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| Question |
| **Should a room temperature at 23ºC vs. room temperature at 20ºC be used for late preterm and term neonates (≥ 34 weeks' gestation, or equivalent birth weight) immediately after birth?** |
| **Population:** | Late preterm and term neonates (≥ 34 weeks' gestation or equivalent birth weight) immediately after birth |
| **Intervention:** | Room temperature at 23ºC |
| **Comparison:** | Room temperature at 20ºC |
| **Main outcomes:** | Survival until hospital discharge, Normothermia on admission to neonatal unit or postnatal ward; body temperature; hypoglycemia; moderate hypothermia (temperature <36ºC); hyperthermia (temperature >37.5ºC); receipt of respiratory support |
| **Setting:** | All |
| **Perspective:** | Population perspective |
| **Background:** | ILCOR has previously recommended room temperatures of 23-25ºC for the births of preterm infants <32 weeks’ gestation to prevent hypothermia. {Perlman 2015 S204} ILCOR also recommended, for newborn infants ≥30 weeks’ gestation born in low-resourced settings, the use of skin to skin contact and use of a plastic bag or wrap, (while noting the absence of evidence for these practices in this gestation group). {Perlman 2015 S204} However, optimal room temperatures for births of late preterm and term infants were not examined in a systematic review.  |
| **Conflict of interests:** | None for this worksheet |

# 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 | A systematic review conducted for ILCOR concluded that "For the critical outcome of mortality, there is evidence from 36 observational studies of increased risk of mortality associated with hypothermia at admission (low-quality evidence but upgraded to moderate-quality evidence due to effect size, dose-effect relationship, and single direction of evidence)". {Perlman 2015 S204} The same systematic review concluded that "There is evidence of a dose effect on mortality, suggesting an increased risk of at least 28% for each 1° below 36.5°C body temperature at admission and dose-dependent effect size". {Perlman 2015 S204} Although the size of effect in this estimate was influenced by inclusion of studies that enrolled very preterm infants, there was also evidence of adverse effects of hypothermia on survival in late preterm and term infants. A systematic review estimated that hypothermia was common in infants born in hospitals (prevalence range, 32% to 85%) and homes (prevalence range, 11% to 92%), even in tropical environments. {Lunze 2013 24} | WHO has recommended ambient temperatures for birthing rooms of 25ºC{World Health Organization (WHO) 1996 } |

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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 | The systematic review found one cluster-randomized trial that examined operating room temperatures. The study was considered at overall, high risk of bias. However, the risk of bias was only due to concerns about the lack of blinding of the allocation sequence and of the clinicians involved. It showed that for **an operating room temperature 23ºC vs an operating room temperature of 20ºC**:* For the (critical) primary outcome **survival to hospital discharge,** there were no data.
* For the (important) primary outcome of **normothermia** on admission, there was **possible benefit**

Among important secondary outcomes:* For **mean temperature** on admission, there was **possible benefit**
* For **moderate hypothermia**, there was **possible benefit**

**The rationale for considering the effect moderate was that** mean temperatures on admission were higher by 0.3ºC, a difference that was considered clinically significant. Furthermore, for every 1000 infants exposed to an operating room temperature of 23ºC compared to a temperature of 20ºC* from 55 more to 209 more were normothermic
* 109 fewer to 158 fewer were moderately hypothermic.

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with an operating room temperature 20ºC** | **Risk difference with an operating room temperature at 23ºC** |
| Normothermia on admission to neonatal unit or postnatal ward | 825(1 RCT)1 | ⨁◯◯◯Very lowa,b | **RR 1.26**(1.11 to 1.42) | Study population |
| 499 per 1,000 | **130 more per 1,000**(55 more to 209 more) |
| Body temperature | 825(1 RCT)1 | ⨁◯◯◯Very lowa,b | - | The mean body temperature was **36.40** ºC | MD **0.3 ºC higher**(0.23 higher to 0.37 higher) |
| Hypoglycemia | 825(1 RCT)1 | ⨁◯◯◯Very lowa,b,c | **RR 0.69**(0.20 to 2.42) | Study population |
| 14 per 1,000 | **4 fewer per 1,000**(11 fewer to 20 more) |
| Moderate hypothermia (temperature <36ºC) | 825(1 RCT)1 | ⨁◯◯◯Very lowa,b,d | **RR 0.26**(0.16 to 0.42) | Study population |
| 189 per 1,000 | **140 fewer per 1,000**(158 fewer to 109 fewer) |
| Receipt of respiratory support | 825(1 RCT) | ⨁◯◯◯Very lowa,b,c | **RR 2.06**(0.63 to 6.80) | Study population |
| 10 per 1,000 | **10 more per 1,000**(4 fewer to 55 more) |

1 {Duryea 2016 505.e1} 1. The only RCT reporting on this outcome had a high risk of overall bias
2. Indirectness related to patient population as only c-section neonates were included
3. 95% CI crosses the clinical decision threshold
4. OIS not satisfied
5. 95% CI crosses the clinical decision threshold with the possibility of harm as well as benefit and OIS not satisfied due to low event rate
 | Maternal temperatures at the time of delivery and on admission to the post-operative care area were also slightly improved (p<0.001)

|  |  |  |
| --- | --- | --- |
|  | With room temp. 20ºC | With room temp. 23ºC |
| At time of delivery | 36.2±0.6ºC | 36.6ºC±0.6C |
| At admission to post-operative care area | 36.1±0.6ºC | 36.2ºC±0.6C |
| Maternal hypo-thermia(P=0.008) | 77% | 69% |

. |
| Undesirable EffectsHow substantial are the undesirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Large○ Moderate○ Small○ Trivial○ Varies● Don't know | The systematic review found that from the one trial of **an operating room temperature 23ºC vs an operating room temperature of 20ºC, clinical benefit or harm could not be excluded**

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with an operating room temperature 20ºC** | **Risk difference with an operating room temperature at 23ºC** |
| Hyperthermia | 825(1 RCT)1 | ⨁◯◯◯Very lowa,b,c | **RR 4.13**(0.88 to 19.32) | Study population |
| 5 per 1,000 | **15 more per 1,000**(1 fewer to 87 more) |

