Clinical Performance Guideline
Neonatal Resource Services
Thermoregulation

Medical Necessity Guideline

Purpose: To explain the importance of the principles of thermoregulation and weaning from thermal support in the NICU.

Target Client Population: Any neonate in the NICU; however, these guidelines are applicable to those neonates who are at least 32 weeks gestational age and require assistance in maintaining their neutral thermal environment.

Background	Temperature regulation is one of the critically important factors in physiological maintenance of the neonate in the NICU. The normal axillary temperature in an open crib with appropriate clothing is 36.5-37.4°C (97.7-99.3°F). (Engle, 2007; Riley, 2012) One of the primary factors in heat loss in infants is that the body surface area is high in relation to the infant's weight. Heat loss in the neonate, particularly preterm infants, is due to the properties of the skin including low insulation (i.e., fat), high evaporation and limited ability to vasoconstrict. Growth restricted infants may have reduced glycogen stores putting them at increased risk. The detrimental effects of hypothermia may result in increased oxygen and metabolic demands, acid-base derangements, respiratory and circulatory compromise, hypoglycemia and even death. (Patra, 2016) Maintenance of thermoregulation in the neonate involves reducing one or more of the four mechanisms of heat loss; convection (environmental temperature and air flow), conduction (temperature in which subject resting), evaporation (from the lungs-alveolar ventilation and body surface-relative humidity of the environment) and radiation (solid objects surrounding the subject). The use of an incubator/radiant warmer to facilitate maintenance of a thermoneutral environment is routine practice in the NICU until the neonate is able to maintain his/her own thermoregulatory control. An environmental temperature of 22-26°C (72-78°F) will assist this transition to an open crib. (Riley, 2012) Isolated weight loss is not an indication to place an infant back in an incubator. For infants placed back into the incubator, a repeat trial of weaning to an open crib should be considered within 24 hours if parameters for weaning continue to be met. An evaluation of the NICU environment (temperature and physical location near sources of heat loss) and/or medical reasons for crib failure should be considered. Isolated low temperature readings are not uncommon, and ambient environmental factors challenging the maintenance of a thermoneutral environment should be identified and addressed.
Treatment Criteria	<u>Clinical evidence supports the following in infant thermoregulation:</u> -The infant should be weaned from the incubator or radiant warmer when the following parameters have been met: • When the incubator temperature is less or equal to 28 degrees C. • When the infant's ability to self-regulate temperature is demonstrated. This is not based on the neonate's actual weight, corrected gestational age or

	attainment of full oral feedings. • When the infant shows consistent weight gain (10-15 g/kg/d) in the incubator or is demonstrating expected weight gain based on the infant's gestation and corrected gestational age. • When the infant shows evidence of cardiovascular stability (i.e., stable vital signs). - Infants have the ability to begin successful incubator weaning as early as 1500 grams without adversely affecting or sacrificing weight gain. (New, 2011; Zecca, 2010; Barone, 2014) -Crib failure leading to placement back in an incubator should be based on axillary temperature measurements less than 36.5°C (97.7°F) while appropriately dressed and bundled. (Engle, 2007; Riley, 2012) -Weaning from a thermoregulated environment should occur prior to achieving full enteral feeds. This proactive approach has been shown to reduce length of stay (LOS). -The use of servo temperature control"™" during weaning is considered the preferred method. Servo temperature control is an electronic feedback system which functions as a thermostat to maintain a constant temperature at the site of the probe, usually on the skin over the abdomen, to maintain a constant abdominal skin temperature at 36C - 36.5C, thereby reducing the risks of cold stress or overheating. There is insufficient clinical evidence to support the theory that infants will not gain weight at the same trajectory when in a crib compared to an incubator. (Schneiderman, 2009)
Clinical Evidence	• A clinical trial by (NICHD) is evaluating incubator weaning at a lower weight in moderately preterm infants (29-34 weeks' gestation and birth weight <1600 grams) and its effect on LOS from birth to home discharge as the primary outcome. Comparators included incubator weaning at a lower weight of 1600 grams versus a higher weight of 1800 grams. A total of 366 infants met eligibility for the study. Randomization included 187 infants to the lower weight cohort and 179 infants to the higher weight group. Per most recent January 2018 trial update, 178 infants in the higher weight cohort and 185 infants in the lower weight group had discharge data available. Average length of hospital stay for the 1600 grams group is noted to be 43 days (median range 32-55 days and for the 1800 grams group noted to be 41 days (median range 33-52 days). No statistical analysis has been performed as of yet. No deaths were reported in either group and the lower weight group had one serious adverse event reported to be a pneumoperitoneum. Details can be accessed at: https://clinicaltrials.gov/ct2/show/NCT02160002. • A meta-analysis by the Cochrane Neonatal Collaborative Review Group (1998, 2002 and 2008), included data from two randomized/quasi randomized clinical trials in which servo-control of the abdominal skin temperature at 36C was measured against incubator air temperature at 31.1-32.2C. The findings showed that by keeping the baby's temperature at 36C by servo-control reduced the newborn death rate in low birth weight babies rather than setting a constant incubator temperature of 31.8C. • A retrospective nonrandomized study by Schneiderman et al (2009), found that on average for every additional 100 g an infant weighed at an open crib was associated with an increase in time to achieve full PO feeding by 0.8

days, a decrease in weight gained per day by 1 g and an increased LOS by 0.9 days.

