



Implementation of Thermoregulation Bundle to Improve Admission Temperature in Preterm Infants: A Quality Improvement Study

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ABSTRACT:

Background: Admission hypothermia remains a frequent and preventable complication among preterm neonates and is independently associated with increased mortality and morbidity. Despite established recommendations for thermal care at birth, implementation gaps persist, particularly in routine clinical settings. Quality improvement (QI) approaches offer a pragmatic framework to translate evidence into sustained practice change. This study aimed to reduce the incidence of admission hypothermia in preterm neonates (≤ 36 weeks' gestation) by at least 50% through implementation of a comprehensive thermoregulation bundle using Plan-Do-Study-Act (PDSA) methodology.

Methods: We conducted a prospective QI study over six months (April-September 2019) at a tertiary care teaching hospital. All inborn preterm neonates (24-36 weeks' gestation) were included. Using the World Health Organization Point-of-Care QI model, a multidisciplinary team implemented a thermoregulation bundle comprising delivery room temperature standardization (25-26°C), pre-warmed towels during delayed cord clamping, polyethylene occlusive wraps, woolen caps, transport incubators, and structured staff education. The primary outcome was NICU admission temperature. Secondary outcomes included delivery room ambient temperature and infant temperature at the time of transport. Outcomes were assessed across pre-implementation, implementation, and post-implementation phases.

Results: Fifty-four preterm neonates were evaluated. Mean delivery room temperature increased from $19.00 \pm 3.10^\circ\text{C}$ to $24.00 \pm 1.10^\circ\text{C}$ ($p < 0.001$). Infant temperature at transport improved from $35.22 \pm 0.50^\circ\text{C}$ to $36.50 \pm 0.10^\circ\text{C}$ ($p < 0.001$). Mean NICU admission temperature increased from $35.65 \pm 0.55^\circ\text{C}$ to $36.87 \pm 0.47^\circ\text{C}$ ($p = 0.002$). The prevalence of admission hypothermia decreased from 88% at baseline to 15% post-implementation, representing an 83% relative reduction.

Conclusion: A bundled thermoregulation strategy implemented through PDSA-based quality improvement substantially improved thermal stability and reduced admission hypothermia among preterm neonates. These findings support routine adoption of structured thermoregulation bundles as a scalable, low-cost intervention in neonatal care settings.

INTRODUCTION

Hypothermia remains one of the most common and preventable contributors to morbidity and mortality in preterm neonates, particularly during the immediate postnatal transition period. Preterm infants are inherently vulnerable to heat loss due to a constellation of physiological factors, including reduced brown adipose

tissue, immature skin barrier, limited vasomotor control, and a disproportionately large surface area relative to body weight.^{1,2} Even brief exposure to suboptimal thermal environments during delivery and transport can result in rapid declines in core temperature, with clinically significant consequences.



The adverse impact of neonatal hypothermia is well established. The World Health Organization classifies neonatal hypothermia into mild (36.0–36.5°C), moderate (32.0–35.9°C), and severe (<32.0°C) categories, each associated with progressively worse outcomes.³ Large multicenter data from the Neonatal Research Network have demonstrated a clear dose–response relationship between admission temperature and outcomes, with every 1°C decrease in admission temperature increasing mortality by approximately 28% and late-onset sepsis by 11%.³ Hypothermia is also associated with metabolic acidosis, hypoglycemia, respiratory distress, coagulation abnormalities, and impaired immune function, further compounding the risk of adverse neonatal outcomes.²

Despite the availability of clear evidence-based recommendations, admission hypothermia remains highly prevalent worldwide, particularly in low- and middle-income settings. Studies from both high-resource and resource-constrained environments report hypothermia rates ranging from 30% to over 80% among preterm infants at NICU admission.⁴ These findings underscore a critical implementation gap between established guidelines and routine clinical practice. Environmental factors such as low delivery room temperature, inconsistent use of thermal protection devices, delays in transport, and variable staff adherence to protocols have been repeatedly identified as modifiable contributors.⁴

International guidelines, including those from the World Health Organization and Neonatal Resuscitation Program, recommend maintaining delivery room temperatures between 25–26°C, using preheated radiant warmers, minimizing evaporative heat loss through polyethylene wraps, applying head coverings, and ensuring thermally controlled transport to the NICU.^{4–6}

Quality improvement (QI) methodology offers a structured approach to bridging this evidence–practice gap. Unlike traditional clinical trials, QI initiatives focus on real-world implementation, emphasizing process optimization, multidisciplinary collaboration, and continuous monitoring to achieve sustainable improvements in care delivery. The Plan–Do–Study–Act (PDSA) cycle is a widely accepted QI framework that facilitates iterative testing of interventions, identification of barriers, and refinement of strategies based on outcome data.