1 {Duryea 2016 505.e1} 1. The only RCT reporting on this outcome had a high risk of overall bias
2. Indirectness related to patient population as only c-section neonates were included
3. 95% CI crosses the clinical decision threshold with the possibility of harm as well as benefit and OIS not satisfied due to low event rate
 | Measures to prevent hypothermia may increase risk for hyperthermia, because preterm or very ill neonates may have deficient thermoregulation and their capacity to maintain normothermia is limited. The 2015 ILCOR NLS CoSTR stated that; "A by-product of [these] interventions to prevent hypothermia is more-frequent hyperthermia (temperature greater than 37.5°C). Hyperthermia (temperature greater than 37.5°C) also increases the risk for neonatal mortality and morbidity in both term and preterm infants".{Perlman 2015 S204}A recent study in a low resource setting found that "mortality rate was estimated to be at minimum at admission temperature of 37.5 °C" with higher mortality above and below that level. {Cavallin 2020 722} Of particular relevance to late preterm and term infants, the adverse outcomes of hypoxic ischaemic encephalopathy (which are mitigated by controlled, therapeutic hypothermia) are exacerbated by hyperthermia. While it is possible that some of these effects are confounded by the presence of infection (e.g chorioamnionitis, sepsis) there are plausible reasons why hyperthermia may itself compound brain injury. {Kasdorf 2013 379}  |
| 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 | The certainty of evidence for all outcomes was very low, with downgrading for very serious risk of bias, and serious indirectness and imprecision in the one included RCT.  | The single trial examined only operating room temperatures, but the results were thought likely to also apply to other birthing rooms.  |
| 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 outcome of survival to hospital discharge (or its converse, mortality) have been judged by both care givers and parents to be the highest ranked outcomes of importance. {Strand 2020 F328, Webbe 2020 425}  | Other outcomes such as admission temperatures or presence of various degrees of hypothermia have not been ranked. However, they are likely to be ranked as important because of their potential effect on mortality. Cold stress is common, particularly among late preterm infants and has been associated with higher rates of NICU admission. {Laptook 2006 24} |
| 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 | The review found evidence of benefit for four outcomes (normothermia, temperatures on admission, hypothermia and moderate hypothermia), without evidence of harm. Although in this single trial, more infants became hyperthermic, (a result that was not statistically significant) a much higher number avoided moderate hypothermia.  | The balance of effects may be influenced by other concurrent interventions. For example, if other effective measures such as skin to skin care and use of a plastic bag or wrap are routine, a higher room temperature may make less difference, or may increase the risk of hyperthermia to unacceptable levels.  |
| 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 was no description of costs incurred when increasing the temperature in the operating theatres. | Maintaining any defined temperature for birthing rooms and operating rooms in most locations will require air conditioning, which is not available in all settings. The extent to which room-by-room adjustment of temperatures is available in settings that have air conditioning may vary.  |
| 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 | The single study to address this comparison did not provide an estimate of costs or resources required.  | The costs may be site specific, and depend on prevailing temperatures and availability and design of air conditioning systems.  |
| 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 | There were no studies addressing cost-effectiveness.  |  |
| 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 studies addressed health equity.  | The effect on health equity may depend on the costs and feasibility of changing operating room or birthing room temperatures in lower vs higher-resourced settings, which are unknown.  |
| AcceptabilityIs the intervention acceptable to key stakeholders? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes○ Yes○ Varies● Don't know | Operating room temperatures between 20 and 23.9ºC have been recommended {Association of Operating Room Nurses 2018 }, although the preferred range of temperatures for individual operating room staff may differ. {Joseph 2018 137} | The ambient temperature of operating theatres is often determined by the need to provide a safe, comfortable working environment for theatre personnel.  |
| FeasibilityIs the intervention feasible to implement? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes○ Yes● Varies○ Don't know | The operating room temperature was able to be altered for the cited study. {Duryea 2016 505.e1} Maintaining temperatures 23º to >25ºC in operating theatres and birthing rooms was also a focus of five quality improvement (observational) studies that were included in the review. {Aley-Raz 2020 476, Datta 2017 e000183, Patodia 2021 277, Shaw 2018 126, Sprecher 2021 270} All five included multiple interventions, none fully documented the extent of adherence to this component and none provided data in a form that allowed assessment of the specific effects of maintaining higher temperatures in theatres and birthing rooms. However, these studies suggest that the intervention is feasible in some locations in both high income and middle income countries.  | Controlling ambient temperatures is likely to be difficult or impossible in low resourced settings.  |

# 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

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| Recommendation |
| In late preterm and term infants (≥34 weeks' gestation), we suggest the use of room temperatures of 23ºC compared to 20ºC at birth in order to maintain normal temperature (weak recommendation, very low certainty evidence).  |
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| Justification |
| * In the included study, raising operating room temperature to 23ºC appeared to be safe for most infants born by caesarean section, improved their body temperatures and reduced the risk of hypothermia, when compared to 20ºC. However, the certainty of evidence is very low.
* Although more infants became hyperthermic in the higher operating room group in the one included study (not statistically significant), hypothermia was avoided in many more. Maternal hypothermia was also reduced. The balance of effects is likely to favour operating room temperatures of 23ºC vs 20ºC.
* Because of the location and selection criteria for the one included study, the effects on infants other than those born by caesarean section are unknown. Although only operating room temperatures were studied, the NLS Task Force considered the effects were likely to apply to other birth locations.
* Although only a small increment in body temperature was noted, it was considered clinically significant, because maintaining normothermia may take a combination of interventions, each making a small contribution. Raising delivery room temperatures to 23ºC to 25ºC has been recommended among a combination of interventions to maintain normothermia for preterm newborn infants <32 weeks’ gestation. {Perlman 2015 S204}
* Several included quality improvement studies confirmed feasibility, but the resources required, and effects on equity have not been assessed.
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| Subgroup considerations |
| There were insufficient data to undertake any subgroup analyses. In the one included study, which was performed in a high income country (USA) the timing of umbilical cord clamping was not stated.  |

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| Implementation considerations |
| Raising the operating room or delivery room temperature appears feasible, in that it has been used as an intervention not only in the RCT analysed in this systematic review, but also as a component of multifaceted interventions in 5 included observational studies (using quality improvement models). {Aley-Raz 2020 476, Datta 2017 e000183, Patodia 2021 277, Shaw 2018 126, Sprecher 2021 270}However, feasibility may be location specific. |

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| Monitoring and evaluation |
| Ongoing monitoring of temperatures is recommended to assess the balance of benefits and risks, which may vary by location and depending on other concurrent interventions to maintain normal temperature. {Perlman 2015 S204} |

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| Research priorities |
| * 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 20ºC or 23ºC) for operating rooms or birthing rooms.
* 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.
* The effect of maternal hypothermia or hyperthermia on newborn infants’ temperatures.
 |

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| --- |
| Question |
| **Should skin to skin care vs. no skin to skin care (routine hospital care as defined by study authors) be used for late preterm and term infants (≥ 34 weeks’ gestation, or equivalent birth weight) immediately after birth?** |
| **Population:** | Late preterm and term infants (**≥** 34 weeks’ gestation or equivalent birth weight), immediately after birth |
| **Intervention:** | Skin to skin care |
| **Comparison:** | No skin to skin care (routine hospital care as defined by study authors) |
| **Main outcomes:** | Survival to hospital discharge; normothermia on admission to neonatal unit or postnatal ward; body temperature; hypoglycemia; admission to neonatal intensive or special care unit; any hypothermia < 36.5º C; cold stress/mild hypothermia (temperature 36.0 – 36.4ºC); moderate hypothermia (temperature 32.0-35.9ºC); severe hypothermia (temperature <32.0ºC); |
| **Setting:** | Any |
| **Perspective:** | Population perspective  |
| **Background:** | ILCOR 2015 {Perlman 2015 S204} NRP 793 Maintaining Infant Temperature During Delivery Room Resuscitation (which focused on newborn infants ≥30 weeks’ gestation) made the following treatment recommendations:* There are no data examining the use of plastic wrap during resuscitation/stabilization. To maintain body temperature or prevent hypothermia during transition (birth to 1–2 hours of life), we suggest that after a well newborn infant of greater than 30 weeks of gestation has been dried, his or her trunk and limbs may be put in a clean food-grade plastic bag and swaddled compared with open crib or cot and swaddling (weak recommendation, very-low-quality evidence).
* There are no data on skin-to-skin contact during resuscitation/ stabilization. To maintain normal body temperature or prevent hypothermia during transition (birth to 1–2 hours after delivery), we suggest well newborns of greater than 30 weeks of gestation be nursed with skin-to-skin contact or kangaroo mother care compared with a cot/open crib and swaddling or incubator (weak recommendation, very-low-quality evidence).
 |
| **Conflict of interests:** | None for this worksheet |

