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| Question |
| **NLS 5140- Tactile stimulation for resuscitation immediately after birth**  |
| **Population:** | Term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations  |
| **Intervention:** | Any tactile stimulation performed within 60 seconds after birth and defined as one or more of the following: rubbing the chest/sternum; rubbing the back; rubbing the soles of the feet; flicking the soles of the feet; combination of these methods. This intervention should be done in addition to routine handling with measures to maintain temperature.  |
| **Comparison:** | Routine handling with measures to maintain temperature, defined as care taken soon after birth, including positioning, drying and additional thermal care. |
| **Main outcomes:** | Spontaneous breathing without positive pressure ventilation (yes or no); time to the first spontaneous breath or crying from birth; and time to heart rate ≥100 bpm from birth.  |
| **Setting:** | Delivery room or any other place of birth |
| **Perspective:** |  |
| **Background:** | Tactile stimulation has been suggested in the initial steps of stabilization of the newborn infant in the treatment recommendations from ILCOR in 1999, 2006, 2010, 2015 and 2020 {Kattwinkel 1999 1927; ILCOR 2006 e-978; Perlman 2010 S516; Perlman 2015 S204; Wyckoff 2020 S185}. These recommendations are largely based on many years of experience and expert opinion. Because the effectiveness of tactile stimulation to facilitate breathing at birth has never been systematically evaluated by ILCOR, this PICOST was prioritized by the Neonatal Life Support Task Force. |
| **Conflict of interests:** | None  |

# Assessment

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| ProblemIs the problem a priority? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | Each year approximately 10% of 140 million neonates born globally are delivered with absent or poor respiratory effort and need some degree of support to achieve cardiopulmonary stability {Ersdal 2012 869}. Basic resuscitation interventions immediately after birth in these infants are essential in preventing progression to circulatory collapse and death. One of the most common interventions to stimulate breathing at birth is tactile stimulation. For decades, tactile stimulation has been suggested in the initial steps of stabilization of the newborn infant {Wyckoff 2020 s185}, but its effectiveness was never systematically assessed.  |  |