Several QI initiatives have demonstrated success in reducing admission hypothermia through bundled

interventions targeting multiple mechanisms of heat loss.^{1,7} However, heterogeneity in bundle components, variable adherence, and limited reporting of process measures continue to hinder reproducibility and scalability, particularly in tertiary care centers within developing health systems.

Given the high baseline prevalence of hypothermia, the availability of low-cost evidence-based interventions, and the persistent gap between recommendations and practice, there is a compelling need for systematic implementation of thermoregulation bundles using QI methodology. This study aimed to reduce the incidence of admission hypothermia in preterm neonates (≤ 36 weeks gestation) by at least 50% through the implementation of a comprehensive thermoregulation bundle using PDSA cycles, while simultaneously evaluating process compliance and sustainability within a tertiary care setting.

MATERIALS AND METHODS

Study Design and Setting

This prospective quality improvement study was conducted over a six-month period from April 2019 to September 2019 at the Department of Neonatology, at a tertiary care hospital in Tamil Nadu, India. The study was approved by the Institutional Ethics Committee of Chettinad Hospital and Research Institute. Reporting was guided by the SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines.

Study Population

All inborn preterm neonates with a gestational age between 24 and 36 weeks delivered during the study period were eligible for inclusion. Exclusion criteria included outborn neonates and infants requiring extensive resuscitation involving chest compressions, as such interventions could independently influence thermal outcomes. Written informed consent was waived as the interventions represented standard-of-care quality improvement measures.

Quality Improvement Framework

The study utilized the World Health Organization Point-of-Care Quality Improvement Model based on the Plan–Do–Study–Act (PDSA) cycle methodology. A multidisciplinary QI team comprising neonatologists, pediatricians, obstetricians, nursing staff, and hospital administrators was constituted. The team met regularly to identify barriers,



review performance data, and implement corrective strategies.

Baseline Assessment and Root Cause Analysis

A baseline assessment of delivery room practices and neonatal admission temperatures was conducted during the pre-implementation phase. Root cause analysis was performed using a fishbone (Ishikawa) diagram to systematically identify factors contributing to admission hypothermia. These included environmental factors (low delivery room temperature), process gaps (delayed thermal protection, inconsistent transport practices), equipment-related issues (lack of transport incubators), and human factors (variable staff awareness and adherence). The fishbone analysis is illustrated in Figure 1, which guided the selection of targeted interventions.

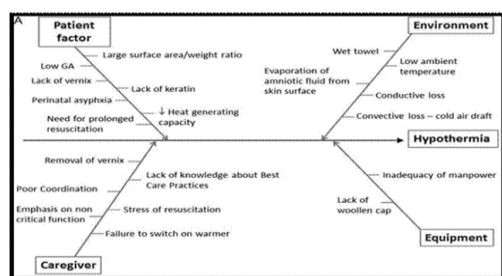


Figure 1: Fishbone Diagram Identifying Root Causes of Hypothermia in Preterm Neonates

Intervention: Thermoregulation Bundle

Based on the root cause analysis, a comprehensive thermoregulation bundle was developed and implemented. The bundle included:

1. **Environmental control:** Standardization of delivery room and operation theater ambient temperature to 25–26°C.
2. **Evaporative heat loss prevention:** Immediate application of polyethylene occlusive wraps from neck to toe without prior drying, maintained until the infant's core temperature exceeded 36.5°C in a stable thermal environment.
3. **Head covering:** Application of woolen caps following initial stabilization.
4. **Conductive heat loss prevention:** Use of pre-warmed sterile towels during delayed cord clamping (≥ 30 seconds).

5. **Transport optimization:** Transfer of neonates in dedicated transport incubators from delivery room to NICU.
6. **Staff education:** Structured training sessions for medical and nursing staff, including demonstrations, posters, and periodic reinforcement.

Implementation Phases

The study was conducted in three sequential phases:

- **Pre-implementation phase:** Baseline data collection.
- **Implementation phase:** Introduction of the thermoregulation bundle with active monitoring.
- **Post-implementation phase:** Evaluation of outcomes and sustainability.

Data Collection and Outcome Measures

Temperature measurements were recorded at three predefined time points: delivery room ambient temperature, infant temperature at the time of shifting, and NICU admission temperature. All measurements were performed using calibrated digital thermometers by trained personnel. Demographic and clinical variables including gestational age, birth weight, mode of delivery, and APGAR scores were also recorded.

