JOHNS HOPKINS ALL CHILDREN'S HOSPITAL

Neonatal Tracheal Intubation Clinical Pathway

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Rationale

Neonatal tracheal intubation (TI) is one of the most common procedures performed by neonatologists, however, the procedure is difficult and high risk. Neonates who endure the procedure often experience adverse events, including bradycardia and severe oxygen desaturations. Because of low first attempt success rates, neonates are often subjected to multiple intubation attempts before the endotracheal tube is successfully placed [1]. Multiple intubation attempts have been associated with adverse events such as intraventricular hemorrhage [2], pneumothorax, direct airway trauma, cardiorespiratory arrest and death [3] [4]. Interventions to improve patient safety during intubation have been proposed. [5]Simulation based training has become a safe alternative to train pediatric practitioners on the procedure in view of the current decrease in patient intubation opportunities. Standardizing training and competency assessment among all pediatric trainees and providers may improve patient safety by decreasing number of intubation attempts and adverse outcomes [6] .

Background / Published Data and Levels of Evidence

1. Endotracheal intubation safety

   Performing a successful neonatal TI is task that involves many factors that are associated with the performer (competency and expertise), practice characteristics (medications and equipment), patient (size, age physiologic stability and airway anatomy) and system characteristics (safety culture and staffing model). While acquiring the technical skills needed to perform neonatal intubation is critical, building a system to support safety is equally important [1]. The physician training level has been shown to impact the neonatal tracheal intubation success rates on first intubation attempt [7] [8]. Data from the National Emergency Airway Registry including 11 centers in north America Asia and Europe identified that among physicians, the first-attempt success rates differed across physician training levels (60% neonatologist, 53% fellow and 23% resident; p <0.001) [7] . At the 2019 report pediatric residents attempted 15% of NICU and 2% of DR intubations, however at the 2021 report first attempts were performed by residents 30% of the time (61% by fellows). Neonatal endotracheal intubation is an activity described by the American Board of Pediatrics as Entrustable Professional Activity for a general pediatrician [9]. The success rate of first attempt among advanced practice practitioners or respiratory therapists was not reported, despite the fact that in the NICU setting the most common first airway providers were APPs (38%), followed by NPM fellows (30%), pediatric residents (15%) and neonatologists (7%). In the DR neonatal fellows were the

most common first airway providers (49%). Respiratory therapists were the first providers 2% of the time in the NICU and 1% of the time in the DR [8]. There is still limited available information regarding rates of success of endotracheal intubation among respiratory therapists, nurse practitioners or any other professional category.

Adverse events during endotracheal intubation (TIAE) have been classified as severe (cardiac arrest, esophageal intubation with delayed recognition, emesis with witnessed aspiration, hypotension requiring intervention, laryngospasm, malignant hyperthermia, pneumothorax/pneumomediastinum, direct airway injury) or non-severe (mainstem bronchial intubation, esophageal intubation with immediate recognition, emesis without aspiration, hypertension requiring therapy, epistaxis, lip trauma, gum or oral trauma, medication error, dysrhythmia, pain/agitation requiring extra medication and causing delay in intubation) [3]. The most common TIAE is severe desaturation (51%) [3] . In 2 prospective observational studies, factors associated with less TIAE included use of muscle relaxants and first intubation attempt success, whereas more TIAEs were noted with greater intubation urgency and number of intubation attempts. In both studies gestational age, birth weight and gender were not associated with any trends in occurrence of TIAEs [4 10]. Recent data with 2,608 tracheal intubations found no statistically significant difference in TIAEs comparing physician level of training (resident 22%, fellow 20%, and attending 25%; p = 0.34), however desaturation occurred more frequently with residents (60%), compared to fellows and attendings (46 and 53%; p < 0.001) [7].

