PROTOCOL TEMPLATE: INTERVENTION STUDY (CLINICAL TRIALS)

Title:	**Improving safety and quality of tracheal intubations in neonatal ICUs**
Short Title	Tracheal intubation coaching in NICUs
Drug or Device Name(s):	Video laryngoscope
FDA IND:	Not applicable
Regulatory Sponsor:	
eIRB Number:	
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ABBREVIATIONS AND DEFINITIONS OF TERMS

TI	Tracheal Intubation
NICUs	Neonatal Intensive Care Units
VL	Video Laryngoscopy
NEAR4KIDS	National Emergency Airway Registry for Kids
TIAE	Tracheal Intubation Associated Event
DCC	Data Coordinating Center
NIH	National Institute of Health
AE	Adverse Event
SAE	Severe Adverse Event

ABSTRACT

Context: (Background)

Tracheal intubation (TI) is the most common life-saving intervention for resuscitation and stabilization of critically ill neonates in Neonatal Intensive Care Units (NICUs).

Recently, video laryngoscopy (VL) has become available in neonatal clinical practice to allows trainees and frontline providers to perform standard direct airway visualization (i.e., traditional laryngoscopy) while the supervisor can simultaneously view a real-time video displaying what the laryngoscopist is seeing. However, VL associated coaching during TI has not been rigorously evaluated.

Objectives: (primary and important secondary objectives)

To determine if a video laryngoscope assisted real-time coaching intervention can reduce adverse TI associated events and desaturation across academic NICUs.

Study Design:

A quasi-experimental before-after design with educational quality improvement interventions at multiple NICUs with randomly staggered timing for educational intervention (as known as stepped-wedge design) based on the NICU characteristics.

Setting/Participants:

Neonatal ICUs in academic centers across the United States and Canada.

Approximately 10 NICU sites with up to 24 faculty at each site (up to 240 faculty,senior nurse practitioners, physician assistants and respiratory therapists with at least 5 years of clinical neonatology experience).

Approximately 1800 trainees and frontline providers who are qualified to perform tracheal intubation under attendings supervision.

Study Interventions and Measures:

Study intervention is a VL coaching training for site neonatology attendings,nurse practitioners, physician assistants, and respiratory therapists. Each site leader/key educator will be trained remotely by expert co-investigators. Site leaders and key educators will train their attendings, NPs, Pas, and RTs. The quality of VL coaching skills will be verified by randomly auditing 20% of attending providers, NPs, PAs, and RTsat each site for their skill assessment by remote simulation during the transition/post-intervention phase. The timing of VL coaching implementation will be randomly staggered between 6-12 months.

The primary endpoint is the occurrence of adverse tracheal intubation associated events in primary intubations in NICUs. These data points are recorded through the existing observational registry study: NEAR4KIDS CHOP IRB number 09-007253.

The secondary endpoint is the successful completion of all faculty staff training at participating sites, and their performance in the follow up skill evaluation using audio-recording as well as the change in the occurrence of severe oxygen desaturation (absolute oxygen saturation drop >20% from baseline) across 10 academic NICUs