The primary outcome was NICU admission temperature. Secondary outcomes included delivery room temperature, temperature at the time of transport, incidence of hypothermia ($< 36.5^\circ\text{C}$), and compliance with individual bundle components.

Statistical Analysis

Data were analyzed using SPSS version 20. Continuous variables were expressed as mean \pm standard deviation and compared across phases using appropriate parametric or non-parametric tests based on data distribution. Categorical variables were summarized as frequencies and percentages. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 54 preterm neonates delivered between 24 and 36 weeks of gestation were included in the study across the pre-implementation, implementation, and post-implementation phases. The baseline demographic and



clinical characteristics of the study population remained comparable across the three phases, indicating that observed changes in outcomes were unlikely to be influenced by case-mix variation. The mean gestational age of the infants was 31.02 ± 3.12 weeks, with a mean birth weight of 2054.31 ± 779.77 grams. The majority of neonates were delivered by caesarean section (75%), and the mean APGAR score at birth was 7.23 ± 0.81 . No statistically significant differences were observed in gestational age, birth weight, or APGAR scores across study phases (Table 1).

Table 1: Baseline Characteristics and Intervention Outcomes Across Study Phases (N = 54)

Parameter	Pre-QI	During QI	Post-QI	P value
Gestational age (weeks)	30.02 ± 2.12	31.05 ± 3.20	31.23 ± 2.40	0.23
Birth weight (grams)	1980.11 ± 600.66	2020.20 ± 753.23	2056.31 ± 653.43	0.34
APGAR score	7.01 ± 0.61	6.93 ± 0.92	7.53 ± 0.43	0.06
Delivery room temperature (°C)	19.00 ± 3.10	22.00 ± 6.20	24.00 ± 1.10	<0.001*
Temperature at shifting (°C)	35.22 ± 0.50	36.60 ± 0.40	36.50 ± 0.10	<0.001*
NICU admission temperature (°C)	35.65 ± 0.55	36.90 ± 0.45	36.87 ± 0.47	0.002*

Footnote:

Values are expressed as mean \pm standard deviation. *P* values <0.05 are considered statistically significant.

The primary outcome, NICU admission temperature, demonstrated a significant and sustained improvement following implementation of the thermoregulation bundle. During the pre-implementation phase, the mean admission temperature was $35.65 \pm 0.55^\circ\text{C}$, indicating a high prevalence of hypothermia at NICU entry. With initiation of the quality improvement interventions, admission temperature increased to $36.90 \pm 0.45^\circ\text{C}$ during the implementation phase and remained stable at $36.87 \pm 0.47^\circ\text{C}$ in the post-implementation phase. This improvement of 1.22°C from baseline was statistically significant ($p = 0.002$) and clinically meaningful (Table 1).

Secondary outcomes showed parallel improvements in upstream thermal control measures. Delivery room ambient temperature increased significantly from a baseline mean of $19.00 \pm 3.10^\circ\text{C}$ to $22.00 \pm 6.20^\circ\text{C}$ during the implementation phase and further to $24.00 \pm 1.10^\circ\text{C}$ in the post-implementation phase ($p < 0.001$). This represented successful achievement of the recommended thermal range for preterm deliveries. Similarly, infant temperature at the time of shifting from the delivery room to the NICU improved significantly from $35.22 \pm 0.50^\circ\text{C}$ at baseline to $36.60 \pm 0.40^\circ\text{C}$ during implementation and stabilized at $36.50 \pm 0.10^\circ\text{C}$ post-implementation ($p < 0.001$) (Table 1).

The incidence of admission hypothermia, defined as a NICU admission temperature below 36.5°C , decreased markedly following implementation of the thermoregulation bundle. At baseline, 88% of preterm neonates were hypothermic on admission. This proportion decreased substantially to 15% in the post-implementation phase, corresponding to an 83% relative reduction in hypothermia prevalence. The calculated number needed to treat to prevent one episode of admission hypothermia was 1.37, indicating high effectiveness of the intervention.

Process compliance with individual components of the thermoregulation bundle improved progressively throughout the study period. The use of polyethylene occlusive wraps increased from 0% at baseline to 95% post-implementation, while application of woolen caps improved from 10% to 98%. Maintenance of delivery room temperature within the target range increased from 15% to 92% following implementation. Root cause analysis informing these interventions is summarized in the fishbone diagram (Figure 1).

