# **AHRQ Grant Final Progress Report**

Title: Evaluating safety and quality of tracheal intubation in pediatric ICUs

PI: Akira Nishisaki, MD, MSCE Team Members: Vinay Nadkarni, MD, MS, Arun Rao, CIM, BE, Jessica Leffelman

Organization: Center for Simulation, Advanced Education and Innovation, The Children's Hospital of Philadelphia

Inclusive Dates of Project: 10/1/2012 - 12/31/2013

Federal Project Officer: Denise Burgess, (301) 427-1318, <u>denise.burgess@ahrq.hhs.gov</u>

Grant Management Specialist: Steven Young, (301) 427-1458, steven.young@ahrq.hhs.gov

Acknowledgement of Agency Support:

Grant Award Number: R03 HS21583-01

# STRUCTURED ABSTRACT

## Purpose:

To characterize tracheal intubation (TI) processes and outcomes across 15 diverse pediatric ICUs (PICUs) using a prospective data collection tool (NEAR4KIDs). To identify candidate factors to target for pediatric TI quality improvement by analyzing NEAR4KIDs multicenter data.

## Scope:

TI is a life-saving procedure; however, it is often associated with adverse outcomes in PICUs. Our preliminary single-PICU data documented adverse TI-associated events (TIAEs) occur among >20%. These findings cannot be generalized simply due to different ICU characteristics.

# Methods:

The multicenter pediatric TI registry, NEAR4KIDs, was expanded to 15 diverse PICUs. Specific patient, provider, and practice characteristics were evaluated in relation with adverse TIAEs.

# **Results:**

Principal findings:

In total, 1715 TIs were reported from 15 PICUs over 18 months. Though 98% of primary TIs were successful, adverse TIAEs were reported in 20%, and severe TIAEs were reported in 6%. Risk factors included pre-existing hemodynamic instability, history of difficult airway, and resident trainee participation as a laryngoscopist. Multivariate analysis confirmed trainee levels as an important factor for TIAEs (fellow vs. resident: odds ratio 0.42; 95% CI 0.31-0.57).

# Discussion:

Adverse TI events were common across diverse pediatric ICUs. Risk factors were identified.

# Implication:

A bundled, checklist-based intervention was successfully developed to improve TI safety across diverse pediatric ICUs. (200 words)

# Key words:

Pediatric Critically ill Intubation Tracheal intubation Safety

# **PURPOSE:**

The long-term goal of this project is to develop a national collaborative network to benchmark and implement quality improvements for tracheal intubations across diverse pediatric ICUs. The specific objectives of this project were to systematically evaluate the current practice in pediatric TIs across 15 diverse pediatric ICUs in the existing Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) network and to generate a bundled quality improvement intervention to reduce the occurrence of adverse TI events.

# SCOPE:

Emergent tracheal intubation is a life-saving procedure performed for a wide range of indications, with known associated risks in critically ill children. However, the landscape of safety and process of care for this procedure in diverse PICUs has not been reported. Single-center data from a large tertiary PICU demonstrated that adverse tracheal intubation-associated events (TIAEs) are common, occurring in approximately 20% of tracheal intubation attempts, with 3% of these complications characterized as severe. A similar incidence of TIAEs has been reported in pediatric patients undergoing tracheal intubation prior to referral to a tertiary PICU. As demonstrated in these single-center investigations, it is likely that substantial variation exists across PICUs in both the safety and process of tracheal intubation. There are numerous possible factors that may contribute to the variation associated with tracheal intubation across centers, but three potentially major direct driving factors are patient condition, provider competence, and practice/planning. To characterize the process and safety of the tracheal intubation procedures across a diverse spectrum of PICUs in North America, the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network adopted and modified the National Emergency Airway Registry (NEAR) tools, creating the NEAR4KIDS, national airway registry for children. This registry was piloted in a large tertiary-care referral center and then implemented across 15 PICUs in North America as a multicenter quality improvement initiative. We set two specific aims to achieve our objectives, to analyze factors influencing the safety of tracheal intubation and to generate bundled quality improvement intervention. Those specific aims are the following: Specific Aim #1. To characterize TI process and outcomes across 15 diverse Pediatric ICUs throughout the Pediatric Acute Lung Injury and Sepsis Investigators Network (PALISI), using an existing feasible prospective data collection tool (NEAR4KIDs), high compliance to minimize reporting bias, and standard consensus operational definitions. Specific Aim #2. To identify the key candidate variables to target for pediatric TI quality improvement in Pediatric ICUs by analyzing the descriptive NEAR4KIDs multicenter data.

# **METHODS**:

This study was conducted across 15 academic PICUs in North America. Sites were recruited through the PALISI Network (Appendix 1). NEAR4KIDS was developed by members of the PALISI Network in conjunction with the NEAR investigators.