PROTOCOL SYNOPSIS

Study Title	Improving safety and quality of tracheal intubations in neonatal ICUs
Funder	National Institutes of Health (NIH)
Clinical Phase	Not applicable
Study Rationale	Tracheal intubation (TI) is the most common life-saving intervention for resuscitation and stabilization of critically ill neonates in Neonatal Intensive Care Units (NICUs). More than 400,000 neonates are admitted to NICUs in the US annually, and 10%-15% of these infants (>40,000) require TI to sustain life. TI procedures are high risk. Adverse TI associated events are frequent (20%) and severe desaturation during TI (>20% absolute decrease in oxygen saturation) occurs in >50%. Neonatal TIs have unique risks related to difficult airway anatomy (e.g., anterior larynx) and physiology (e.g. limited pulmonary oxygen reserve) requiring prompt procedural success. Provider technical skills, suboptimal TI approach such as underuse of neuromuscular blockade, and communication errors contribute to neonatal TI risks. Previous TI studies indicate that training level and multiple attempts are associated with adverse TI associated events and severe desaturation. Video laryngoscopy (VL) is now available in neonatal practice, but standard direct laryngoscopy technique for TI remains a core clinical skill. Newer VL technology allows trainees and frontline providers to perform standard traditional laryngoscopy while their supervisor can simultaneously view a real time video display of what the trainee/laryngoscopist is actually seeing. This technology enables expert "coaching" by a supervisor for the hazardous TI procedure.
Study Objective(s)	**Primary** • To determine if a novel video laryngoscope assisted real-time coaching intervention can reduce adverse TI associated events across approximately 10 academic NICUs **Secondary** • To determine if a novel video laryngoscope assisted real-time coaching intervention can reduce severe oxygen desaturation (absolute oxygen saturation drop >20% from baseline) across 10 academic NICUs • To determine duration till completion of faculty training and evaluate faculty performance during transition/post-intervention phase

Study Design	A quasi-experimental before-after design with educational quality improvement interventions.
Subject Population key criteria for Inclusion and Exclusion:	**Inclusion Criteria** • Subjects age 22-above • VL coach: Neonatology attending physician position at each neonatal ICU, or Senior trainees who are anticipated to graduate within next 6 months to become neonatology attending physicians, nurse practitioners with over 5 years of clinical experience, physician assistants and respiratory therapists with over 5 years of clinical neonatology experience. • VL coach receivers: Trainees (medical students, residents, fellows except those graduating within next 6 months) and frontline providers (nurse practitioners, hospitalists, physician assistants, respiratory therapists, others who perform tracheal intubations under attending physicians' supervision): **Exclusion Criteria** • None
Number Of Subjects	Total Number of Subjects: 240 faculty across approximately 10 NICUs, Total Number of Sites: 10 sites
Study Duration	Each subject's participation will last for 2 years The entire study is expected to last 2 years
Study Phases **Screening** **Study Treatment** **Follow-Up**	This study have 3 phases. Pre-intervention phase: evaluation of tracheal intubation with or without video laryngoscopy use as a baseline Transition phase: From initiation of remote site leader training ('train the trainer' session) until the pre-defined site-level uptake (>70% VL use for trainee/frontline TIs per month). Post-intervention phase: We will continue to capture all TIs after VL use meets criteria >70%.
Efficacy Evaluations	Occurrence of adverse TIAEs
Safety Evaluations	The occurrence of adverse TIAEs, desaturation, and multiple attempts
Statistical And Analytic Plan	For primary and secondary endpoint (adverse TIAEs, severe desaturation rate), the event rates will be compared between pre-intervention phase and post-intervention phase. We plan to censor the transition phase for the primary analysis. For secondary endpoint (duration till completion of faculty training and faculty performance during transition/post-intervention phase),

	a summary statistics will be developed and will be compared against effect size (decrease in adverse TIAE rates) and VL use.
DATA AND SAFETY MONITORING PLAN	The plan for tracheal intubation data accuracy and safety is under NEAR4KIDS protocol CHOP IRB number 09-007253. Regarding the neonatology faculty training data, data manager will be in charge for the accuracy, quality and safety of the data. Data will be kept in REDCap database with only limited access to PI, Data Coordinator and Data manager.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Screening/ Training**	**Follow up**
Visit Number	**1**	**2**
Study Days		
Informed Consent	X	
Review Inclusion/Exclusion Criteria	X	
Demographics	X	X
Training by site leader	X	
Remote simulation for skill assessment		

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Tracheal intubation (TI) is the most common life-saving intervention for resuscitation and stabilization of critically ill neonates in Neonatal Intensive Care Units (NICUs). More than 400,000 neonates are admitted to NICUs in the US annually, and 10%-15% of these infants (>40,000) require TI to sustain life. TI procedures are high risk. Adverse TI associated events are frequent (20%) and severe desaturation during TI (>20% absolute decrease in oxygen saturation) occurs in >50%. Neonatal TIs have unique risks related to difficult airway anatomy (e.g., anterior larynx) and physiology (e.g. limited pulmonary oxygen reserve) requiring prompt procedural success. Provider technical skills, suboptimal TI approach such as underuse of neuromuscular blockade, and communication errors contribute to neonatal TI risks.