# Assessmen

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| --- |
| ProblemIs the problem a priority? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don’t know | A systematic review conducted for ILCOR concluded that “For the critical outcome of mortality, there is evidence from 36 observational studies of increased risk of mortality associated with hypothermia at admission (low-quality evidence but upgraded to moderate-quality evidence due to effect size, dose-effect relationship, and single direction of evidence)”. {Perlman 2015 S204} The same systematic review concluded that “There is evidence of a dose effect on mortality, suggesting an increased risk of at least 28% for each 1° below 36.5°C body temperature at admission and dose-dependent effect size”. {Perlman 2015 S204} Although the size of effect in this estimate was influenced by inclusion of studies that enrolled very preterm infants, there was also evidence of adverse effects of hypothermia on survival in late preterm and term infants. A systematic review estimated that hypothermia was common in infants born in hospitals (prevalence range, 32% to 85%) and homes (prevalence range, 11% to 92%), even in tropical environments. {Lunze 2013 24} |  |
| Desirable EffectsHow substantial are the desirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Trivial○ Small● Moderate○ Large○ Varies○ Don’t know | This systematic review found that that **for skin to skin care, when compared to no skin to skin care for late preterm and term infants**:* For the critical primary outcome of **survival to hospital discharge**, clinical benefit or harm cannot be excluded.
* For the important primary outcome of **normothermia on admission** to a neonatal unit or postnatal ward, clinical benefit or harm cannot be excluded

Among secondary outcomes:* **Mean body temperature on admission** was 0.32 ºC higher
* For **hypoglycemia**, there was possible clinical benefit
* For **admission to a neonatal special or intensive care unit**, there was possible benefit

**The rationale for considering the effect moderate was that** although no difference was found in primary or several of the secondary outcomes, mean temperatures on admission were higher by 0.32ºC, a difference that was considered clinically significant. For every 1000 infants exposed to skin to skin care compared to routine hospital care, * from 153 fewer to 309 fewer were hypoglycemic
* from 12 fewer to 60 fewer were admitted to a neonatal intensive or special care unit.

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with standard hospital care** | **Risk difference with skin to skin care** |
| Survival to hospital discharge | 203(1 RCT)1 | ⨁◯◯◯Very lowa,b | **RR 1.00**(0.99 to 1.01) | Study population |
| 1,000 per 1,000 | **0 fewer per 1,000**(10 fewer to 10 more) |
| Normothermia on admission to neonatal unit or postnatal ward | 551(3 RCTs)1,2,3 | ⨁◯◯◯Very lowc,d,e,f | **RR 1.39**(0.91 to 2.12) | Study population |
| 614 per 1,000 | **239 more per 1,000**(55 fewer to 688 more) |
| Body temperatureassessed with: digital or mercury or contactless thermometer, axillary, rectal or other defined site | 1048(8 RCTs)1,2,3,4,5,6,7,8 | ⨁◯◯◯Very lowc,g,h,i,j | - | The mean body temperature was **36.5** ºC | MD **0.32 ºC higher**(0.10 higher to 0.54 higher) |
| Hypoglycemia | 100(1 RCT)6 | ⨁◯◯◯Very lowb,k,l | **RR 0.16**(0.05 to 0.53) | Study population |
| 326 per 1,000 | **273 fewer per 1,000**(309 fewer to 153 fewer) |
| Admission to neonatal intensive or special care unit | 512(3 RCTs)1,7,9 | ⨁◯◯◯Very lowc,d,i | **RR 0.34**(0.14 to 0.83) | Study population |
| 70 per 1,000 | **46 fewer per 1,000**(60 fewer to 12 fewer) |
| Any hypothermia < 36.5º C | 197(1 RCT)8 | ⨁⨁⨁◯Moderatec | **RR 0.54**(0.28 to 1.06) | Study population |
| 210 per 1,000 | **97 fewer per 1,000**(151 fewer to 13 more) |
| Cold stress/mild hypothermia (temperature 36.0 – 36.4ºC) | 443(2 RCTs)1,2 | ⨁◯◯◯Very lowc,d,i,m | **RR 0.10**(0.00 to 557.45) | Study population |
| 214 per 1,000 | **192 fewer per 1,000**(214 fewer to 118,878 more) |
| Moderate hypothermia (temperature 32.0-35.9ºC) | 626(4 RCTs)1,10,3,6 | ⨁◯◯◯Very lowc,d,i,o | **RR 0.54**(0.20 to 1.52) | Study population |
| 309 per 1,000 | **142 fewer per 1,000**(247 fewer to 161 more) |
| Severe hypothermia (temperature <32.0ºC) | 203(1 RCT)1 | ⨁◯◯◯Very lowa,b,p | not estimable | Study population |
| 0 per 1,000 | **0 fewer per 1,000**(0 fewer to 0 fewer) |

