Appendix A

Neonatal Life Support – 2026 Evidence to Decision Tables

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Respiratory Function Monitor (RFM) Feeback Devices for Training (NLS 5854)

QUESTION

Respiratory function monitor (RFM) feedback during neonatal resuscitation training	
POPULATION:	Trainees or health care professionals who receive neonatal resuscitation training
INTERVENTION:	Use of a respiratory function monitoring device (RFM) during simulation training
COMPARISON:	no use of RFM device during simulation training
MAIN OUTCOMES:	***Outcomes:*** *Training performance (measured in simulation setting):* • Knowledge at training conclusion, up to 1 year and beyond 1 year (important) • Skill performance at training conclusion, up to 1 year and beyond 1 year (important). Outcomes related to skill performance included mask leak, tidal volume (V_T), peak inflation pressure (PIP), ventilation rate, positive end expiratory pressure (PEEP), time to effective ventilation, duration of sustained effective ventilation, and time to identify and correct any problems with positive pressure ventilation (PPV). These outcomes were evaluated at various time points, including during and immediately after the training session, and at various follow-up intervals up to a maximum of three months after the initial training. *Transfer to clinical performance (measured in delivery room (DR) setting):* • Quality of performance in actual resuscitations. (critical) *Clinical outcomes (effectiveness of training in improving clinical outcomes):* • Patient survival (critical) • Respiratory clinical outcomes during PPV in the DR (important) • Time to heart rate ≥ 100 breaths per minute. (important) *Financial outcomes:* • Cost-effectiveness of using RFM in neonatal resuscitation training (important)
SETTING:	Simulation-based training setting
PERSPECTIVE:	Training outcomes: the trainee; Clinical outcomes: the patient
BACKGROUND:	The International Liaison Committee on Resuscitation has identified the need for high-quality randomized trials of training interventions that improve the effectiveness of resuscitation skills. PPV is a critical skill during neonatal life support, that must be performed effectively, to avoid harm from underventilation or overventilation. Mask PPV skills have been found to be poor even after training, indicating the need for better teaching methods and/or technology. [1] RFM can be used to evaluate the effectiveness of face mask PPV. [2-4] RFM is capable of measuring and displaying V_T, gas flow, airway pressure, and mask leak in real time. [2-4] This review is complementary to NLS 5360 - Respiratory Function Monitoring for Neonatal Resuscitation – which examined the impact of RFMs during actual resuscitations on clinical outcomes. [5]
CONFLICT OF INTERESTS:	The following Task Force members and other authors declared an intellectual conflict of interest, and this was acknowledged and managed by the Task Force Chairs and Conflict of Interest committees: • Author Schmölzer has conducted and published articles related to respiratory function monitoring (RFM) during simulation. [2,6-11] • Author Thio has conducted and published studies evaluating RFM in simulation. [3,12] These authors were excluded from participation in decisions about inclusion of studies and risk of bias adjudication for the articles that they have authored.

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	While most neonates breathe immediately after birth, a proportion require PPV, which can be lifesaving. PPV using a face mask is widely used at birth. Optimal mask PPV is a difficult skill to master. It requires recognition and correction of any gas leak around the mask, recognition of airway obstruction and prevention of under- and over-ventilation. [13,14] Avoiding under- and over-ventilation requires awareness of V_T, PIP, and ventilation rate. [1] RFM devices provide real-time direct feedback on these variables, and when used in the setting of simulation-based task training they have the potential to improve trainees' proficiency in PPV. [2-4] This feedback may be particularly valuable during face mask ventilation, because of the specific risks of leak between the mask and the face and of pharyngeal obstruction. Chest rise and fall has been shown to be an unreliable measure of tidal volume. [15,16]	

Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know	Sixteen studies, including three RCTs [3,6,17], five crossover RCTs [2,7,18-20], two observational studies with crossover designs [21,22] and six other studies [4,12,23-26] were included in the systematic review. All studies were conducted in simulation settings and all examined PPV provided to term or preterm infant mannikins using a face mask, except one which assessed PPV via a tracheal tube. [23] None of the included studies reported on any of the pre-specified critical outcomes namely, quality of performance in actual resuscitations and survival. Outcomes in simulation of the PICOST question were assessed by three types of comparison. Comparison 1 most directly addressed the PICOST question by comparing the use of RFM with a screen visible or concealed. Comparison 2 addressed transfer of skills from training with an RFM to performance without an RFM. Comparison 3 addressed the RFM use as an alternative to feedback from an instructor using an RFM or to enhance team leader feedback in a simulated resuscitation. **Comparison 1. RFM screen visible to the participants in the intervention group and masked in the control group during both training and outcome assessment phase.** Three RCTs [3,6,17], three crossover RCTs [7,19,20], and three non-RCTs [21,22,24] addressed this comparison, although not all of the presented data were suitable for meta-analysis. One study assessed skill retention at follow up. [12] *Face Mask Leak (important)* Evidence from RCTs: The **use of RFM with screen visible** during training **probably reduced the mean percentage of mask leak** (measured as a proportion of inspired V_T) when participants were assessed at the completion of training. Mean mask leak was 43.8%	

