



**Maintaining normal temperature immediately after birth in late preterm and term infants (NLS 5100/NRP 599)
Evidence Update Worksheet**

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COI: Several authors with conflicts of interest in the original SR, none in this evidence update.

Task Force: Neonatal Life Support Task Force

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PICOST / Research Question:

Population: In late preterm and term infants (≥ 34 weeks' gestation, or equivalent birth weight), immediately after birth

Intervention: Increased room temperature $\geq 23.0^{\circ}\text{C}$, thermal mattress, plastic bag or wrap, hat, heating and humidification of gases used for resuscitation, radiant warmer (with or without servocontrol), early monitoring of temperature, warm bags of fluid, warmed swaddling/clothing, skin to skin care with a parent, or any combination of these interventions

Comparators: Drying, without any of the above interventions.

Outcomes:

Primary outcomes:

- Survival (critical)
- Rate of normothermia on admission to neonatal unit or postnatal ward (important)

Secondary outcomes:

- Rate of either hypothermia or hyperthermia on admission to neonatal unit or postnatal ward (important)
- Response to resuscitation- e.g., need for assisted ventilation, highest FiO_2 (important)
- Important morbidity e.g., rates of admission to neonatal special or intensive care nursery, need for respiratory support (important)

Outcomes ratings using the GRADE classifications of critical or important were decided according to a consensus for international neonatal resuscitation guidelines {Strand 2020 328}. Outcomes were converted into main outcomes and additional outcomes for submission to PROSPERO {CRD42021270739}

Potential subgroups were defined *a priori*: by gestation groups, early vs later umbilical cord clamping, by low- vs high-resourced setting or by inborn vs outborn status) for any comparison.

Study Design: Randomized controlled trials (RCTs), quasi-RCTs, observational studies including retrospective and prospective cohort studies, controlled before-after studies, interrupted time series studies and quality improvement (QI) initiatives were included. Conference abstracts, unpublished studies and study protocols were excluded.

Time Frame: all years and languages were included provided there was an English abstract. The literature was first searched on 2nd August 2021 and updated on 20 July 2022.

Year of last full review: 2022 {Ramaswamy 2022 81}

2022 ILCOR Consensus on Science and Treatment Recommendation for this PICOST:

Twenty five RCTs {Agrawal 2018 1335; Belsches 2103 e656; Cardona-Torres 2012 129; Carfoot 2005 71; Chaput de Saintonge 1979 570; Christensson 1992 488; Crenshaw 2019 731; Duryea 2016 e1; Greer 1988 265; Huang 2019 68; Johanson 1992 859; KoC 2017 1; Kollman 2017 e0168783; Lang 20904 843; Leadford 2013 e128; Marin Gabriel 2010 1630; Omene 1978 300; Raman 1992 117; Ramani 2018 492; Safari 2018 32; Shabeer 2018 1324; Srivastava 2014 22; Stirparo2013 186; Travers 2021 55; Walsh 2021 95} and 10 non-RCTs {Agudelo 2020 105020; Albuquerque 2016 e2741; Aley-Raz 2020 476; Andrews 2018 e } 20171214; Datta 2017 e000183; Hill 1979 287; Nissen 2019 1; Patodia 2021 277; Shaw 2018 126; Sprecher 2021 270} were identified for inclusion

Ambient temperature of birthing environment

1. In late preterm and term infants (≥ 34 weeks' gestation), we suggest the use of room temperatures of 23°C compared to 20°C at birth in order to maintain normothermia (weak recommendation, very low certainty evidence).

Skin to Skin (SSC) versus no SSC

2. In late preterm and term infants (≥ 34 weeks' gestation) at low risk of needing resuscitation, we suggest the use of skin to skin care immediately after birth rather than no skin to skin care to maintain normal temperature (weak recommendation, very low certainty evidence).

Plastic Bag or Wrap (PBW) vs no PBW

3. The NLS Task Force considered that in late preterm and term infants ≥ 34 weeks' gestation, for routine use of a plastic bag or wrap vs no plastic bag or wrap, the balance of desirable and undesirable effects was uncertain and the certainty of evidence was very low. Furthermore, cultural values and maternal preferences in relation to this specific intervention and cost implications are not known, and therefore no treatment recommendation for routine use can be formulated. The NLS Task Force considered it important to promote skin to skin care. In some situations where skin to skin care is not possible, it is reasonable to consider the use of a plastic bag or wrap, among other measures to maintain normothermia (weak recommendation, very low certainty evidence).