1 {Ramani 2018 492} 2 {Srivastava 2014 22} 3 {Safari 2018 32} 4 {Christensson 1992 488} 5 {Huang 2019 68} 6 {KoÇ 2017 1} 7 {Kollmann 2017 e0168783} 8 {Carfoot 2005 71} 9 {Marín Gabriel 2010 1630} 10 {Johanson 1992 859}1. Infants born by caesarean section and those at risk for needing resuscitation were excluded
2. The only included study had a high risk of overall bias
3. 95% CI crosses the clinical decision threshold
4. All studies were at high risk of overall bias
5. I2 = 90% but the high value might be due to differences between small and large magnitude of effect
6. Most of the studies included only well term newborns
7. All but one of the studies were judged to be at high risk of bias
8. I2 = 95%
9. Studies excluded all or most infants who needed resuscitation
10. Most studies only included vaginal births, some included only caesarean births
11. Single study underpowered for this outcome
12. All vaginal births, infants excluded if they developed a health problem during skin to skin care
13. I2 = 87%
14. I2 = 84%
15. No events in either study group
 |  |
| Undesirable EffectsHow substantial are the undesirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Large○ Moderate○ Small○ Trivial○ Varies● Don't know | The current review found no studies that reported whether skin to skin care, when compared to standard hospital care, altered rates of hyperthermia or other adverse outcomes.  | Measures to prevent hypothermia may increase risk for hyperthermia, because preterm or very ill neonates may have deficient thermoregulation and their capacity to maintain normothermia is limited. The 2015 ILCOR NLS CoSTR stated that; "A by-product of [these] interventions to prevent hypothermia is more-frequent hyperthermia (temperature greater than 37.5°C). Hyperthermia (temperature greater than 37.5°C) also increases the risk for neonatal mortality and morbidity in both term and preterm infants".{Perlman 2015 S204}A recent study in a low resource setting found that "mortality rate was estimated to be at minimum at admission temperature of 37.5 C" with higher mortality above and below that level. {Cavallin 2020 722} Of particular relevance to late preterm and term infants, the adverse outcomes of hypoxic ischaemic encephalopathy (which are mitigated by controlled, therapeutic hypothermia) are exacerbated by hyperthermia. While it is possible that some of these effects are confounded by the presence of infection (e.g., chorioamnionitis, sepsis) there are plausible reasons why hyperthermia may itself compound brain injury. {Kasdorf 2013 379}  |
| 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 | The certainty of evidence for all outcomes was very low except 'any hypothermia' which was moderate. Of the 9 studies that reported results for the comparison between skin to skin care and routine hospital care, 6 included only normal vaginal births, {Christensson 1992 488, KoÇ 2017 1, Marín Gabriel 2010 1630, Ramani 2018 492, Safari 2018 32, Srivastava 2014 22} 2 included only caesarean births, {Huang 2019 68, Kollmann 2017 e0168783} and all but 2 {Johanson 1992 859, Ramani 2018 492} excluded infants who needed, or were at increased risk of needing resuscitation. Only one study enrolled infants ≥34 weeks {Johanson 1992 859} , one ≥35 weeks {Marín Gabriel 2010 1630} , two ≥36 weeks {Carfoot 2005 71, KoÇ 2017 1}, and the remainder only term infants. Thus, of the infants the systematic review intended to include, many of those at risk of hypothermia and other adverse outcomes are not represented in the data. The likely effect of these selection criteria on effect sizes was considered in judging risk of bias and indirectness. The different ways that studies reported temperature (e.g., different cut-off points) limited the opportunities for meta-analysis. This could have resulted in underestimation of beneficial effects.  | The review focused on the effects of skin to skin care from birth or very soon after, so studies commencing skin to skin care 20 min after birth were not included. Furthermore, other well established benefits of skin to skin care commenced during and continued after hospital care were not assessed in this review. These include benefits for mother-infant bonding, decreased maternal pain profiles and stress levels, establishing a normal microbiome, establishment of breast feeding, and on survival of preterm infants.  |
| 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 outcome of survival to hospital discharge (or its converse, mortality) have been judged by both care givers and parents to be the highest ranked outcomes of importance. {Strand 2020 F328, Webbe 2020 425} | Other outcomes such as admission temperatures or presence of various degrees of hypothermia have not been ranked. However, they are likely to be ranked as important because of their potential effect on mortality. Cold stress and hypothermia are common, particularly among late preterm infants and have been associated with higher rates of NICU admission. {Laptook 2006 24}  |
| 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 | The review found evidence of benefit for three outcomes (temperatures on admission, decreased risk of hypoglycemia as well as that of neonatal special or intensive care unit admission) with skin to skin care. None of the outcomes suggested the likelihood of harm.  | The task force noted the possibility of unmeasured risks of skin to skin care. These could include accidental newborn suffocation. {Bartick 2020 11, Bass 2018 104, Steinhorn 2020 7} However the risks of uncommon or rare serious life-threatening events (sudden unexpected postnatal collapse {Matzner 2020 344}) have not been compared in sufficient-sized studies to determine whether the rate is higher with skin to skin care or routine hospital care.  |
| 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 | None of the studies provided estimates of costs or resources required, (except in some cases, to specify training of staff in correct methods for the study). Several of the studies took place in low income countries with limited healthcare resources, and noted that skin to skin care was considered a low-cost intervention.  | The use of skin to skin care could reduce the need for multiple use or disposable equipment such as warming devices.  |
| 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 studies provided sufficient detail about costs to determine the certainty of evidence for required resources. |  |
| 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 studies included in the review examined cost effectiveness, noting that the focus of the review was on initiating skin to skin care within minutes after birth, and not on its use for subsequent hospital care.  | A study has assessed the cost effectiveness of "Kangaroo ward care" compared with "Intermediate Intensive Care" in the context of a randomised controlled trial. {Sharma 2016 64} The study, conducted in India, found statistically significant, substantial cost savings for parents and hospital with the use of Kangaroo Mother Care, of which skin to skin care with the mother was a critical component.  |
| 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 | Skin to skin care is likely to be an intervention applied equally easily in low-resourced settings as in high-resourced settings. The included studies were done in high-income countries (Sweden, Austria, UK, Spain), middle-income countries (Turkey, India, China, Iraq) and low-income countries (Zambia). Use of skin to skin care to reduce the need for equipment that may be unaffordable (or should be prioritised to the smallest and sickest infants) in low resource settings may improve equity.  |  |
| AcceptabilityIs the intervention acceptable to key stakeholders? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no● Probably yes○ Yes○ Varies○ Don't know | Three included studies provided information about acceptability of skin to skin care. {Carfoot 2005 71, Huang 2019 68, Nissen 2019 1} Carfoot et al. reported that a larger proportion of mothers were very satisfied with their assigned study treatment in the skin to skin care group (90%) than in the control group (59%) and expressed that they would prefer to receive the same care in the future (86% vs 30%). {Carfoot 2005 71} Huang et al. (in a study of fathers providing skin to skin care in circumstances where the mother could not) reported significantly lower scales of anxiety and depression and better role attainment than those in the control group. {Huang 2019 68} Nissen at al. reported in an observational study that before the intervention, no mothers undertook 1 hour's uninterrupted skin to skin contact with their newborns, compared to 54.8% after an educational and promotional intervention. {Nissen 2019 1} In a qualitative study that aimed "to identify barriers and enablers to conducting safe uninterrupted skin-to-skin contact (SSC) in the first hour after birth in a low-resource setting and to evaluate how health care professionals coped with the identified barriers after completion of an intervention package", Mbalinda et al identified various factors. Of note, when the mother and infant had to move to the post-natal ward within one hour after birth there were difficulties maintaining skin to skin care during transportation. A few mothers were considered unwilling to keep the infant skin to skin. {Mbalinda 2018 95} | There is a larger literature supporting the use of skin to skin care at later time points, for a variety of maternal, and neonatal outcomes. Studies report some barriers to use, but overall, it is judged to be acceptable for use in postnatal care. {Gill 2021 1407, Gupta 2021 2310, Ionio 2021 4695} It is likely that this acceptability applies to use immediately after birth.  |
| FeasibilityIs the intervention feasible to implement? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no● Probably yes○ Yes○ Varies○ Don't know | Some of the included studies documented withdrawal of infants from the study at rates ranging from 2.4% to 16.9% because of reasons including that the infant required resuscitation, or the mother was unable to commence or continue to provide skin to skin care. {Huang 2019 68, Johanson 1992 859, Kollmann 2017 e0168783, Ramani 2018 492, Safari 2018 32, Srivastava 2014 22} The range of circumstances in which skin to skin care cannot be utilised effectively might have been underestimated because many of the studies specifically included only well mothers and newborns. In an observational study in Uganda that was included in the review and which examined the effects of skin to skin care, an educational and promotional intervention resulted in 54.8% of eligible infants receiving 1 hour of uninterrupted skin to skin care from immediately after birth after the intervention vs none before the intervention. {Nissen 2019 1}  | There may be cultural values that encourage or present barriers to skin to skin care.  |

# 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 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).  |
| Justification |
| **Overall justification*** Skin to skin care is simple, appears to be safe for most infants and improves their body temperatures, when compared to no skin to skin care. However, because of the selection criteria of included studies, there is insufficient evidence to make a recommendation for infants at high risk of needing resuscitation.
* Skin to skin care, when compared with no skin to skin care, increased body temperatures on admission to a neonatal unit or postnatal ward, and reduced the risk of hypoglycemia, and NICU admission. No benefits were found for other outcomes of the review, but small samples, study selection criteria and the limited range of outcomes reported by several of the included studies may have limited the detection of benefits.
* No undesirable effects were identified. None of the included studies reported hyperthermia.
* Most of the evidence is of very low certainty. Importantly, most studies excluded mothers who were not well, and infants who had needed or were at risk of needing resuscitation. Infants 34-36 weeks’ gestation were under-represented among the included studies.
* The balance of effects is likely to favour skin to skin care commenced within minutes after birth over other care, which in most studies consisted of drying and wrapping the infant and placing the baby in a hospital cot. There are other well-described benefits of skin to skin care for the ongoing care of neonates.
* The task force noted the possibility of unmeasured risks of skin to skin care. These could include accidental newborn suffocation. However, the risks of uncommon or rare serious life-threatening events have not been compared in sufficient-sized studies to determine whether the rate is higher with skin to skin care or no skin to skin care.
* Skin to skin care from immediately after birth is likely to be cost-effective, acceptable and feasible in high-, middle- and low-income countries.
 |
| Subgroup considerations |
| There were insufficient data to undertake meaningful subgroup analyses. Some studies specified early umbilical cord clamping and none specified that delayed umbilical cord clamping was routinely performed, or provided a breakdown by timing of cord clamping. For setting, since only one outcome was reported by sufficient studies to consider a subgroup analysis by income of country, a subgroup analysis was not considered meaningful. There were no studies that involved outborn infants.  |
| Implementation considerations |
| Skin to skin care has been widely applied for ongoing care of well newborns, and as part of neonatal intensive or special care. Depending on location, practice change strategies may be required to promote skin to skin care within minutes after birth.  |
| Monitoring and evaluation |
| Neonate's temperatures on admission to post-natal wards or neonatal intensive or special care units should continue to be monitored, as an important indicator of the quality of care. {Perlman 2015 S204} |
| Research priorities |
| * The role of skin to skin care in maintaining normal temperature in infants requiring 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.
 |