in participants when the RFM screen was concealed and absolute risk difference (ARD) was 21% lower (95% confidence intervals (CI) 32% lower to 9% lower) when the RFM screen was visible in 2 RCTs including 499 participants; **moderate certainty evidence**, downgraded for serious inconsistency. [3,6].

Evidence from non-RCTs and cross-over RCTs:

The **use of RFM with screen visible** during training **probably reduced the mean percentage of mask leak** (measured as a proportion of inspired V_T). Mean mask leak was 37.2% when the RFM screen was concealed and ARD was 7% lower (95% CI 14% lower to 1% lower) when the RFM screen was visible in 3 non-randomized studies including 108 participants; **moderate certainty evidence**, downgraded for serious imprecision. [7,20,22]

Tidal volume (V_T) (important)

Evidence from RCTs:

The **use of RFM with screen visible** during training **probably increased the delivered V_T** (measured as expiratory V_T in mL). Mean V_T was 18.2 mL when the RFM screen was visible vs 14.9 mL when the screen was concealed, (mean difference (MD) 3.5 mL, 95% CI 2.4 mL higher to 4.6 mL higher) in 1 RCT including 388 participants, **moderate certainty evidence,** downgraded for serious imprecision. [3]

Peak inflation pressure (PIP) and inflation rate

In RCTs and non RCTs that reported **PIP** and **inflation rate** there was either little or no difference, and certainty of evidence ranged from very low to moderate. [3,6,7,19,20,22,23,25,26] In one study, the use of RFM with screen visible possibly increased the proportion of inflations delivered to a term manikin using a self-inflating bag within a PIP range of 20-35 cm H_2O (very low certainty evidence). [25]

Table 1. Improvement in face mask leak and tidal volume with use of an RFM for training.

Outcomes (importance)	**Participants (studies)**	**Certainty of evidence (GRADE)**	**Anticipated absolute effect (95% CI)**	
			Mean* with RFM screen concealed	**Mean Difference (95% CI) with RFM screen visible**
Face mask leak (% of inspired V_T) (important)	499 participants (2 RCTs) [3,6]	Moderate	43.8%	21% lower (32% lower to 9% lower)
	318 participants (2 crossover RCTs [7,20] and non RCT [22]	Moderate	37.2%	7% lower (14% lower to 1% lower)
Tidal volume (V_T) (mL or mL/Kg) (important)	388 participants (1 RCT) [3]	Moderate	N/A	3.5 mL higher (2.4 mL higher to 4.6 mL higher)
	204 participants (1 crossover RCT) [20]	Moderate	N/A	1.1 mL higher (0.3 mL lower to 2.5 higher)
	32 participants (1 crossover RCT) [7]	Low	N/A	1.2 mL/kg** higher (1.3 mL/kg** lower to 3.7 mL/kg higher)

* Means were calculated from medians reported in studies [27]

** Weights estimated by authors, not actual manikin weights

Effective ventilation (author's definition) was probably achieved earlier and sustained longer, and the time to correct airway assessment (in conditions where gas leak or airway obstruction had been created in a manikin by the investigators) was probably reduced in one RCT including 300 participants [17] (moderate certainty evidence).
Three varied studies with small numbers of participants assessed whether the use of an RFM improved the provision of PPV within an investigator-defined range of safety. [19,21,24] All three suggested improvement (very low certainty evidence).

Comparison 2. RFM screen masked during a baseline phase, visible to the participants during a training phase, and masked again in the outcome assessment phase. The outcome phase was compared to the baseline phase, to measure transfer of skills to performance when no RFM was available.

