre-new protocol group (A) and post new protocol group (B) with a two tailed independent T test. This was performed to examine if the mean of positive CAPD scores were not statistically significant for group A and B. The results of this t test show a p value of 0.304 which suggests there was no statistical significance between the pre and post intervention group. The results are shown in Table 2 and a bar graph in Figure 1. The Bar plot of means contains error bars for each mean. The error bars represent 95% of confidence interval for normal distribution and show how much error or uncertainty there is in the measurement.

Secondary outcome measures of this project included days of mechanical ventilation and PICU length of stay. Table 3 includes data for the pre-new protocol and post- new protocol groups comparing the averages. The average LOS for Group B was 10.6 down from Group A at 10.9. The average days of MV decreased from seven in Group A to 6.4 in Group B. Although there was a decrease in both secondary outcome measures, they are not statistically significant. Children between the age of one month to one year had the highest number of days of MV, with the pre new protocol Group A at 9.5 days and Group B with an average of seven days. After implementation of the new

protocol, the age group that had the largest decrease of MV were those 15-21 years old from 10.8 days to an average of five days.

The PICU length of stay after protocol decreased most significantly for children 15-21 years of age from 20.3 days in group A and 6.5 in group B, shown in Table 3. Comparing the patients' race and PICU LOS had minimal change. Black patients in group A had a LOS of 12.2 and in group B it decreased to 9.9 while the white patients had a slight increase in average LOS from 10.2 to 11.5 after implementation of protocol. Fifty percent of patients in Group A were male and 50% were female compared to Group B with 60% being male and 40% female. Comparing the sex and length of stay is skewed because there is not the same exact number of male and females in each study. The average LOS before intervention was 10.5 for males and 11.3 days for females compared to group B with an increase in males at 11.4 days. Females in group B decreased to 9.4 days.

Discussion

After the implementation of the new sedation protocol the percent positive CAPD scores increased from 67% to 78%. The implementation of the new sedation protocol did not decrease CAPD scores by 10% in the three-month period post implementation. Within this PICU, many patients have developmental delay which can skew their CAPD scores falsely higher. This was not distinguished within the exclusion criteria.

A CAPD score is subjective and requires education which nurses on this unit are accustomed to, but due to the Covid-19 pandemic there was a large amount of turnover for nursing staff resulting in over half of staff with less than two years' experience. The score is subjective and those using the scale to rate a CAPD might not have the

confidence to accurately score a CAPD. Alternatively, because there was education placed on the unit the adherence rate of CAPD scores charted grew from 50% to 53.5% after implementation of new protocol. The staff was newly educated on new protocol. The increase in positive CAPD scores could be from staff being more aware of delirium due to new training on the topic. The higher percentage of positive scores could be due to staff being more aware and capturing delirium sooner, which was shown by the increase in adherence rates from Group A to Group B.

Data from Group A was collected from spring to summer while Group B was completed in the fall. Historically, the PICU has more respiratory and higher acuity patients in the fall due to respiratory illnesses that impact children. This was not considered before starting this project and could contribute to CAPD scores being elevated more in group B. When patients require higher level of care, needing increased ventilator or respiratory support, it is often they require higher sedation. A consideration for further research on this subject is to compare groups within the same exact time for each cohort. This would show if the protocol helped decrease delirium with the same type of patients during the same season of the year.

After reviewing this data, it was apparent some patients were not on the sedation protocol. This was for various reasons including allergies, quicker steady state time, different diagnosis such as trauma and physician preference. To sustain a change, it will be necessary for each provider to follow the new protocol to fully understand if these changes are making a difference in ICU delirium.

Conclusion

Pediatric delirium is a neurocognitive disorder that presents most frequently in patients requiring an ICU admission with mechanical ventilation and sedating medications. Pediatric delirium has many negative impacts on a child's health and wellbeing, but also increases length of stay in hospital and continued costs in healthcare. The use of a CAPD score helps institutions find early signs and symptoms of delirium to stop the negative consequences by creating a positive or negative score. Certain medications increase delirium which has many lasting negative outcomes for patients and healthcare. A protocol was put in place to decrease the use of these types of medications. After the new protocol was in place, there was no statistical difference from previous protocols. Considerations for this type of data are acuity of illness, age and developmental delay that may cause inaccurate CAPD scores.

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Appendix A

Appendix A

Table 1

Two-Tailed Independent Samples t-Test for X_Positive_CAPD_scores by Group_A_and_Group_B

Variable	Group A		Group B		<i>t</i>	<i>p</i>	<i>d</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
X_Positive_CAPD_scores	0.62	0.33	4.05	18.12	-1.04	.304	0.27

Note. N = 60. Degrees of Freedom for the *t*-statistic = 58. *d* represents Cohen's *d*.