Trend analysis demonstrated sustained improvement in neonatal thermal outcomes over time. Weekly monitoring revealed consistent increases in delivery room temperature, infant temperature at transfer, and NICU admission temperature across the study timeline, with stabilization achieved during the post-implementation phase. These trends are illustrated in Figure 2, highlighting the durability of the intervention effects beyond the initial implementation period.



Figure 2: Temperature Trends Across Study Timeline

Correlation analysis showed a significant positive association between gestational age and NICU admission temperature ($r = 0.67$, $p < 0.001$), as well as between birth weight and thermal stability ($r = 0.58$, $p < 0.01$), confirming that smaller and more premature infants were at greater risk of hypothermia despite intervention.

DISCUSSION

This quality improvement initiative demonstrates that the systematic implementation of a comprehensive, evidence-based thermoregulation bundle, guided by Plan-Do-Study-Act (PDSA) methodology, can profoundly reduce the incidence of hypothermia in preterm neonates. The observed 83% reduction in hypothermia prevalence and the clinically significant improvement of 1.22°C in mean admission temperature represent outcomes that not only exceed established benchmarks for neonatal thermal care but also align with the core targets of quality improvement in perinatal medicine.⁸ These results underscore the profound impact achievable through standardized, multidisciplinary protocols targeting a known, modifiable risk factor in this vulnerable population.

The pathophysiology of heat loss in preterm infants, occurring through radiation, conduction, convection, and evaporation, is particularly severe due to their decreased brown adipose tissue, high skin surface area to body weight ratio, and immature thermoregulatory mechanisms.⁸ The success of the intervention bundle stems from its multifaceted design, which directly and concurrently addresses each of these pathways. The use of polyethylene occlusive wraps immediately at birth effectively curtailed massive evaporative losses from the thin, permeable skin of the preterm infant. Simultaneously, the systematic increase in delivery room ambient temperature directly minimized radiative and convective losses. Furthermore, the protocol ensuring all resuscitation surfaces and linens were pre-warmed mitigated conductive heat transfer to cooler objects. This synergistic approach ensured a thermally protected environment from the moment of birth.

A cornerstone achievement of this project was the significant system-level change in the delivery room thermal environment, with ambient temperature increasing from a baseline mean of 19°C to a sustained 24°C . This transformation required coordinated, multidisciplinary effort and commitment, highlighting that environmental control is a fundamental, yet often overlooked, component of neonatal resuscitation. Previous research has consistently identified delivery room temperatures below 25°C as an independent risk factor for neonatal hypothermia.⁹ Therefore, achieving and maintaining temperatures within the recommended $25\text{--}26^{\circ}\text{C}$ range, as demonstrated here, proves the feasibility of implementing this critical evidence-based modification in routine clinical practice and establishes a stable foundation for all other thermoregulatory interventions.

The findings of this quality improvement study are strongly corroborated by evidence from randomized controlled trials (RCTs) on individual bundle components. For instance, Vohra *et al.* reported significantly higher admission temperatures in very low birth weight infants wrapped in polyethylene occlusive material compared to standard care.⁶ Similarly, Leadford *et al.* demonstrated that the use of plastic bags increased the probability of normothermia in preterm infants in resource-limited settings.⁷ This study extends the validity of those RCT findings by demonstrating that these individual interventions, when integrated into a standardized bundle and implemented through iterative quality improvement cycles, are equally effective in the complex, real-world environment of clinical practice. The bundle approach ensures that no single element of thermal care is neglected, creating a reliable and reproducible system.

Central to the sustainability of this improvement was the comprehensive educational component, which fostered staff engagement and protocol adherence. Successful implementation required a paradigm shift in the team's approach to thermal care from the moment of delivery. The structured education program, comprising initial in-depth training followed by regular reinforcement, feedback, and data sharing, was crucial for ensuring consistent application across all shifts and staff disciplines. As emphasized in prior quality improvement literature, multidisciplinary buy-in and continuous education are pivotal determinants of success in neonatal care initiatives.¹⁰ This project reaffirms that principle, showing that knowledge translation and team



engagement are as vital as the clinical interventions themselves.

When viewed against international benchmarks, the initial baseline hypothermia rate of 88% highlighted a critical gap in care within our setting, substantially exceeding the 53.4% prevalence reported in European neonatal intensive care networks.¹¹ This disparity underscored the urgent need for targeted quality improvement. The post-intervention rate of 15%, however, compares favorably with established international standards, demonstrating that systematic, evidence-based interventions can rapidly bridge quality gaps and achieve outcomes commensurate with global best practices. This dramatic improvement also confirms the particular vulnerability of our patient population, which exhibited a clear inverse correlation between gestational age, birth weight, and thermal stability. This relationship reinforces the necessity for risk-stratified thermal care protocols, with heightened vigilance and possibly augmented interventions for the most extremely preterm infants.