Three single arm (pre- and post-training) studies including a total of 463 participants, [22,25,26] measured this outcome. Two studies assessed skill retention at follow up. [4,23]

Tidal volume (V_T)

The **use of RFM during training probably improved delivered V_T (or V_{TE})** after training compared to before training, both with RFM concealed (MD 3.7 mL higher, 95% CI 3.1 mL higher to 4.3 mL higher) in one non-RCT including 412 participants; **moderate certainty evidence,** downgraded for serious risk of bias. [26]

For all other outcomes reported, there was either no difference, or the certainty of evidence was very low, or both. [22,23,25,26]

Table 2. Transfer of skills acquired during training with a visible RFM to condition with concealed RFM

Outcomes (importance)	Participants (studies)	Certainty of evidence (GRADE)	Anticipated absolute effect (95% CI)	
			Mean with RFM screen concealed	Mean Difference (95% CI) with RFM screen visible
Face mask leak (% of inspired V_T) (important)	437 participants (2 non-RCTs) [22,26]	Very low	N/A	17% lower (35% lower to 2% higher)
Tidal volume (V_T) (mL or mL/Kg) (important)	412 participants (1 non-RCT) [26]	Moderate	N/A	3.7 mL higher (3.1 mL higher to 4.3 mL higher)
* Means were calculated from medians reported in studies. [27]				

Four studies assessed whether training with a visible RFM improved the trainees provision of PPV within an investigator-defined range of safety when assessed after training with a concealed RFM. [22,23,25,26] One study utilised an intubated preterm manikin. [23] All four suggested improvement (very low certainty of evidence).

Skill retention at follow-up: Two studies addressed this outcome at one month [4] and two months [23] after training. Results suggested that

	transfer and retention were not achieved, (very low certainty evidence). **Comparison 3. Inclusion of instructor/team leader's feedback**: Two studies addressed this comparison. [2,6] Binder et al. assessed a simulation scenario where manikins received chest compressions. Participants providing face mask ventilation received feedback from either an RFM screen or from a simulated team leader, or both. There was inconclusive evidence of better performance by the participant in response to feedback from a team leader using an RFM (very low certainty evidence). [2] Dvorsky et al recruited novice medical students to electively intubate a manikin in preparation for surgery. [6] The study suggested that verbal feedback from an instructor visualising an RFM may have improved inflations within a predefined target range and reduced mask leak (very low certainty evidence.)	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ○ Small ○ Trivial ○ Varies ● Don't know	None of the studies were designed to examine adverse outcomes in detail. Such adverse outcomes could include cognitive overload or excessive task load complexity, that might paradoxically lead to reduced retention of knowledge and skills. These concerns might be most important in inexperienced trainees and for those with lower psychological flexibility. [28] One included study suggested that visual attention to the manikin was reduced by using an RFM, and improved by using a complementary LED light indicator for HR and ventilation quality. [19] One study compared two devices, one with coloured graphic display vs another which displayed flow curves. Only the coloured graphic display improved face mask leak [20] The design and location of the RFM device screens and the characteristics of the display varied between the included studies. This may impact on visual attention and cognitive load but it has not been sufficiently studied.	Optimal duration of attention on an RFM display is unknown. Devices that depend on user interpretation of waveforms or complex numerical displays may add additional levels of task load complexity.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	The overall certainty of evidence for the important outcomes was **very low,** although **for a few outcomes the certainty of evidence was moderate.**	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	The Task Force considered that there would be no important uncertainty about the value of the critical outcomes, but no evidence was found for these. The relative importance of each of the specific training knowledge and skill outcomes has not been measured, nor has their relationship to resuscitation performance in clinical settings. However, it is likely that awareness of mask leak and the need to achieve optimal tidal volumes during PPV are key to performance in clinical settings.	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	There was very low to moderate certainty evidence for improvement and no harms were demonstrated.	

Resources required

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	The additional cost of implementing RFM in neonatal resuscitation training includes the RFM devices themselves, its accessories and maintenance, leak-free manikins, time & cost to train the trainers on RFM use, and the extended training time for learners. An Australian study reported that the cost of one RFM device ('Juno RFM') was approximately 950 USD (2025 base value) [12] Another study from Tanzania calculated the cost of another RFM device ("AIR") to be 125 USD [29]	The approximate costs of RFM devices may vary based on device model and setting.

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Very low ○ Low ○ Moderate ○ High ● No included studies	No included studies assessed or reported a full estimate of resources.	

Cost effectiveness

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ● No included studies	No included studies reported the cost-effectiveness.	One modelling simulation cost-effectiveness study assessed the implementation of HBB program in Tanzania including the AIR RFM device. [30] However, this study did not model the specific effects of the RFM.

