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Improvement in thermoregulation outcomes following the implementation of a thermoregulation bundle for preterm infants

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Aim: Hypothermia is associated with increased morbidity and mortality in preterm infants. A local audit revealed 60% preterm infants ≤32 weeks gestation and/or very low birth weight (VLBW) infants (<1500 g) had an abnormal body temperature at admission. This study compares thermoregulatory outcomes before and after the implementation of a thermoregulation bundle in the birthing environment.

Methods: This retrospective cohort study reviewed thermoregulatory data for all inborn preterm (<32 weeks) and/or VLBW infants for a period of 30 months before (Group 1: 1st January 2013 to 30 June 2015) and after changes to thermoregulation practice (Group 2: 1st July 2015 to 31 December 2017). The key practice changes included: improved anticipation and staff preparedness, wrapping infant in a polyethylene sheet, using a polyethylene lined bonnet, using servo-control mode at birth and during transport.

Results: There were 282 and 286 infants in group 1 and group 2 respectively, with similar baseline characteristics. A clinically and statistically significant improvement was observed in the proportion of infants with normothermia (33% in group 1 to 60% in group 2, P < 0.0001) including the sub-group of extremely preterm (<28 weeks gestation) infants (38 to 60%, P = 0.0083). A higher mean admission temperature was observed for group 2 (36.10° C \pm 0.78 in group 1 vs 36.52° C \pm 0.61 in group 2, P < 0.0001). Moderate hypothermia was reduced by two-thirds in group 2 (41–12%, P = <0.0001).

Conclusions: The introduction of a thermoregulation bundle improved admission temperature, improved the proportion of normothermia and reduced moderate hypothermia in preterm infants.

Key words: hypothermia; preterm infant; quality improvement.

What is already known on this topic

- 1 Hypothermia in preterm infants is a major contributor to infant morbidity and mortality.
- 2 For preterm infants \leq 32 weeks gestation there is a 'U-shaped' relationship between admission temperature and composite adverse outcomes.

World-wide, hypothermia is a major contributor to infant morbidity and mortality.¹⁻⁸ Newborn infants, especially those who are born preterm (<37 weeks gestation) and/or who have low birthweight (<2500 g) are at a greater risk of hypothermia because of their large surface area to body mass ratio, immature skin structure and lack of brown adipose tissue.9 The World Health Organization defines normothermia as a body temperature measurement between 36.5°C and 37.5°C, and grades hypothermia as mild (36-36.4°C), moderate (32–35.9°C) and severe ($<32^{\circ}C$).¹⁰ In infants weighing less than 1500 g at birth, for each degree Celsius

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What this paper adds

- 1 Better staff preparedness and consistency in thermoregulation practices improved thermoregulatory and some clinical outcomes.
- 2 Thermoregulatory bundle reduced moderate hypothermia in preterm infants.
- 3 Better thermoregulatory outcomes could possibly improve cardiovascular stability in preterm infants.

decrease in admission temperature below the normal range (36.5-37.5°C), there is an associated increase in mortality by 28% and an increase in late-onset sepsis by 11%.¹¹ Recently, a large study from Canada on preterm infants <33 weeks gestation identified a 'U-shaped' relationship between admission temperature and composite adverse outcomes, including severe neurological injury, severe retinopathy of prematurity (ROP), bronchopulmonary dysplasia, necrotising enterocolitis (NEC), nosocomial infection and increased duration of mechanical ventilation.⁶ Implementing interventions in the delivery room such as polyethylene occlusive wraps,^{12,13} increasing ambient temperature^{14,15} and exothermic mattresses,¹⁶ have previously been shown to reduce the incidence of hypothermia in preterm infants.¹⁷

Our neonatal intensive care unit (NICU) is a tertiary perinatal centre. In 2014, an audit of infants born ≤32 weeks gestation and/or <1500 g found that only 40% of preterm infants were normothermic at admission to NICU. An extensive

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multidisciplinary review identified the following reasons for the above problem:

- A lack of a local thermoregulation guideline for preterm infants.
- A lack of staff awareness/education on the importance of normothermia in preterm infants.



Fig. 1 Infant wrapped in a polyethylene sheet and bonnet.



Fig. 2 Radiant heat source and bed. The radiant warmer has power supply during transport.

