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Neonatal airway management training using simulation-based educational methods and technology

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ABSTRACT

Airway management is a fundamental component of neonatal critical care and requires a high level of skill. Neonatal endotracheal intubation (ETI), bag-mask ventilation, and supraglottic airway management are complex technical skills to acquire and continually maintain. Simulation training has emerged as a leading educational modality to accelerate the acquisition of airway management skills and train interprofessional teams. However, current simulation-based training does not always replicate neonatal airway management needed for patient care with a high level of fidelity. Educators still rely on clinical training on live patients. In this article, we will a) review the importance of simulation-based neonatal airway training for learners and clinicians, b) evaluate the available training modalities, instructional design, and challenges for airway procedural skill acquisition, especially neonatal ETI, and c) describe the human factors affecting the transfer of airway training skills into the clinical environment.

Background

Airway management is a fundamental component of neonatal critical care and requires a high level of technical skill, even for anatomically normal airways.[1] Compared to older age groups, the neonate's unique anatomy and physiology, specifically including laryngeal hyperexcitability, ventilatory depression with hypoxia, and low respiratory reserve (short interval between apnea and desaturation), present challenges for the clinician.[1,2] Neonatal airway management includes technical skills such as endotracheal intubation (ETI), bag-mask ventilation, and supraglottic airway (SGA) placement. These skills primarily aim to maintain the patient's oxygenation and ventilation.[3] Since respiratory failure is common in the transitional period after birth, especially in preterm infants, teams must be adequately trained and prepared to provide optimal airway management routinely and during emergencies. This article focuses on using simulation for airway management training, particularly for ETI, as much research has been conducted in this area.

Airway management procedures, particularly intubation, may lead to adverse events (AE),[4] airway and lung injury, and may negatively impact neurological outcomes.[5–7] AE, including main stem intubation, airway trauma, or bradycardia, occur in approximately 17–57 % of neonates undergoing ETI, and 31–51 % of neonates experience a severe oxygen desaturation (decrease of ≥20 % from baseline).[4,8,9] AEs have been documented during both nasotracheal[8] and orotracheal ETI. Fortunately, most are minor with only 5–9 % classified as severe (e.g., cardiac arrest, laryngospasm, or delayed recognition of esophageal intubation). Non-modifiable patient factors such as weight, age at intubation, emergent intubation, and hemodynamic instability increase the potential for AEs[4,9] However, addressing modifiable risk factors, such as the use of video laryngoscopy (VL),[8,10,11] properly functioning and appropriately sized equipment,[8] use of paralytic medications,[12–17] and more advanced levels of provider training,[4,9,13,18–22] potentially decrease the risk. Therefore, neonatal intubation safety is contingent upon a) selecting clinical management strategies that improve the likelihood of success, b) developing new algorithms, particularly for difficult airways, c) developing new equipment to aid clinicians, d) providing an optimal environment for ETI, and e) accelerating

Abbreviations: AE, adverse event; AR, augmented reality; BAPM, British association for perinatal medicine; DL, direct laryngoscopy; DR, delivery room; ETI, endotracheal intubation; JIIT, just in time training; LMA, laryngeal mask airway; NICU, neonatal intensive care unit; PPV, positive pressure ventilation; SGA, supraglottic airway (device); SBT, simulation-based training; VL, video laryngoscopy; VR, virtual reality.

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procedural skill acquisition.

Simulation-based training (SBT) has emerged as a leading educational modality to teach novices technical skills, maintain competency for established clinicians, and provide interdisciplinary team training in neonatal resuscitation where airway management is critical.[23,24] SBT addresses both technical skill competency as well as other factors impacting intubation success and safety (including human factors, crew resource management, environmental design, and stress and resilience of team members). SBT allows team members to practice airway management skills without exposing patients to adverse events and has supplemented, but not eliminated, the need for clinical practice on patients during initial skill acquisition. SBT has also minimized the need for airway training on animals, which has both ethical concerns and technical issues related to fidelity.[25] In this article we will a) review the available training modalities, instructional design, and challenges for each type of airway procedural skill, with a particular focus on neonatal ETI, and b) describe the difficulty of transfer of airway training skills into the clinical environment.

