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Assessment and Quality Improvement of Endotracheal Intubation in the Pediatric Intensive Care Unit at Morgan Stanley Children's Hospital of New York Presbyterian as part of the National Emergency Airway Registry For Children (NEAR-4-KIDS) a Multi-Institutional Prospective Registry

Background: Study Purpose and Rationale.

NEAR-4-KIDS is the National Emergency Airway Registry For Children, which is both a multi-institutional prospective registry as well as a quality improvement tool initially established by members of the PALISI (Pediatric Acute Lung Injury and Sepsis Investigators) by modifying the previously established national Emergency Airway Registry (NEAR) – the adult tool set. The tool set consists of a questionnaire (see attached – Appendix A) to be filled out by a member of the care team who present at the bedside during the time of an emergent intubation in the pediatric ICU.

Dr. Vinay Nadkarni of Children's Hospital of Philadelphia is the Principal Investigator overseeing 15 plus participating children's hospitals throughout the world with the goal to characterize and assess the safety practices of emergent endotracheal intubation and to further develop teaching tools and interventions, which could improve these practices. Nishisaki et al (2013) was able to establish the feasibility of the tool to characterize PICU tracheal intubation procedural process of care and safety outcomes.

Based on previously collected data from the NEAR-4-KIDS registry from July 2010 to December 2011: it is reported that adverse tracheal intubation associated events (see Appendix B) were reported in 20% of intubations, with severe tracheal intubation associated events in 6%. Ninety-eight percent of primary tracheal intubation were successful; 86% were successful with less than or equal to two attempts. It was also discovered that overall average of first attempt success rate was 60% with resident 1st time success rate of 37%, fellow success rate of 70% and PICU attending success rate of 72%.

Currently we, as an institution, do not have this data in terms of who is intubating, success rates and defined adverse tracheal intubation associated event rates. The goal of this project would be to establish Morgan Stanley Children's Hospital of New York Presbyterian as a site for NEAR-4-KIDS and to use the collected data to identify areas of improvement at our home institution.

Study Design

This study is a prospective observational cohort.

Statistical Procedures

As this is an observational study there is technically no power calculation indicated -- although for the purpose of this presentation we will be looking at the first time success rates of emergent endotracheal intubation in our ICU as compared to the national average i.e. 60% as previously mentioned. I have made the assumption that we as an institution will have an increased success rate of approximately 15% higher than the national average – 75%. To show that our institution's presumed success rate of 75% is superior to the national average I will be using a chi-squared analysis of proportions to assess the number intubations needed to show that we are in fact superior. Calculations will be adjusted to account for the fact that our comparison group will be the national average with a significantly larger sample size.

Per NEAR-4-KIDS PROTOCOL – as it pertains to the entire projected data points:

"The primary outcome is proportion of advanced airway events with Tracheal Intubation associated events (TIAE), and secondary outcomes include severe TIAEs, and number of intubation attempts per event. The secondary site level variables include: number of beds, presence/absence of residents, presence/absence of critical care/emergency medicine fellowship, 24 hours Attending Physician on-site coverage, nursing/patient ratio and case mix. The patient event-level variables include Patient, Provider, and Practice characteristics.

Descriptive statistics will be provided for primary and secondary outcomes and site-level and case-level variables. Description of continuous variables will be reported using means, medians, inter-quartile ranges, and standard deviations. All nominal and ordinal variables will be summarized by frequency tables which include counts and percentages."

Study Locations

Morgan Stanley Children's Hospital Pediatric Intensive Care Unit

Study Subjects

PRIMARY AIRWAY EVENTS IN THE PICU INCLUDING:Primary Airway Events in the PICU including: tracheal Intubation, laryngeal mask placement and emergency tracheostomy and/or cricothyrotomy. Failed extubation attempts or unplanned etubations that require re-intubation will be considered a new primary intubation.

Study Procedures

This study is survey based (Appendix A) and encompasses every patient who fulfills the inclusion criteria as noted above. After an airway event, a member of the care team will be fill out the survey at which point the survey will be given to the site's data coordinator at which point the data is uploaded to a protected CHOP-owned web-based registry portal by out research team.

Study Questionnaires -- See Appendix A

Recruitment
There will be no recruitment as this is an observational study.