Previous TI studies indicate that training level and multiple attempts are associated with adverse TI associated events and severe desaturation. Video laryngoscopy (VL) is now available in neonatal practice, but standard direct laryngoscopy technique for TI remains a core clinical skill. Newer VL technology allows trainees and frontline providers to perform standard traditional laryngoscopy while their supervisor can simultaneously view a real time video display of what the trainee/laryngoscopist is actually seeing. This technology enables expert "coaching" by a supervisor for the hazardous TI procedure.

1.2 Name and Description of Investigational Product or Intervention

Novel video laryngoscope assisted real-time coaching intervention can reduce adverse TI associated events. All neonatology attendings, NPs, PAs and RTs will be trained for video laryngoscope real-time coaching education and 20% of them will be assessed by remote simulation.

1.3 Findings from Non-Clinical and Clinical Studies

1.3.1 Clinical Studies in Adults

Many adult studies on urgent endotracheal intubations in emergency departments and adult medical intensive care units have demonstrated the utility of video laryngoscopy over direct laryngoscopy to achieve higher first-attempt and ultimate success rates for tracheal intubation. (Reference 1-5) Direct laryngoscopy requires that the laryngoscope operator align the oral, pharyngeal, and laryngeal axes to obtain a clear view of the glottis inlet. In contrast, manipulation of a video laryngoscopy does not require alignment of these 3 axes in order to achieve a view of the glottic inlet on a video screen due to a magnified and panoramic view projected from a light source and micro-video camera mounted on the end third of the laryngoscope blade. (Reference 6)

A recently published prospective randomized control study in French ICUs showed video laryngoscopy use without appropriate training was not associated with higher first attempt success rate (Reference 7). This study demonstrated that video laryngoscopy is a different technique. Therefore we plan to use video laryngoscopy as a traditional laryngoscopy device

and as a method to provide necessary information to supervisors to coach standard tracheal intubation.

1.3.2 Clinical Studies in Children

A recent meta-analysis evaluating video laryngoscopy in operating suites revealed equivocal results. (Reference 8) A retrospective study analysis from a large pediatric ICU and ED patients showed the use of video laryngoscopy is associated with a decreased occurrence of adverse tracheal intubation associated events, especially in esophageal intubations. (Reference 9)

Recent studies from neonatal ICUs showed substantial safety gaps in tracheal intubation success rates, adverse tracheal intubation associated events rate and multiple attempt rates. (Reference 9). A report from our collaborating sites showed the use of video laryngoscopy improved the success rate during trainee's learning process. (Reference 10)

1.4 Relevant Literature and Data

As described above, there are large body of evidence to support video laryngoscopy use in operating and non-operating environment. A limited number of literature in pediatrics and neonatal fields demonstrated that the use of video laryngoscopy is helpful in improving procedural success. There is evidence that the use of video laryngoscopy is becoming more common across pediatric practice. (Reference 9)

1.5 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, 21 CFR Parts 50, 54, and 56.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to determine the efficacy of video coaching training for neonatology attending providers on tracheal intubation procedural outcomes in neonatal ICUs.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the whether the video coaching skill training for neonatology attendings, NPs, PAs, and RTs reduces the occurrence of adverse tracheal intubation associated events among all tracheal intubations in neonatal ICUs over 2 years before and after intervention.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Determine if video coaching training is feasible to all neonatology attending physicians, NPs, PAs and RTs using train the trainer approach with a remote simulation
- Determine the video coaching skill competency among neonatology attending physicians, NPs, PAs and RTs who completed the training using a remote simulation

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Screening Phase

Our study intervention subjects are neonatology attending physicians, nurse practitioners, physician assistants and respiratory therapists. They will be identified by each site leader (also a neonatology attending physician) participating in this multicenter study.