One retrospective study of 308 infants with a birth weight (BW) lower than 750 grams who were intubated in the NICU, found an increased number of intubation attempts in the first four days of life to be associated with severe IVH (univariable and multivariable analysis adjusted for other significant covariates). Infants with BW <750 grams who had severe IVH also were significantly more likely to have had greater than 3 intubation attempts compared with those with mild or no IVH [OR 27.8, 95% CI 2.963-261.117 P=0.004]. In addition, for all VLBW (1500 grams) infants who were intubated only in the DR, those with mild or no IVH had significantly fewer intubation, compared with those with severe IVH [Multivariate analysis OR1.448 95% CI 1.091-1.923, p0.010]. The mean attempts were 2.99 in the mild or no IVH group and 3.95 in the severe IVH group [2].

Another retrospective study (n=88 ELBW) evaluating the association between successful intubation on the first attempt for ELBW infants within the first 10 minutes of life and the neurodevelopment outcomes identified that death or neurodevelopmental impairment occurred in 29% of infants intubated on the first attempt, compared with 53% of infants that required multiple attempts, adjusted odds ratio 0.4 (95% confidence interval 0.1 to 1.0), P<0.05[7].

Interventions to improve patient safety during intubation in the NICU have been reported. Intubation timeout and checklist, premedication for endotracheal intubation algorithm, intubation computerized provider order entry have resulted in 10% absolute reduction in TIAEs in a quality report. Implementation of a standardized checklist for intubation made the greatest impact [5]. From the national Emergency Airway Registry for Neonates study, practices independently associated with reduced TIAEs in the NICU included video laryngoscope (adjusted odds ratio 0.46, 95% confidence interval 0.28-

0.73) and paralytic premedication (adjusted odds ratio 0.38, 95% confidence interval 0.25-0.57) [8].

2. Endotracheal intubation procedure

Detailed description on the indications, necessary equipment and technique are available at the 8th edition of the Textbook of Neonatal Resuscitation [11]

Additional visual endotracheal intubation technique resources are available on the video https://www.youtube.com/watch?v=lGTaA_UdIXw&t=11s [12]

According to the latest edition of the Neonatal Resuscitation Textbook [13], the intubation procedure should ideally be performed under the following standards:

- The appropriate laryngoscope blade for a term newborn is size No. 1. The correct blade for a preterm newborn is size No. 0 (size No. 00 *optional* for extremely preterm newborn).
- The intubation procedure ideally should be completed within 30 seconds. Effective teamwork is required to perform this procedure quickly.
- Demonstrating exhaled carbon dioxide (CO_2) and observing a rapidly increasing heart rate are the primary methods of confirming endotracheal tube insertion within the trachea.
- Endotracheal tube insertion depth can be estimated using the nasal-tragus length (NTL) or the baby's gestational age; however, the depth estimate should be confirmed by auscultating equal breath sounds. If the tube is to remain in place, obtain a chest x-ray for final confirmation.

3. Sedative premedication uses before intubation

According to the NRP prior to a non-emergent intubation in the NICU, premedication is recommended because it alleviates pain, decreases the number of attempts needed to complete the procedure, and minimizes the potential for intubation related airway trauma. When emergency intubation is performed as part of resuscitation, there is generally insufficient time or vascular access to administer sedative premedication [13].

"An ideal strategy for premedication for intubation eliminates the pain, discomfort, and physiologic abnormalities of the procedure, helps to carry out intubation expeditiously, minimizes the chances for traumatic injury to the newborn and has no adverse effects. An ideal approach would be to administer supplemental oxygen, then a vagolytic agent (prevent bradycardia during intubation and decrease bronchial and salivary secretions), followed by analgesic **and/or** hypnotic medications before infusion of a muscle relaxant" [14] [15].

An ideal analgesic agent would have a rapid onset, be of short duration and no adverse effects on respiratory mechanics, and possess predicable pharmacokinetic properties. None of the currently available agents fit this profile. Fentanyl is the most frequently used synthetic opioid in neonates. It is preferable to morphine for pain control for intubation because of a more rapid onset of action. Its impact on cerebral and systemic hemodynamics was studied with a short-term infusion in 15 preterm infants and there were no significant changes in the systemic or cerebral perfusion or pressure. Chest wall rigidity, an adverse effect of fentanyl use, can be reduced by slow administration and can be treated with either naloxone or muscle relaxants [16].

