abstract

BACKGROUND AND OBJECTIVE: Hypothermia during delivery room stabilization of very low birth weight (VLBW) newborns is independently associated with mortality, yet it occurred frequently both in collaborative networks and at our institution. We aimed to attain admission temperatures in the target range of 36°C to 38°C in ≥90% of inborn VLBW neonates through implementation of a thermoregulation bundle.

METHODS: This quality improvement project extended over 60 consecutive months, using sequential plan–do–check–act cycles. During the 14 baseline months, we standardized temperature measurements and developed the Operation Toasty Tot thermoregulation bundle (including consistent head and torso wrapping with plastic, warmed blankets, and a closed stabilization room). We introduced this bundle in month 15 and added servo-controlled, battery-powered radiant warmers for stabilization and transfer in month 21. We provided results and feedback to staff throughout, using simple graphics and control charts.

RESULTS: There were 164 inborn VLBW babies before and 477 after bundle implementation. Introduction and optimization of the bundle decreased the incidence of hypothermia, with rates remaining in the target range for the last 13 study months. The incidence of temperatures >38°C was ∼2% both before and after bundle implementation.

CONCLUSIONS: This thermoregulation bundle resulted in sustained improvement in normothermia rates during delivery room stabilization of VLBW newborns. Our benchmark goal of ≥90% admission temperatures above 36°C was met without increasing hyperthermia rates. Because these results compare favorably with those of recently published research or improvement collaboratives, we aim to maintain our performance through routine surveillance of admission temperatures. Pediatrics 2014;133:e218–e226

AUTHORS: Joaquim M.B. Pinheiro, MD, MPH,a Susan A. Furdon, MS, RN, NNP-BC,b Susan Boynton, BSN, RNC,b Robin Dugan, RNC, BSN, Christine Reu-Donlon, MS, RN, NNP-BC,b and Sharon Jensen, RN, MHA, CPHQ,c

Departments of aPediatrics, bNursing, and cQuality Management, Albany Medical Center, Albany, New York

KEY WORDS
hypothermia, resuscitation, infant, newborn, quality indicators, health care

ABBREVIATIONS
VLBW—very low birth weight
VON—Vermont Oxford Network

Dr Pinheiro contributed to the initial design and implementation of the project, collaborated in data acquisition, performed interim and final data analyses and interpretation, and drafted the initial manuscript; Ms Furdon contributed to the initial design and implementation of the project, collaborated in data acquisition, performed interim data analyses and interpretation, and collaborated in the initial draft and revisions of the manuscript; Ms Boynton, Ms Dugan, and Ms Reu-Donlon contributed to the initial design and implementation of the project, collaborated in data acquisition, and reviewed and revised the manuscript; Ms Jensen contributed to the initial design and implementation of the project, performed data analyses and interpretation in the early phases of the project, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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Address correspondence to Joaquim M. B. Pinheiro, MD, MPH, Department of Pediatrics/Neonatology, Albany Medical Center MC-101, 47 New Scotland Ave., Albany, NY 12208. E-mail: pinheij@mail.amc.edu

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Very low birth weight (VLBW) neonates (birth weight ≤1500 g) are particularly susceptible to cold stress and hypothermia during postnatal transition, and these derangements have been consistently associated with increased neonatal mortality.\(^1\) It remains unclear whether hypothermia is an epiphenomenon of complicated resuscitations or whether it independently mediates resuscitation outcomes. Still, the recently reported incidence of hypothermia in VLBW neonates on admission to technologically advanced NICUs ranges from 31% to 90%.\(^1,2,4\)

In this context, the Vermont Oxford Network (VON) started collecting admission temperature data on VLBW neonates in 2006, thus enabling Albany Medical Center, a type C VON member NICU, to conduct routine surveillance of these data. In 2007, a sudden, unplanned removal of chemical exothermic packs from our center resulted in increased frequency of hypothermia at NICU admission,\(^12\) with incidence increasing from 39% to 68%, a rate similar to the contemporary VON average.\(^8\) Those events prompted us to ask whether we could decrease hypothermia rates in VLBW neonates without using warming packs. Because heat loss is a physical phenomenon that occurs through 4 mechanisms (conduction, convection, radiation, and evaporation),\(^13\) a bundle of interventions is necessary to optimize thermoregulation. We thus undertook an interdepartmental and interdisciplinary project to standardize thermoregulatory processes during stabilization, aiming to maintain admission temperatures in the target range of 36°C to 38°C in ≥90% of inborn VLBW neonates.