PBW with SSC versus SSC alone

4. The Task Force considered that in late preterm and term infants ≥ 34 weeks' gestation, for routine use of a plastic bag or wrap in addition to skin to skin care immediately after birth compared to skin to skin care alone, the balance of desirable and undesirable effects was uncertain. Furthermore, the cultural values and maternal preferences in relation to the use of plastic bags or wraps and the cost implications are not known, and therefore no treatment recommendation can be formulated.

For the following comparisons, or for any combination of these interventions, the systematic review found no RCTs:

- Heating and humidification of gases used for resuscitation, vs. any other intervention or standard hospital care
- The use of a radiant warmer, vs any other intervention or standard hospital care
- Early monitoring of temperature vs no early monitoring of temperature
- Warm bags of fluid compared to any other intervention or standard hospital care
- Warmed swaddling/clothing vs any other intervention or standard hospital care

Task force Knowledge Gaps

- The balance of risks and benefits for each evidence-based intervention when combined with other interventions is unknown or highly uncertain.
- There is a need for studies to examine the effectiveness of interventions for which no evidence was available or for which evidence was insufficient to make treatment recommendations. The Task Force considered that priorities among these included:
 - Use of a thermal mattress, which may assume greater importance if a parent is unable to provide skin to skin care
 - Caps made of various materials

- Use of heated, humidified gases for resuscitation, for those infants who receive assisted ventilation, particularly in the context of advanced resuscitation
- Early monitoring of temperature vs no early monitoring of temperature
- The role of low or moderately low-cost interventions such as prewarmed bags of IV fluid placed around the baby, or prewarmed swaddling and clothing.
- The effect of maternal hypothermia or hyperthermia on newborn infants' temperatures.
- Since nearly all the included studies excluded infants who received or were at high risk of receiving resuscitation, more studies are needed to determine the best methods of maintaining normothermia in these infants.
- Standardising the timing and method of recording temperature for all infants would enhance the potential both for benchmarking and for meta-analysis of studies in future reviews.

Gaps in relation to room temperature:

- The balance of risks and benefits when combined with other measures to maintain normothermia (e.g. skin to skin care, plastic bag or wrap).
- The effect of other set temperatures (besides 20°C or 23°C) for operating room or birthing room temperatures.
- The effect of measures to control room temperatures in various settings on risk of airborne diseases.
- Whether the results found for operating room temperatures are applicable to other birthing locations.

Gaps in relation to skin to skin care

- The role of skin to skin care in maintaining normal temperature in babies requiring the resuscitation: (a) Can some resuscitation manoeuvres be performed during skin to skin care and (b) for infants who have required some resuscitation interventions, when can skin to skin care be safely commenced?
- The role of skin to skin care in maintaining normal temperature in the setting of delayed umbilical cord clamping.
- The balance of risks and benefits of skin to skin care in the setting of various ambient temperatures.

Gaps in relation to use of plastic bags or wraps

- The balance of risks and benefits of plastic bag or wrap in the setting of various ambient temperatures and maternal temperatures, and depending on the use of other concomitant measures to maintain normothermia in late preterm and term infants.
- Is there a role for adding a plastic bag or wrap as a serial or supplementary intervention, if other measures are insufficient?
- The role of plastic bags or wraps for out-of-facility births.
- The acceptability to parents and carers

Gaps in relation to use of a plastic bag or wrap with skin to skin care

- The balance of risks and benefits of plastic bag or wrap in combination with skin to skin care in the setting of various ambient temperatures, and depending on the use of other concomitant measures to maintain normothermia in late preterm and term infants.
- Is there a role for adding use of a plastic bag or wrap as a serial or supplementary intervention, if skin to skin care alone is insufficient to maintain normothermia, with the goal of sustaining skin to skin care?
- The acceptability to mothers and clinicians of addition of a plastic bag or wrap, in the setting of provision of skin to skin care.