Confidentiality of Study Data

The minimum necessary PHI (date of advanced airway event) will be collected. The data-coordinating center (CHOP) will never obtain readily identifiable information from any of the participating sites/investigators. After uploading data to the national database the date of advanced airway event will be removed from the data and the original data collection forms will be stored in a secure location under lock and key by the PI.

Potential Risks

No potential risk for the patient, as this is an observational survey based study filled out by a care team member after the intubation has occurred.

Potential Benefits

There are no direct benefits to the patients that are surveyed. The greater benefit is obtaining baseline data for the success rates and safety outcomes of endotracheal intubation in our pediatric ICU here at Morgan Stanley Children's Hospital. Obtaining this baseline data provides the ability to identify potential interventions to improve outcomes.

Alternatives

N/A

CONSENT ISSUES

The study meets the regulatory requirements for waiver of informed consent and assent under 45 CFR 46.116(d) and HIPAA authorization under 45 CFR 164.512(i)(2)(ii).

This is an observational study that cannot practically be carried out without the waiver of consent. It will be required that all advanced airway events be be included to avoid a reporting bias. The high quality of the data is essential due to the fact that the purpose of this data is to create a quality improvement benchmark.

The only PHI in this study is the date of the airway event as it is one of the important variables that may be associated with the primary and secondary outcomes.

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Appendix A: SURVEY DATA

National Emergency Airway Registry for Children Database

1. Encounter Date
2. Encounter Time
3. Dosing Weight
4. Sex
5. Diagnostic Category
6. Site of Intubation
7. Type of Intubation (Primary/Tube change)
8. Rating of Encounter (Teamwork, communication, situation awareness, roles and responsibilities, knowledge sharing, stress level of team members)
9. Issues with Monitoring, medication preparation and administration, and preparation of intubation equipment
10. Presence of family members (Yes/No)
11. # of Courses
12. # of Attempts
13. Intubator training level (Attending, Fellow, Resident, etc)
14. Discipline of Intubator (ICU, ENT, CCM, Surgery, etc)
15. Attending years of experience (NICU only)
16. PGY Level
17. NP years of experience
18. PA years of experience
19. Hospitalist years of experience
20. ETT Type
21. ETT size
22. Stylet used (yes or no)
23. Prior to attempt, Cricoid pressure/External Laryngeal Manipulation Provided
24. During Attempt, Cricoid Pressure/External Laryngeal Manipulation Provided
25. Difficult Airway Evaluations
26. Difficult to Bag-Mask Ventilate (yes or no)
27. Medications used for intubation
28. Method of intubation
29. Device used during intubation
30. Glottic Exposure during intubation
31. Tracheal Intubation Associated Events
32. Pulse Oximetry (%)
33. Known Cyanotic disease (yes or no)
34. Heart rate (bpm)
35. Number of providers attempted to achieve success
36. Length of PICU Stay
37. Length of mechanical ventilation
38. Encounter ID during current PICU stay
39. Extubation within 24 hours? (yes/no)
40. PICU Mortality (yes/no)
41. PIM2 Score
42. Duration between NIV initiation and NIV end
43. Duration between NIV end and intubation
44. Type of NIV: HFNC, CPAP, NIV with two level of support
45. Type of airway interface used: Nasal cannula, nasopharyngeal tube, nasal mask, bucco-nasal mask, full face mask, helmet
46. Reason for NIV use: Primary NIV, Planned post-extubation NIV, Rescue post-extubation
47. NIV settings after 1 hour of NIV support: FiO2, PEEP, Inspiratory Pressure, respiratory rate, cardiac rate, SpO2, PCO2 (arterial, capillary, or transcutaneous) if available
48. NIV settings in the hour preceding intubation: FiO2, PEEP, Inspiratory Pressure, respiratory rate, cardiac rate, SpO2, PCO2 (arterial, capillary, or transcutaneous) if available

Appendix B: Adverse Tracheal Intubation Associated Events

SEVERE TIAE'S:	NON-SEVERE TIAE'S:
Cardiac arrest	Mainstem bronchial intubation
Esophageal intubation with delayed recognition	Esophageal intubation with immediate recognition
Emesis with witnessed aspiration	Emesis without aspiration
Hypotension requiring intervention	Hypertension requiring therapy
Laryngospasm	Epistaxis
Malignant Hyperthermia	Dental or lip trauma
Pneumothorax/pneumomediastinum	Medical error
Direct airway injury	Arrhythmia
	Pain/agitation requiring medication resulting in delayed intubation