**METHODS**

**Study Interventions**

We obtained institutional review board approval to collect, analyze, and report quality assurance data submitted to the VON database, exempt from individual consent. Inborn VLBW neonates admitted to the NICU over 60 consecutive months, starting in January 2007, were eligible; we excluded outborn infants and those who died in the delivery room. The baseline period comprised months 1 to 14, during which removal of the warming packs (month 3) triggered a variety of provider-specific thermoregulatory interventions. Common features of postnatal thermoregulation included the use of radiant warmers (without battery packs) for stabilization and transfer to the NICU, located 1 floor and <10 minutes away; use of receiving blankets and variably applied prewarmed blankets; and inconsistent wrapping of the head or body with polyvinylidene chloride plastic (saran type). Infants were not completely dried, but excess fluid and blood were gently blotted off the skin. The measurement and timing of admission temperatures were inconsistent until they were standardized in month 9.

We formed an interdepartmental workgroup (NICU, Delivery Room and Quality Management), reviewed admission temperature data and thermoregulatory processes, searched literature on prevention of neonatal hypothermia, and designated unit champions to maximize expertise and interdisciplinary collaboration. Based on recommendations in the Neonatal Resuscitation Program,\(^14\) *Guidelines for Perinatal Care,\(^15\)* and evidence from literature, we identified locally available components of a thermoregulation bundle that counteracted all 4 physical mechanisms of postnatal heat loss (Table 1). We sought to standardize thermoregulation processes in the delivery room while integrating them with other aspects of stabilization. Thus, we began implementation of the bundle with newborns of gestational age ≤28 weeks, whose stabilization was already standardized, including an expanded team for prophylactic administration of surfactant; this procedure also prolonged the delivery room stay, further increasing the risk for hypothermia in these most vulnerable newborns. The quality improvement initiative was incrementally modified through plan–do–study–act cycles.

Four of the 14 delivery rooms in our institution, and also the operating rooms, have an adjoining infant stabilization room separated by a door. Most VLBW deliveries occur in operating rooms. We estimate that about two-thirds of VLBW neonates are resuscitated in stabilization rooms; the remainder, including multiples beyond the firstborn, are stabilized in the mother’s delivery room or operating room proper. Deliberations with plant facility engineers revealed that operating room temperatures could not be increased for deliveries. However, the stabilization room temperature should increase if delivery room staff turned on the radiant warmer and closed the door when calling the NICU team.

For internal marketing purposes, the improvement project was named Operation Toasty Tot. Colorful signs reading “Operation Toasty Tot—Warming in Progress—Please keep door closed” were placed on stabilization room doors, to remind staff and to help communicate the process to families. The signage and approach to prewarming the room became an element of our bundle.

Other aspects of the bundle (see Table 1) included standardization of interventions already used, such as applying separate sheets of plastic wrap to the head and torso, auscultating or palpat ing through the wrap, and specifying a location for warming blankets and a staff member for obtaining them. The initial bundle was implemented during month 15, after an annual Learning Skills Fair, where staff was educated on neonatal hypothermia and...
on our standardized normothermia bundle. After the fair, admission temperatures were plotted on scatter graphs at the NICU front desk for review by staff attending deliveries. Stacked bar graphs depicting the proportions of hypothermic, normothermic, and hyperthermic infants were also posted and reported monthly at pediatric residency conferences.

During the next cycle, starting in month 21, the bundle was modified as battery-powered radiant warmers (Panda; GE Healthcare, Little Chalfont, United Kingdom) were introduced for stabilization and transfer to NICU. Application of a skin temperature probe set at 37°C, for servo-controlled thermoregulation by 5 minutes of age, became standard. In month 27, after data analysis revealed a significant reduction in hypothermia rates from VLBW neonates ≥29 weeks’ gestation (who were still receiving baseline thermoregulation), bundle interventions were extended to all infants with expected weight <1500 g. irrespective of surfactant prophylaxis.

### Evaluation Methods

Throughout the study, admission temperatures were measured using Exergen model LXN-1 infrared thermometers (Watertown, MA), whose readings approximate core temperature. Axillary temperature was obtained immediately on admission to NICU by the nurse who attended the delivery, before transfer to a prewarmed incubator or warmer. To avoid selective recording of measurements, the method for confirming and recording out-of-target range readings were explicitly standardized in month 9 of the baseline period. Temperature data displayed as simple graphs provided continuous feedback to staff.