A data collection form was developed and piloted in a tertiary-care pediatric ICU and refined for the NEAR4KIDS investigators.

Institutional Review Board (IRB) approval was obtained at each participating site. Fifteen centers volunteered to participate and maintain high compliance with this quality improvement initiative. Following each center's IRB approval, each site project leader developed a site-specific compliance plan to ensure greater than 95% tracheal intubation encounter capture rate and the highest accuracy of the data. Two compliance officers reviewed and approved the compliance plan for each site based on the available local resources. Data collection was then initiated for each tracheal intubation that occurred in the PICU at each center.

# Definitions and Outcome Measures

Undesired events were a priori defined as TIAEs with two categories: severe TIAEs and non-severe TIAEs. Severe TIAEs include cardiac arrest, esophageal intubation with delayed recognition, emesis with witnessed aspiration, hypotension requiring intervention (fluid and/or pressors), laryngospasm, malignant hyperthermia, pneumothorax/pneumomediastinum, or direct airway injury.

Non-severe TIAEs include mainstem bronchial intubation, esophageal intubation with immediate recognition, emesis without aspiration, hypertension requiring therapy, epistaxis, dental or lip trauma, medication error, arrhythmia, and pain and/or agitation requiring additional medication and causing delay in intubation. Mainstem bronchial intubation was considered only when it was confirmed on chest radiograph or recognized after the clinical team secured the tracheal tube.

# Collection of Site Characteristics

Separately from individual TI data collected on the patient, provider, and practice characteristics, each participating center submitted information pertaining to the individual site characteristics: size (number of PICU beds), number of PICU admissions per year, presence of a residency program, fellowship training program, case mix, and presence of in-hospital 24-hour critical care attending physicians.

# Quality Improvement Bundle Development

A NEAR4KIDS Quality Improvement (QI) bundled intervention was developed through the following steps. First, univariate analysis was performed to identify risk factors associated with adverse tracheal intubation associated events (see below: Statistical Methods). A multidisciplinary QI committee across the sites was formed. Then, a workflow analysis of tracheal intubation was conducted. A preliminary QI checklist was developed by incorporating the identified risk factors (factors associated with TIAEs with p<0.1 with univariate analysis) and findings from workflow analysis and committee discussion. Subsequently, a pilot-testing of the checklist was performed to develop the Airway Bundle Checklist: a checklist to improve safety of tracheal intubations in the PICUs across the NEAR4KIDS network.

# Statistical Methods

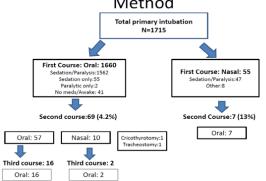
Statistical analysis was performed using STATA 11.2 (Stata Corp., College Station, TX). Summary statistics were described with mean and SD for parametric variables and median with interquartile range for nonparametric variables. For categorical variables with dichotomous outcomes, the contingency table method was used with the chi-squared test or Fisher's exact test, as appropriate. The Wilcoxon rank-sum test was used for comparison of nonparametric variables. Logistic regression was performed for a dichotomous outcome to evaluate the association with exposure variables while adjusting for covariates. A p value < 0.05 was considered significant for all hypotheses to avoid being too conservative and missing important exploratory findings. For the evaluation of the impact of provider training level, multivariate logistic regression model was developed to account for indication, previous history of a difficult airway, and patient age to evaluate success of tracheal intubation at the first attempt as well as overall success in TIs performed by pediatric providers. It is speculated that a senior-level airway provider may have more difficult cases that may result in a higher incidence of TIAEs or lower likelihood of success; we evaluated this effect modification by including an interaction term. The interaction term was kept in the multivariate regression model when its coefficient was p < 0.1.

# **RESULTS:**

Landscape of Tracheal Intubation Practice and Adverse TIAEs

One thousand seven hundred fifteen tracheal intubation encounters were reported from July 2010 to December 2011, averaging 1/3.4 days, or 1/86 bed days (see Method graphic below for encounter summary). Ninety-eight percent of primary tracheal intubations were successful; 86% were successful with less than or equal to two attempts. The first attempt was by pediatric residents in 23%, pediatric critical care fellows in 41%, and critical care attending physicians in 13%; the first attempt success rate was 62%, and the first provider success rate was 79%. The first method was oral intubation in 1,659 (98%) and nasal in 55 (2%). Direct laryngoscopy was used in 96%. Ninety percent of tracheal intubations were with cuffed tracheal tubes. Adverse TIAEs were reported in 20% of intubations (n = 372), with severe TIAEs in 6% (n = 115), as shown in Table 1. Esophageal intubation with immediate recognition was the most common TIAE (n = 167, 9%). History of difficult airway, diagnostic category, unstable hemodynamics, and resident provider as first airway provider were associated with occurrence of tracheal intubation-associated events