	Whole	group	GA <27 ⁻	-6 weeks	GA 28 ⁺⁰ to	31 ⁺⁶ weeks
Baseline characteristics	Group 1 ($n = 282$)	Group 2 ($n = 286$)	Group 1 ($n = 71$)	Group 2 ($n = 77$)	Group 1 ($n = 211$)	Group 2 ($n = 209$)
Maternal						
Caesarean section, n (%)	183 (65)	195 (68)	35 (49)	44 (57)	148 (70)	151 (72)
Antenatal steroid,† any, n (%)	262 (93)	270 (94)	64 (90)	74 (96)	198 (94)	196 (94)
PROM >18 h, <i>n</i> (%)	70 (25)	66 (23)	23 (32)	22 (29)	47 (22)	44 (21)
Multiple gestation, n (%)	76 (27)	80 (28)	17 (24)	18 (23)	59 (28)	62 (30)
Chorioamnionitis,‡ n (%)	81 (29)	90 (31)	38 (54)	40 (52)	43 (20)	50 (24)
Infant						
GA, weeks, median (IQR)	29 (27–31)	29 (27–31)	26 (25–27)	25 (25–27)	30 (28–31)	30 (28–31)
Birthweight, g, mean \pm SD	1242 ± 367	1251 ± 354	836 ± 185	896 ± 199	1379 ± 365	1382 ± 297
Male gender, n (%)	143 (51)	141 (49)	35 (49)	39 (51)	108 (51)	102 (50)
Apgar score <6 at 5 min, n (%)	19 (7)	22 (8)	8 (11)	9 (12)	11 (5)	13 (6)
† Antenatal steroids included <24 h p rupture of membranes; SD, standard c	orior to delivery. ‡ Histopath deviation.	ologically proven. Percentag	e rounded to the nearest w	hole number. GA, gestation	ial age; IQR, interquartile rar	ige; PROM, premature

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• A lack of consistency amongst medical and nursing staff on thermoregulation practice.

This led to the implementation of changes to thermoregulation practices for preterm infants at birth. The aim of this study was to compare thermoregulatory outcomes before and after the implementation of a thermoregulation bundle for preterm infants \leq 32 weeks gestation and/or very low birthweight infants (<1500 g) on admission to NICU.

Methods

The study participants for this retrospective cohort study included inborn preterm infants ≤32 weeks gestation and/or with birthweight <1500 g born between 1 January 2013 and 31 December 2017 and admitted to NICU. Infants who were outborn, infants with major congenital malformations or admitted for palliation, and infants requiring ex-utero transfer to a surgical NICU immediately after birth, and infants where the NICU team was not present at birth were excluded. Study periods were group 1 (before changes to thermoregulation practices) from 1 January 2013 to 30 June 2015 and group 2 (after changes to thermoregulation practices) from 1 July 2015 to 31 December 2017. Eligible infants were identified from the NICUs database. The NICUs database is a prospective data collection system of preterm infants (≤32 weeks and/or very low birthweight infants) admitted to all tertiary NICUs in New South Wales and the Australian Capital Territory that collates maternal, perinatal and neonatal clinical data. This data was collected and verified by designated audit officers by following standardised definitions for clinical outcomes.

A literature review of studies pertaining to quality initiatives in the delivery room and 'golden hour' (first hour of life) management for preterm infants was undertaken. Fundamental principles of the clinical practice improvement methodology framework as outlined by the Clinical Excellence Commission (https://www.cec. health.nsw.gov.au) were used to review, identify and understand causes for failure in local thermoregulation practices as well as to design better processes to improve admission temperatures in this population.

A thermoregulation guideline incorporating current evidencebased practices for thermoregulation in preterm infants at birth was written. As per local hospital policy, prior to approval, this guideline was reviewed by a multi-disciplinary local team. Changes to clinical practice for thermoregulation occurred on 1 July 2015.

Key changes to clinical practice (referred as a thermoregulation bundle) as per the thermoregulation guideline included:

- Improved anticipation and staff preparedness prior to delivery.
- Wrapping the infant in a polyethylene sheet (reduces evaporative and convection heat loss) and ensuring the infant was wrapped during transport and throughout the entire admission process in the NICU to maintain the thermal environment (Fig. 1).
- Use of a polyethylene-lined bonnet to cover the head and reduce evaporative heat loss (Fig. 1).
- Use of a servo-controlled mode for the radiant-heat warmer (reduces conductive and radiation heat loss) during transfer of the infant from birthing place to the NICU (Fig. 2). Our NICU is not adjacent to the birthing unit and to the operating theatres.
- Ensuring the infant had an axillary temperature of 36.8– 37.3°C prior to transfer.
- Uniformity in recording admission temperatures (from axilla) by using a digital thermometer at admission to the NICU.