The iterative nature of the PDSA methodology was instrumental in refining the intervention. This framework allowed for real-time feedback, identification of unforeseen barriers (e.g., logistical challenges in maintaining delivery room temperature, variations in wrap application), and the development of practical, sustainable solutions. By systematically tracking both process measures (e.g., compliance with bundle steps, delivery room temperature logs) and outcome measures (admission temperature), the team could understand not just *if* the intervention worked, but *how* it worked, facilitating continuous refinement and robust knowledge transfer to other clinical areas.

While the bundle proved highly effective, the literature suggests opportunities for further optimization and personalization. For example, Ibrahim *et al.* demonstrated that adjunctive technologies like self-heating gel mattresses could virtually eliminate admission hypothermia in infants below 28 weeks gestation, pointing to potential enhancements for our most vulnerable subset.¹¹ Furthermore, Çağlar *et al.* compared materials for skin occlusive wrapping, finding vinyl bags superior to polyethylene wraps in maintaining temperature in infants ≤ 32 weeks, suggesting an avenue for evidence-based refinement of a specific bundle component.¹² These studies indicate that thermoregulation bundles are not static but

should evolve with emerging evidence and technological advancements.

The implications of sustaining normothermia extend far beyond a simple temperature metric. Appropriate thermal maintenance is physiologically foundational, associated with improved glucose homeostasis, reduced metabolic stress and oxygen consumption, enhanced immune function, and decreased risk of complications such as respiratory distress and late-onset sepsis.¹² Consequently, this intervention bundle, which requires minimal capital investment, possesses a highly favorable cost-effectiveness profile. By potentially preventing a cascade of costly neonatal morbidities, it represents a particularly impactful strategy for both high-resource and resource-constrained healthcare environments.

The observed correlations between gestational age, birth weight, and admission temperature confirm that the smallest and most premature infants remain at highest risk for hypothermia despite improvements in care processes. This finding is consistent with prior studies demonstrating a dose–response relationship between degree of prematurity and hypothermia-related morbidity and mortality^{3,14}. The systematic documentation of both outcome measures and process indicators provided valuable insights into mechanisms of improvement and facilitated knowledge transfer to other clinical contexts, consistent with SQUIRE 2.0 recommendations¹⁵.

This study has several limitations that must be acknowledged. Its single-center, before-after design, without a concurrent control group, introduces the possibility of temporal confounding or regression to the mean, though the magnitude and sustained nature of the change strongly suggest a true intervention effect. The relatively small sample size may limit the generalizability of findings to centers with different patient demographics, resource levels, or baseline practices. Importantly, while the study measured a crucial process outcome (admission temperature), it did not assess longer-term clinical endpoints such as mortality, major morbidity, length of hospital stay, or neurodevelopmental outcomes, which are the ultimate goals of improved thermal care.

Future research and quality improvement efforts should build upon these findings. Priorities include longitudinal sustainability assessment and long-term outcome monitoring to definitively link improved thermoregulation with enhanced neurodevelopmental and health outcomes.



Formal cost-effectiveness analyses comparing the minimal cost of the bundle with the expenses associated with hypothermia-related complications would strengthen the case for widespread adoption. Multi-center implementation studies are needed to validate the bundle's effectiveness across diverse healthcare settings and cultures. Additionally, investigating staff satisfaction, workflow integration, and the potential of emerging technologies will be key to optimizing implementation strategies and ensuring that the standard of normothermia on admission becomes a universal reality for all preterm newborns.

CONCLUSION

The implementation of a comprehensive thermoregulation bundle using Plan-Do-Study-Act quality improvement methodology resulted in a substantial and sustained reduction in admission hypothermia among preterm infants in our NICU. The 83% decrease in hypothermia prevalence and significant improvement in admission temperatures demonstrate the effectiveness of systematic, evidence-based interventions in improving neonatal thermal care. This study reinforces the importance of multidisciplinary collaboration, staff education, and structured implementation strategies in translating guidelines into practice. Routine adoption of thermoregulation bundles has the potential to reduce hypothermia-associated morbidity and improve outcomes for vulnerable preterm neonates.

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Conflict of Interest
The authors declare no conflict of interest.

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Author's Contribution

AMA- Study concept and design, data collection, manuscript preparation; VKS- Study supervision, methodology development, manuscript revision; GS- Study oversight, critical review; SK- Clinical protocol development, data analysis; B, V, M- Data collection, patient care implementation, manuscript review

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