(Table 2). Severe TIAEs were associated with diagnostic category and pre-existing unstable hemodynamics. Elective tracheal intubation status was associated with fewer severe TIAEs. Method



Severe	TIAEs	Non-seve	ere TIAEs
Any severe TIAEs	115 (6.3%)	Any non-severe TIAEs	284 (15.6%)
Cardiac arrest-died	8 (0.4%)	Mainstem bronchial	54 (3.0%)
		intubation	
Cardiac arrest-survived	24 (1.3%)	<b>Esophageal intubation</b>	167 (9.2%)
		immediate	
		Recognition	
<b>Esophageal intubation</b>	6 (0.3%)	Emesis	14 (0.8%)
delayed recognition		without aspiration	
Emesis with aspiration	15 (0.8%)	Hypertension	4 (0.2%)
		requiring medication	
Hypotension requiring	61 (3.4%)	Epistaxis	10 (0.6%)
intervention			
Laryngospasm	4 (0.2%)	Dental/lip trauma	31 (1.7%)
Malignant	0 (0%)	Medication error	2 (0.1%)
hyperthermia			
Pneumothorax	4 (0.2%)	Dysrhythmia*	28 (1.5%)
Pneumomediastinum			
		Pain/agitation	9 (0.5%)
		delaying procedure	

# Table 1. Incidence of tracheal intubation-associated events

Analysis includes a total of 1821 courses.

TIAE denotes tracheal intubation--associated events.

Any TIAEs were reported in 372 courses (20.4%). Please note that some courses had more than one

TIAE, or had both severe and non-severe TIAEs.

\*Dysrhythmia includes symptomatic bradycardia.

Table 2. Patient, provider, and practice	e factors associated courses with TIAEs
--	---

Category	<b>Characteristics</b>	With	Without	р	With	Without	р
		TIAEs	TIAEs	value	severe	severe	value
			(n=1449)		TIAEs	TIAEs	
		(n=372)			(n=115)	(n=1706)	
Patient*	Age (year)	1 (IQR:0-	1 (IQR:0-	0.17	1	1 (IQR:0-	0.79
		7)	7)		(IQR:0-	7)	
					7)		
	Weight (kg)	10.8	10.0	0.20	10.0	10.4	0.84
		(IQR:5.3-	(IQR:4.9-		(IQR:	(IQR: 5.2-	
		22)	22.5)		5.9-19.4)	22.2)	
	Gender (Male)	57.9%	58.7%	0.78	52.2%	59.0%	0.16
	History of DA	14.8%	11.0%	0.04	16.5%	11.4%	0.10
	Diagnostic			0.015			0.003
	category <sup>#</sup>						
	Resp-upper	10.3%	10.6%		10.9%	10.5%	
	Resp-lower	34.6%	34.0%		34.6%	34.1%	
	Cardiac-	10.0%	8.6%		10.0%	8.8%	
	surgical	5.6%	5.2%		7.3%	5.1%	

	Cardiaa	12 20/	0.00/		15 50/	0.10/	
	Cardiac-	12.3%	8.8%		15.5%	9.1%	
	medical	13.5%	19.1%		5.5%	18.9%	
	Sepsis/shock	0.6%	3.1%		0.0%	2.8%	
	Neurological	13.2%	10.5%		16.4%	10.7%	
	Trauma						
	Other						
	Oxygenation	39.3%	34.4%	0.08	51.3%	34.4%	< 0.001
	failure						
	Ventilation	37.9%	33.5%	0.11	47.8%	33.5%	0.002
	failure						
	Therapeutic	3.0%	3.0%	0.99	5.2%	2.8%	0.14
	hyperventilation						
	Neuromuscular	4.3%	4.0%	0.80	4.4%	4.0%	0.87
	weakness	н.370	4.070	0.00	<b>т.</b> т/0	4.070	0.07
	Impaired airway	6.7%	7.7%	0.51	7.0%	7.6%	0.81
		0.770	1.170	0.51	7.070	7.070	0.81
	reflex	14.00/	15.00/	0.44	C 10/	16.00/	0.004
	Elective	14.3%	15.9%	0.44	6.1%	16.2%	0.004
	procedure						
	Upper airway	10.2%	11.1%	0.62	10.4%	11.0%	0.86
	obstruction						
	Pulmonary toilet	5.7%	3.9%	0.13	5.2%	4.2%	0.59
	Unstable	16.9%	11.9%	0.01	33.0%	11.6%	< 0.001
	he modynamics						
Practice <sup>†</sup>	Method			0.77			0.42
	Oral	96.5%	96.9%		95.5%	96.9%	
	Nasal	3.5%	3.1%		4.5%	3.1%	
	Device	5.570	5.170	0.51	1.570	5.170	0.79
	Laryngoscope	96.5%	95.8%	0.51	96.4%	95.9%	0.75
	Other	3.5%	4.2%		3.6%	4.1%	
				0.001			0.00
	Use of	42.9%	33.0%	0.001	39.6%	34.7%	0.29
	vagolytics						
	Fentanyl	62.3%	63.4%	0.70	63.1%	63.2%	0.99
	Midazolam	58.8%	55.9%	0.34	53.2%	56.7%	0.46
	Ketamine	21.6%	23.1%	0.56	27.9%	22.4%	0.18
	Propofol	7.5%	12.7%	0.007	6.3%	12.0%	0.07
	Etomidate	0.9%	1.7%	0.27	0.0%	1.6%	0.18
	Thiopental	0.3%	0.4%	0.70	0.9%	0.4%	0.40
	Non-	89.3%	88.4%	0.62	84.7%	88.8%	0.18
	depolarizing	07.570	00.770	0.02	01.770	00.070	0.10
	paralytics	0.60/	0.00/	0.66	1.00/	0.70/	0.10
D 11 7	Succinylcholine	0.6%	0.8%	0.66	1.8%	0.7%	0.19
Provider <sup>‡</sup>	Training level			< 0.001			0.21
	Resident	34.9%	20.1%		25.2%	22.9%	
	Fellow	33.7%	43.3%		33.3%	41.9%	
	Non-Physician	6.3%	10.0%	0.035	7.2%	9.4%	0.44
	Provider						
	(NP, RRT)						
TIAE = tracket	(NP, RRT)		DA = Diffici				