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|  |
| --- |
| Question |
| **Should a plastic bag or wrap vs. no plastic bag or wrap be used for late preterm and term neonates (≥34 weeks' gestation, or equivalent birth weight), immediately after birth?** |
| **Population:** | Late preterm and term neonates (≥34 weeks' gestation, or equivalent birth weight), immediately after birth |
| **Intervention:** | A plastic bag or wrap  |
| **Comparison:** | No plastic bag or wrap Note that in the studies identified for this comparison; * Studies that provided drying or no drying prior to the application of the plastic bag or wrap were combined.
* Care in the control group included care under a radiant warmer or an incubator or a cot with or without drying and swaddling with a blanket and with or without a head covering.
 |
| **Main outcomes:** | Survival to hospital discharge; normothermia on admission to neonatal unit or postnatal ward; body temperature; hypoglycemia; any hypothermia <36.5ºC; hypothermia <35ºC; moderate hypothermia (temperature 32.0-35.9ºC); hyperthermia (temperature >37.5ºC) |
| **Setting:** | All |
| **Perspective:** | Population perspective |
| **Background:** | ILCOR 2015 {Perlman 2015 S204} NRP 793 Maintaining Infant Temperature During Delivery Room Resuscitation (which focused on newborn infants ≥30 weeks’ gestation) Treatment Recommendations:There are no data examining the use of plastic wrap during resuscitation/stabilization. To maintain body temperature or prevent hypothermia during transition (birth to 1–2 hours of life), we suggest that after a well newborn infant of greater than 30 weeks of gestation has been dried, his or her trunk and limbs may be put in a clean food-grade plastic bag and swaddled compared with open crib or cot and swaddling (weak recommendation, very-low-quality evidence).The current systematic review found a small number of studies in late preterm and term infants examining the use of a plastic bag or wrap to prevent hypothermia, enabling metanalysis.  |
| **Conflict of interests:** | None for this worksheet |

# Assessment

|  |
| --- |
| ProblemIs the problem a priority? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | A systematic review conducted for ILCOR concluded that "For the critical outcome of mortality, there is evidence from 36 observational studies of increased risk of mortality associated with hypothermia at admission (low-quality evidence but upgraded to moderate-quality evidence due to effect size, dose-effect relationship, and single direction of evidence)". {Perlman 2015 S204} The same systematic review concluded that "There is evidence of a dose effect on mortality, suggesting an increased risk of at least 28% for each 1° below 36.5°C body temperature at admission and dose-dependent effect size". {Perlman 2015 S204} Although the size of effect in this estimate was influenced by inclusion of studies that enrolled very preterm infants, there was also evidence of adverse effects of hypothermia on survival in late preterm and term infants. A systematic review estimated that hypothermia was common in infants born at hospitals (prevalence range, 32% to 85%) and homes (prevalence range, 11% to 92%), even in tropical environments. {Lunze 2013 24} |  |
| Desirable EffectsHow substantial are the desirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Trivial○ Small● Moderate○ Large○ Varies○ Don't know | This systematic review found that **for use of a plastic bag or wrap versus no plastic bag or wrap:*** For the primary (critical) outcome of **survival to hospital discharge,** **clinically significant benefit or harm cannot be excluded** (**very low certainty of evidence**
* For the primary (important) outcome of **normothermia on admission**, there was **possible benefit**

Among secondary outcomes:* **Body temperature** was higher
* For any **hypothermia <36.5ºC**, there was **possible benefit**
* For **hypothermia <35ºC**, there was **possible benefit**
* For **moderate hypothermia (temperature 32.0-35.9ºC)**

**The rationale for considering the effect moderate was that** mean temperatures on admission were higher by 0.29ºC, a difference that was considered clinically significant. Furthermore, for every 1000 infants exposed to a plastic bag or wrap (with or without prior drying) compared to no plastic bag or wrap, * from 81 more to 362 more were normothermic
* from 128 fewer to 261 fewer had hypothermia <36.5ºC
* from 4 fewer to 48 fewer had hypothermia <35ºC

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with standard hospital care (other care)** | **Risk difference with a plastic bag or wrap with either prior drying or no drying** |
| Survival to hospital discharge | 305(2 RCTs)1,2 | ⨁◯◯◯Very lowa,b,c,d | **RR 0.95**(0.60 to 1.51) | Study population |
| 981 per 1,000 | **49 fewer per 1,000**(392 fewer to 500 more) |
| Normothermia on admission to neonatal unit or postnatal ward | 305(2 RCTs)1,2 | ⨁◯◯◯Very lowa,c,e | **RR 1.50**(1.20 to 1.89) | Study population |
| 406 per 1,000 | **203 more per 1,000**(81 more to 362 more) |
| Body temperature | 425(3 RCTs)1,2,3,f | ⨁◯◯◯Very lowg,h |  | The mean body temperature was **36.3ºC** | MD **0.29ºC higher**(0.2 higher to 0.38 higher) |
| Hypoglycemia | 201(1 RCT)1 | ⨁◯◯◯Very lowc,d,i | **RR 0.99**(0.48 to 2.03) | Study population |
| 130 per 1,000 | **1 fewer per 1,000**(68 fewer to 134 more) |
| Any hypothermia <36.5ºC | 425(3 RCTs)1,3,f | ⨁◯◯◯Very lowe,g,h | **RR 0.57**(0.45 to 0.73) | Study population |
| 474 per 1,000 | **204 fewer per 1,000**(261 fewer to 128 fewer) |
| Hypothermia <35ºC | 400(2 RCTs)1,4 | ⨁◯◯◯Very lowc,e,h | **RR 0.21**(0.05 to 0.91) | Study population |
| 50 per 1,000 | **40 fewer per 1,000**(48 fewer to 4 fewer) |
| Moderate hypothermia (temperature 32.0-35.9ºC) | 199(1 RCT)1 | ⨁◯◯◯Very lowd,j | **RR 0.96**(0.66 to 1.38) | Study population |
| 370 per 1,000 | **15 fewer per 1,000**(126 fewer to 141 more) |

1 {Shabeer 2018 1324} 2{Leadford 2013 e128} 3 {Cardona-Torres 2012 129} 4 {Johanson 1992 859}.1. Two studies had high risk of overall bias
2. I2 = 98%
3. Though the mean gestational age of enrolled neonates was >34 weeks, some neonates of lesser gestational age were also enrolled in one study
4. 95% CI crosses clinical decision threshold
5. OIS not satisfied
6. One trial had one control group, with two experimental groups
7. Though mean gestational age of the enrolled neonates was > 34 weeks, studies enrolled some neonates of gestational age less than 34 weeks
8. All RCTs had high risk of bias
9. 1 study had a high risk of bias
10. Indirectness related to patient population as only vaginal births were included
 |  |
| Undesirable EffectsHow substantial are the undesirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Large○ Moderate○ Small○ Trivial○ Varies● Don't know | For **hyperthermia**, benefit or harm could not be excluded (very low certainty evidence from 3 RCTs enrolling 425 participants, downgraded for very serious risk of bias, serious indirectness and very serious imprecision). The event rate was sufficiently low that an absolute risk difference was not calculable.