While there were no changes to the actual process of recording axillary temperature using a digital thermometer, the use of servocontrol mode during transport and normothermia prior to transfer to NICU were the changes in practice. The primary outcomes that were compared included the mean admission temperature and the



Fig. 3 Proportion of infants with hypothermia, normothermia and hyperthermia between the two groups. *Significant difference in the admission temperature between the two groups. (a), Group 1; (a), group 2.

Australasian College of Physicians).

Primary clinical outcomes	Group 1 (<i>n</i> = 282)	Group 2 (<i>n</i> = 286)	P value	95% CI
Admission temperature, °C, mean \pm SD	$\textbf{36.10} \pm \textbf{0.78}$	36.52 ± 0.61	<0.001***	-0.53, -0.30
Proportion of normothermic infants (36.5–37.5°C), n (%)	92 (33)	174 (61)	<0.001***	-0.36, -0.20

*** *P* < 0.001. No cases of severe hypothermia were reported. Percentage rounded to the nearest whole number. CI, confidence interval; SD, standard deviation.



Fig. 4 Admission temperature timeline for the two groups. *Significant difference in the admission temperature between the two groups. (------), Group 1; (------), group 2; (-------), trend.

proportion of normothermia (body temperatures between 36.5° C and 37.5° C) of infants in each group. The secondary outcomes included the severity of hypothermia (mild, moderate and severe), the incidence of hyperthermia (> 37.5° C), the time to admission from birth, the cardio-respiratory status in the first 72 h, the need for umbilical venous catheters, the proportion of infants receiving enteral feeding in the first 72 h, the incidence of serious adverse outcomes such as any intraventricular haemorrhage (IVH, based on Papille's classification), ¹⁸ the clinical risk index for babies (CRIB II) scores, and the presence of ROP, NEC, chronic lung disease or late-onset sepsis.

Data analysis was performed using statistical analysis software (Stata, version SE14, StataCorp, College Station, TX, USA). Descriptive statistics are used to summarise the study cohort. Continuous variables, when symmetrically distributed, are described as mean with standard deviation, and when asymmetrically distributed are described as median with interquartile range. The primary outcome and secondary outcomes were compared between the two time periods using χ^2 tests or proportion tests if indicated. Parametric analysis was performed using a two-sided *t*-test to calculate

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statistical significance. All *P* values reported are two-sided, statistical significance is considered when *P* is <0.05. Differences are described with appropriate confidence intervals where possible. The study was approved by the local Human Research Ethics Committee.

Results

Between 1 January 2013 and 31 December 2017, a total of 634 preterm infants were identified; of these, 568 infants met the inclusion criteria (group 1: 282 infants, group 2: 286 infants). We excluded 66 infants: 55 due to the presence of congenital anomalies or the need for transfer to the surgical NICU immediately after birth, and 11 infants due to the absence of the NICU team at birth. There were no significant differences in the baseline characteristics of the infants in the two groups. This remained true when results were stratified by gestational age (<28 weeks and \geq 28 weeks at birth) as shown in Table 1.

Primary outcomes

Figure 3 and Table 2 show the improvement in the proportion of infants admitted with normothermia in group 2. Additionally, there is a significant improvement in the mean admission temperature from 36.10° C in group 1 to 36.52° C in group 2 (P = 0.0001, Table 2). A timeline trend for improvement in admission temperature between the two groups is shown in Figure 4. The mean admission temperature and proportion of normothermic infants were higher for infants born between 28 and 31^{+6} weeks in comparison to infants born before 28 weeks, the mean admission temperatures between the two groups were not

significant (P = 0.061) but the proportion of normothermic infants in group 2 was significantly higher than in group 1 (P = 0.008, Table 3).