- A prospective randomized clinical trial by Zecca et al (2010) studied infants who transferred from an incubator to an open crib at 1600 g versus 1800 g. The authors concluded that weaning moderately premature infants at a body weight of 1600 g versus 1800 g was safe and reduced the average LOS by 9.5 days. The trial noted that the time spent in the open crib was the same for both groups. The infants in the early transfer group did not require more time to achieve full feeding competency, and the breast feeding amount was similar to that in the standard transition group.
- A multicenter randomized controlled trial reviewed by New et al (2012), reached a similar conclusion. The authors concluded that medically stable infants can be transferred to open cots at a birth weight of 1600 g without any significant adverse effects on temperature stability or weight gain. However, this study noted that an earlier transfer to an open cot did not necessarily result in a shortened LOS. A possible explanation as to why the LOS was not impacted was that achieving full oral feeds had more influence on the timing of discharge. It was noted that the feeding milestone is one of the last milestones to be achieved by preterm infants born less than 32 weeks.
- Another randomized clinical trial regarding weight at weaning preterm infants from the incubator conducted by Berger, et al (2013), came to the same conclusions that weaning very low birth weight infants from an incubator to a warming bassinet at a body weight of 1500 g is feasible with no significant deleterious effects on weight gain or resting energy expenditure.
- An observational trial by West et al (2005) attempted to determine whether premature infants could be safely weaned from an incubator to an open crib at a bodyweight of 1,500 grams. Sixty-one infants with a birthweight <1,500 grams were divided into four cohorts and the thermal weaning process was initiated when each cohort reached a targeted weight of 1,500 grams (n=15), 1,600 grams (n=15), 1,700 grams (n=16) and 1,800 grams (n=15) respectively. No differences in temperature control were noted between the cohorts and only three infants overall needed to be returned to the incubator (one in the 1,700 g cohort, two in the 1,500 g cohort). There were no hypoglycemic episodes or medical complications in the three infants that failed transfer. The rate of weight gain did not differ between the four cohorts and both gestation and weight were similar at discharge.
- An AAP clinical report by Engle et al (2007) provided guidelines for the evaluation and management of the late-preterm infant. The authors described a late-preterm infant as physiologically immature and more likely than a term infant to be diagnosed with temperature instability. Minimum discharge criteria should include an axillary temperature of 36.5-37.4°C (97.7-99.3°F) while in an open crib appropriately clothed.
- Schafer et al (2014) evaluated the accuracy of skin sensor placement in the assessment of neonatal body temperature. Skin sensors were placed on the right upper abdomen, left flank and right axilla of 36 hemodynamically stable neonates. Digital axillary temperatures from the left axilla were compared to the three skin sensor sites in the supine placed neonates. The authors found no statistically significant differences in temperature between the skin sensor locations. In addition, the differences between the skin sensor readings and the digital axillary temperature were also not found to be significant.

	• A feasibility study by Barone et al (2014) evaluated early weaning from an incubator to an open crib at 1,600 grams. Eighty neonates successfully transitioned to an open crib when their weight registered between 1,600 and 1,699 grams without any adverse effects related to temperature stability or weight gain. Twenty-one neonates transferred from an incubator at a weight of ≥ 1,700 grams and the need for respiratory support was identified as the main reason for delayed weaning. A significantly reduced LOS was associated with the early weaning. • New et al (2011) analyzed the data on preterm infants' body weight as they transitioned from incubators to open cribs. Four randomized/quasi-randomized studies met the authors' inclusion criteria comparing infants transferred to open cribs at higher versus lower body weights. After analysis of these trials, the authors concluded that medically stable preterm infants of 1,600 grams could be transferred to an unheated open crib without any detrimental effects on temperature stability or weight gain.

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Revision History

The following are approved changes incorporated into the revision numbers indicated below.

Revision	Date	Description of Change
1.0	05/16/2013	New guideline (MB)
2.0	05/01/2014	Job aid revised into medical necessity clinical guideline. (LK)
2.0	09/08/2014	Will replace JA2229744 on 01/01/2015. (CE)
3.0	05/03/2015	Annual review with update by RS. (CE)
3.1	05/05/2016	Annual review with update by RS. No changes to criteria. (CE)
3.2	05/05/2017	Annual review by AJ. References updated. Information on growth restricted infants and the detrimental effects of hypothermia added. (CE)
3.3	05/04/2018	Annual review by AJ. Information on NICHD clinical trial updated. (CE)