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	No studies evaluated effects in equity. There was insufficient data for subgroup analysis by study participants' level of experience.	Most studies have been done in high-income settings. Equity might be increased if RFMs improved clinical performance of face mask PPV in settings where few other options are available. However the cost of the devices may be a barrier in low-resource settings.

Acceptability

Is the intervention acceptable to key interest-holders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

o No o Probably no ● Probably yes o Yes o Varies o Don't know	In one included study, clinicians of all experience levels reported a high level of satisfaction with a training package including an RFM. [12] Participants in a Nepalese study also reported improved confidence in mask ventilation skills after participating in a training package including an RFM. [18]	A study nested within a clinical RCT, reported high user satisfaction with the use of an RFM. [31]

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes ● Varies o Don't know	The implementation of RFM in training is theoretically feasible because it has been utilised in studies in both high and low income countries, but its widespread implementation has not been reported.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	**Don't know**
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	**No included studies**
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	**Don't know**
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	●	○

CONCLUSIONS

Recommendation

In training health care providers to perform neonatal resuscitation during simulation with manikins, where resources permit, respiratory function monitoring may be used as an adjunct to improve face mask ventilation skills (conditional recommendation, very low certainty of evidence).

Justification

The moderate certainty evidence for improvement in trainees' awareness and performance in relation to mask leak and tidal volume suggested that utilizing RFMs during training in face mask ventilation can improve training outcomes. However, the overall evidence for transfer of skills, even immediately after training, to providing PPV to a manikin without a visible RFM display and of retention of skills after training was inconclusive and of very low certainty. No studies addressed effects of simulation-based training using an RFM on performance (with or without an RFM) in clinical settings after training, or on patient outcomes. There were also no studies that had comprehensively examined costs, cost benefits or effects on equity. Hence, resource implications may limit adherence to the treatment recommendation.

Subgroup considerations

There were insufficient data for the following pre-planned subgroup analyses: type of RFM, type of PPV device, manikin type and operator experience.

Implementation considerations

- Widespread implementation of RFMs in training will require specific training programs designed to make best use of the RFM.
- The training workforce (trainers or trainers-to-be) will also require specific training on RFM, which increases the task complexity for the trainer.
- A training budget will be required which will include not only devices and leak-free manikins, but also any additional training time for both trainers and trainees.

Monitoring and evaluation

RFM devices allow downloading of data which could potentially be used to monitor the effectiveness of training.

Research priorities

- The best user-interface and location for display of RFM information
- Whether follow-up with high frequency, short duration reinforcement skill stations using an RFM improve transfer (both to skills without an RFM and to clinical settings) and retention, with or without enhancement by an instructor
- Whether the added cognitive load of having RFM data displayed affects overall operator or team performance during simulation
- Costs and cost-effectiveness of routine use of RFMs in neonatal resuscitation

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Initial Vascular Access for Neonatal Resuscitation (NLS 5652)

QUESTION

Initial vascular access for neonatal resuscitation	
POPULATION:	Infants requiring emergency vascular access between birth and 28 days of age or 44 weeks postmenstrual age
INTERVENTION:	Any type of vascular access (umbilical vein, intraosseous, peripheral vein or other)
COMPARISON:	Any other type of vascular access (umbilical vein, intraosseous, peripheral vein or other)
MAIN OUTCOMES:	Main outcomes • Time to achieve heart rate >100 bpm (important) • Time required to successfully place the device (important) Additional outcomes • Successful vascular access at the first attempt (important) • Number of attempts until successful vascular access (important) • Complications associated with the procedure (important) • Death during the event requiring emergency vascular access (critical) • Death before hospital discharge (critical) The prioritization of critical and important outcomes was made according to Strand et al. [1] Task force discussion was used for outcomes not included in Strand.
SETTING:	Birthing area, critical care unit, emergency department, or out-of-hospital environment
PERSPECTIVE:	Individual patients, their families and providers caring for those patients
BACKGROUND:	Establishing emergency vascular access for the administration of medications, fluid, or blood products is an important procedure during resuscitation and stabilization of newborn infants with persistent bradycardia that do not respond to assisted ventilation and chest compressions, cardiopulmonary arrest, cardiac arrythmias, and shock. This procedure may be required for infants in the birthing area, critical care unit, emergency department (ED), or out-of-hospital environment. Establishing vascular access can be challenging, especially in the setting of cardiac arrest or altered perfusion. Although few infants will require this intervention [2,3] healthcare professionals in various settings must be proficient at establishing emergency vascular access because delayed administration of resuscitation medications is associated with decreased survival.[4,5] In the first hours after birth, the umbilical vein is usually patent, accessible, and provides direct central access. The duration of umbilical vein patency varies and may not extend throughout the neonatal period. In some clinical scenarios, including infants with periumbilical congenital anomalies, umbilical vein catheterization may not be feasible. Moreover, healthcare professionals without neonatology specialty training may lack confidence and proficiency in umbilical vein catheterization [6]. Healthcare professionals working in pre-hospital settings and the emergency department may prefer to insert an intraosseous access device into the medullary cavity of a long bone. [7,8] While this procedure may provide rapid access, serious complications have been described. [8] Peripheral intravenous administration may offer another alternative; however, successful cannulation is more difficult in young children, may delay medication administration, and may not be feasible among infants with cardiovascular collapse. [9,10] The International Liaison Committee on Resuscitation (ILCOR) Neonatal Life Support Task Force (NLS TF) has identified emergency vascular access as a priority for review. The topic was last reviewed in 2020 as part of a larger (nodal) systematic review including adult and pediatric populations (NLS 616). At the time, no neonatal studies were identified to include in the review. In 2024, an evidence update (NLS 652) identified potentially relevant observational studies suggesting that a new systematic review focused on the neonatal population was justified. Although the focus of this PICOST is to make treatment recommendations for emergency vascular access during delivery room resuscitation, the studies included in this systematic