Comparison between clinical and simulation-based intubation training

Clinical training and SBT for neonatal ETI both play an important role in procedural skill acquisition. However, neither approach has led to a dramatic improvement in trainee performance.[26] Trainee first attempt success rates for neonatal ETI, which have been primarily studied using direct laryngoscopy (DL), remain low, varying from 20 % to 70 %.[18–20,22,27–29] In the clinical environment, low tolerance to hypoxia and bradycardia may lead clinicians to interrupt the procedure, necessitating multiple intubation attempts with potential for additional complications.[2,30,31] Furthermore, each clinical setting comes with its own challenges. In the delivery room (DR), intubation is most often performed emergently, and may be associated with high levels of stress, especially if airway or circulatory compromise is unanticipated and when multiple intubation attempts are required. Additionally, in the DR, trainees may not recognize an unsuccessful ETI attempt if meconium is present in the airway.[32] Although the need for intubation in the neonatal intensive care unit (NICU) may be anticipated, emergent intubations still occur. For example, infants with an unplanned extubation may need to have their airway secured rapidly and without warning; these aspects may increase the number of attempts and difficulty of the procedure. SBT provides a controlled environment that allows for infinite repetition, experimentation, and protection of patients from potential harm related to suboptimal technique, thus minimizing the risk of AEs. Despite numerous advantages of SBT, however, learners often prefer training on live patients rather than a simulator.[33,34] Potential disadvantages of each method are described in Table 1. Disadvantages of one training method reflect advantages of the other.

Table 1
Disadvantages of clinical intubation training compared to simulation-based intubation training.

Clinical intubation training	Simulation-based intubation training[34]
- Not available on demand	- No transfer of skills to the clinical environment[72]
Limited opportunity[14] due to: - Duty hour restrictions - Reduction in NICU rotations[20,21,97–99] - Increased use of non-invasive ventilation[50] and less prophylactic surfactant administration - Elimination of routine intubation for meconium aspiration[51]	- Simulator is rigid, frequently requiring excess force - The simulator doesn't allow incorporation of secretions or tongue motion - Predictable, limited to a single configuration with limited variations
	- SBT may not be challenging enough to maintain skills once competency is acquired
- Competing training priorities[49] with other professions, such as transport nurses and advanced practice providers	- High cost of equipment and instructor time
- High stakes and high stress with an uncontrollable environment	- Low stakes and controlled artificial environment, may not adequately portray stressors
- Risk of adverse events to the patient	- SBT for intubation may not be multidisciplinary and focuses on technical skills only

Simulation-based training methods and equipment for neonatal intubation

SBT for neonatal ETI can be structured in various ways using different training modalities and equipment.[35] Preparation for hands-on training has traditionally involved didactics targeted at procedural steps, review of indications/contraindications,[36] review of videos[32,37] or images, smartphone apps,[38] and instructor demonstrations. Review of prerecorded videos in addition to participating in simulation-based practice was shown to decrease intubation attempt duration and decrease rates of esophageal intubation. The improvement in speed persisted even after three months.[37]

Just in time training (JITT) or "rolling refreshers" allow clinicians to brush up on didactics and practice on a simulator immediately before performing a procedure clinically. This educational methodology is based on the principle of deliberate practice.[39] Pre-shift JIIT did not impact first-attempt or overall success rates during pediatric ETI in the pediatric intensive care unit.[40] In neonates, a randomized controlled trial of 65 pediatric residents comparing JITT using a 5-min video vs video plus SBT demonstrated improvement in first-attempt success rates, but did not impact overall procedural success.[41] However, in this study there were high rates of video laryngoscopy (VL) use (32–48 %) and high pre-intervention success rates (60 %) in both groups. Notably, there was an increase in traumatic events in the SBT group, raising concerns about the fidelity of the training equipment.