Because multiple factors affect thermoregulation during delivery room resuscitation, we did not prospectively collect comprehensive patient-level process measures. Rather, we characterized thermal environment data and retrospectively reviewed information on hypothermic neonates to identify measurable and perceived process problems.

Environment-level data, including the operating room set temperature and surface temperatures of the delivery and resuscitation rooms, were obtained from a convenience sample of 27 deliveries, using a digital infrared thermometer (Cen-Tech model 93983, China).

At the individual patient level, the resuscitation documentation record was redesigned with checkboxes for the various thermoregulation interventions used. These were reviewed specifically when a neonate was hypothermic on admission, and additional information was obtained from staff involved in the resuscitation. We did not independently verify the accuracy of this documentation or assess whether the checkboxes served as prompts to initiate specific interventions. Information on thermoregulatory interventions in hypothermic cases was analyzed qualitatively during the first cycle of Operation Toasty Tot. Subsequently, such information was used retrospectively, to troubleshoot equipment or process problems. A competency tool (Appendix) was used during the second Learning Skills Fair to define roles within the team attending deliveries. An evaluation tool (mirroring the competency tool) was completed by the NICU nurse attending the delivery of each VLBW infant for 3 months after another Skills Fair. Unit champions used and reviewed the evaluation tool in real time to identify issues of individual noncompliance or system problems associated with hypothermia. Residual noncompliance with using plastic head wrap in larger VLBW infants was noted and resolved through feedback. Process data from normothermic neonates

### TABLE 1 Thermoregulatory Bundle With Local Specifications for Delivery Room Stabilization

<table>
<thead>
<tr>
<th>Type of Heat Loss</th>
<th>Common Causes</th>
<th>Primary Interventions Specified in Bundle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduction</td>
<td>Direct contact with cold bed surfaces</td>
<td>Turn on radiant warmer when delivery is anticipated to prewarm resuscitation bed. Make additional prewarmed blankets available for transfer.</td>
</tr>
<tr>
<td>Radiation</td>
<td>Large skin surface area exposed to cooler surroundings; blockage of radiant heat source</td>
<td>Turn warmer on early and close door to selectively warm the separate resuscitation room (when available). Lean back, do not block infant’s access to heat. Set servo-controlled warmer to 37°C by 5 min of age (in phase 2).</td>
</tr>
<tr>
<td>Evaporation</td>
<td>Wet skin or nonocclusive wrappings; low humidity of ambient air or inspired gas</td>
<td>Rapidly blot off excess fluid and blood; no need to dry completely. Apply plastic wrap to head immediately. Apply stockinette hat over the plastic wrap. Apply plastic wrap around body of infant when &lt;29 wk gestational age.</td>
</tr>
<tr>
<td>Convection</td>
<td>Cool air flowing over skin, cold gases flowing over mucous membranes</td>
<td>Increase temperature of stabilization room using warmer. Reduce air drafts by closing door; raising sides of warmer; keep all sides up and use additional blankets, with only face exposed, for transfer. Keep baby’s skin covered with plastic wrap; add large blanket for transfer. Transfer to prewarmed, humidified incubator on admission (after temperature measured).</td>
</tr>
</tbody>
</table>

Adapted from the basic steps in the Neonatal Resuscitation Program, aiming to minimize all 4 physical mechanisms of heat loss. References indicate key published evidence or rationale for the bundle elements.
were not examined further. After month 21, individual hypothermia events were reviewed monthly with neonatologists, fellows, and midlevel staff at the morbidity and mortality conference and with nursing staff through the NICU newsletter.

**Analysis**

Hypothermia was defined as an admission temperature $<36.0°C$. Using QI Macros 2013.07 (Denver, CO), we generated a 2-stage statistical process control chart of the proportion of hypothermic neonates by month, with 3-sigma control limits, which allow for a false alarm probability of 0.0027 (similar to a type I error). Monthly proportions within the control limits indicate common cause variation, whereas values beyond the control limits are out of statistical control, prompting investigation for special causes. Taking the incidence of hyperthermia (temperature $\geq 38°C$) as the key balancing measure, we aggregated the cases into 3 periods, namely, prebundle, bundle implemented, and bundle extended (to neonates $\geq 28$ weeks’ gestation); we compared the proportions of neonates who were hypothermic, normothermic (36°C–38°C), and hyperthermic during those periods using $\chi^2$ or exact statistics and the mean admission temperatures between periods using analysis of variance and Dunnett’s post hoc test. Finally, to evaluate a potential impact of thermoregulatory tasks on the efficacy of resuscitation, we examined the annual incidence of Apgar scores $\leq 4$ at 5 minutes, use of chest compressions or epinephrine, and mortality.