3.1.2 Study Treatment Phase (start of the study intervention)

Pre-intervention phase: evaluation of tracheal intubation without video laryngoscopy coaching language use as a baseline. Each site tracheal intubation outcomes (adverse tracheal intubation associated events rate, first attempt success rate) will be documented.

3.1.3 Transition Phase

Transition phase: From initiation of remote site leader training ('train the trainer' session) between the overall PI and site leaders, until the pre-defined site-level uptake (>70% VL use for trainee/frontline TIs per month). The tracheal intubation data during this period will be censored for a primary analysis, and will be used for secondary analyses.

3.1.4 Follow-up Phase

Post-intervention phase: We will continue to capture all TIs after VL use meets criteria >70% for up to 2 years at each participating neonatal ICU.

3.2 Allocation to Treatment Groups and Blinding

All neonatal attending providers,nurse practitioners, physician assistants and respiratory therapists will receive a video coaching training by a site leader if a written consent is obtained. There is no allocation of treatment groups.

After their initial video coaching training, 20% of the neonatology attending physicians, nurse practitioners, physician assistants and respiratory therapists will be randomly chosen to participate in a follow up skill evaluation with a remote simulation. This 20% will be chosen by DCC to provide a random number for a given number of neonatology attendings, nurse practitioners, physician assistants and respiratory therapists who participated in the initial training. Each participated neonatologist, NP, PA and RT will be assigned a number based on the order of participation to the training. For example, if there are 20 neonatologists participated in the initial training in one neonatal ICU, 4 of them will be

invited for remote simulation based on a 4 random numbers (between 1-20) provided by DCC for this site.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject (neonatologist attendings, NPs, PAs and RTs) will be up to 18 months, the longest. After their initial video coaching training, 20% of the attending physicians, NPs, PAs, and RTs will be randomly chosen to participate in a follow up skill evaluation with a remote simulation.

The study duration per subject (nurse practitioners, hospitalists, physician assistants, respiratory therapists, others who perform tracheal intubations under attending physicians' supervision) will be up to 24 months, the longest. They may be approached for study consents before their NICU rotation.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at approximately 10 investigative sites in the United States and Canada.

Recruitment will stop when a total of 2 years of study participation at the site has been completed.

We plan to recruit all neonatology attending physicians, nurse practitioners, physician assistants and respiratory therapists practicing in participating sites. We anticipate this will be approximately 240 providers.

We plan to recruit all trainees and frontline providers who are qualified to perform tracheal intubation under attendings supervision. We anticipate this will be approximately 1800 providers.

3.4 Study Population

3.4.1 Inclusion Criteria

Two types of study population exist in this protocol.

1) VL coach: Neonatology attending physician position at each neonatal ICU, or Senior trainees who are anticipated to graduate within next 6 months to become neonatology attending physicians, nurse practitioners with over 5 years of clinical experience, physician assistants, and respiratory therapists with over 5 years of clinical neonatology experience.