Midazolam can cause hypotension in preterm and term infants, decreased cerebral bold flow velocity in premature infants and prolonged half-life in premature infants. The AAP publication recommends that midazolam should not be used in preterm infants but can be considered in older infants as part of the premedication sequence for elective intubation in the NICU [17].

Muscle relaxant can be avoided in newborn infants that are not vigorous, for example those with an extremely low birth weight, those that are severely asphyxiated and those affected by muscular disorders. Succinylcholine, the only depolarizing agent in clinical use, blocks neuromuscular transmission by binding to the acetylcholine receptor of the muscle membrane and depolarizing the membrane. It has rapid onset and short duration of action and it has been studied in premature infants without adverse events, however need caution [18] [19]. Non-depolarizing agents compete with acetylcholine for receptors on the motor endplate but do not result in depolarization of the membrane. Rocuronium is a metabolic derivative of vecuronium and has quicker onset to paralysis and shorter duration of action compared with vecuronium [17].

Premedication regimens:

a) Atropine (0.01–0.02 mg/kg) plus fentanyl (2 mcg/kg over at least five minutes) plus succinylcholine (suxamethonium) (2 mg/kg) **or** rocuronium (0.5–1 mg/457 kg) immediately prior to intubation. Moderate quality of evidence. Conditional recommendation.
b) Hemodynamically stable infants with a postconceptional age of >32 weeks: atropine (0.01–0.02 mg/kg) plus fentanyl (2 mcg/kg over at least five minutes) plus midazolam (0.1 mg/kg). Low quality of evidence. Conditional recommendation [20]

4. Video Laryngoscopy

The updated Cochrane systematic review included eight studies, which provided data on 759 intubation attempts in neonates who were undergoing endotracheal intubation in national and international hospitals. Different video laryngoscopy devices (including C-MAC, Airtraq, and Glidescope) were used in the studies. For the primary outcomes; video laryngoscopy **may not reduce the time required for successful intubation when compared with direct laryngoscopy** (mean difference [MD] 0.74, 95% confidence interval [CI] -0.19 to 1.67; 5 studies; 505 intubations; low-certainty evidence). Video laryngoscopy **may result in fewer intubation attempts** (MD -0.08, 95% CI -0.15 to 0.00; 6 studies; 659 intubations; low-certainty evidence). Video laryngoscopy **may increase the success of intubation at the first attempt** (risk ratio [RR] 1.24, 95% CI 1.13 to 1.37; risk difference [RD] 0.14, 95% CI 0.08 to 0.20; number needed to treat for an additional beneficial outcome [NNTB] 7, 95% CI 5 to 13; 8 studies; 759 intubation attempts; low-certainty evidence). For the secondary outcomes; the evidence is very uncertain about the effect of video laryngoscopy on desaturation or bradycardia episodes, or both, during intubation (RR 0.94, 95% CI 0.38 to 2.30; 3 studies; 343 intubations; very-low certainty evidence). Video laryngoscopy **may result in little to no difference in the lowest oxygen saturations during intubation compared with direct laryngoscopy** (MD -0.76, 95% CI -5.74 to 4.23; 2 studies; 359 intubations; low-certainty evidence). Video laryngoscopy **likely results in a slight reduction in the incidence of airway trauma during intubation attempts compared with direct laryngoscopy** (RR 0.21, 95% CI 0.05 to 0.79; RD -0.04, 95% CI -

0.07 to -0.01; NNTB 25, 95% CI 14 to 100; 5 studies; 467 intubations; moderate-certainty evidence). **There were no data available on other adverse effects of video laryngoscopy.**