	review extend beyond the delivery room setting. The inclusion criteria for the population, intervention, and comparison are broader than typically included in NLS TF systematic reviews and, therefore, may provide indirect evidence related to delivery room resuscitation. The primary indication for emergency vascular access during the first minutes after birth is to administer epinephrine for treatment of persistent bradycardia or asystole unresponsive to assisted ventilation or chest compressions. This is a rare event and there may be insufficient direct evidence to answer the question for this very narrow population and indication. In making the decision to include a broader population, we recognized that emergency vascular access may be needed during the neonatal period (first 28 days after birth or until 44 weeks postmenstrual age) in multiple settings and for a wide range of indications including volume resuscitation or medications for sepsis, hemorrhage, shock, arrythmias, or congenital heart disease. Emergency vascular access may be inserted outside the hospital by first responders, in the emergency department, or in the neonatal intensive care unit (NICU). We appreciate that the preferred method of vascular access may vary based on the time after birth, location, and indication but suggest that a broader review may be valuable for health care providers that encounter newborn infants in these settings. We have, therefore, included neonates who have any emergency indication in the population for this PICOST, not just resuscitation immediately after birth, recognizing that we may need to use indirect evidence to support recommendations made for emergency vascular access during DR resuscitation.
CONFLICT OF INTERESTS:	The following Task Force members have no conflicts of interest to declare: Daniele Trevisanuto, Gary M Weiner, Juin Yee Kong, Mandira D Kawakami, Maria Fernanda de Almeida, Marta Thio, Nicole Yamada, Ruth Guinsburg, Tetsuya Isayama, Helen G Liley, Yacov Rabi, Georg M. Schmölzer. Dr. Myra Wyckoff is a co-author of studies examining the response to epinephrine administered through an umbilical vein catheter and did not participate in decisions related to inclusion of these studies. [4,11-13]