Neonatal airway simulation training equipment has undergone significant improvements over the past decade. Task trainers are single configuration, low-technology airway models that are available in term and preterm sizes. Only one difficult airway model for Pierre Robin is available (Trucorp, Ireland, https://trucorp.com/product/airsim-pierre-robin-x/). Commercial high-technology mannequins are full body models with features that allow procedural practice as part of SBT. Some models contain internal sensors that detect endotracheal tube placement and lung inflation. Comparisons of the different types of neonatal airway simulators, including their features and capabilities, have been extensively described.[35,42] Recently, virtual reality (VR) airway training equipment has been developed based on scans of neonatal airways.[43,44] VR and augmented reality (AR) trainers[45] incorporate advanced assessment tools that track laryngoscope and head motion. In these models, motion and force measurements can be used to develop performance metrics. The versatility of the VR airway trainers permits dynamic changes to the airway (e.g., decreasing airway size, increasing tongue thickness) to prevent learner acclimation to a single configuration. Studies exploring the application of "game theory" to improve intubation performance on VR or AR simulators, including rewarding participants with increasing difficulty when an appropriate amount of force is applied, are under investigation, but have yet to show efficacy.[46] This approach highlights the potential benefits of self-directed learning compared to instructor-led learning, particularly for maintenance of skills and continuous education amongst experienced providers. Wearable eye-glasses which reveal the intubator's view, and can be used to provide real-time feedback, have also shown promise in decreasing time to intubation in SBT and have increased self-confidence of medical students.[47]

SBT for ETI could be scheduled at different intervals and variable sequence based upon learner needs (e.g. JITT). SBT for neonatal ETI may be programmed as stand-alone training or as part of a course (e.g. bootcamp or neonatal resuscitation training program), both for initial procedural skills acquisition and maintenance. Alternatively, ETI training can be included in clinical quality improvement programs developed to test new airway management protocols in realistic in-situ simulation scenarios which recreate the high level of stress during difficult intubations.

Video laryngoscopy for intubation training

Video laryngoscopy (VL) magnifies and clarifies neonatal airway anatomy,[48,49] which is one of the first steps in teaching and learning intubation. In the clinical environment, VL improves first attempt success rates and decreases number of attempts, but does not decrease the overall time to intubation or AE.[11] In SBT studies, mixed results have been found when comparing intubation success using VL vs. DL. Several controlled trials on mannequins demonstrate equal efficacy of DL and VL in intubation success and/or similar overall intubation duration during the initial SBT of students,[50] pediatric residents and staff.[48,51,52] It is well known that VL has a steeper learning curve in clinical practice and, thus also in SBT, which may lead to longer time to intubation.[50,52–55] Not surprisingly, experienced providers using DL during SBT intubated more quickly compared to VL, but VL improved visualization.[51,52,56] Novice intubators using VL in SBT reported increased success,[49,54,57] improved airway visualization,[49,51] increased confidence and satisfaction,[52] decreased number of attempts[51] and decreased duration of intubation compared to DL.[49] The benefit of VL in SBT is greater for novice learners, as it allows them to understand how laryngoscope motion facilitates visualization of anatomic landmarks.[58] Once the skill is learned using VL, it can be transferred to DL during SBT, underscoring the importance of effective visualization of the airway anatomy as a critical learning milestone.[54,57] In the clinical environment, it is notable that use of VL along with real-time feedback and coaching improves intubation outcomes.[59] However, variations in study outcomes may be explained by differing definitions of "success," whether learners were permitted to utilize the image on the VL screen (vs relying on the view obtained through DL), and the type of VL used. Therefore, trial results must be interpreted carefully and take into account the type of device used.

AR VL has been evaluated in intubation training and may offer the additional benefit of allowing supervisors to guide novice learners by directly pointing on the screen or annotating the image that is projected onto the AR glasses (telestrating).[45] Increased visualization, better identification of anatomic landmarks, and psychological safety for novices may be an intermediate step that will later translate to improved clinical success, but a direct correlation to clinical success has not yet been made.

Assessment of competency in neonatal intubation

A clear definition for an expected level of competency in neonatal ETI has not been established. It is estimated that approximately 4 or more cumulative successful intubations are required to reach a likelihood of >75 % success on the subsequent neonatal intubation,[60] while data from the anesthesia literature cites a requirement of at least 43 DL intubations to reach competency.[61]

A variety of evaluation methods have been developed to monitor skill progression and competency acquisition, but each has advantages and disadvantages. Progression of individual skill development can be monitored using personalized evaluative measures such as cumulative sum analysis (Cusum) for intubation. Cusum is a statistical method by which individual intubations are tracked cumulatively over time for each trainee. Each successful intubation brings the trainee closer to the predefined competency threshold, while each failure moves them towards a deficiency threshold until an acceptable a priori failure rate is achieved. Supervisors can theoretically use the resulting trends to determine competency for unsupervised practice. A registry study has shown that only 45 % of neonatal perinatal medicine fellows achieve competency in clinical practice (defined as >80 % success within 2 consecutive intubation attempts, which approximates an attending-level success rate) during fellowship and that approximately 8–46 intubations are required to achieve competence.[62,63] However, the Cusum method is only a quantitative assessment of success rates and does not give information about intubation quality.