Video laryngoscopy may increase the success of intubation on the first attempt and may result in fewer intubation attempts, but may not reduce the time required for successful intubation (low-certainty evidence). Video laryngoscopy likely results in a reduced incidence of airway-related adverse effects (moderate-certainty evidence). These results suggest that video laryngoscopy may be more effective and potentially reduce harm when compared to direct laryngoscopy for endotracheal intubation in neonates.[21]

An international, multi-center, single-blinded, non-inferiority, randomized controlled trial (RCT) compared tracheal intubation using either direct laryngoscopy or video laryngoscopy with supplementary oxygen of 1 L/kg. Intubations occurred in the operating room after induction of anesthesia. This study included 244 infants in the intention to treat analysis with an average postmenstrual age on day of intubation of 44 weeks in the direct laryngoscopy group and 46 weeks in the video laryngoscopy group. The primary outcome in the study was first-attempt tracheal intubation success. Analysis of the results demonstrated that the use of video laryngoscopy is associate with a significantly higher first-pass success rate (108 [89.3%; 95%CI 83.7 to 94.8] of 121 patients when compared to direct laryngoscopy (97 [78.9%; 71.6 to 86.1] of 123 patients) with an adjusted absolute risk difference of 9.5% (0.8 to 18.1; p=0.0333). The rate of complications did not differ between groups nor did the number of attempts, however the complication rate increased with the number of attempts [22].

5. Oxygen support during procedure

An RCT comparing use of nasal nigh-flow nasal therapy with supplemental oxygen in neonates undergoing oral endotracheal intubation at 2 Australian tertiary NICUs (N=251 intubations in 202 infants) concluded that use of nasal high flow therapy improved the likelihood of successful intubation in the first attempt without physiologic instability in the infant (62 of 124 intubations (50.0%) in the high-flow group and in 40 of 127 intubations (31.5%) in the standard-care group (adjusted risk difference, 17.6 percentage points; 95% confidence interval [CI], 6.0 to 29.2), for a number needed to treat of 6 (95% CI, 4 to 17) for 1 infant to benefit[23].

6. Intubation practices among trainees

The exposure of pediatric trainees and neonatal providers to neonatal intubation has become less frequent than in previous eras [24]. Factors associated with different approach to delivery room management of meconium exposed infants from NRP guidelines [11], increased use of non-invasive ventilation to support premature infants [25] and limited months of pediatric residents in NICU rotations have decreased the procedural opportunities for trainees to achieve intubation competency [26].

Intubation performance by pediatric trainees has been reported to be suboptimal [27]. In a prospective multicenter evaluation attending physicians and 3rd year neonatal fellows had the highest success rates; 72.2% and 70%, respectively. Pediatric residents had the lowest success rate (20.3%). The median duration of attempts was 30 s for residents, 25 s for fellows, and 20 s for neonatal attending physicians. The most common reasons cited for failure were inability to visualize the vocal cords (25%), patient decompensation (desaturation/bradycardia, 41%) and

esophageal TI (19%). Patient factors (weight, gestational age, or number of previous TI attempts) were not associated with TI success [28].

There is no uniformly accepted definition for neonatal intubation competence. Studies reporting intubation success rates have identified success rates of 60% on first attempt to 72-88% on second attempt for attending neonatologists [8] [28] [29]In a multi-center cohort study of neonatal intubation encounters (n=2297) performed by neonatal fellows (n=98) from North American academic centers 77% of intubations were successful within 2 attempts. Among the 45% of fellows who achieved a pre-defined competence criteria (successful intubation 80% of the time) during the study period the number of intubations to meet this threshold was variable, with an absolute range of 8 to 46 procedures. After adjusting for patient and practice characteristics, advancing quarter of training was independently associated with an increased odd of successful intubation. The conclusion from the study is that an individualized approach to assess trainees' progression toward intubation competence is warranted and some learners may require adjunctive educational strategies[30]

Evidence supporting simulation-based procedure training is accumulating and may be the alternative to increase intubation competency in view of limited procedure opportunities [31]. Meta-analysis has shown that simulation-based medical education with deliberate practice and mastery learning yields improvement in patient care/outcomes [31,32]. In addition, video laryngoscopy has been shown to be useful to allow real-time feedback to trainees as they master their intubation skills [33]

A checklist-based tool for performance assessment of competence during simulation-based neonatal intubation training has been developed and validated, providing formative and summative assessment tool to aid with entrustment decisions [6].