**RESULTS**

The analysis included 641 inborn VLBW neonates: 164 during the 14 months before initiation of the Toasty Tot bundle and 477 subsequently. Infants born during both periods had similar birth weights, with overall mean (±SD) of 1044 ± 307 g and gestational age of 28.0 ± 2.9 weeks. Environmental temperature settings were unaltered during the project. From the deliveries sampled, mean operating room set temperature was 19.0°C (thermostat range, 15.8°C–22.6°C); the corresponding mean wall surface temperature was 20.4°C (17.0°C – 23.6°C). Mean temperatures of delivery room (22.4°C) and resuscitation room walls (23.0°C) were well below the surface temperature of receiving blankets on the warmer (mean 41.6°C; range 29.9°C – 47.4°C).

The control chart (Fig 1) shows a shift toward lower monthly proportions of hypothermia with introduction of the thermoregulatory bundle. After final modification and expansion of the bundle to all VLBW neonates, the proportion of hypothermic neonates has remained below our benchmark of 10%, and these results have been sustained without additional intervention for >2 years. Mean admission temperature (±SD) was 36.2°C (±0.9°C) during the baseline period; it increased to 36.6°C (±0.7°C) and 36.8°C (±0.5°C) after bundle introduction and extension, respectively ($P < .001$ for both, by Dunnett’s test). As shown in Table 2, temperatures in the normothermic range increased from 65% of neonates during the baseline period to 94% after introduction and extension of the bundle to all VLBW neonates, and hypothermia decreased to 4.6% ($P < .001$).

Concurrently, the proportions of hyperthermic neonates remained at about 2% across project periods (Table 2), and the maximum temperatures observed were 38.8°C before and 38.5°C after the bundle introduction, respectively. The annual proportions of neonates with Apgar scores $<4$ at 5 minutes, receiving chest compressions or epinephrine, or dying in NICU, were also unchanged (data not shown).

**FIGURE 1**

P-chart showing the proportions of hypothermic VLBW neonates during 80 consecutive months (diamonds), subdivided into 14-month baseline and subsequent intervention periods. Mean hypothermia rates by period (dashed-dotted line), upper and lower 3-sigma control limits (UCL, LCL), and the 10% benchmark (dotted line) are also displayed. Arrows show introduction of major interventions including the thermoregulation bundle, transport warmer, and expansion of the population to which the bundle was applied.
Qualitative analysis of processes associated with hypothermic neonates revealed some patterns and specific opportunities for improvement. There was universal implementation of pre-heating the warmer, setting the target temperature, closing the door with signage to the stabilization area, drying the infant, and applying the hat. However, reinforcement by unit champions was necessary to minimize variable application or subsequent lifting of the plastic wrap. Most residual occurrences of hypothermia were attributed to occasional unavailability of warmed blankets, rare instances of prolonged delivery room resuscitation, and failure of transport warmer batteries.

**DISCUSSION**

Hypothermia after delivery room stabilization remains exceedingly common in preterm newborns, even where radiant warmers are used routinely. Basic and clinical research on additional methods to prevent heat losses during neonatal resuscitation through convective, evaporative, and conductive mechanisms has neither resulted in strong evidence for thermoregulatory practice nor translated into expectations of normothermia on admission of high-risk newborns. Evidence continues to show a consistent independent association of hypothermia with neonatal mortality, suggesting that it may directly contribute to mortality. In this context, the sudden removal of chemical warming packs from our setting provided impetus for this project while facilitating interdepartmental and multidisciplinary collaborations needed to change our thermoregulation processes. By implementing a bundle of interventions, we attained hypothermia rates <10% in VLBW newborns, without hyperthermia (the key balancing measure) or other obvious adverse effects. The decrease in hypothermia is probably attributable to the thermoregulation bundle, because visual inspection of the control chart reveals an abrupt decrease in hypothermia immediately after the initial intervention. Temperature measurements had been previously standardized and remained unchanged. There were no obvious concurrent changes in possible confounders, including patient risk factors or the resuscitation environment. The greatest impact on hypothermia rates occurred with the initial introduction of the bundle, which essentially standardized existing practices. The addition of the battery-powered warmer and extension of the bundle intervention to include larger VLBW neonates produced additional improvements, although these cannot be disentangled from increasing staff experience with the standardized procedures. It is noteworthy that as mean admission temperature increased across the phases of the project, the SD of this measure also decreased, and the control limits on the p-chart narrowed, suggesting more precise thermoregulatory control.