Qualitative assessments using checklists, global rating scales, and entrustable professional activities assessments can differentiate between experience levels, provide structured feedback for formative assessment, determine whether learners may be granted more autonomy, and standardize research tools.[25,29,63,64] Checklists evaluate adherence to sequential procedural steps, but may not emphasize the relative importance of the steps. For example, highly experienced clinicians may be able to skip routine steps without affecting the ultimate intubation outcome. To overcome the limitation of lack of differentiation in the importance of steps in checklists, one study of an ETI checklist added or subtracted more points for the number of attempts and the duration of intubation.[63] This method rewarded more experienced providers for accuracy and speed. Checklists also do not allow for objective assessment of laryngoscope motion, trajectory and smoothness, or adequacy of internal airway views during DL as evidenced by low interrater reliability of items such laryngoscope handling.[63] VR models based on real neonatal airway scans with built-in assessment tools have been developed to objectively assess various aspects of motion related to intubation success.[43] These tools use different machine learning algorithms to predict successful intubation, but large trials are needed to establish their reliability and validity.

Different types of qualitative assessment tools are needed to address milestones of competency and proficiency, such as the ability to detect and respond to technical variations (e.g., subtle normal anatomical variations, management of secretions, etc.), and ability to handle cognitive load and tune out distractions. Experienced providers have developed these unconscious skills over time. The expert's cognitive shortcuts and ability to handle emergent novel situations differentiates them from novices. New methods, such as eye tracking software, may potentially expand assessment capabilities. Eye tracking technology analyzes visual attention and quantifies specific areas of interest during intubation.[65] An observational SBT study has shown less distraction and higher visual attention in experienced providers who focus on the areas most relevant to the task and have higher situational awareness compared to novices.[66] These technologies may complement existing tools to assess competency and procedural readiness.

Team training and human factors during airway management

Airway management in the newborn often occurs under stressful conditions in the NICU and DR. SBT should therefore address human factors and prepare teams to deal with the stress of the clinical situation through realistic scenarios. Learners and instructors alike acknowledge that heightened emotions (such as anxiety and fear of harming the infant), the high stakes, and environmental cultural factors differentiate intubation training in the clinical environment from SBT.[34,67] A study of clinical intubations highlighted increased AEs in situations with high team stress levels (such as a patient with hemodynamic instability).[68] However, not all environmental factors affect performance and not all stress is harmful; indeed, a moderate amount of stress may even enhance performance.[69] Stressors in the form of external observers did not affect intubation performance in SBT but learners still experienced an elevation in heart rate, a rough physiologic indicator of stress.[70] Objective techniques that apply measurement of heart rate variability to evaluate imbalances between the sympathetic and parasympathetic systems are better markers of the stress response and could be used to study its effect on intubation performance.[71] Additionally, incorporating factors to increase the level of stress in the training environament may be beneficial in building resilience and bridging the gap in transfer from simulation to the bedside.[72] Incorporating time pressure and distractions into scenarios may elevate the complexity for more advanced learners. Additional knowledge about the various types of stressors (e.g., noise, sight etc.) that elicit a stress response in SBT and how types of cognitive load affect intubation performance is needed.

Non-technical skills such as situational awareness, communication, teamwork and team preparedness are essential factors for successful airway management in clinical practice.[8] Improvements in communication and teamwork have been shown to improve safety in emergent intubations.[73] Training in airway management therefore needs to address these factors in addition to the psychomotor skills. After attaining a competent individual performance level, a graded scaffolded approach will allow learners to practice their skills in the context of the whole team. As learners advance, difficulty of the airway and the scenario can be advanced. Some SBT programs offer interprofessional cross-training with providers who normally don't intubate to provide an understanding of the challenges faced by their colleagues and allow development of a shared mental model regarding the main challenges and objectives.