Clinical Management

Proposed recommendations:

1. Neonatal Intubation procedure
    a. Should be performed and documented under same standards as any neonatal procedure
    b. The goal is for placement of the endotracheal tube into the trachea on first attempt, within 30 seconds, without adverse events or complications
    c. The American Academy of Pediatrics recommends premedication for all nonemergent neonatal intubations
    d. An intubation attempt should be aborted if patient develops bradycardia, if the attempt takes longer than 30 seconds, or if there is bleeding
    e. The neonatologist for the patient is ultimately responsible for determining the most appropriate team member to manage the airway at all times and should be informed prior to any intubation
    f. Neonatologist on duty for the patient should be informed about any intubation being performed and is encouraged to be present during the procedure. Presence mandated if neuromuscular blockage being used
    g. Neonatology on duty for the patient should be informed if elective removal of ETT and reintubation are suspected to be necessary. Maneuvers to verify

endotracheal tube position within the trachea have to be performed and documented prior to elective exchange of the ETT for dislodgement

h. Neonatologist on duty for the patient should be informed immediately if 2 unsuccessful intubation attempts are reached
i. If available, a video laryngoscope is preferred
j. If possible, depending on the nasal interface being used, continue patient on oxygen support via nasal interface while intubation procedure is being performed
k. If airway emergency is identified, initiate airway emergency response algorithm as outlined in Difficult Airway CPG (PG013)

2. Definitions:
    a. Intubation attempt: placement of the laryngoscope in the baby's mouth
    b. Successful intubation: an attempt that leads to placement of the endotracheal tube in the baby's trachea. Evidence of successful intubation includes auscultation of breath sounds, chest expansion, and improvement in clinical condition, improvement or maintenance of heart rate above 100, mist in the endotracheal tube and CO2 confirmation via colorimetric or waveform capnography device.
    c. Intubation associated adverse event:
        i. **Severe**: cardiac arrest, esophageal intubation with delayed recognition, emesis with witnessed aspiration, hypotension requiring intervention, laryngospasm, malignant hyperthermia, pneumothorax/pneumomediastinum, direct airway injury)
        ii. **Non severe**: bradycardia, desaturation, main stem bronchial intubation, esophageal intubation with immediate recognition, emesis without aspiration, hypertension requiring therapy, epistaxis, lip trauma, gum or oral trauma, medication error, dysrhythmia, an pain/agitation requiring extra medication and causing delay in intubation
    d. Trainee: any individual in training for endotracheal intubation who has not attained validated competency.
    e. Levels of competency based on American Board of Pediatrics Entrustable Professional Activity

Level of competency	Entrustable Professional Activity
Novice	Observe activity only, not ready to perform on patient*
Advanced beginner	Ready to perform procedure under **direct supervision**
Competent	Ready to perform procedure under **indirect supervision** (available within minutes)
Proficient	Ready to perform procedure **without direct supervision** (under clinical oversight)
Expert	Ready to provide supervision to juniors learning the procedure

3. Neonatal Intubation procedure training pathway for all **new** neonatal intensive care unit providers
    a. NRP training
    b. Review of NRP Lesson 5 8th edition https://doi-org.proxy1.library.jhu.edu/10.1542/9781610025256-5
    c. Review Intubation technique checklist
    d. Intubation video (https://www.youtube.com/watch?v=lGTaA_UdIXw&t=11s)
    e. Simulation training (Full term, premature task trainers, direct laryngoscopy and video laryngoscopy) 30 min session
    f. Intubation proficiency exam (90%)
    g. Perform live intubation under direct supervision of a neonatologist or Proficient RT or NNP