A major strength of this initiative is the effectiveness of our bundle in preventing hypothermia, to a greater extent than that reported recently on similar populations. Furthermore, the large sample size and our consistent rates of normothermia indicate that these results did not occur by chance. From a safety perspective, our ability to prevent hypothermia without incurring hyperthermia or other obvious complications of resuscitation is important, because this has been a concern in some previous studies, and it may also contribute to morbidity.

Qualitative, unplanned observations of staff dynamics raised the possibility that standardizing temperature measurements, which was aimed at maximizing accuracy and avoiding biases, serendipitously became an intangible intervention. As the nurse who attended the delivery took the admission temperature, the result served as an “instant outcome,” which provided ownership to the team implementing the bundle. This afforded both positive feedback and an immediate opportunity for debriefing on thermoregulatory issues. We witnessed openly enthusiastic behaviors, and interested concern in response to individual results, which continue to be observed.

A possible limitation of this study is its generalizability. Stabilization area designs and methods used for thermoregulation vary across centers. Whereas several methods have been shown effective in improving temperature control in randomized trials, single interventions such as higher delivery room temperatures, exothermic mattresses, plastic caps, or body wrap, even when added to a radiant warmer, remain inadequate in fully preventing hypothermia in VLBW newborns. Interventions with multiple components are more effective in preventing hypothermia, and it is likely that the efficacy of each component interacts with other elements of the thermal milieu. We reasoned that a postnatal thermoregulatory bundle should minimize all 4 physical

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**TABLE 2** Percentage of Neonates in Each Target Temperature Range, by Epoch of the Intervention

<table>
<thead>
<tr>
<th>Epoch</th>
<th>n</th>
<th>&lt;36°C, %</th>
<th>36°C–38°C, %</th>
<th>&gt;38°C, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>164</td>
<td>34.1</td>
<td>64.6</td>
<td>1.2</td>
</tr>
<tr>
<td>Bundle introduced</td>
<td>62</td>
<td>17.7</td>
<td>79.0</td>
<td>3.2</td>
</tr>
<tr>
<td>Bundle extended</td>
<td>440</td>
<td>4.6</td>
<td>93.5</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Hyperthermia (temperature >38°C) was the key balancing measure for hypothermia (temperature <36°C).
paths of heat loss while providing adequate and controllable exogenous heat.

It is notable that we succeeded in maintaining normothermia without increasing delivery room temperatures and without using exothermic packs or mattresses, heated respiratory gases, or an incubator for transfer. The absence of these elements was probably compensated by other aspects of our bundle. A separate stabilization room with a closed door and prewarmed radiant device allows for a slight increase in room temperature, minimization of convective heat losses, and prewarming of the bed surface. Although we measured surface rather than air temperature in the resuscitation room, it was probably lower than the 25°C (77°F) recommended by the World Health Organization or the 26°C recommended in the Guidelines for Perinatal Care. Our scrupulous attention to the technique of applying plastic wrap with separate pieces for the head and body, using a material that permits visualization, auscultation, and cord palpation without lifting the plastic, minimized evaporative and convective heat losses. Another advantage of polyvinylidene sheets over plastic bags is that they allow easy access to the right arm for pulse oximeter probe application.

As an exothermic heat source during transfer to the NICU, we began using large warmed blankets to replace chemical warming packs. These blankets seem suboptimal because of their low heat capacity and rapid drop in surface temperature once they are opened; still, they provide insulation, protect against convection during transfer in an open warmer, and are not associated with hyperthermia or skin burns. We later introduced battery-operated warmers for stabilization and transfer, routinely set on servo-control with a skin probe; this probably decreased the variance of the admission temperatures. Our approach allows us to forgo the use of a transport incubator, which does not reduce hypothermia in plastic-wrapped newborns and is less convenient for hands-on airway management during transfer.