Simulation-based intubation training for difficult airways

Difficult ETI, defined as the need for more than two intubation attempts, has a higher incidence in neonates than in older children.[2] Based on this definition, up to 14 % of infants in the NICU[74] and 6 % of infants in the operating room may be classified as having difficult intubations despite having normal airways and no prior indication of anatomic aberrancy.[2] Screening tests for difficult intubations have poor predictive value.[74] Difficult intubations are therefore hard to anticipate, requiring teams to train a priori on the use of alternative airways and rescue techniques, and incorporate elements of advanced planning, rapid escalation in emergency situations, and use of clear communication techniques. The importance of advanced planning and practice to prepare teams to respond adequately to difficult neonatal airway situations has been demonstrated by anesthesiologists.[75] SBT prepares providers for the technical and non-technical requirements for dealing adequately with an unexpected difficult airway situation, which is often associated with high levels of stress. SBT is also a means of training teams on the use of "cognitive aids," such as difficult airway algorithms. These algorithms distinguish between a "cannot intubate/can ventilate" situation where alternative airways can be used, such as bag-mask ventilation or a supraglottic airway (SGA), and a "cannot intubate/cannot ventilate" situation in which a failed airway requires rapid escalation. In spite of the high rate of difficult neonatal intubations, few institutions have well-defined difficult neonatal airways algorithms. Guidelines such as the British Association for Perinatal Medicine (BAPM) guideline may be useful for rapid and adapted escalation according to predefined steps.[75,76] Simulation-based in-situ training with staff can be used to adapt these algorithms to each institution's needs and to ensure that escalation systems work, proper personnel (e.g., anesthesia and otorhinolaryngology) respond, and appropriate equipment is available.

Bag-mask ventilation training

Positive pressure ventilation (PPV) using a facemask with a bag or a T-piece constitutes the first step in current neonatal resuscitation algorithms.[3,77,78] Achieving effective ventilation with minimal mask leak or airway obstruction[79,80] at a consistent rate can be challenging, even for experienced providers. Providers must coordinate the placement of the mask appropriately without extensive pressure, provide adequate volumes while minimizing leak and keep their hands and the patient's tongue and jaw from obstructing the airway. Often the amount of leak and volume delivered is underestimated. Application of excessive volumes during ventilation may be harmful and cause complications such as air leaks, as well an increase in long term morbidities, particularly in preterm infants. Learning bag-mask ventilation has traditionally been through practice on task trainers or whole-body mannequins. A small study showed a significant 24 % reduction in mask leak after giving providers written instruction followed by practice on a mannequin with 2 different types of facemasks.[81] Similarly, coaching by a designated performance coach during SBT sessions has shown improvement in nurses' ability to reduce peak inspiratory pressure, attain adequate tidal volumes and reduce mask leak in a pilot study.[82] However, these results may not be sustained if performed on live patients due to differences in the mechanical properties of the simulator compared to an infant. Through simulation, learners gain experience attaining an appropriate seal and achieving adequate chest rise. Other cues, such as improvement in heart rate and color, can be simulated by the instructor. Instructors assess adequacy of PPV by visual inspection or use of respiratory function monitors (RFM) or software in high-technology mannequins. Bag-mask ventilation checklists with itemized scores can be used to assess procedural sequence and execution and determine competency.[83] However, itemized checklists are only able to differentiate between medical students vs all other training levels. Global rating scales and entrustment scores are better at differentiating between training levels, suggesting that multiple varied ways of assessment of bag-mask ventilation competency are needed. Like most procedures, bag-mask ventilation is subject to skill decay. In a small randomized controlled trial, Kamath-Rayne et al[84] demonstrated that pediatric interns who are retrained on bag-mask ventilation in situ on the simulator every 1 or 3 months establish effective bag-mask ventilation in a shorter time than those in the control group who did not receive any retraining.

Respiratory function monitors during training

Respiratory function monitors (RFM) are devices that provide real-time feedback on respiratory function and ventilation parameters such as mask leak, respiratory rate, and expiratory volumes.[85] By offering direct visual access to the RFM, learners can self-adjust technique to achieve targeted parameters (Fig. 1). Several factors such as optimal monitor placement, provider experience, and type of device can significantly impact the quality of ventilation.[86] In simulation-based studies of RFM, tidal volumes were more effectively maintained within a pre-defined target range (4–8 ml/kg) by continuously adapting peak inspiratory pressure (PIP), and mask leak was approximately halved.[86] This study using newly developed neonatal RFM demonstrated that giving direct visual access to RFM and VL to both supervisors and learners is beneficial in improving the quality of bag-mask ventilation and intubation compared to no access or supervisor-only access. The advantage may be limited to novice learners as experienced providers have incorporated visual (e.g., chest wall motion) and tactile cues to adjust ventilation parameters without using RFM. RFM may therefore add additional cognitive load to an already busy environment and may not offer significant benefit to this group.[87] Although SBT studies have