4. Premedication regimens for elective intubations in the NICU
    a. Preterm neonates <34 weeks
        - Premedication is optional and discouraged if extubation is aimed within next 12-24 hours
        - Atropine (0.01–0.02 mg/kg) plus fentanyl (0.5-2 mcg/kg over at least five minutes)
        - Benzodiazepines should not be used

    b. Infants with suspected or confirmed difficult airway
        - Atropine (0.01–0.02 mg/kg) plus fentanyl (0.5-2 mcg/kg over at least five minutes)
        - Neuromuscular blockers should not be used
        - Contact Emergency airway team ACH, Airway STAT -74300 and state if medical (anesthesia) or surgical (ENT, general surgery/EATs) emergency airway team assistance is needed

    c. Neonates > 34 weeks at birth or PMA
        - Atropine (0.01 mg/kg) + fentanyl (1-2 mcg/kg over at least five minutes) + rocuronium (0.1 mg/ kg; max=1mg/kg) immediately prior to intubation. Moderate quality of evidence. Conditional recommendation

5. Neonatal Intubation procedure on patients when performed by trainees
    a. The trainee should be allowed a maximum of 2 attempts
    b. If unsuccessful, the next person to attempt should be a health care professional highly skilled in endotracheal intubation. (Neonatologist, senior trainee, NNP or RT). The highest skilled provider to attempt intubation should be identified prior to the procedure
    c. The physical presence of the neonatologist on duty is required for advanced beginner physician trainees and recommended if difficulties are encountered at any time during any intubation procedure. The neonatologist on duty is encouraged to be present at any intubation performed by any trainees to provide feedback

d. Additional attempts in excess of 2 may be allowed per Neonatologist discretion based on patient stability and prioritizing patient safety
e. Neonatal Perinatal Fellow Year one (PGY-4)
    i. Will be given priority for performing endotracheal intubations during the first 4 clinical months of fellowship (August-November)
    ii. Follow standardized procedure for emergent and non-emergent intubations
    iii. Must be directly supervised by faculty neonatologist until determined competent for indirect supervision
    iv. Competency with the procedure will be determined by Program director and Associate program director after careful review of evaluation forms and assessment every 3 months
    v. Must be evaluated by faculty following the check list provided at the end of this document. Fellow is responsible for collecting the evaluation form and handing it to the fellowship coordinator
f. Resident/NNP/RT
    i. Will be given the opportunity if NPM fellow is determined competent or if not available for the procedure
    ii. Must be supervised by a Neonatologist or competent NPM fellow or RT or NNP
    iii. Must be evaluated following the check list provided at the end of this document

6. Neonatal Intubation competency assessment
    a. INSPIRE Procedure Checklist – Neonatal Intubation will be the assessment tool for all providers
    b. Each trainee is responsible for collection of procedure check list filled by the supervising observer of the procedure
    c. Competency will be determined based on skills and not by number of procedures performed. It is suggested that once at least 80% of the most recent 5 successful intubations are performed on the first or second attempt the individual is considered competent [30].
    d. If learner/trainee not competent to perform procedure please refer for remedial simulation training

Glossary

Adverse events during endotracheal intubation – TIAE
APP – advance practitioner provider
Birth weight - BW
Carbon dioxide (CO_2
Delivery room – DR
Extremely low birth weight – ELBW

Endotracheal tube – ETT
Intraventriuclar hemorhage – IVH
Nasal-tragus length - NTL
Neonatal intensive care unit – NICU
Neonatal nurse practitioner – NNP
Neonatal pediatric medicine - NPM
Randomized controlled trial (RCT)
Respiratory therapist – RT
Tracheal intubation - TI

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Neonatal Tracheal Intubation Clinical Pathway

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