We have sustained our improvement during the last 2 years, using only routine surveillance data monitoring and reporting, with brief reviews of cases with an admission temperature outside the target range. Potential causes underlying occasional residual hypothermia events include multiple births stabilized in open operating rooms, a few warmer battery failures, and 2 clearly erroneous thermometer readings recorded per protocol.

Areas for future review include tracking trends in admission temperature data as a new NICU under construction is located farther from the delivery rooms.

If our approach produces similar results elsewhere, it may add significant value to neonatal care. Mortality increases with hypothermia on admission, by an estimated 28% per degree centigrade in VLBW newborns, yielding a number needed to harm of 29 (95% confidence interval 20–50). This association is consistent across studies, but causality remains unproven in randomized trials. We did not quantify material costs of the thermoregulatory bundle, but it was less expensive than other alternatives considered. Rolls of plastic wrap are substantially less expensive than medical-grade bags, and reusable blankets cost less than exothermic mattresses. The new warmers replaced older equipment. Overall, the interventions resulted in increased value, given improved quality (measured as admission temperatures) without increased cost. There was no evidence of opportunity costs of diverting attention from other key aspects of resuscitation, because we found neither lower Apgar scores nor more intensive resuscitation. Most bundle components can be implemented readily and at minimal cost (or even savings), which should allow its application in other centers.

We conclude that minimal rates of hypothermia during stabilization of VLBW newborns can be achieved through the use of a thermoregulation bundle, which avoids hyperthermia and could be easily implemented elsewhere. We speculate that using the admission temperature as instant feedback to the resuscitation team may focus attention on thermoregulation and help in attaining lower rates of hypothermia.

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REFERENCES


APPENDIX  Competency Tool: Maintaining VLBW temperature in DR (Goal: 36°C –38°C)

<table>
<thead>
<tr>
<th>Team Member 1: Airway and Thermoregulation</th>
<th>Team Member 2 Airway Assistant and Thermoregulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When NICU team called for delivery, verify the following:</td>
<td></td>
</tr>
<tr>
<td>a. Blankets available in blanket warmer.</td>
<td></td>
</tr>
<tr>
<td>b. ID bands (manual version) are filled out or available.</td>
<td></td>
</tr>
<tr>
<td>c. Panda is turned on, manual mode with 100% heat output.</td>
<td></td>
</tr>
<tr>
<td>d. Side rails on warmer are up.</td>
<td></td>
</tr>
<tr>
<td>e. Door to anteroom is closed (to warm the room).</td>
<td></td>
</tr>
<tr>
<td>f. Baby blankets (2) are on top of mattress (opened), and receiving drape is open on top of them.</td>
<td></td>
</tr>
<tr>
<td>2. Upon arrival of the pediatrics team, nurse should verify all of the above in context of verifying resuscitation equipment.</td>
<td></td>
</tr>
<tr>
<td>3a. Dry head with sterile drape; place plastic wrap turban, then hat for all infants estimated to be &lt;1500g. Clear airway with bulb syringe. Provide BBO2 BMV as indicated.</td>
<td></td>
</tr>
<tr>
<td>3b. Concurrently as team member 1 is drying head, dry infant’s torso with warmed drape, then towel; remove wet linen.</td>
<td></td>
</tr>
<tr>
<td>4. Place probe on abdomen and switch to servo control set at 37°C.</td>
<td></td>
</tr>
<tr>
<td>5. For infants meeting surfactant criteria, place 1 piece of plastic wrap under the infant; place oximeter probe on right hand. Secure temperature probe to abdomen. Wrap plastic across infant’s torso.</td>
<td></td>
</tr>
<tr>
<td>6. When ready for transfer, wrap infant in 2 prewarmed blankets from the blanket warmer (leaving the plastic on) and drape warmed blanket across head.</td>
<td></td>
</tr>
<tr>
<td>7. Maintain servo control modality for transfer; monitor skin temperature on display.</td>
<td></td>
</tr>
<tr>
<td>8. Obtain admission temperature before transfer to incubator or radiant warmer.</td>
<td></td>
</tr>
</tbody>
</table>

**BBO2 BMV, blow-by O2, bag-mask ventilation; DR, Delivery Room.**
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