Secondary outcomes

There was no difference in the proportion of infants with hyperthermia (>37.5°C), seven (2%) infants in both groups had hyperthermia. Reassuringly, hyperthermia in group 2 was of mild degree (37.6–38°C). A substantial reduction in the proportion of infants with moderate hypothermia was observed (Fig. 3 and Table 4). In terms of other secondary outcome measures, a

Table 3 Sub analysis of primary outcomes for extremely preterm and very preterm infants

		GA <27 ⁺⁶ weeks				GA between 28 ⁺⁰ and 31 ⁺⁶ weeks			
Primary clinical outcomes	Group 1 (n = 71)	Group 2 (n = 77)	P value	95% CI	Group 1 (n = 211)	Group 2 (n = 209)	P value	95% CI	
Admission temperature, °C, mean \pm SD	36.19 ± 0.86	36.44 ± 0.74	0.061	-0.51, 0.11	36.07 ± 0.75	36.56 ± 0.56	<0.001***	-0.61, -0.36	
Proportion of normothermic infants, <i>n</i> (%)	27 (38)	46 (60)	0.008**	-0.37, -0.05	65 (31)	128 (61)	<0.001***	-0.39, -0.21	

Table 4 Overall comparison of secondary outcomes between the two groups

Secondary clinical outcomes	Group 1 (<i>n</i> = 282) Group 2 (<i>n</i> = 286)		P value	95% CI	
Age of admission, min, mean \pm SD	21 ± 9	24 ± 11	0.601	-1.21, 2.09	
Mild hypothermia (36–36.4°C), n (%)	66 (23)	70 (24)	0.763	-0.05, 0.08	
Moderate hypothermia (32–35.9°C), n (%)	117 (42)	35 (12)	<0.001***	-0.36, 0.22	
Required and/or received treatment within first 72	h of life, <i>n</i> (%):				
Surfactant therapy	171 (61)	157 (55)	0.166	-0.02, 0.13	
Any blood transfusion	63 (22)	33 (12)	0.001**	0.04, 0.16	
Breast milk	191 (68)	246 (86)	<0.001***	-0.25, -0.11	
Inotropes	40 (14)	17 (6)	0.001**	0.03, 0.13	
Umbilical catheters	115 (41)	85 (30)	0.006**	0.03, 0.18	
NEC (stage ≥2), <i>n</i> (%)	3 (1)	4 (1)	0.718	-0.02, 0.01	
IVH, n (%)					
None	226 (80)	248 (87)	0.035*	-0.12, -0.00	
Severe, grade III–IV, n (%)	8 (3)	5 (2)	0.743	-0.01, 0.02	
ROP, n (%)					
None	213 (76)	237 (83)	0.031*	-0.13, -0.00	
Severe ≥stage 2, n (%)	59 (21)	30 (10)	0.014*	0.008, 0.07	
Chronic lung disease, n (%)	48 (17)	57 (20)	0.372	-0.09, 0.03	
Late-onset sepsis, n (%)	21 (7)	24 (8)	0.677	-0.05, 0.03	
Mortality (first 72 h)	3 (1)	4 (1)	0.718	-0.02, 0.01	
Mortality, n (%)	6 (2)	9 (3)	0.449	-0.03, 0.01	

* P < 0.05; **P < 0.01; ***P < 0.001. Percentage rounded to the nearest whole number. CI, confidence interval; IVH, intraventricular haemorrhage; NEC, necrotising enterocolitis; ROP, retinopathy of prematurity; SD, standard deviation.