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with standard hospital care (other care)** | **Risk difference with a plastic bag or wrap with either prior drying or no drying** |
| Hyperthermia (temperature >37.5ºC) | 425(3 RCTs)1,2,a | ⨁◯◯◯Very lowb,c,d | **RR 15.91**(0.17 to 1448.75) | Study population |
| Not applicable | Not applicable |

1 {Cardona-Torres 2012 129} 2 {Shabeer 2018 1324}1. One trial had one control group, with two experimental groups
2. Though mean gestational age of the enrolled neonates was > 34 weeks, both Shabeer 2018 and Cardona-Torres 2012 studies enrolled some neonates who were of gestational age less than 34 weeks
3. Very low event rate and not satisfying OIS ; with 95% CI indicating substantial benefit and harm
4. All RCTs had high risk of bias
 | Measures to prevent hypothermia may increase risk for hyperthermia, because preterm or very ill neonates may have deficient thermoregulation and their capacity to maintain normothermia is limited. The 2015 ILCOR NLS CoSTR stated that; "A by-product of [these] interventions to prevent hypothermia is more-frequent hyperthermia (temperature greater than 37.5°C). Hyperthermia (temperature greater than 37.5°C) also increases the risk for neonatal mortality and morbidity in both term and preterm infants". {Perlman 2015 S204}A recent study in a low resource setting found that "mortality rate was estimated to be at minimum at admission temperature of 37.5 °C" with higher mortality above and below that level. {Cavallin 2020 722} Of particular relevance to late preterm and term infants, the adverse outcomes of hypoxic ischaemic encephalopathy (which are mitigated by controlled, therapeutic hypothermia) are exacerbated by hyperthermia. While it is possible that some of these effects are confounded by the presence of infection (e.g chorioamnionitis, sepsis) there are plausible reasons why hyperthermia may itself compound brain injury. {Kasdorf 2013 379}  |
| 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 | The certainty of evidence was very low for all primary and secondary outcomes. All four studies included in this comparison included births <34 weeks as well as late preterm and term infants ≥34 weeks' gestation, but did not provide data in a form that allowed exclusion of infants <34 weeks. The likely effect of these selection criteria on effect sizes was considered in judging risk of bias and indirectness.  |  |
| 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 outcome of survival to hospital discharge (or its converse, mortality) have been judged by both care givers and parents to be the highest ranked outcomes of importance. {Strand 2020 F328, Webbe 2020 425} | Other outcomes such as admission temperatures or presence of various degrees of hypothermia have not been ranked. However, they are likely to be ranked as important because of their potential effect on mortality. Cold stress is common, particularly among late preterm infants and has been associated with higher rates of NICU admission. {Laptook 2006 24} |
| 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 | The review found evidence of benefit for the outcomes of normothermia, temperatures on admission, hypothermia <36.5ºC and hypothermia <35º with use of a plastic bag or wrap. None of the outcomes suggested the likelihood of harm.  | The task force considered that there might be unmeasured adverse effects, including potential effects on promotion of early and successful breast feeding. There was concern that although hyperthermia was not demonstrated in the included studies with the use of a plastic bag or wrap, there might be increased risk of hyperthermia in the setting of care with a radiant warmer or in an incubator. There was concern that use of a plastic bag or wrap might be regarded as a substitute to encouraging skin to skin care.  |
| 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 | A clean food-grade plastic bag or wrap suitable for a newly born infant is likely to be of very low cost. In two studies included in this systematic review, the cost was estimated at USD 0.03 in 2013. {Belsches 2013 e656, Leadford 2013 e128}Purpose-designed sterile bags packaged for clinical use are more expensive, and wraps are intermediate in cost.  | The task force also considered the environmental impact of recommending widespread use of plastic bags or wraps. However, this must be weighed against benefits, and also compared with the widespread use of other disposables in clinical care. While the cost of plastic bags or wraps may be low for individual babies, the cost to clinical services may be high if they are used for a high proportion of late preterm and term-born infants.  |
| 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 studies estimated resource requirements. |  |
| 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 studies included in the review examined cost effectiveness. | The effects of use of a plastic bag or wrap in increasing rates of normothermia on admission to a neonatal unit or postnatal ward may offset the minimal costs of the plastic bags or wraps themselves.  |
| 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 | The four included studies were from low- or middle-income countries (Zambia, India, Mexico and Nepal).  | Plastic bags or wraps are likely to be available in both low and high income countries, and in low resource settings, may offset the lack of availability of more expensive devices and equipment.In low-resourced settings, there is a possibility that the use of plastic bags or wraps for late preterm and term infants might divert their use from very preterm infants who might derive greater benefit.  |
| AcceptabilityIs the intervention acceptable to key stakeholders? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes○ Yes○ Varies● Don't know | The authors of one study in the review commented that; “The wrap procedure was well accepted by the neonatal staff and did not interfere with resuscitation in the delivery room”. {Travers 2021 55} |  |
| FeasibilityIs the intervention feasible to implement? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no● Probably yes○ Yes○ Varies○ Don't know | The included studies were performed in low or middle income countries.  | Plastic bags or wraps have been recommended for use in more preterm infants for more than a decade.  |

# 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 |
| 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 normal temperature (weak recommendation, very low certainty evidence).  |
| Justification |
| * The systematic review found evidence to support the use of a plastic bag or wrap in the setting of standard hospital care to improve rates of normothermia and reduce risk of hypothermia in late preterm or term newborn infants (≥34 weeks' gestation, or equivalent birth weight) without evidence of adverse effects. Because of a low number of studies and enrolled infants, studies in with and without prior drying were combined. The certainty of evidence was very low for all outcomes.
* Because of a low number of studies and enrolled infants, studies with and without prior drying were combined in the meta-analysis.
* The Task Force was concerned that there may be unmeasured adverse effects, such as adverse effects on establishment of a normal neonatal microbiome and on promotion of early breast feeding.
* There was also concern that the plastic bag or wrap might be regarded as a substitute to encouraging skin to skin care.
* The resources required are likely to be inexpensive, but costs may be large if the intervention is applied to all newborn infants. A clean, food-grade plastic bag or wrap is necessary, but costs may increase if purpose-designed sterile bags packaged for clinical use are used. Cost-effectiveness is unknown, but could be positive if improved rates of normothermia and avoidance of hypothermia results in avoidance of any admissions to a neonatal special or intensive care unit.
* Use of this low-cost fairly simple intervention may improve equity. The four studies suggesting benefit were conducted in middle- or low-income countries, suggesting feasibility in these settings. However, the overall effect on equity remains unknown. Equity could be adversely affected if use of plastic bags or wraps was diverted from more preterm infants for who potential to benefit is greater.
 |
| Subgroup considerations |
| There were insufficient data to conduct subgroup analyses. Although the included studies enrolled both late preterm and term infants, no breakdown of data by gestation were provided. None of the studies provided any information about timing of umbilical cord clamping. All were from middle- or low-income countries (Zambia, India, Mexico, Nepal) but overall sample sizes for the various comparisons were insufficient to allow meaningful subgroup analysis by country income.  |
| Implementation considerations |
| Neither of the included studies reported any problems with adherence to the use of a plastic bag or wrap in addition to other care. Practice change strategies may be required to promote the use of a plastic bag or wrap within minutes after birth.  |
| Monitoring and evaluation |
| Neonate's temperatures on admission to post-natal wards or neonatal intensive or special care units should continue to be monitored, as an important indicator of the quality of care. {Perlman 2015 S204}  |
| Research priorities |
| * The balance of risks and benefits of plastic bag or wrap in the setting of various ambient temperatures and maternal temperatures, and in the setting of combinations of measures to maintain normothermia.
* 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 caregivers.
 |