TIAE = tracheal intubation--associated events; DA = Difficult Airway; NP = nurse practitioners; RRT = respiratory therapists.

\*Analysis includes each course of the encounter.

 $^{\#}n = 1,622$  (data missing in 199).

<sup>†</sup>Analysis includes the first course of each encounter.

<sup>‡</sup>Analysis includes the airway management by pediatric resident and pediatric critical care fellows.

# Evaluation of the provider training level on tracheal intubation outcomes

Overall, 1265 orotracheal intubation encounters were performed by pediatric residents, fellows, and attendees during July 2010 to December 2011. Of 1265 encounters, 763 (60%) were successful on the first attempt by the initial provider (laryngoscopist), and 988 (78%) were successful overall by the initial provider (Table 3).

	Provider performed attempt <sup>a</sup>			Success rate		
	1 <sup>st</sup> Attempt	2 <sup>nd</sup> Attempt	3 <sup>rd</sup> Attempt	1 <sup>st</sup> Attempt <sup>b</sup>	Overall <sup>c</sup>	
Resident, Pediatrics	384 (23.1%)	124 (19.8%)	10 (4.2%)	141 (36.7%)	196 (51.0%)	
Fellow, PICU	679 (40.9%)	254 (40.5%)	92 (38.8%)	477 (70.3%)	603 (88.8%)	
Attending, PICU	202 (12.2%)	135 (21.5%)	90 (38.0%)	145 (71.8%)	189 (93.6%)	
Resident, EM	71 (4.3%)	13 (2.1%)	2 (0.8%)	46 (64.8%)	51 (71.8%)	
Resident, ANE	29 (1.8%)	10 (1.6%)	4 (1.7%)	21 (72.4%)	29 (100%)	
Fellow, ANE	7 (0.4%)	9 (1.4%)	4 (1.7%)	4 (57.1%)	7 (100%)	
Attending, ANE	22 (1.3%)	8 (1.3%)	6 (2.5%)	16 (72.7%)	18 (81.8%)	
ENT	20 (1.2%)	7 (1.1%)	1 (0.4%)	15 (75.0%)	19 (95.0%)	
NP, PICU	120 (7.2%)	28 (4.5%)	9 (3.8%)	78 (65.0%)	100 (83.3%)	
RRT	34 (2.1%)	13 (2.1%)	4 (1.7%)	19 (55.9%)	27 (79.4%)	
Other	92 (5.4%)	26 (4.2%)	15 (6.3%)	58 (63.0%)	71 (77.2%)	
Total	1,660	627	237	1,020	1,310	
	(100%)	(100%)	(100%)	(61.5%)	(78.9%)	

## Table 3. Provider characteristics—tracheal intubation course

1<sup>st</sup>: first, 2<sup>nd</sup>: second, 3<sup>rd</sup>: third

PICU: pediatric intensive care unit, EM: Emergency Medicine, ANE: Anesthesiology, ENT: Ear nose throat, NP: nurse practitioner, RRT: registered respiratory therapist

<sup>a</sup>Percentage of providers who participated in the first, second, and third attempt, respectively. <sup>b</sup>Percentage of success at the first attempt