Current Search Strategy (for an existing PICOST) included in the attached approved PICOST

New Search strategy: (for a new PICOST should be outlined here as per Evidence Update Process)

PubMed (2203 results)

See Appendix 1

Database searched: PubMed

Time Frame: (existing PICOST) – updated from end of last search 20th July 2022

Date Search Completed: 28th April 2024

Search Results (Number of articles identified and number identified as relevant):**Identified:** 313**Full-text screening:** 66**Included:** 3**Summary of Evidence Update:**

Two randomized control trials addressing the PICOST were found. One non-randomized study was identified.

Relevant Guidelines or Systematic Reviews: none**RCT addressing the PICOST:**

Study Acronym; Author; Year Published	Aim of Study; Study Design; Study Size (N)	Patient Population	Study Intervention (# patients) / Study Comparator (# patients)	Endpoint Results (Absolute Event Rates, P value; OR or RR; & 95% CI)	Relevant 2° Endpoints (if any); Study Limitations; Adverse Events
	<u>Study Aim:</u> <u>Study Design:</u>	<u>Inclusion Criteria:</u>	<u>Intervention:</u> <u>Comparison:</u>	<u>1° endpoint:</u>	<u>Study Limitations:</u>
Ambia 2023 {Ambia, 2024 #118} Relevant subgroup data have been obtained from the study authors	<u>Study Aim</u> To measure the effect of Operating Room (OR) temperature on neonatal morbidity (note that infants received resuscitation, if needed, in the same OR) <u>Study Design</u> Cluster (RCT) (weekly allocation) (N=5221, of whom 4948 were ≥34 weeks' gestation)	<u>Inclusion Criteria</u> Caesarean delivery, newborns without congenital anomalies <u>Intervention</u> ≥34 weeks (w) (n=2268) <u>Comparator</u> ≥34 w (n= 2680)	<u>Intervention</u> OR 24°C <u>Comparator</u> OR 20°C	<u>1° endpoint</u> Proportion of newborns with temperature < 36.5°C on arrival to the nursery <u>Intervention</u> n= 406 (18.2%) <u>Comparator</u> n=1142 (43.4%)	<u>2° Endpoints</u> Proportion of newborns with hyperthermia (temperature >37.5 °C) on admission to NICU/PNW <u>Intervention</u> n= 201 (9.0%) <u>Comparator</u> n=81 (3.1%), No statistically significant difference between groups in the composite outcome of neonatal morbidities namely, the type of respiratory support, sepsis, hypoglycemia, and neonatal mortality (p=0.11) <u>Study Limitations</u> Single center Resistance from obstetricians and OR personnel to work in the higher ambient temperature

<p>Chanvorachote 2022</p> <p>{Chanvorachote, 2022 #22}</p>	<p>Study Aim To compare the efficacy of Aluminum Coated Fabric (ACF), cotton swaddle, and combined method to prevent neonatal hypothermia.</p> <p>Study Design Randomized controlled trial (N=175)</p> <p>Not stated when swaddling commenced after birth</p>	<p>Inclusion Criteria: BW >2500 grams, Apgar at 5 min >7 DR temperature of 27°C Transport to the nursery by crib</p>	<p>Intervention Ia. ACF (n=55) Ib. ACF+Cotton swaddle (n=60)</p> <p>Comparator Cotton swaddle (n=60)</p>	<p>1° endpoint Mean rectal temperature (SD) before swaddling in DR and at nursery admission.</p> <p>Before swaddling in the DR Intervention 1a: 36.7 (0.3)°C 1b: 36.7 (0.3)°C Comparator 36.6 (0.2)°C</p> <p>Nursery admission Intervention 1a: 36.6 (0.3)°C 1b: 36.7 (0.2)°C Comparator 36.7 (0.2)°C</p>	<p>2° Endpoints No difference between groups at any timepoint in the proportion of infants with hypothermia <36.5°C; or hyperthermia >37.5°C</p> <p>None of the reported outcomes showed any statistically significant or clinically relevant differences between the groups</p> <p>Study Limitations Small sample size (underpowered) Single center</p>
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Nonrandomized Trials, Observational Studies addressing the PICOST