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|  |
| --- |
| **Question** |
| **Should a plastic bag or wrap combined with skin to skin care vs. skin to skin care alone be used for late preterm and term neonates (≥34 weeks or equivalent birth weight)?** |
| **Population:** | Late preterm and term neonates (≥34 weeks or equivalent birth weight) |
| **Intervention:** | A plastic bag or wrap combined with skin to skin care  |
| **Comparison:** | Skin to skin care |
| **Main outcomes:** | Survival to discharge; normothermia on admission to neonatal unit or postnatal ward; body temperature; admission to neonatal intensive or special care unit; any hypothermia < 36.5 ºC; cold stress/mild hypothermia (temperature 36.0-36.4ºC); moderate hypothermia (temperature 32.0-35.9ºC); hyperthermia (temperature >37.5ºC); |
| **Setting:** | All |
| **Perspective:** | Population perspective |
| **Background:** | ILCOR 2015 {Perlman 2015 S204} NRP 793Treatment Recommendations:There are no data examining the use of plastic wrap during resuscitation/stabilization. To maintain body temperature or prevent hypothermia during transition (birth to 1–2 hours of life), we suggest that after a well newborn infant of greater than 30 weeks of gestation has been dried, his or her trunk and limbs may be put in a clean food-grade plastic bag and swaddled compared with open crib or cot and swaddling (weak recommendation, very-low-quality evidence).There are no data on skin-to-skin contact during resuscitation/ stabilization. To maintain normal body temperature or prevent hypothermia during transition (birth to 1–2 hours after delivery), we suggest well newborns of greater than 30 weeks of gestation be nursed with skin-to-skin contact or kangaroo mother care compared with a cot/open crib and swaddling or incubator (weak recommendation, very-low-quality evidence).The current systematic review found a small number of studies that compared the use of a plastic bag or wrap with no plastic bag or wrap for term and late preterm infants who were receiving skin to skin care, enabling metaanalysis.  |
| **Conflict of interests:** | None for this worksheet |

**Assessment**

|  |
| --- |
| **Problem**Is the problem a priority? |
| **Judgement** | **Research evidence** | **Additional considerations** |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | A systematic review conducted for ILCOR concluded that "For the critical outcome of mortality, there is evidence from 36 observational studies of increased risk of mortality associated with hypothermia at admission (low-quality evidence but upgraded to moderate-quality evidence due to effect size, dose-effect relationship, and single direction of evidence)". {Perlman 2015 S204} The same systematic review concluded that "There is evidence of a dose effect on mortality, suggesting an increased risk of at least 28% for each 1° below 36.5°C body temperature at admission and dose-dependent effect size". {Perlman 2015 S204} Although the size of effect in this estimate was influenced by inclusion of studies that enrolled very preterm infants, there was also evidence of adverse effects of hypothermia on survival in late preterm and term infants. A systematic review estimated that hypothermia was common in infants born at hospitals (prevalence range, 32% to 85%) and homes (prevalence range, 11% to 92%), even in tropical environments. {Lunze 2013 24} |  |
| **Desirable Effects**How substantial are the desirable anticipated effects? |
| **Judgement** | **Research evidence** | **Additional considerations** |
| ○ Trivial○ Small● Moderate○ Large○ Varies○ Don't know | The systematic review found that **using a plastic bag or wrap, compared to no plastic bag or wrap for late preterm and term infants who are receiving skin to skin care:*** For the critical primary outcome **survival to hospital discharge,** the effect of the intervention could not be evaluated because all infants survived in the one RCT enrolling 271 participants that reported this outcome.
* For the important primary outcome of **normothermia** on admission, there was **possible benefit**

Among secondary outcomes:* For **mean temperature** on admission there was **possible benefit**
* For **hypothermia <36.5ºC** there was **possible benefit**
* For **moderate hypothermia**, there was **possible benefit**

**The rationale for considering the effect moderate** was that for every 1000 infants exposed toa plastic bag or wrap with skin to skin care, compared to skin to skin care alone* from 18 more to 174 more were normothermic
* 23 fewer to 148 fewer were hypothermic <36.5ºC
* 83 fewer to 200 fewer were moderately hypothermic.

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with skin to skin care alone** | **Risk difference with a plastic bag or wrap combined with skin to skin care**  |
| Survival to discharge | 271(1 RCT)1 | ⨁⨁◯◯Lowa,b | **RR 1.00**(0.99 to 1.01) | Study population |
| Not applicable |  |
| Normothermia on admission to neonatal unit or postnatal ward | 692(2 RCTs)1,2 | ⨁⨁◯◯Lowa,c | **RR 1.39**(1.08 to 1.79) | Study population |
| 221 per 1,000 | **86 more per 1,000**(18 more to 174 more) |
| Body temperature | 692(2 RCTs)1,2 | ⨁⨁◯◯Lowa,b,c | - | The mean body temperature was **36.0** ºC | MD **0.2 ºC higher**(0.1 higher to 0.3 higher) |
| Admission to neonatal intensive or special care unit | 275(1 RCT)1 | ⨁⨁◯◯Lowc,d | **RR 0.26**(0.03 to 2.26) | Study population |
| 29 per 1,000 | **21 fewer per 1,000**(28 fewer to 36 more) |
| Any hypothermia < 36.5 ºC | 692(2 RCTs)1,2 | ⨁⨁◯◯Lowa,c | **RR 0.89**(0.81 to 0.97) | Study population |
| 777 per 1,000 | **85 fewer per 1,000**(148 fewer to 23 fewer) |
| Cold stress/mild hypothermia (temperature 36.0-36.4ºC) | 692(2 RCTs)1,2 | ⨁⨁◯◯Lowa,b | **RR 1.19**(0.98 to 1.44) | Study population |
| 341 per 1,000 | **65 more per 1,000**(7 fewer to 150 more) |
| Moderate hypothermia (temperature 32.0-35.9ºC) | 692(2 RCTs)1,2 | ⨁⨁◯◯Lowa,b,e | **RR 0.66**(0.54 to 0.81) | Study population |
| 436 per 1,000 | **148 fewer per 1,000**(200 fewer to 83 fewer) |

1 {Belsches 2013 e656} 2 {Travers 2021 55}1. There was indirectness related to the neonates enrolled as one study enrolled neonates born via vaginal delivery while there was no information for the other.
2. Optimal information size not met
3. 95% confidence interval crosses decision threshold
4. Belsches 2013 has not provided information on whether both vaginal and c-section neonates were enrolled
5. Though I2 value is >50%, the high value might be due to differences between small and large magnitude of effect. The point estimates and the 95% CI are overlapping as well. Hence, the certainty of evidence was not downgraded for inconsistency.
 |  |
| **Undesirable Effects**How substantial are the undesirable anticipated effects? |
| **Judgement** | **Research evidence** | **Additional considerations** |
| ○ Large○ Moderate○ Small○ Trivial○ Varies● Don't know | For **hyperthermia**, **benefit or harm could not be excluded**

| **Outcomes** | **№ of participants(studies)Follow-up** | **Certainty of the evidence(GRADE)** | **Relative effect(95% CI)** | **Anticipated absolute effects\* (95% CI)** |
| --- | --- | --- | --- | --- |
| **Risk with skin to skin care alone** | **Risk difference with a plastic bag or wrap combined with skin to skin care**  |
| Hyperthermia (temperature >37.5ºC) | 692(2 RCTs)1,2 | ⨁◯◯◯Very lowa,b | **RR 1.02**(0.08 to 12.85) | Study population |
| 3 per 1,000 | **0 fewer per 1,000**(3 fewer to 34 more) |