<sup>c</sup>Percentage of success after overall attempts by the initial provider (includes more than 1 attempt by the respective provider)

The first tracheal intubation attempt was performed by a pediatric resident in 384 cases, a pediatric critical care fellow in 679 cases, and a PICU attending physician in 202 cases. First and overall attempt success rates varied among pediatric residents (37%, 51%), pediatric critical care fellows (70%, 89%), and PICU attending physicians (72%, 94%) (Table 3). After adjusting for patient-level covariates (previous history of difficult airway, elective intubation as indication, and age), fellow participation was associated with a higher rate of first-attempt success (odds ratio [OR], 4.29; 95% confidence interval [CI], 3.24–5.68; p < .001) in comparison with resident providers (Table 4). Pediatric critical care fellows were more likely to have overall success in patients without a previous history of a difficult airway (OR, 9.27; 95% CI, 6.56–13.1; p < .001).

	First Attempt Success <sup>a</sup>		Overall Success <sup>b</sup>	
	Odds Ratio (95% CI)	p Value	Odds Ratio (95% CI)	p Value
Fellows (vs. Residents)	4.29 (3.24-5.68)	< 0.001	9.27 (6.56-13.1)	< 0.001
History of DA <sup>#</sup>	1.71 (0.27-11.0)	0.57	4.47 (0.72-27.9)	0.11
Fellows*History of DA <sup>#</sup> (interaction)	0.58 (0.21-1.62)	0.30	0.26 (0.09-0.74)	0.01
Elective intubation	1.06 (0.75-1.49)	0.74	1.10 (0.74-1.64)	0.64
Age <sup>c</sup>				
Infant (<1 year)	Reference		Reference	
1-7 years	1.14 (0.84-1.54)	0.40	1.03 (0.72-1.47)	0.90
$\geq$ 8 years	1.08 (0.77-1.51)	0.64	1.09 (0.73-1.64)	0.67

# Table 4. Multivariate analysis for first attempt and overall tracheal intubation success performed by pediatric resident or pediatric critical care fellow

Analysis includes first course of each encounter when pediatric resident or pediatric critical care fellow were the first laryngoscopists. N=1063

# DA denotes Difficult Airway

<sup>a</sup>Logistic regression Pseudo  $R^2 = 0.081$ , p < 0.0001, <sup>b</sup>Logistic regression Pseudo  $R^2 = 0.167$ , p < 0.0001<sup>c</sup>Comparison to infants (<1 year)

# Site Variance in tracheal intubation and adverse TIAEs

Nine to 410 TIs per site were reported during July 2010 to December 2011. This corresponded to a frequency of one TI every 1.3-26.8 days. The overall incidences of TIAEs and severe TIAEs were 20.3% and 6.5%, respectively. The prevalence of TIAEs varied significantly across the sites, from 0 to 44.1% (p < 0.001). The prevalence of severe TIAEs was also significantly variable: 0-20.4% (p < 0.001) (Figure 1).

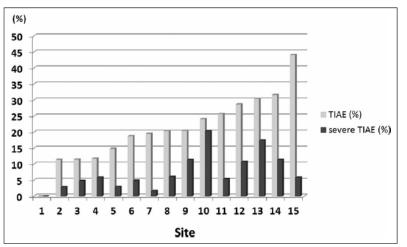


Figure 1. Prevalence of tracheal intubation-associated events (TIAEs) and severe TIAEs.

Table 5 describes the univariate and multivariate analyses for the association between sitelevel characteristics and incidence of TIAEs. The larger size of the ICUs (>26 beds: more than median value) was associated with fewer TIAEs (TIAE: 17.8% vs. 23.3%, p = 0.006). Presence of PICU fellowship, however, was not associated with prevalence of TIAEs (20.4% vs.18.0%, p = 0.58). With multivariate analysis adjusting for patient and provider characteristics, neither the size of the ICUs and the presence of fellowship were associated with TIAEs (OR 0.83; 95% CI: 0.52-1.33, p = 0.44; OR 1.62: 95% CI:0.80-3.31, p = 0.18, respesctively). Mixed ICU with cardiac surgical patients was associated with a higher prevalence of TIAEs in both univariate and multivariate analyses (TIAE: 25.2% vs.14.9%, p < 0.001; multivariate OR 1.81; 95% CI: 1.29-2.53, p = 0.001). This analysis result remained significant when we further adjusted for the patient diagnostic

category, for cardiac condition (OR 1.80; 95% CI: 1.28-2.54, p = 0.001).