Study Acronym; Author; Year Published	Study Type/Design; Study Size (N)	Patient Population {Chanvorachote, 2022 #22}	Primary Endpoint and Results (include P value; OR or RR; & 95% CI)	Summary/Conclusion Comment(s)
	Study Design:	Inclusion Criteria: GA	1° endpoint:	
<p>Gopalakrishnan 2022</p> <p>{Gopalakrishnan, 2022 #120}</p>	<p>Retrospective observational (n=256)</p> <p>Intervention Use of a thermal mattress (comprised of phase-changing material) on a radiant warmer during resuscitation or stabilization immediately after birth (n=154)</p> <p>Control No thermal mattress (n=102)</p>	<p>Inclusion Criteria BW 1500 to 2499 g without malformations or asphyxia</p> <p>GA Intervention 33.2 (1.6) w Comparator 33.6 (1.8) w</p>	<p>Mean Axillary temperature mean (SD) in DR before transport and at arrival in the PNW/NICU.</p> <p>DR Intervention 36.3 (0.8) °C Comparator 36.2 (0.6) °C (p=0.28)</p> <p>Admission temperature at PNW/NICU Intervention 36.6 (0.6)°C Comparator 36.4 (0.5)°C (p<0.01)</p>	<p>Use of a conductive thermal mattress in the DR was feasible and an effective method of preventing hypothermia.</p> <p>No hyperthermia (temperature > 37.5°C) was reported in either of the groups.</p>

Reviewer Comments: (including whether this PICOST should have a systematic or scoping review)

This update of the evidence found two RCTs {Ambia, 2024 #118; Chanvorachote, 2022 #119} and one observational study addressing the PICOST. {Gopalakrishnan, 2022 #120} In addition, we found one systematic review, two RCTs and one QI study providing indirect evidence regarding management of thermoregulation soon after birth. The systematic review with clinical guidelines by Tourneux {Tourneux, 2022 #56} focused on warming methods that could be used during, or as an alternative to skin to skin care, either in the delivery area or soon after admission to a NICU or postnatal ward. The review and recommendations included both preterm and term neonates. Recommendations from the Tourneux review are similar to those in our previous Systematic Review (SR). Search strategies were similar and were conducted with similar date limits (Tourneux search completed on 31st December 2021 and the ILCOR SR on 2nd Aug 2021).

We found two RCTs that measured the effect of SSC during transfer from the DR to the NICU or post-natal ward. Singh {Singh 2023 109840} enrolled 100 neonates comparing SSC with use of a radiant warmer soon after birth. The authors found a statistically significant increase in the incidence of cold stress (36-36.4°C) at 60 min after birth in neonates nursed skin to skin compared to those under a radiant warmer. In addition to the above RCT we found one observational study {Toprak 2022 103489} and one QI study {M'Rini 20201379763} examining the effect of SSC. Toprak compared neonates held SSC by their father with standard care and found that the SSC group had a significantly lower temperature at 30 min after birth. However, the mean temperatures of both groups were within the normal range {Toprak 2022 103489}. The single-arm QI study by M'Rini showed that among neonates requiring NICU admission, in the sub-group of term neonates, almost half were hypothermic on admission to NICU following transfer to the NICU with SSC combined with a customized transfer device.

The skin to skin intervention in these studies was started after initial resuscitation when infants were ready for transfer to the NICU or postnatal ward. They provide evidence for management of thermoregulation during transfer and not immediately after birth and provide at best, indirect evidence for the PICOST addressed in this evidence update. However, the question regarding the best method of transfer after initial resuscitation could be explored in a scoping review.

Ambient temperature of birthing environment

We found one RCT that compared OR ambient temperature of 24°C with an OR temperature of 20°C.

There was evidence of **benefit** for the important secondary outcome of **hypothermia < 36.5°C** on admission among neonates born at ≥ 34 weeks' gestation (RR: 0.42 (95%CI: 0.38 – 0.46), $P < 0.00$, NNTB: 4 (95%CI: 3 – 5)), the absolute risk difference (ARD) being 291 fewer per 1000 (from 311 fewer to 270 fewer) {Ambia 2023 1553}.

For the outcome **hyperthermia > 37.5** on admission there was evidence of **harm**; (RR: 2.93 (95%CI: 2.28 – 3.77), $P < 0.00$, NNTH: 17 (95%CI: 14 – 22), ARD being 69 more per 1000 (from 45 more to 98 more) {Ambia 2023 1553}.