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| Desirable EffectsHow substantial are the desirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Trivial○ Small○ Moderate○ Large○ Varies● Don't know | Based on the systematic review, the very limited available data suggest a benefit to tactile stimulation in decreasing the need of tracheal intubation in preterm infants, but the certainty of evidence is very low {Dekker 2017 61}. Observational studies showed that, although the methods of stimulating were variable, infants that received tactile stimulation responded with crying, grimacing and body movements {Katheria 2016 75; Gaertner 2018 F132; Pietravalle 2018 306; Van Henten 2019 F661}.A single center RCT compared single vs. repetitive tactile stimulation in preterm infants immediately after birth. Patients in the repetitive stimulation group had higher oxygen saturation levels and lower oxygenrequirements at the start of transport to the NICU {Dekker 2018 37}.A single center RCT compared two different techniques of tactile stimulation (back rubbing vs foot flicking). Among 186 infants >1500g who did not cry at birth, 77% presented with spontaneous breathing without PPV. No differences were found between the techniques {Cavallin 2021 137}.In studies that analyze a bundle of procedures to stimulate respiratory transition at birth in low resource settings, tactile stimulation together with upper airway suction triggered the initiation of spontaneous respirations {Ersdal 2012 869; Msemo 2013 e353}.  | Tactile stimulation has the potential to trigger respiratory movements in apneic newly born infants and to increase the depth and the frequency of respirations in infants with irregular or shallow breathing {Dekker 2019}. If this is true, an important percentage of the 14 million newborns that need help to initiate breathing at birth each year globally would benefit from a non-invasive procedure available in all settings, but there are no randomized controlled studies to affirm this potential beneficial effect.This assumption would be correct only if the method (type, number, body region, duration) of tactile stimulation is an evidence-based recommendation. However, there are no data on the optimal means by which to deliver tactile stimulation. In a systematic review of 15 studies on tactile stimulation to terminate or to prevent apnea of prematurity, tactile stimulation, manual or mechanical, has been shown to shorten the duration of apnea, hypoxia, and or bradycardia or even prevent an apnea, although the review did not assess the tactile stimulation in delivery-room resuscitation just after birth. This provides indirect evidence that tactile stimulation may be effective to stimulate breathing in newborn infants with absent, intermittent or shallow respiration immediately after birth {Cramer 2018 45}. |
| Undesirable EffectsHow substantial are the undesirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Large○ Moderate○ Small○ Trivial● Varies○ Don't know | Based on a narrative review, there are some concerns related to possible adverse effects of tactile stimulation in delaying the initiation of ventilation beyond 60 seconds after birth, which may then compromise the efficacy of the overall resuscitation {Cavallin 2021 137; KC 2021 235; Pietravalle 2018 306}. Also, there is a report of soft tissue trauma after tactile stimulation {Kalaniti 2017 84]. Pietravalle et al observed 150 term newborn infants with apnea, hypotonia or both at birth in a single center in Mozambique. Tactile stimulation was performed in 68% of these infants. First stimulation was provided at a median of 134 seconds (IQR 53-251) after birth. Only 9 (9%) infants who received tactile stimulation responded with spontaneous breathing without need for PPV {Pietravalle 2018 306}. KC et al observed 22,752 births in Nepal, Bangladesh and Tanzania, and 5,330 did not cry within 1 minute after birth. Among them, 2,055 (39%) received tactile stimulation, 1,907 (36%) were suctioned immediately after birth, and 677 (13%) received bag and and mask ventilation. Most newborns (71–95%) who did not respond to stimulation did receive bag and mask ventilation, but only 1% within the recommended 1 minute after birth {KC 2021 235}.Cavallin et al observed 186 infants >1500g who did not cry at birth in a single center in Uganda. Among the 42 infants who did not demonstrate spontaneous breathing after tactile stimulation, the median time to initiate PPV was 60 seconds, i.e. in half of the infants PPV was delayed (started after 60 seconds). No skin lesions were reported in these infants {Cavallin 2021 137}.A case report of soft tissue trauma, with bruises and scratches to the infant’s back, has been reported during/after tactile stimulation {Kalaniti 2017 84}.No studies systematically report possible adverse outcomes of tactile stimulation in newborn infants with absent, intermittent or shallow respiration immediately after birth in relation to admission to a neonatal special unit or intensive care unit, neurodevelopment or survival.  |  Possibly, the adverse effects depend on the training and expertise of health care providers. |
| Certainty of evidenceWhat is the overall certainty of the evidence of effects? |
| Judgement | Research evidence | Additional considerations |
| ● Very low○ Low○ Moderate○ High○ No included studies | Overall, the certainty of evidence was very low or absent. For the important outcome of tracheal intubation in the delivery room, evidence of very low certainty (downgraded for risk of bias, indirectness, and imprecision, and upgraded by the strong association) from 1 observational trial {Dekker 2017 61} involving 245 preterm newborns showed possible benefit from receiving tactile stimulation in addition to routine handling with measures to maintain temperature compared to routine handling (RR0.41, 95%CI 0.20-0.85). There are concerns related to:Indirectness: All studied infants (n=245) were put on CPAP before tactile stimulation in contrast to the common practice of tactile stimulation before CPAP or positive pressure ventilation. Selection bias: A total of 673 infants were video recorded, of whom only 321 recordings were complete and of good quality. From these, 245 recordings included stabilization at birth of infants born with a gestational age <32 weeks and were included in the analysis. Confounding: the indication of tactile stimulation was retrospectively assessed and not clear. Among the 81 infants that did not receive tactile stimulation, 72 presented apnea/irregular breathing, hypoxia and/or braycardia immediately after birth. Among the 164 infants that received tactile stimulation, it was not possible to determine the number of infants that had indication for the procedure. The authors report that these 164 infants received 585 episodes of tactile stimulation, but in 198 (34%) episodes the clinical indications for the procedure could not be retrieved. | One study that could not be included in the systematic review due to a critical risk of bias did not find a beneficial effect of tactile stimulation. In a single center in Austria, Baik-Schneditz et al reported that respiratory support in the first 15 minutes after birth was applied in 24/43 (56%) neonates who received tactile stimulation and in 31/57 (54%) of non-stimulated infants {Baik-Schneditz 2018 952}.For the important primary outcomes of establishment of spontaneous breathing without PPV, time to the first spontaneous breath or crying, and time to heart rate ≥100 bpm, no data were reported. For the critical secondary outcomes of survival, neurodevelopmental outcomes, and intraventricular hemorrhage in preterm infants <34 weeks, no data were reported. For the important secondary outcomes of admission to a neonatal special or intensive care unit and oxygen and/or respiratory support at admission, no data were reported. |
| ValuesIs 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 valuation of the main outcomes is consistent with the values assigned by the ILCOR NLS task force and a larger group of neonatal resuscitation experts. {Strand 2020 328}.  |  |