Figure 1

The mean of X_Positive_CAPD_scores by levels of Group_A_and_Group_B with 95.00% CI Error Bars

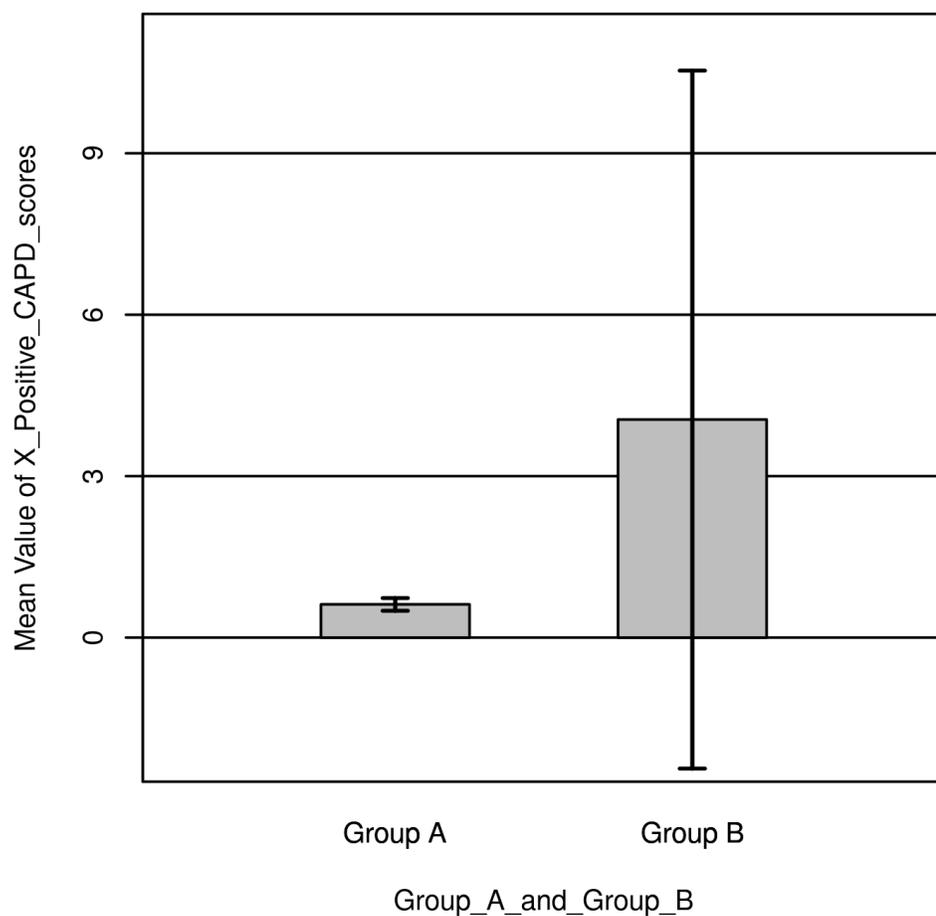


Table 2

Patient Demographics

	A		B	
	N	%	N	%
<u>Patient Age</u>				
<1 month	1	3.3%	3	10.0%
1 month - 1 year	10	33.3%	9	30.0%
1-5 years	7	23.3%	9	30.0%
5-10 years	2	6.7%	3	10.0%
10-15 years	6	20.0%	4	13.3%
15-21 years	4	13.3%	2	6.7%

Patient sex

M	15	50%	18	60%
F	15	50%	12	40%

Patient Race

Black	11	37%	15	50%
White	19	63%	13	43%
Pacific Islander	0	0%	1	3%
Hispanic	0	0%	1	3%

Table 3
Secondary Outcome Measures

<u>Patient</u>	A				B			
	Avg. # of Days of Mechanical Ventilation	Avg. # of PICU days Length of Stay	N	%	Avg. # of Days of Mechanical Ventilation	Avg. # of PICU days Length of Stay	N	%
<u>Age</u>								
<1 month	2.0	5.0	1	3.3%	6.0	7.7	3	10.0%
1 month -								
1 year	9.5	13.1	10	33.3%	7.0	10.3	9	30.0%
1-5 years	4.0	6.7	7	23.3%	6.9	13.1	9	30.0%

5-10 years	5.5	7.5	2	6.7%	4.7	6.0	3	10.0%
10-15 years	5.3	7.8	6	20.0%	6.5	13.3	4	13.3%
15-21 years	10.8	20.3	4	13.3%	5.0	6.5	2	6.7%
<u>Patient sex</u>								
M	6.9	10.5	15	50%	6.6	11.4	18	60%
F	7.2	11.3	15	50%	6.2	9.4	12	40%
<u>Patient Race</u>								
Black	7.9	12.2	11	37%	5.8	9.9	15	50%
White	6.5	10.1	19	63%	7.0	11.5	13	43%
Pacific Islander		N/A	N/A	0 0%	9.0	11.0	1	3%
Hispanic		N/A	N/A	0 0%	6.0	8.0	1	3%