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	GA <27 ⁺⁶ weeks				GA between 28^{+0} and 31^{+6} weeks			
Secondary clinical outcomes	Group 1 (n = 71)	Group 2 (n = 77)	P value	95% CI	Group 1 (n = 211)	Group 2 (n = 209)	P value	95% CI
Age of admission, min, mean \pm SD	24 ± 12	26 ± 9	0.108	-6.10, 0.60	21 ± 8	23 ± 11	0.011*	-4.29, -0.54
Mild hypothermia (36–36.4°C), <i>n</i> (%)	17 (24)	19 (25)	0.974	-0.14, 0.13	49 (23)	51 (24)	0.777	-0.09, 0.06
Moderate hypothermia (32–35.9°C), n (%)	25 (35)	11 (14)	0.003**	0.07, 0.34	92 (44)	24 (11)	<0.001***	0.24, 0.40
Required and/or received treatr	nent within first	72 h of life, n (%	%)					
Surfactant therapy	70 (99)	70 (91)	0.039*	0.007, 0.14	101 (48)	87 (42)	0.198	-0.03, 0.15
Any blood transfusion	46 (65)	26 (34)	<0.001***	0.15, 0.46	17 (8)	7 (3)	0.038*	0.002, 0.09
Breast milk	31 (44)	61 (79)	<0.001***	-0.50, -0.20	160 (76)	185 (89)	0.001**	-0.19, -0.0
Inotropes	22 (30)	13 (17)	0.044*	0.004, 0.27	18 (9)	4 (2)	0.002**	0.02, 0.10
Umbilical catheters	67 (94)	58 (75)	0.001*	0.08, 0.30	48 (23)	27 (13)	0.009**	0.02, 0.17
NEC, advanced, n (%)	2 (3)	3 (4)	0.717	-0.06, 0.04	1 (1)	1 (1)	0.995	-0.01, 0.01
Severe IVH, grade III–IV, n (%)	7 (10)	5 (7)	0.454	-0.05, 0.12	1 (1)	O (O)	0.319	0.00, 0.14
Severe ROP ≥stage 2, n (%)	41 (58)	28 (36)	0.009**	0.05, 0.37	18 (9)	2 (1)	<0.001***	0.03, 0.11
Chronic lung disease, n (%)	48 (17)	57 (20)	0.372	-0.16, 0.15	14 (7)	20 (10)	0.270	-0.08, 0.02
Late-onset sepsis, n (%)	11 (16)	17 (22)	0.307	-0.19, 0.05	10 (5)	7 (3)	0.470	-0.02, 0.05
Mortality (first 72 h)	3 (4)	4 (5)	0.781	-0.07, 0.05	O (O)	O (O)	_	_
Mortality, n (%)	6 (8)	8 (10)	0.687	-0.11, 0.07	0 (0)	1 (1)	0.314	-0.01, 0.00

 Table 5
 Sub analysis of secondary outcomes for extremely preterm and very preterm infants

* *P* < 0.05; ***P* < 0.01; ****P* < 0.001. Percentage rounded to the nearest whole number. CI, confidence interval; IVH, intraventricular haemorrhage; NEC, necrotising enterocolitis; ROP, retinopathy of prematurity; SD, standard deviation.

statistically significant reduction in the requirement for umbilical catheterisation, inotropic support and blood transfusions as well as an early commencement of enteral feeding was found for group 2 (Table 4). There were no differences in mean CRIB II scores (group 1: 6.5 and group 2: 6.4). Overall, there was no difference in the need for exogenous surfactant replacement therapy, but for extremely preterm infants, a significant reduction in this need was observed (P = 0.039) (Table 5).

In group 2, two other changes were observed. First, a higher proportion of infants had absence of IVH, and this difference was statistically significant (P = 0.035, Table 4). However, there were no significant improvements in the numbers of infants with severe grades of IVH (Table 4). Second, a reduction in the proportion of infants with stage II and III ROP (P = 0.01) as well as an increase in proportion of infants without ROP (P = 0.031) (Table 4). Overall, there were no significant differences between the two groups in morbidities such as late-onset sepsis, NEC and chronic lung disease, and mortality prior to discharge, after the initial 72 h of hospitalisation.

Following the implementation of the changes, we did not observe any significant differences between the two groups in the time to admission following birth (group 1: 21 min, group 2: 24 min; P = 0.6, Table 4).

Discussion

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This study demonstrates that by identifying and reviewing local problems regarding thermoregulation practices, implementing an evidence-based guideline, and improving staff awareness and education, the proportion of normothermia and the mean admission temperatures in preterm infants could be significantly improved. These findings align with the admission temperature for preterm infants <32 weeks gestation reported by the Australian and New Zealand Neonatal Network,19 and are consistent with the reported literature on prevention of hypothermia,^{13,20} supporting the need for greater thermal support. Preterm infants are prone to hypothermia due to a large body surface area and physiological immaturity of the thermoregulatory mechanisms such as limited stores of brown fat and low levels of thermogenin.²¹ Hypothermia can lead to physiological instability by causing hypoglycaemia, hypoxaemia, acidosis and decreased cardiac output.²¹ Along with an improvement in the proportion of normothermia, it was pleasantly surprising to find an improved cardiovascular stability in the form of a reduced need for inotropic support, reduced umbilical catheter use and a reduced need to administer blood transfusion, as well as an increase in the early commencement of enteral feeding in the first 72 h, reflecting improved overall stability. Possible reasons for an improvement, mainly in moderate hypothermia could reflect either a baseline level of cold stress which is difficult to overcome by our current practice and/or a small sample size of the cohort.