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	Although only 0.1% to 0.8% of newborn infants will receive epinephrine (adrenaline) for resuscitation after birth [3,14], rapidly establishing emergency vascular access is critically important because delayed administration of epinephrine is associated with decreased survival. [4,5] Establishing vascular access can be challenging, especially in the setting of cardiac arrest or altered perfusion. Identifying the most rapid, safe, and effective procedure for establishing vascular access has been prioritized by the ILCOR NLS TF.	Establishing emergency vascular access for the administration of anti-arrhythmic medications, vasopressors, prostaglandin E1, fluids, antibiotics, or blood products may be a lifesaving procedure during resuscitation and stabilization of newborn infants with persistent bradycardia that does not respond to ventilation and chest compressions, cardiopulmonary arrest, cardiac arrythmias, and shock.
Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ● Don't know	Our review did not find any clinical trials directly comparing one vascular access device with another. Because of the variable and often small number of included infants, heterogeneous settings and indications, and lack of within study comparisons between infants receiving different types of vascular access, no summary effect estimate for desirable effects could be generated. Instead, the results were narratively summarized. The included studies consisted of ten descriptive case series [11,12,15-22] and six case reports.[23-28] In the included case series, both umbilical vein catheters (UVC) inserted in the delivery room and intraosseous (IO) access devices inserted in the ED, NICU, and out-of-hospital settings frequently achieved vascular access in a timeframe consistent with neonatal resuscitation guidelines. The desirable effects of establishing effective emergency vascular access are anticipated to be large, but the evidence is insufficient to compare the efficacy of UVCs with IO access devices, or any other device. Peripheral vein (PIV) access was achieved in a small case series in the delivery room; however, none of the infants included in this series were bradycardic at the time of catheter insertion. [15] In another study, attempts at PIV access were successful in 0/3 newborn infants during resuscitation with chest compressions after birth and in 3/7 neonates <28 days in an out-of-hospital setting. [17]	In a newborn lamb model of asphyxial arrest, epinephrine administered through a low-lying UVC (inserted to a tip position below the porta hepatis) achieved a similar return of spontaneous circulation (ROSC), time to ROSC, and peak plasma epinephrine levels by 1 minute as epinephrine administered directly into the right atrium. [13] In another newborn lamb model of asphyxial arrest, epinephrine administered through an IO needle inserted into the femur achieved ROSC at a similar rate, with a similar number of epinephrine doses, and achieved similar peak plasma epinephrine levels as epinephrine administered into the central venous circulation via a jugular vein catheter. [29] Simulation studies suggest that clinicians with neonatal resuscitation training may achieve emergency vascular access faster using an IO device compared with inserting a low-lying UVC. [30,31]
Undesirable Effects How substantial are the undesirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ● Don't know	Our review did not find any clinical trials directly comparing one vascular access device or route of access with another. Because of the variable and often small numbers of included infants, heterogeneous settings and indications, and lack of within study comparisons between infants receiving different types of vascular access, no summary effect estimate for undesirable effects could be generated. Instead, the results were narratively summarized. We recognize that the reporting of complications associated	Unsuccessful, delayed, or ineffective emergency vascular access during neonatal resuscitation may delay or compromise the success of the resuscitation efforts. Delayed administration of epinephrine for bradycardia or asystolic newborn infants after birth is associated with a decreased probability of ROSC. [4] Although no studies described complications specifically associated with emergency UVC insertion, accessing the central venous circulation with a UVC for routine administration of

	with emergency vascular access devices in case series and case reports is subject to publication bias and confounding by indication. We did not identify studies describing complications associated with emergency UVC insertion. One study described gangrene of the buttocks following attempted umbilical vein needle puncture for epinephrine administration. [24] Severe complications associated with IO device insertion have been described including tibial fractures, compartment syndrome, severe soft tissue necrosis, osteomyelitis, soft tissue infection, and limb amputation. [16,19-21,23,25-28] In the largest case series, IO access was associated with a 35% (55/155) risk of all complications and a 6% (9/155) risk of serious complications. [21] The undesirable effects of unsuccessful, delayed, or ineffective emergency vascular access are anticipated to be large, but the evidence is insufficient to compare the safety of the UVC with the IO access device. No complications were reported with the insertion of a PIV in the delivery room; however, none of the included infants in the small case series were in cardiac arrest or bradycardic at the time of PIV insertion. [15]	parenteral nutrition, medications, blood products, and fluids is associated with complications including thrombosis, vessel perforation, arrhythmia, hepatic injury, and bloodstream infection. [32-34] Insertion of an IO access device requires penetrating the infant's skin and bone cortex. Insertion of a UVC may require transection of the umbilical cord, with a risk of bleeding, but does not require puncture of the infant's skin or other structure. Cadaver studies suggest that correct positioning of the IO access device within the bone marrow cavity may be difficult to achieve with a commercially available IO needles whether inserted by hand-twisting or using a semi-automatic drill, particularly among very-low birthweight infants. [35,36] Successful placement in the bone marrow cavity was < 50% for a commercially available access device (43% hand twisted, 40% drill inserted) and 61% using a butterfly needle. Among preterm and term stillborn infants (median 29.2 weeks, IQR 27.2-38.4 weeks), the median diameter of the bone marrow cavity was only 4.0 mm (IQR 3.3-4.7). An ultrasound study suggested that insertion of an IO needle in the proximal tibia of both term and preterm infants would frequently violate the study authors' pre-defined safe distance (10 mm) from the tibial growth plate. [37]

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies?	The overall certainty of the evidence was very low due to the absence of studies directly comparing the different intravascular access devices. The evidence is limited to case series and case reports.	No clinical trials directly comparing one vascular access device with another were found. The included studies consist of ten descriptive case series and six case reports.