1 {Belsches 2013 e656} 2 {Travers 2021 55}1. There was indirectness related to the neonates enrolled as one study enrolled neonates born via vaginal delivery while there was no information for the other.
2. Very low event rate with wide 95% CI consistent with either appreciable harm or benefit
 | Measures to prevent hypothermia may increase risk for hyperthermia, because preterm or very ill neonates may have deficient thermoregulation and their capacity to maintain normothermia is limited. The 2015 ILCOR NLS CoSTR stated that; "A by-product of [these] interventions to prevent hypothermia is more-frequent hyperthermia (temperature greater than 37.5°C). Hyperthermia (temperature greater than 37.5°C) also increases the risk for neonatal mortality and morbidity in both term and preterm infants".{Perlman 2015 S204}A recent study in a low resource setting found that "mortality rate was estimated to be at minimum at admission temperature of 37.5 °C" with higher mortality above and below that level. {Cavallin 2020 722} Of particular relevance to late preterm and term infants, the adverse outcomes of hypoxic ischaemic encephalopathy (which are mitigated by controlled, therapeutic hypothermia) are exacerbated by hyperthermia. While it is possible that some of these effects are confounded by the presence of infection (e.g, chorioamnionitis, sepsis) there are plausible reasons why hyperthermia may itself compound brain injury. {Kasdorf 2013 379}  |
| **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 GRADE certainty of evidence for all outcomes was **low or very low**. The two included studies enrolled only term infants, {Belsches 2013 e656, Travers 2021 55} and both excluded some high risk infants so there is indirectness of evidence with respect to preterm infants and those at high risk of adverse outcomes. The likely effect of these selection criteria on effect sizes was considered in judging risk of bias and indirectness.  |  |
| **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 outcome of survival to hospital discharge (or its converse, mortality) have been judged by both care givers and parents to be the highest ranked outcomes of importance. {Strand 2020 F328, Webbe 2020 } | Other outcomes such as admission temperatures or presence of various degrees of hypothermia have not been ranked. However, they are likely to be ranked as important because of their potential effect on mortality. Cold stress is common, particularly among late preterm infants and has been associated with higher rates of NICU admission. {Laptook 2006 24} |
| **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 low certainty evidence of benefit for one primary and two secondary outcomes of the review, although for most outcomes, there was insufficient data or clinically significant benefit or harm could not be excluded.  | The Task Force considered that there might be unmeasured adverse effects, including potential effects on establishment of a normal neonatal microbiome, and on promotion of early and successful breast feeding. On the other hand, if skin to skin care is not succeeding in maintaining normothermia, the addition of a plastic bag or wrap might be beneficial for the mother baby pair when compared to transferring the baby to a radiant warmer or cot. The question of safety was also considered, as a baby in a plastic bag or wrap might be more at risk of unsafe positioning or falling. However, there are no data to estimate this risk. Unclean bags might also pose an infection risk.  |
| **Resources required**How 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 | A clean food-grade plastic bag or wrap suitable for a newborn infant is likely to be of very low cost. In two studies included in this systematic review, the cost was estimated at USD 0.03. {Belsches 2013 e656, Travers 2021 55} Purpose-designed sterile bags packaged for clinical use are more expensive, and wraps are intermediate in cost.  | The Task Force also considered the environmental impacts of recommending widespread use of plastic bags or wraps. However, this must be weighed against benefits, and also compared with the widespread use of other disposables in clinical care. While the costs of plastic bags or wraps may be low for individual babies, the costs to clinical services may be high if they are used for a high proportion of late preterm and term-born babies.  |
| **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 studies estimated resource requirements.  |  |
| **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 formally assessed cost effectiveness, and for the outcome of admissions to a neonatal intensive or special care unit benefit or harm could not be excluded on the basis of the available data.  | A study has assessed the cost effectiveness of "Kangaroo ward care" compared with "Intermediate Intensive Care" in the context of a randomised controlled trial. {Sharma 2016 64} The study, conducted in India, found statistically significant, very substantial cost savings for parents and hospital with the use of Kangaroo Mother Care, of which skin to skin care with the mother was a critical component. If the additional, temporary use of a plastic bag or wrap in addition to skin to skin care in approximately the first hour after birth had a positive effect on this balance by preventing hypothermia it could improve confidence in skin to skin care and its subsequent uptake, and thereby could have an indirect beneficial effect on cost-effectiveness.  |
| **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 | The two included studies were conducted in a low-income country (Zambia).  | Plastic bags or wraps are likely to be available in both low and high income countries, and in low resource settings, may offset the lack of availability of more expensive devices and equipment. The use of a plastic bag or wrap with skin to skin care in the interval immediately after birth might have benefits in improving confidence in subsequent skin to skin care, thereby reducing barriers to its use.In low-resourced settings, there is a possibility that the use of plastic bags or wraps for late preterm and term infants might divert their use from very preterm infants who might derive greater benefit.  |
| **Acceptability**Is the intervention acceptable to key stakeholders? |
| **Judgement** | **Research evidence** | **Additional considerations** |
| ○ No○ Probably no○ Probably yes○ Yes○ Varies● Don't know | No study specifically reported acceptability to all stakeholders. However, in one of the included studies, Belsches et al reported that the plastic bag was readily accepted by the labor and delivery staff after demonstrating that term infants frequently develop hypothermia and that it did not interfere with neonatal resuscitation. {Belsches 2013 e656} The other study reported that decreased compliance with polyethylene bags over time may have been related to soiled bags or cultural norms of dressing infants in new baby clothes. In addition, lack of masking (of the trial) may have encouraged mothers to remove the polyethylene bag when infants were no longer hypothermic. {Travers 2021 55} | There may be cultural concerns about the use of plastic bags or wraps compared to clothing. |
| **Feasibility**Is the intervention feasible to implement? |
| **Judgement** | **Research evidence** | **Additional considerations** |
| ○ No○ Probably no● Probably yes○ Yes○ Varies○ Don't know | The included studies were both performed in a low income country. Rates of withdrawal due to inability to continue study treatment were low. Plastic bags or wraps have been recommended for use in more preterm infants for more than a decade.  |  |

**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** |
| 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.  |
| **Justification** |
| * The systematic review found evidence to support the use of a plastic bag or wrap as an adjunct to skin to skin care to improve rates of normothermia and reduce risk of any hypothermia or moderate hypothermia in late preterm or term newborn infants (≥34 weeks' gestation, or equivalent birth weight) without evidence of adverse effects. However, the overall balance of risks and benefits was considered to be uncertain.
* The certainty of the evidence was low or very low for all analysable outcomes.
* Despite the findings of the review, the Task Force remained uncertain about the balance of effects. There was concern plastic bags or wraps might impair the acceptability or safety of skin to skin care, and thereby cause harm.
* The resources required are likely to be inexpensive for individual babies, but costs may be a barrier if the intervention is applied to a high proportion of births. The cost-effectiveness is unknown, but could be positive if any admissions to a neonatal special or intensive care unit are prevented, or if confidence in and uptake of skin to skin care is improved.
* Use of this low-cost fairly simple intervention could improve equity. The two studies suggesting benefit were conducted in low-income countries, and suggested feasibility in these settings. However, the full range of effects on equity is unknown.
 |
| **Subgroup considerations** |
| There were insufficient data to conduct subgroup analyses. Neither study provided any information about timing of umbilical cord clamping. Both were from a single hospital in a low income country (Zambia).  |
| **Implementation considerations** |
| Practice change strategies may be required to promote the use of a plastic bag or wrap as an adjunct to skin to skin care within minutes after birth.  |
| **Monitoring and evaluation** |
| Neonate's temperatures on admission to post-natal wards or neonatal intensive or special care units should continue to be monitored, as an important indicator of the quality of care. {Perlman 2015 S204} |
| **Research priorities** |
| * 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 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.
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