There were no changes to clinical practice that may have accounted for improved cardiovascular stability. With the reduction of moderate hypothermia and the maintenance of normothermia, improved overall stability in the first 72 h of life was demonstrated. Although most secondary outcomes did not reach

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statistical significance after adjusting for confounders, the changes in secondary outcomes based on proportion testing were significant. This may reflect the small number of events observed as secondary outcomes.

A review of the literature shows that strategies such as increasing ambient environmental temperature and the use of an exothermic mattress and plastic wrap^{22–25} are effective interventions for reducing hypothermia in preterm infants. In this study, a thermoregulation bundle implemented similar strategies to those reported in the literature; however, it also incorporated better preparation at birth including the presence of a senior medical team (senior registrar, nurse practitioner, neonatal fellow or consultant), standardising practices by using local guideline, wrapping the infant's body and head with polyethylene sheet, adequately stabilising the temperature by not transferring infants from the place of birth to the NICU until they achieved a target temperature range of 36.8-37.3°C and providing radiant heat using a servo control mode during transport. It is also important to note that allowing stabilisation of body temperature before departing the birthing place did not significantly prolong the time to admission and provision of essential care. A rise in the proportion of infants with hyperthermia was not observed; hence, these changes did not lead to harm.

Hypothermia is significantly associated with mortality and morbidities, including NEC and ROP, requiring therapy in preterm infants.^{6,7,23} Tay et al. reported an increased association of advanced NEC with hypothermia.7 We were unable to demonstrate differences in NEC in the two groups due to the low baseline incidence of NEC and the relatively small sample size. A significantly higher incidence of severe ROP requiring laser therapy with lower admission temperatures is described in the literature.²³ Similar results were observed in the current audit; however, we cannot attribute the improvement in ROP to hypothermia prevention only. Other changes in unit practices, such as a modification of oxygen saturation (SpO₂) targets, happened around the same time, which potentially played a role in ROP reduction. Similarly, we can only speculate whether the reduction in IVH seen in group 2 was related to better thermoregulation, as the study was not powered for this outcome. Contrary to the literature, an association between hypothermia and late-onset sepsis¹¹ was not found, which could be due to the small sample size and the possibility that hypothermia may not carry the risk of late-onset sepsis.

It has been noted in the literature that decreased delivery room temperatures can induce thermal stress in premature infants,³ and it is recommended that delivery rooms be kept at 25°C or higher.¹⁰ Studies have shown that increasing ambient temperature,^{14,17,26} and the use of humidified heated gases^{27–29} during the stabilisation of preterm infants at birth improves admission temperatures and decreases cold stress. As we were unable to alter the ambient birthing environment temperature and provide humidified heated gases at resuscitation, future directions include these quality improvement initiatives. The effect of delayed cord clamping on admission temperature could also be studied.

The key strengths of this study were data retrieval from the NICUs database, and the standardisation of thermoregulation practice by the generation of an evidence-based guideline and implementation strategies. This enabled the association between hypothermia and neonatal outcomes to be evaluated.

The current study is a single-centre study and therefore the results may not be generalisable to other centres that have different thermoregulation practices. The data should also be interpreted with caution due to the small sample size. There is an inherent bias from a retrospective study design, which was minimised by incorporating data that used standardised definitions for clinical outcomes and were validated by data audit officers. Other clinical improvement activities in the department may also have contributed to changes in short term clinical outcomes in the first 72 h of life. Finally, recording axillary temperature is an acceptable practice albeit it is a sub-optimal surrogate measure of core body temperature.

Future directions include the alteration of birthing environment temperatures and the introduction of humidified heated gases during the stabilisation of preterm infants at birth.

Conclusions

The implementation of a thermoregulation bundle demonstrated a clinical improvement in the proportion of infants with normothermia, specifically a decrease in moderate hypothermia as well as an improved mean admission temperature in preterm infants. Heat-preservation measures at the birthing environment should be an integral part of neonatal care.

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