Fig. 1. Photo from a simulation session at A. Béclère hospital - APHP, using a neonatal respiratory function monitor (RFM) (Monivent® Neo100, Monivent AB) during bag-mask ventilation. The real-time RFM information allows team members to adjust their ventilation to achieve targeted tidal volumes and avoid under/overventilation. The placement of the RFM monitor is important since visual attention significantly impacts the quality of ventilation.

shown benefit in using RFMs in teaching bag-mask ventilation,[88–90] there is insufficient evidence from clinical trials to support their use during neonatal resuscitation.[85] The difference in the mechanical properties of the mannequin compared to a compliance of the neonatal lung also casts doubt on transferability of this skill from SBT to the real-world clinical environment. The use of RFMs for training therefore needs to be further investigated in terms of gains stratified by experience level and to evaluate retention of knowledge and skills over time. Patient outcomes, such as the incidence of AE, should also be considered using tiered training outcome models such as the Kirkpatrick model.[91]

Supraglottic airway device training

Supraglottic airway devices (SGA) or Laryngeal Mask Airways (LMA) are the most common alternative airway devices recommended by the American Heart Association and the European Resuscitation council for neonatal resuscitation.[77] Their use may be lifesaving for term and late preterm infants when tracheal intubation is difficult or impossible and/or in a "cannot-intubate- cannot ventilate" scenario where bag-mask ventilation is inadequate. These devices act as a bridge between bag-mask ventilation and tracheal intubation. SGAs are also under consideration as first line airway management devices as they are easy to insert blindly. They have proven very effective in decreasing intubation rates and lowering failure rates of positive pressure ventilation with bag and mask.[92,93] SGA insertion is easy to learn, with a high success rate clinically on the first attempt reaching 80–90 % and a high degree of skill retention using SBT.[94] However, a recent small SBT randomized controlled trial reported that medical students, representing novices with limited experience, took longer to achieve effective ventilation of ten breaths with SGAs compared to face mask (median 82 vs. 43 s, $p < 0.01$).[95] Although the mannequin was calibrated using an experienced provider, the rigidity and lack of adequate seal made it difficult to transfer the skills to the clinical environment. Nevertheless, the study provides insight into the challenge of adequately training community providers who may be more likely to need these skills. Interestingly, a multidisciplinary survey of North American providers reported that in spite of receiving training on LMAs (80 %), providers had low confidence and low skill levels in placement and many had never placed an LMA clinically (79–90 %).[96] Most respondents (76 %) also found the current biennial training model to be insufficient.

Conclusion and future directions

The optimal training model for neonatal airway management remains to be determined and will likely need to be individualized to each learner. Learners of different experience levels respond differently to training modalities. There is probably no universal training method that fits all, and it may be necessary to use multiple methods to cover all aspects of airway management.

In the future, various approaches are needed to improve training outcomes, and ultimately patient safety. Further technical advances in the design of airway simulators are essential since current simulators lack many essential capabilities. Training modalities with self-directed and learner-centered components may alleviate challenges related to the time and cost of coaching and instruction. SBT is evolving and there is a need for increased focus on non-technical skills and training for resilience to overcome stressors. A better understanding of optimal training methods may be achieved by more research on the effect of stress on intubation performance using simulation. Advancement in procedural assessment methods is necessary to set appropriate benchmarks for clinical competency. Quality improvement studies in SBT need to be further developed to reduce variability in training outcomes and to accelerate learning acquisition and maintenance, as is the norm in other high-risk industries. Finally, translation of results from simulation-based studies to the clinical environment must be a priority. Simulation-based studies should not only evaluate immediate outcomes, but also evaluate distal outcomes using the Kirkpatrick model.[91] For this purpose, it is essential to include data from clinical quality improvement initiatives that monitor adverse events and outcomes of neonatal airway management to ultimately improve patient care, which is the goal of any medical training program.

Declaration of Competing Interest

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