The new evidence supports the current recommendation to use a higher ambient temperature in operating rooms. Since the trial evaluated in the previous systematic review included only 825 participants, this new trial which included overall 5221 neonates may increase the certainty of evidence and therefore justify updating the SR for this sub-question. The direction of effect was similar to that found in our previous review, but there was additional information about an ambient temperature higher than that examined in detail in the previous review.

Skin to Skin (SSC) versus no SSC

No new studies were found

Plastic Bag or Wrap (PBW) vs no PBW

We found one three-arm RCT including 175 participants that compared use of an aluminum coated fabric with or without cotton swaddling compared with cotton swaddling alone which reported little effect on temperature outcomes at any time including admission. {Chanvorachote 2022 1966}

The evidence from this new trial is not sufficient to change the current recommendation or to elicit a new systematic or scoping review.

Thermal mattress versus standard care

We found one retrospective observational study enrolling 256 neonates comparing exothermic mattress versus standard care during transport from the birth area to the NICU or postnatal ward. {Gopalakrishnan 2022 S49}. On admission to the NICU, there

was a significant reduction in hypothermia among neonates transported on the exothermic mattress. Importantly, there was no hyperthermia in either of the two groups.

This study does not provide sufficient new direct evidence about use of thermal mattresses for care immediately after birth to warrant a new SR or to formulate a new good practice statement.

Other comparisons

No new studies were found addressing any of the other comparisons evaluated in the previous SR (PBW vs no PBW, PBW along with SSC vs SSC alone, PBW with and without drying, PBW compared to a thermal mattress, early vs late SSC, continuously active warming blankets with SSC vs standard care, SSC vs PBW, or woolen vs cotton cap) , or among the comparisons between interventions that could not be addressed in the review because no studies were found at the time.

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Appendix 1

Current Search Strategy (for an existing PICOST) included in the attached approved PICOST

New Search strategy: (for a new PICOST should be outlined here as per Evidence Update Process)
PubMed (2203 results)

(newborn*[tiab] OR "new born"*[tiab] OR "Infant, Newborn"[Mesh] OR neonat*[tiab] OR neo-nat*[tiab] OR "newly born"[tiab] OR premature[tiab] OR prematurity[tiab] OR preterm[tiab] OR "pre term"[tiab] OR "Premature Birth"[Mesh] OR "low birth weight"[tiab] OR "low birthweight"[tiab] OR VLBW[tiab] OR LBW[tiab] OR postnatal[tiab] OR post-natal[tiab] OR "golden hour"[tiab] OR "Perinatal Care"[Mesh]) AND

("room temperature"[tiab] OR "ambient temperature"[tiab] OR "admission temperature"[tiab] OR "radiant warm"*[tiab] OR mattress*[tiab] OR "radiant heat"*[tiab] OR skin-to-skin[tiab] OR kangaroo*[tiab] OR swaddling[tiab] OR covering*[tiab] OR "plastic bag"*[tiab] OR wrap*[tiab] OR hat[tiab] OR hats[tiab] OR cap[tiab] OR caps[tiab] OR "warm bag"*[tiab] OR "warm fluid"*[tiab] OR polyethylene[tiab] OR polythene[tiab] OR polyurethane[tiab] OR woolen[tiab] OR transwarmer*[tiab] OR trans-warmer*[tiab] OR humidifi*[tiab] OR servo-control*[tiab] OR protocol*[tiab] OR checklist*[tiab] OR project*[tiab] OR "care bundle"*[tiab] OR "quality improvement"[tiab] OR "Heating"[Mesh])

AND

(temperature[tiab] OR "Body Temperature"[Mesh] OR normothermi*[tiab] OR normo-thermi*[tiab] OR euthermi*[tiab] OR hypothermi*[tiab] OR hypo-thermi*[tiab] OR "Hypothermia"[Mesh] OR hyperthermi*[tiab] OR hyper-thermi*[tiab] OR "Hyperthermia"[Mesh] OR thermoregulat*[tiab] OR thermo-regulat*[tiab] OR thermoprotect*[tiab] OR thermo-protect*[tiab] OR "heat loss"*[tiab] OR "cold stress"*[tiab])

NOT (animals[mh] NOT humans[mh])