Site characteristic <sup>#</sup>		Univariate analysis	Multivariate analysis
		(Odds Ratio, 95% CI)	(Odds Ratio, 95% CI)
Annual admission	(>1300 vs.≤1300)	0.95 (95% CI:0.74-1.23,p=0.74)	1.01 (95% CI:0.62-
			1.65,p=0.97)
ICU beds	(>26 vs. ≤26)	0.71 (95% CI:0.56-0.90,	0.83 (95% CI: 0.52-1.33,
		p=0.006)	p=0.44)
fellowship	(present vs. absent)	1.13 (95% CI:0.73-1.78,p=0.66)	1.62 (95% CI:0.80-
			3.31,p=0.18)
Cardiac surgery	(present vs. absent)	1.92 (95% CI:1.51-2.46,	1.81* (95% CI: 1.29-
		p<0.001)	2.53, p=0.001)

# Table 5. Site-level characteristics associated with occurrence of TIAEs

TIAE denotes adverse tracheal intubation--associated events.

# All sites had pediatric residency programs.

\* The odds ratio was 1.80 (95% CI: 1.28-2.54) when the multivariate model included cardiac diagnostic category as a patient-level factor.

# Development of tracheal intubation quality improvement bundled intervention

The quality improvement committee followed the process of the development of a tracheal intubation safety checklist, as shown in Figure 2. First, clinical variables were evaluated for potential risk factors for TIAEs and severe TIAEs. A univariate analysis was performed on clinical variables from July 2010 to December 2011 in the NEAR4KIDS registry (see Table 2). The variables associated with occurrence of non-severe or severe TIAEs were considered for entry into a checklist. Particular attention was paid to checklist development centered around the interdisciplinary workflow of tracheal intubation: identification of a patient at risk for tracheal intubation, generation of an airway management plan, pre-procedure time out and confirmation for readiness immediately before tracheal intubation, and post-tracheal intubation debriefing.

After these iterated steps, the OI committee developed a draft of the Airway Bundle Checklist. This draft was then reviewed by the multidisciplinary members of each site for a comment period of 12 weeks. These members included pediatric critical care physicians, PICU nurses, and respiratory therapists.

After receiving recommendations, the QI committee carefully redrafted the checklist via biweekly meetings and electronic communication in order to reach consensus for the first pilot version of the Airway Bundle Checklist. The committee carefully balanced the amount of information being asked for in the different phases of intubation while being cognizant of the amount of work that would be placed on providers.

Finally, the Airway Bundle Checklist was piloted at seven centers to assess for feasibility and usability prior to distributing to all sites for implementation. This feedback was carefully reviewed and addressed. Specifically, the usability of the preprocedure time out on the back page was addressed with simpler wording and the introduction of "7 Rights" (adapted from "5 Rights" of medication safety), familiar to many practitioners [19]. Simultaneously, the committee developed a OI implementation plan. This included a required endorsement letter from the PICU practice/OI committee at each site, benchmarking data available to each site, and monitoring and feedback of compliance data to each site.

# Figure 2

Process of developing NEAR4KIDS Airway Bundle Checklist Formulation of multidisciplinary team of pediatric airway experto identify important process in airway management Initiate collection of multicenter baseline data to understand the landscape of pediatric airway management. Analysis of provider, practice, and patient characteristics of safe airway management. Formulation of the NEAR4KIDS Airway Bundle Checklist. Consensus development through NEAR4KIDS quality improvement committee. Preliminary draft of the NEAR4KIDS Airway Bundle Checklist Comment period for all NEAR4KIDS members. Redraft of the NEAR4KIDS Airway Bundle Checklist. Pilot of Airway Bundle Checklist at 7 centers to assess feasibility of use. Finalization of NEAR4KIDS Airway Bundle Checklist through NEAR4KIDS quality improvement committee. Initiate use of Airway Bundle Checklist at sites with adequate baseline data.

# Discussion:

We were able to describe our current tracheal intubation safety practice and outcomes across the 15 diverse PICUs with our research and OI network. NEAR4KIDS. We identified that adverse TIAEs are common seen in 20% of all tracheal intubations, and certain patient, provider, and practice factors are associated with their occurrence. This information was quite helpful to develop a QI bundled intervention.

We also conducted a detailed analysis in the association between pediatric trainees and outcomes of tracheal intubation. First attempt and overall success rates were lower for pediatric residents compared to fellows, and the difference remained significant even after adjustment for patient-level factors. The incidence of TIAEs was also significantly higher in tracheal intubations attempted by resident providers. Our findings suggest that the training of pediatric residents is not sufficient prior to "live" tracheal intubations in the critical care setting. The higher incidence of TIAEs associated with airway management initiated by pediatric residents brings into question whether the PICU is the appropriate setting to train pediatric resident intubation skills on "live patients," given that this skill will be rarely needed in a general pediatric practice. A focused structured training and setting demonstrating competence in tracheal intubation skills may be needed for pediatric residents who are going into acute care practice/training.