2) VL coach receivers: Trainees (medical students, residents, fellows except those graduating within next 6 months) and frontline providers (nurse practitioners, hospitalists, physician assistants, respiratory therapists, others who perform tracheal intubations under attending physicians' supervision):

3.4.2 Exclusion Criteria

- None

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening/Initial training Visit

- Informed Consent (neonatology attending providers, NPs, PAs and RTs)
    - A written informed consent will be obtained by all participating neonatology attending providers, nurse practitioners, physician assistants and respiratory therapists at each site.
    - A verbal informed consent will be obtained by all participating trainees and frontline providers.
- Demographic information (neonatology attending providers, NPs, PAs, RTs, trainees and frontline providers)
    - After informed consent is obtained, demographics information outlined in section 5.1.1. will be obtained.
- Initial video laryngoscopy coaching training to neonatology attending providers by a site leader

  Each neonatology attending provider, NP, PA and RT will receive a video laryngoscopy coaching training using a C-MAC video laryngoscope and an intubation training manikin available at each site by a site leader. During the training, site leader will act as a trainee confederate, and each neonatology attending provider, NP, PA, and RT will be trained to coach a trainee utilizing video images from C-MAC video laryngoscope and a cognitive aid with standardized language in a laminated card. This training part typically takes approximately 15-30 minutes including consenting process.

  Each site leader will be trained by PI or PI's designee using remote simulation. In this remote simulation, each site leader will coach an actor at CHOP using a profile video image and C-MAC video laryngoscopy image through CHOP approved video conferencing software. A standardized language will be taught to each site leader with a cognitive aid (laminated card).

4.2 Follow Up Phase

4.2.1 Visit 1

Selected neonatology attendings, NPs, PAs and RTs will participate in a remote simulation session.

A follow up of simple demographic information will be collected.

Follow up skill evaluation utilizes a remote simulation. Selected neonatology attendings, NPs, PAs and RTs will remotely coach an actor at the Children's Hospital of Philadelphia using the C-MAC video laryngoscope images and a standardized language. (A repeat of initial coaching training). Their coaching skills regarding how they used video laryngoscope images and coaching languages appropriately will be assessed by analyzing audio-recorded communication between an actor at the Children's Hospital of Philadelphia and site neonatology attendings,NPs, PAs, and RTs.

Trainees will be coached as usual during their supervised intubation events and the results of these events as described under CHOP IRB# 09-007253 will be used as part of the analysis.

4.3 Subject Completion/Withdrawal

Subjects (neonatology attending providers, NPs, PAs, RTs, trainees and frontline providers) may withdraw from the study at any time without prejudice to their practice. However, overall tracheal intubation safety practice data (rate of adverse tracheal intubation associated events) at each site will be collected throughout regardless of the provider's status under CHOP IRB# 09-007253. Participating sites may also be discontinued from the study at the discretion of the Principal Investigator for lack of adherence of site leader to educate neonatologists.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Demographic Data Collection

Brief demographic data of each neonatology attending, NP, PA, and RT participant (subject) will be obtained. These data points are listed below:

- Age
- Gender
- Years of experience as neonatology attending
- Years of experience in Neonatology as a Nurse Practitioner
- Years of experience in Neonatology as a Respiratory Therapist
- Years of experience in Neonatology as a PA
- Year of neonatology fellowship completion
- Year of completed NP training
- Year of completed RT training
- Year of completed PA training
- Experience in video laryngoscopy use

- Months of experience in video laryngoscopy use

Brief demographic data of each neonatology trainees and frontline providers will be obtained. These data points are listed below.

- Age
- Gender
- Training level
- Training experience (type and length of residency training, type and length of fellowship training)
- Training experience before joining post-graduate education in the United States
- Experience in laryngoscopy use (number of previous intubation in patients)
- Confidence in laryngoscopy use (Likert scale)

5.1.2 Other Evaluations, Measures

A remote simulation session will be held to assess neonatology attending,NP, PA, and RT (subject)'s coaching skills. This session will be conducted between the Children's Hospital of Philadelphia and each participating site for 20% of randomly selected neonatologists. The session will be video and audio recorded. The session will be transcribed without any identifiable information, and the original recording video and audio information will be destroyed once the audio is transcribed and annotation is made for each step of tracheal intubation. This transcribed information will be assessed for the accuracy of the coaching language during video laryngoscopy tracheal intubation by trainees. Each subject's score will not be shared with their local site leader, and only summary statistics (mean and standard deviation or median and interquartile range) will be shared.