Values
Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or	The evaluation of the main outcomes is consistent with the importance assigned by	

variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	the ILCOR NLS Task Force and a larger group of neonatal resuscitation experts. [1]	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ Don't know	There are no human clinical trials to directly compare the safety and efficacy of the UVC, IO device, and PIV for emergency vascular access during neonatal resuscitation.	Given the accessibility of the umbilical vein immediately after birth without the need to puncture the infant's skin or bone cortex, it is reasonable to assume that the balance of effects favors a low-lying UVC for emergency vascular access in the delivery room. If the umbilical vein is no longer patent, or UVC insertion is not feasible, it is reasonable to assume that the balance of effects favors insertion of an IO access device. There is insufficient evidence to evaluate the balance of effects for the use of a PIV for emergency vascular access in the setting of neonatal cardiac arrest or bradycardia. In the setting of cardiovascular collapse, it is reasonable to assume that it may be difficult to insert a PIV.

Resources required

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know	There are no published data on the resources required to train clinicians or to use the different vascular access devices during neonatal resuscitation.	The cost of purchasing and maintaining IO access devices that require dedicated equipment (needles and/or drills) that would be used infrequently may be higher than a UVC or PIV because these devices, and the necessary supplies, are already routinely used in many newborn infant care settings. However, sterile UV catheters are also expensive and may not be routinely available in low-resource settings or alternate locations where neonates are resuscitated (out-of-hospital settings, emergency departments). Because severe adverse effects have been mainly reported when using intraosseous access devices, further

		resources may be necessary to care for potential complications.

Certainty of evidence of required resources
What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies	There are no published data on the resources required to train clinicians or to use different vascular access devices during neonatal resuscitation.	

Cost effectiveness
Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention○ Varies ● No included studies	No studies reported the cost-effectiveness of the vascular access devices.	The UVC and PIV may be more cost-effective because these devices, and the supplies required to insert them, are already routinely maintained in many newborn infant care settings. Purchasing and maintaining the supplies required to insert an IO device, which would be used infrequently, may be less cost-effective. However, in low-resource settings, neither sterile UVCs nor IO devices may be routinely available.

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	No studies reported the impact on health equity.	All included studies were from high resource countries, and the findings may not be generalizable to other contexts. In low-resource settings, equipment and personnel trained in advanced vascular access, such as umbilical vein or intraosseous access, are often limited. An intervention that relies on simpler, widely teachable techniques is more likely to improve health equity globally, particularly in settings with the highest burden of critically ill newborns who require emergency vascular access.

Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	No included study evaluated the acceptability of the different vascular devices.	The acceptance of a particular vascular access by different clinicians may be influenced by their experience, clinical setting, and the infant's postmenstrual age. In a survey of clinicians working in German NICUs and special care nurseries, 61% of neonatologists and 53% of non-neonatologists preferred insertion of an emergency UVC compared to an IO access device for DR resuscitation of a term newborn. [6] However, emergency UVC placement was rated very difficult to impossible by 27% of neonatologists and 46% of non-neonatologists. In contrast, non-emergency placement of a UVC in the DR was only rated as very difficult or impossible by 4% of neonatologists and 14% of non-neonatologists. Emergency placement of an IO device in the DR was rated very difficult or impossible by 3% of neonatologists and 6% of non-neonatologists. Respondents cited lack of clinical experience as the primary reason for their hesitation to place either a UVC or IO access device. 50% of participants stated they had never inserted an IO device and 30% had never inserted a UVC. It is reasonable to assume that both UVC and IO devices are acceptable to key stakeholders because they are both recommended in current national and regional neonatal resuscitation guidelines. [38,39]

Feasibility
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The included case series demonstrate that UVC and IO insertion are generally feasible, but the feasibility and implementation may vary based on the setting, device availability, provider's training, the patency of the umbilical vein (infant's age, presence of abdominal wall anomalies), and the size of the bone marrow cavity. [11,12,16,18-22] The feasibility of PIV insertion in the setting of cardiovascular compromise could not be established from the included studies. [15,17]	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know

DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	**Don't know**
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	**Don't know**
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	**No important uncertainty or variability**			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	**Varies**	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	**Don't know**
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	**No included studies**
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	**Don't know**
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	●	○	○

CONCLUSIONS

Recommendation

During resuscitation of infants immediately after birth, we suggest inserting an umbilical vein catheter as the primary method to obtain emergency vascular access (conditional recommendation, very low certainty evidence).
During resuscitation of infants immediately after birth, if insertion of an umbilical vein catheter is not successful or not feasible, we suggest that inserting an intraosseous device may be a reasonable alternative to obtain emergency vascular access (conditional recommendation, very low certainty evidence).
After the immediate newborn period, when the umbilical vein is no longer patent, we suggest that inserting an intraosseous device is a reasonable method to obtain emergency vascular access (conditional recommendation, very low certainty evidence).
There is insufficient evidence to make a recommendation on the use of a peripheral vein catheter for emergency vascular access in the setting of neonatal cardiac arrest or bradycardia.