Our site variance analysis revealed a significant variability in the occurrence of TI and safety outcomes as well as practice parameters across 15 PICUs. Interestingly, after adjusting for patient and provider characteristics, neither PICU size nor presence of fellowship training program explained site-level variance. Mixed PICUs with cardiac surgical patients were associated with a higher incidence of TIAEs in both univariate and multivariate analyses. The reason for this association requires further investigation.

Last, we were able to develop an initial version of Airway Bundle Checklist for a bundled intervention for airway management safety across diverse PICUs using the baseline data and identified risk factors. The method to develop the bundled checklist and intervention were rigorous and followed the best practice.

Implication:

Our successful NEAR4KIDS collaborative to document our current safety practice in tracheal intubations in diverse 15 PICUs continues to grow across the United States. With our baseline safety data and our newly developed QI Airway Bundled Checklist and bundled intervention, we are ready to implement the tracheal intubation quality improvement project throughout the NEAR4KIDS network. We currently are evaluating the impact of this project with targeted outcomes: adverse TIAEs. Simultaneously, we created a qualitative project to evaluate the promoters and barriers of QI implementation at each PICU using qualitative approach. As there is substantial diversity in tracheal intubation practices and safety profiles across the PICUs, we will continue to seek for the suitable QI implementation strategies for each PICU based on each safety profile.

# LIST OF PUBLICATIONS AND PRODUCTS

**Nishisaki A**, Turner DA, Brown CA III, Walls RM, Nadkarni VM. For the National Emergency Airway Registry for Children (NEAR4KIDS) and Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. A National Emergency Airway Registry for Children (NEAR4KIDS) Landscape of Tracheal Intubation in 15 Pediatric Intensive Care Units. Critical Care Medicine 2013 March;41(3):874-885.

Sanders RC, Giuliano JS, Sullivan JE, Brown CA, Walls RM, Nadkarni VM, Nishisaki A; for the National Emergency Airway Registry for Children Investigators and Pediatric Acute Lung Injury and Sepsis investigators Network. Level of trainee and tracheal intubation outcome. Pediatrics 2013 March;131(3):e821-e828.

Nett ST, Emeriaud G, Jarvis JD, Montgomery V, Nadkarni VM, Nishisaki A, for the National Emergency Airway Registry for Children Investigators and Pediatric Acute Lung Injury and Sepsis Investigators Network. Site-level variance for adverse tracheal intubation associated events across 15 North American Pediatric ICU's: A report from National Emergency Airway Registry for Children (NEAR4KIDS). Pediatric Critical Care Medicine 2014 May;15(4):306-13.

Nishisaki A, Sanders RC, Giuliano JS, Sullivan JE, Brown CA, Walls RM, Nadkarni V. For the NEAR4KIDS and PALISI Investigators: Airway provider training level is associated with tracheal intubation success and adverse tracheal intubation associated events in pediatric ICU's: A report from the NEAR4KIDS multicenter registry. *Critical Care Medicine* December 2012; 40(12 suppl):#616.

Poster Presentation at 42<sup>nd</sup> Critical Care Congress, San Juan Puerto Rico, January 2013.

Nishisaki A, Turner DA, Brown CA, Walls RM, Nadkarni VM. Landscape of tracheal intubation in 15 pediatric intensive care units: A report from National Emergency Airway Registry for Children (NEAR4KIDS). Critical Care Medicine December 2012; 40(12 suppl)#1065.

Poster Presentation at 42<sup>nd</sup> Critical Care Congress, San Juan, Puerto Rico, January 2013.

Foglia EE, Ades A, Napolitano N, Leffelman J, Nadkarni VM, Nishisaki A: Training level and associated outcomes of neonatal intubation: Analysis of the National Emergency Airway Registry for Children (NEAR4KIDS) at a referral neonatal intensive care unit. American Academy of Pediatrics October 2013 Notes: Poster Presentation at American Academy of Pediatrics (AAP) National Conference, Orlando, FL, October 2013.

Napolitano N, Leffelman J, Snyder M, Nadkarni VM, Tucker C, Nishisaki A, Simon L. Assessment of safety of tracheal intubation practice in the pediatric ICU and development of a quality improvement bundle to reduce tracheal intubation associated events. *Respiratory Care Journal* 

Poster Presentation at the American Association for Respiratory Care Open Forum, November 2013, Anaheim, CA.

Napolitano N, Giordano R, Snyder M, Leffelman J, Nadkarni VM, Simon L, Nishisaki A. Can an airway bundle checklist improve the safety of tracheal intubation in pediatric intensive care unit? *Respiratory Care Journal* Poster Presentation at the American Association for Respiratory Care Open Forum, November 2013, Anaheim, CA.