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| Balance of effectsDoes 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 | We have considered the balance between the evidence supporting a possible reduction in the risk of tracheal intubation and the lack of evidence of benefit or harm for other outcomes.  | Although there are some concerns related to delaying the initiation of positive pressure ventilation and possible trauma in depressed newly born infants, the possible benefit of decreasing the need of invasive procedures, such as tracheal intubation in preterm infants {Dekker 2017 61}, that require specialized equipment and trained personnel, influenced our judgement. Also studies that show that a bundle of procedures including tactile stimulation provided to infants who do not adequately breathe immediately after birth may trigger the initiation of respirations in around 50% of them without further need for resuscitation {Ersdal 2012 869} influenced our judgement.  |
| Resources requiredHow large are the resource requirements (costs)? |
| 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 cost data on tactile stimulation immediately after birth  | The procedure per se (tactile stimulation) does not require financial investments, except for training health care providers. There are potential savings if tactile stimulation reduces the need for positive pressure ventilation and tracheal intubation, and the progression to circulatory collapse. These considerations may be applied in both low and high resource settings. |
| Certainty of evidence of required resourcesWhat is the certainty of the evidence of resource requirements (costs)? |
| Judgement | Research evidence | Additional considerations |
| ○ Very low○ Low○ Moderate○ High● No included studies | No data available. No studies were found that estimate the costs of applying tactile stimulation vs. not applying tactile stimulation for term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations  |  |
| Cost effectivenessDoes 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 data available. No studies were found that estimate the cost effectiveness of applying tactile stimulation vs. not applying tactile stimulation for term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations. | Although there are no published cost-effectiveness data, it is possible that tactile stimulation will decrease the cost of delivery room supplies used to offer positive pressure ventilation at birth. There could be a cost if there are (as yet unmeasured) adverse effects.  |

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| EquityWhat 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 data available.   | The use of tactile stimulation in term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations may increase health equity. If a simple and inexpensive procedure that can be equally used in low and high resource settings, without additional resource requirements beyond providers’ training, can decrease the need for positive pressure ventilation at birth, this procedure may increase opportunities to offer adequate resuscitation globally. This assumption would be correct only if the method (time of initiation, type of stimulus, body region, number of stimuli, total duration) of tactile stimulation is an evidence-based recommendation. However, there are no data on the optimal method of tactile stimulation.  |
| AcceptabilityIs the intervention acceptable to key stakeholders? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | Tactle stimulation is probably acceptable, since it is recommended for newly born infants with inadequate respiratory effort at birth in several neonatal resuscitation guidelines and recommendations across the world for decades {Kattwinkel 1999 1927; International Liaison Committee on Resuscitation 2006 978; Perlman 2010 S516; Perlman 2015, S204; Wyckoff 2020 S185; Aziz 2020 S524; Madar 2021 291; Liley 2017 621; Hosono 2020 128; WHO 2012 1}. | Dekker et al, reported that “colleagues of the neonatal team are very reluctant to not stimulate infants as tactile stimulation is one of the most basic interventions during neonatal resuscitation” {Dekker 2018 37}.Lee et al reported that the quality of evidence for stimulation at birth is low, partly because it is considered the standard of care {Lee 2011 S12}. |
| FeasibilityIs the intervention feasible to implement? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | Tactile stimulation is a feasible intervention to implement. Training of health care providers will be necessary in order to avoid delays in the initiation of positive pressure ventilation and tissue trauma in term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations. |  |

Summary of judgements

|  | **Judgement** |
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| **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**

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| 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 |
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# Conclusions

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| Recommendation |
| We suggest it is reasonable to apply tactile stimulation in additionto routine handling with measures to maintain temperature in newborn infants with absent, intermittent, or shallow respirations during resuscitation immediately after birth (weak recommendation, with very low certainty due to risk of bias, indirectness, and imprecision). Tactile stimulation should not delay the initiation of positive pressure ventilation for newborns who continue to have absent, intermittent, or shallow respirations after birth.  |