5.2 Efficacy Evaluations

5.2.1 Diagnostic Tests, Scales, Measures, etc.

The endpoint data will be obtained from the study database (NEAR4NEOS) under "Observation of Multi-center Quality Improvement Project: Improving Safety and Quality of Tracheal Intubation Practice in Pediatric ICUs" (At CHOP, the IRB study number is#09-007253).. The NEAR4NEOS only contains limited dataset with only not readily identifiable data. For each tracheal intubation, involved neonatology attending and trainee or frontline providers will be recorded with subject ID by site team, and therefore the study team will not be able to identify provider subjects. All participating sites have CHOP IRB study #7253 and they will have outcome data available.

Study provider participation in tracheal intubation events will be captured by utilizing the existing NEAR4NEOS REDCap data entry system by adding two data points: provider ID for coach and trainee/frontline providers who received coaching. Specifically provider ID for coach and trainee or frontline providers who received coaching will be recorded for each tracheal intubation encounter. No readily identifiable data related to the patients will be extracted. This limited dataset including provider ID for coach and trainees who received coaching will be extracted by Data Coordinating Center for NEAR4NEOS (the current study coordinator and study PI serves as the core members of Data Coordinating Center for NEAR4NEOS). The dataset will be password protected. Also the study coordinator and PI

will obtain study ID demographics dataset from each participating center (no PHI will be contained in this dataset), and merge these dataset by linking subject IDs. The Merged dataset will not contain any PHIs of the subjects.

5.3 Safety Evaluation

Since the study intervention is an educational intervention to faculty provider, and provider will continue to perform current practice (direct laryngoscopy with the same blades, as opposed to learning new technique using video laryngoscopy), there is no considerable potential harm associated with intervention.

The primary study endpoint is the procedural safety outcome, and we will continue to monitor this outcome throughout the educational intervention and post-intervention phase.

Each site will receive aggregate data feedback periodically for benchmark and quality improvement purposes.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint will be the change in the occurrence of adverse tracheal intubation associated events among all primary tracheal intubations in neonatal ICUs between pre-intervention phase and post-intervention phase.

Secondary endpoints will include the following:

- The change in the occurrence of severe oxygen desaturation (absolute oxygen saturation drop >20% from baseline) across 10 academic NICUs
- The duration to complete neonatology faculty training from the initial train the trainer session for site leaders.
- The coaching skills of randomly selected faculty after initial training at each site

6.2 Statistical Methods

6.2.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for normally distributed continuous variables such as age and median and interquartile range for non-normally distributed continuous variables, and percentages for categorical variables such as gender).

6.2.2 Efficacy Analysis

The primary efficacy endpoint will be the change in the occurrence of adverse tracheal intubation associated events among all primary tracheal intubations in neonatal ICUs between pre-intervention phase and post-intervention phase.

Secondary endpoints will include the change in the occurrence of severe desaturation (absolute oxygen saturation drop >20% from baseline) between pre-intervention phase and post-intervention phase.

6.2.3 Safety Analysis

All primary tracheal intubation data at each site will be included in the safety analysis, regardless of their neonatology attending provider training completion. The frequencies of AEs by type, body system, severity and relationship to study drug will be summarized. SAEs (if any) will be described in detail.

AE incidence will be summarized along with the corresponding exact binomial 95% two-sided confidence intervals.

6.3 Sample Size and Power

For the primary outcome of the occurrence of TIAEs, we plan to obtain a data from ongoing observational study database (NEAR4NEOS) for a total sample size of 2,900 tracheal intubations:145 tracheal intubations during pre-intervention and 145 tracheal intubations during post-intervention phase per site from 10 sites over 2 years (a total of 1450 tracheal intubations before the intervention and 1450 intubations after the intervention).We anticipate a decrease of adverse TIAEs from 20% to 16 % (absolute risk reduction of 4%, relative risk reduction of 20%). Note this estimate is adjusted to account for site-level clustering. Also the number of tracheal intubations will be variant across the sites. Since this study is an educational intervention and pre-post design, we will include all tracheal intubation data during the 2 year study period.