Napolitano N, Doroghue AJ, Hsieh TC, Lavin N, Fogia E, Nadkarni VM, Nishisaki A. Impact of trainee level & provider type on tracheal intubate success & associated adverse events. *Critical Care Medicine* December 2013; 41(12 Suppl)#711. Poster Presentation at the 43<sup>rd</sup> Critical Care Congress, San Francisco, CA.

Napolitano N, Foglia E, Lavin N, Donoghue AJ, Hsieh TC, Nadkarni VM, Nishisaki A. Incidence of tracheal intubation associated events varies in a large tertiary children's hospital *Critical Care Medicine* December 2013; 41(12 Suppl)#708 Poster Presentation at the 43<sup>rd</sup> Critical Care Congress, San Francisco, CA.

Howell J, Tarquinio K, Montgomery V, Turner DJ, Brown C, Walls R, Nadkarni VM, **Nishisaki A**. Association of vagolytic and ketamine use with tracheal associated adverse events. Critical Care Medicine December 2013; 41(12 Suppl):#878. Poster Presentation at the 43<sup>rd</sup> Critical Care Congress, San Francisco, CA.

**Nishisaki A**, Nett S, Emeriaud G, Jarvis D, Montgomery V, Nadkarni VM. Substantial site-level variance exists in adverse tracheal intubation associated events: NEAR4KIDS. *Critical Care Medicine* December 2013; 41(12 Suppl):#416. Poster Presentation at the 43<sup>rd</sup> Critical Care Congress, San Francisco, CA.

Tamburro R, Graciano AL, Thompson A, Fiajoe J, Nadkarni VM, Nishisaki A. Pediatric difficult tracheal intubation: Are we able to predict? – Report from NEAR4KIDS. *Critical Care Medicine* December 2013; 41(12 Suppl):#415. Poster Presentation at the 43<sup>rd</sup> Critical Care Congress, San Francisco, CA.

# Appendix 1



# Airway Bundle Checklist (FRONT and BACK)

Date:

[Place patient sticker/stamp here]

Time:

By\_

Front page completed (check all that apply):

□ On admission □ During rounds □ After Rounds □ Just prior to intubation

## Assessment for ANTICIPATED Airway Management

### Intubation Risk Assessment

Difficult	History of difficult airway?	YES	NO
Airway	Physical? (e.g. small mouth, small jaw, large tongue, or short neck)	YES	NO
At Risk	High risk for rapid desaturation during intubation	YES	NO
For:	Increased ICP, pulmonary hypertension, need to avoid hypercarbia	YES	NO
	Unstable hemodynamics (e.g. hypovolemia, potential need for fluid bolus, vasopressor, CPR)	YES	NO
	Other risk factors?	YES	NO

#### Planning (If answer is YES please include in the planning):

Who will intubate? (specify primary provider who will perform first laryngoscopy. Resident, Fellow, NP, Attending, Anesthesiologist, ENT physician, RT, Other-Specify below)

How will we intubate? (specify the Method: □oral vs.□nasal, specify Device, specify Meds)

When will we intubate? (describe the timing of airway management: e.g. SpO2<85% on XX l/min of O2, mental status change, or at 1pm for MRI, etc)

Backup? (describe the backup plan for the 1<sup>st</sup> attempt and Course failure, specify if equipment or personnel needs to be present at bedside before the Course start)

Front page not filled out: Why? \_\_\_\_\_\_

ver.9 updated 10/26/12

Page 1 of 2

### Immediate Pre-intubation procedure TIME OUT

#### (Complete immediately before intubation)

□ **Right Patient**: Confirm 2 identifiers and allergy status.

□ Right Plan: Review and revise the FRONT PAGE plan

□ Right Prep: Patient accessible and positioned correctly, bed cleared for intubation, working IV?

□ Right Equipment: SOAP (e.g Suction, Oxygen, Airway, Personnel), IV fluid bolus readily available?

□ Right Monitoring: BP cycling frequently, different extremity from pulse ox, pulse ox volume?

Right Rescue plan: Difficult Airway cart/kit and equipment available? Who can we call for assistance? Do we have that contact #?

Right Attitude: State out loud:

"IF anybody has a concern at any time during the procedure please SPEAK UP."

#### Other PATIENT SPECIFIC preparation:

## Post-procedure TIME OUT

What did we do well? Feedback in the following order:

	RT	
2.	Nurse	
3.	Resident	
4.	NP/PA	
5.	Fellow	
6.	Attending	

What can we improve upon?\_\_\_\_\_

Is there any critical equipment of process that we need to follow up on?\_\_\_

Back page Completed by (PRINT): \_\_\_\_\_

Intubated by:

□ NEAR4Kids data form completed after intubation?

ver.9 updated 10/26/12

Page 2 of 2