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| Justification |
| In making these recommendations, the Neonatal Life Support Task Force acknowledges the following:* The very limited available data suggest a possible benefit to tactile stimulation in decreasing the need for tracheal intubation in preterm infants, but the certainty of evidence is very low. This benefit was found in a single retrospective cohort study {Dekker 2017 61} involving 245 preterm newborns <32 weeks of gestational age. The results of this study should be analyzed with caution due to indirectness (all 245 infants were put on CPAP before tactile stimulation in contrast to the common practice of tactile stimulation before CPAP or positive pressure ventilation), possible selection bias (among 673 infants who were video recorded immediately after birth, 245 (36%) were included in the study), and confounding (the clinical indication of tactile stimulation was retrospectively assessed and it could not be determined in 34% of the 585 tactile stimulation episodes).
* Observational studies showed that, in general, infants who received tactile stimulation responded with crying, grimacing and body movements, although the methods of stimulation were variable and the outcomes analyzed were not exactly the same among the studies {Gaertner 2018 F132; Katheria 2016 75; Pietravalle 2018 306; Van Henten 2019 F661}. These studies could not be included in the systematic review due the lack of control groups who did not receive tactile stimulation.
* A single center RCT compared single vs. repetitive tactile stimulation in preterm infants immediately after birth. Patients in the repetitive stimulation group had higher oxygen saturation levels and lower oxygenrequirements at the start of transport to the NICU {Dekker 2018 37}. This study could not be included in the systematic review due to the lack of control group who did not receive tactile stimulation.
* A single center RCT compared back rubbing vs. foot flicking to provide tactile stimulation in preterm and term infants with birthweight >1500g who did not cry at birth. There was no difference between both techniques in achieving effective crying to prevent the need of PPV {Cavallin 2021 137}. This study could not be included in the systematic review due to the lack of a control group who did not receive tactile stimulation.
* In studies that analyze a bundle of procedures to stimulate respiratory transition at birth in low resource settings, tactile stimulation together with upper airway suction triggered the initiation of spontaneous respirations {Ersdal 2012 869; Msemo 2013 e353}. These studies could not be included in the systematic review due to the inability to isolate the effects of tactile stimulation as well as the lack of a control group.

Despite the possible benefits outlined above, there are some concerns related to possible adverse effects of tactile stimulation in delaying the initiation of ventilation beyond 60 seconds after birth, which may then compromise the efficacy of the overall resuscitation {Cavallin 2021 137; KC 2021 235; Pietravalle 2018 306}. Also, there is a report of soft tissue trauma after tactile stimulation {Kalaniti 2017 84].  |
| Subgroup considerations |
| No data were reported regarding subgroups of interest: gestational age (<34 weeks, 34-36 6/7 weeks, and ≥37 weeks), cord management (early and delayed/cord milking), settings (high and low resource), and method of stimulation (type, number and/or duration of stimuli).  |
| Implementation considerations |
| Implementation will require a decison on the optimal methods of tactile stimulation: time of initiation, type of stimulus, body region, number of stimuli, total duration. Once an evidence-based technique is recommended, training should be available to health care providers. |
| Monitoring and evaluation |
| As the recommendation for tactile stimulation is very weak and is based on very low certainty evidence, continued monitoring and evaluation is highly recommended. |
| Research priorities |
| In order to make evidence-based recommendations on the use of tactile stimulation for term or preterm newborn infants immediately after birth with absent, intermittent, or shallow respirations, it is important that research covers the following knowledge gaps:* Effect of tactile stimulation on the main outcomes: breathing without PPV; time to the first spontaneous breath or crying from birth; and time to heart rate ≥100 bpm from birth
* Effect of tactile stimulation on secondary outcomes: death in the delivery room, hospital death; neurodevelopmental outcomes; intraventricular hemorrhage only in preterm infants; oxygen and/or respiratory support at admission to a neonatal special unit or intensive care unit; and admission to a neonatal special or intensive care unit for those not admitted by protocol.
* Effects of tactile stimulation in different gestational ages.
* Effects of tactile stimulation with different cord management strategies.
* Which patients benefit from tactile stimulation (all, patients with apnea, irregular breathing or other): what is the indication of tactile stimulation
* Efficacy of different methods of tactile stimulation (rubbing, flicking or other)
* Efficacy of stimulation in different parts of the body (soles of the feet, back, chest or other)
* When to start tactile stimulation after birth and when to stop
* Duration of each stimulus (seconds)
* Optimal number of stimuli
* Optimal duration of stimulation before providing respiratory support (seconds)
* Adverse effects of tactile stimulation
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