Justification

In making this recommendation for newborn infants requiring emergency vascular access for neonatal resuscitation and stabilization, the Task Force considered that there were no human clinical studies comparing the different access devices (UVC, IO, PIV), so conclusions are based on case series and case reports. Efficacy, effectiveness, cost, resources, equity, acceptability, and safety of one procedure over another could not be directly assessed due to the small number of included infants, heterogeneity of settings and indications, and lack of comparisons between the devices within the same study. This limited evidence base inevitably increases the subjectivity of the judgements, which were concluded by TF consensus.

In the included case series and case reports, emergency vascular access was successfully established using either a UVC or an IO device in a wide range of settings, including the DR, emergency department, NICU, and out-of-hospital locations. When the umbilical vein is patent, insertion of a UVC does not require puncture of the infant's skin or bone cortex. Serious complications have been associated with the use of IO access devices during neonatal resuscitation. Moreover, neither the equipment nor training required to insert an IO device may be routinely available in the birth setting leading to concerns about feasibility. However, insertion of a UVC may not be successful or feasible if an abdominal wall defect is present, after the immediate newborn period when the umbilical vein is no longer patent, or in settings where the provider does not have the training or equipment to access the umbilical vein. In these circumstances, an IO device may be a reasonable method to secure emergency vascular access. The evidence to assess the efficacy and safety of attempting emergency PIV access during neonatal cardiovascular collapse is too limited to make any recommendation.

Subgroup considerations

No data for the planned subgroup analyses were available.
The UVC was primarily used during initial birth resuscitation of term and preterm infants in delivery rooms for severe bradycardia or asystole requiring epinephrine and fluids. [11,12,18,22] The IO device was used in both hospital and out-of-hospital settings with a broader mix of indications and providers. It was used mostly within the first week after birth, but the studies included infants up to 44 weeks' postmenstrual age. [16,17,19-21] The lowest gestational age and birthweight reported for UVC insertion was 23 weeks and 750 grams. [11,12,18,22] The lowest gestational age and birthweight reported for IO access was 24 weeks and 515 grams. [16,19,20] Peripheral vein access was reported in two studies. One described infants immediately after birth in the DR and one reported events occurring among infants <28 days of age receiving chest compressions administered by emergency services personnel outside the hospital setting. [15,17] The lowest gestational age and birthweight reported for PIV access was 24 weeks and 630 grams. [15,17]

Implementation considerations

We anticipate that implementing different methods to secure emergency vascular access into routine clinical practice would require training and cost, and should consider the clinician's experience, the resuscitation setting, and important infant characteristics (size, gestational and postmenstrual age, congenital anomalies). Capable personnel and appropriate equipment and supplies should always be available to establish emergency vascular access during resuscitation and stabilization of newborn infants.

Monitoring and evaluation

Prospective local and international registries should collect information regarding time to achieve heart rate >100 bpm, time required to successfully insert an emergency vascular access device, successful vascular access at the first attempt, number of attempts until successful vascular access is achieved, and complications associated with the procedure. Death during the event requiring emergency vascular access and before hospital discharge should also be recorded.

The clinical context (during initial birth resuscitation vs. any other indication), resuscitation setting (delivery room, emergency department, NICU, out of hospital event), provider (neonatology trained provider vs. other), population (post-menstrual age and calendar age at the time of device insertion) should be monitored.

Research priorities

- Prospective local and international registries should collect information on the success and complications associated with emergency vascular access procedures.
- Future studies should compare the different vascular access methods in newborn infants needing resuscitation and stabilization in different settings (delivery ward, emergency department, NICU and out of hospital settings).
- Studies should evaluate the training of healthcare providers in vascular access procedures and the impact on important outcomes.
- Economic studies should measure the cost-effectiveness of the different vascular access procedures in a range of clinical settings, including high- and low-resource settings.

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