6.4 Interim Analysis.

No stopping rule is applied. Each site performance in tracheal intubation safety and video laryngoscopy use will be reported in aggregate as benchmark data as a part of quality improvement activity during the study period.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

20% of initially trained neonatology attendings, NPs, PAs and RTs (subjects) will be remotely assessed for their coaching skills. A random number will be generated through www.random.org or Stata (STATA Corp, College Station, TX) at the The Children's Hospital of Philadelphia using a total number of neonatologists at each relying site. The number will be randomly selected for 20% (i.e., if there were 20 neonatologists, NPs PAs, and RTs for a given site, 4 numbers from 1-20 will be randomly selected). Each site leader will identify the neonatologists, NPs, PAs, and RTs who participated in the initial training in the order (4^{th}, 16^{th}, 9^{th}, and 2^{nd}, for example) using their initial enrollment log.

8.2 Data Collection and Management

1. Confidentiality.

- Each site will generate a master list of neonatology attending providers, NPs, PAs, and RTs (subjects) being trained using password-protected Excel files. This master list will contain only their name and date of training, and the training order at each site which will be used as subject ID number. The master list should be kept on a separate computer or in a locked file cabinet. This local master list will not be shared with other sites to ensure confidentiality.

- Scores of each site neonatologists, NPs, PAs, and RTs who participated in follow up assessment remote simulation will be kept confidential at The Children's Hospital of Philadelphia and only a summary statistics will be shared with each site leader.

- Relying sites will enter data in the password protected CHOP REDCap database.

2. Security. A copy of this password-protected Excel file will be kept under hospital protected server at each site.

3. Anonymization, de-identification or destruction. This master list will be destroyed upon completion of data collection.

4. The clinical procedural outcome data (adverse TIAE rate) will be obtained from on-going QI research database: NEAR4NEOS (At CHOP, the IRB study number is#09-007253). A limited dataset will be downloaded for the primary and secondary analyses. Except the date of procedure, there is no protected health information of patients is included in this database.

5. This plan is consistent with CHOP Policy A-3-6: Acceptable Use of Technology Resources

8.3 Confidentiality

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates).

8.4 Regulatory and Ethical Considerations

8.4.1 Risk Assessment

Risks for both neonatology attending providers, NPs, PAs, RTs and trainees/frontline providers are not greater than minimal risk, limited to a potential breach of confidentiality. The study design and execution will minimize the risks of harm as described in section 7.2.

In addition, an independent Data Safety and Monitoring Board (DSMB) will be developed with 3-6 experts in neonatology, in human subject protection and regulatory oversight, statistics, and patient safety. The members of DSMB must be independent from study and educational activities involved in this study. The DSMB is required to discuss the study (either face to face close meeting or private conference call without investigators) at least twice a year and review the report independently sent from biostatistician to monitor the safety data. The DSMB may request additional reports from PI for overall activity progress at participating sites.
The Data Safety Monitoring Board (DSMB) will independently review the data related TI associated event rates (primary outcome) and secondary outcomes: proportion of severe desaturation, severe adverse TI associated events, and proportion of TIs required > 2 attempts, to evaluate for negative effects on these outcomes at least every 6 months. If the intervention has statistically significant negative effect on primary or secondary outcomes for two consecutive analyses, DSMB may inform each site to temporarily hold the educational interventions and request to review the process.

8.4.2 Potential Benefits of Trial Participation

The potential direct benefit for the faculty study participation is to receive a standardized education to coach trainee or frontline providers' tracheal intubation procedure using a video laryngoscopy.

The indirect benefits will be the participation in scientific evaluation of the use of coaching language in neonatal tracheal intubation using video laryngoscope. Since this video laryngoscope use is becoming standard of care in many institutions, the evaluation of the impact of standard coaching language will be of merit to the neonatal community.

For the trainees/frontline providers, their direct benefit will be that they may receive clear coaching during tracheal intubation procedure.

The indirect benefits will be similar: the participation in scientific evaluation of the use of coaching language in neonatal tracheal intubation using video laryngoscope.

8.4.3 Risk-Benefit Assessment

The risk of this study participation is limited to breach in confidentiality. Each faculty's assessment will be strictly kept confidential through follow up assessment with remote

simulation. No readily identifiable data related to the patients will be extracted.. Therefore this risk is minimal.

The potential benefit for the faculty study participation is to receive a standardized education to coach trainee or frontline providers' tracheal intubation procedure using a video laryngoscopy.

Given the risk is minimal with a potential benefit, the study participation is justified.

8.5 Recruitment Strategy

Each site leader will communicate with their colleague neonatology attending providers, NPs, PAs, and RTs through electronic mails, their local conference, or meetings.

Each site data coordinator will communicate with trainees/frontline providers through electronic mails, their local conference, or meetings.

8.6 Informed Consent/Assent and HIPAA Authorization

A written informed consent will be obtained from each participating neonatology attending providers,NPs, PAs, and RTs. No readily identifiable data related to the patients will be extracted.. HIPAA does not apply to this study as no health information about the subjects (attendings, NPs, PAs, RTs and trainees) will be collected.

A verbal consent will be requested for trainee/frontline providers.

A verbal consent is requested for trainees and frontline providers because

(1) The study procedures are not greater than minimal risk
(2) The procedures do not require written consent outside of the research context.

8.6.1 Waiver of Consent

Not applicable

8.6.2 Waiver of Assent

Not applicable

8.6.3 Waiver of HIPAA Authorization

Request for a waiver of HIPAA authorization for the transfer of a limited data set from IRB study #7253 to the current protocol.

8.7 Payment to Subjects/Families

8.7.1 Gifts

Neonatology attending providers, NPs, PAs and RTs who are invited to participate in a follow up skill assessment through remote simulation will be given 20 dollar gift card as a token of appreciation.

9 PUBLICATION

The CHOP investigator (Principal Investigator) will have access to the complete data (both neonatology attendings, NPs, PAs, RTs and trainees/frontline providers).

We will analyze the data based on our primary and secondary endpoints, and will present the data in peer review publications regardless of the result.

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APPENDIX I

COGNITIVE AID

SITUATION	COACHING LANGUAGE
Start laryngoscopy attempt	**"Are you ready?"** **'Start"**
Laryngoscope too **deep**	**"Pull back slowly"**
Laryngoscope too **shallow**	**"Advance the blade"**
Laryngoscope too left (tongue visible on right)	**"Move blade to YOUR RIGHT"**
Rocking motion	**"Don't rock" " Pull up and away toward the direction of the handle"**
Floppy epiglottis needs to be lifted up	**"Lift up the epiglottis"**
Seeing glottic opening and ETT to be inserted	**"Do you see the cords?"** **"Insert ETT"**
Check ETT placement with ETCO2	**Simple command is sufficient** **"Check End-tidal CO2"**
Spending long time with desaturation	**"Come Out"**
Bag mask ventilation needs to be started for desaturation	**"bag him/her up"**

APPENDIX II

C-MAC Video Laryngoscope coaching training

Neonatology Attending, NP, PA and RT Training Checklist

Center: _____

Date: _____ **Subject ID: _____**

Trainer: _____

- ☐ State rationale to use video laryngoscope as a primary coaching device
- ☐ C-MAC orientation (how to turn on the switch, how to record and replay, now to change the brightness)
- ☐ Master Coaching language (Hands-on simulation with an actor)
- ☐ Become aware of the follow up evaluation using remote simulation (20% of attendings)