

Implementation of a temperature bundle improves admission hypothermia in very-low-birth-weight infants in China: a multicentre study

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ABSTRACT

Background Hypothermia is a common problem that is associated with increased mortality and morbidity among preterm infants, especially in China. The objective of this study was to evaluate the efficacy of a targeted quality improvement (QI) project that applied hypothermia prevention measures for very-low-birth-weight (VLBW) infants in three tertiary neonatal intensive care units (NICUs) in China.

Problem Between January 2018 and December 2018, we conducted a prospective analysis and found that the incidence of AH was 88.2% among VLBW infants.

Methods The study enrolled preterm infants born at less than 32 weeks' gestation with a VLBW of less than 1500 g who were delivered at three academic tertiary-care hospitals between January 2018 and December 2019. The primary outcome measure was the incidence of hypothermia. The outcomes of the pre-QI group (1 January–31 December 2018) were compared with those of the post-QI group (1 January–31 December 2019).

Interventions Based on the literature, our preliminary findings and the needs of each unit, a temperature bundle that included a transport incubator, prewarmed hats, polyethylene wrap, team training and education, and temperature documentation and workflows were implemented in consecutive plan–do–study–act cycles.

Results Of the 530 VLBW infants, 235 infants (36.9%) belonged to the pre-QI group, and 295 infants (46.4%) belonged to the post-QI group. The incidence of hypothermia decreased significantly, from 92.3% to 62% ($p < 0.001$), and the mean body temperature on admission to the NICU increased significantly, from 35.5°C to 36°C ± 0.7°C ($p < 0.001$). There was one case of hyperthermia during the study period. Infants in the post-QI group had a lower mortality rate (16.1% vs 8.8%, $p = 0.01$).

Conclusions Targeted interventions can dramatically reduce admission hypothermia and improve the outcome of VLBW infants in China.

Trial registration number Chi CTR 1900020861.

INTRODUCTION

Problem description

On 1 January 2018, our neonatal clinical research team established the China regional neonatal collaboration network known as the

Shandong Neonatal Network (SNN). The SNN covers more than 100 million people and prospectively collects neonatal data from participating units. During this time, we found that the incidence of neonatal admission hypothermia (AH) was quite high. Therefore, a retrospective analysis of VLBW infants born between 1 January and 31 December 2017 was conducted to determine key drivers of change. In 2017, the incidence of AH was 87.9% among VLBW infants in the 28 neonatal intensive care units (NICUs).¹ Some projects were carried out in less than 50% of units; interventions included prewarmed hats, places in polyethylene bags (no drying), use of transport incubators and so on. The results showed that there was a negative correlation between the AH rate and the number of quality improvement (QI) measures implemented to prevent hypothermia. Between January 2018 and December 2018, we conducted a prospective analysis and found that the incidence of AH was 88.2% among VLBW infants and that AH was closely related to mortality, especially in cases of moderate-to-severe hypothermia.^{2,3}

Preterm infants, especially very-low-birth-weight (VLBW) infants, have difficulty maintaining their body temperature after birth due to immature physiological development.^{4,5} The incidence of hypothermia on admission to the NICU among VLBW preterm infants is 31%–78%.^{6,7} With improvements in the economy and intensive care technology, the survival rate of preterm infants is increasing in China, but there is still a large gap compared with high-income countries. Yun *et al*⁸ conducted a study that included a total of 2956 VLBW infants (gestational age <34 weeks) and reported an estimated overall mortality of 23.9%. Data collected from 25 level III NICUs in 19 provincial-level administrative regions in China showed that

compared with Canada, China had higher case fatality rates for each birth weight stratification among VLBW infants.⁹

Available knowledge

International thermoregulation guidelines involve multiple modalities divided into four phases: Predelivery preparation, resuscitation, transfer and NICU admission.^{10–14} However, the proportion of AH remains high in clinical practice. After the initiation of a QI project, the incidence of AH significantly declines, and an increasing number of evidence-based QI measures have shown success. Caldas *et al*¹⁵ reported that after the initiation of a QI programme, the incidence of AH in VLBW infants decreased from 37.2% to 14.2%. Choi *et al*¹⁶ showed that after QI measures were initiated, the incidence of AH was reduced to 41%. Andrews *et al*¹⁷ reported that in a QI study of hypothermia in a mother–infant unit, the incidence of hypothermia decreased by 16.5% (before the QI, it was 29.8%). A 3-year QI study showed that the incidence of AH in VLBW infants decreased from 32.4% before the introduction of QI measures to 9.6% after.¹⁸ However, there are few studies on the current situation of hypothermia in preterm infants in China,¹⁹ and multi-centre and large sample studies in particular are lacking.

Rationale

Given these findings and international experience, we hypothesised that the implementation of a targeted QI bundle could reduce the incidence of AH and improve the outcomes of VLBW infants. On 1 January 2019, we established the Shandong Multicentre Study Coordination for Admission Hypothermia in China and initiated a QI project to prevent hypothermia in VLBW infants admitted to all participating NICUs.

Specific aims

The aims of this study were to evaluate the change of the incidence of AH of VLBW infants born at three homogeneous academic, tertiary-care hospitals and to analyse their mortality and morbidity before and after QI. Our target was to maintain the admission temperature between 36.5°C and 37.5°C to the maximum extent possible. The specific, measurable, attainable, relevant and time-bound goal of the QI project was to decrease the incidence of hypothermia by 10% (from a baseline of approximately 90%–80%) over a period of 12 months.

METHODS

Context

This prospective, multicentre, time-series cohort study was carried out from 1 January 2018 to 31 December 2019 in three NICUs. The three recruited NICUs belong to academic tertiary-care hospitals, namely, Eyaost Branch of Provincial Hospital Affiliated to Shandong University, The First Affiliated Hospital of Shandong First Medical University and Liaocheng People's Hospital Affiliated to Shandong First Medical University; these hospitals have

an average of 59 beds in the Neonatology Department and 40 beds in the NICU. All deliveries of VLBW infants are attended by a dedicated resuscitation team that includes a resuscitation nurse, a nurse practitioner, an obstetric physician and a neonatal attending doctor. The roles of the team members are well defined, and their skills and knowledge are validated by regular assessments through simulations and reports. Measures taken to keep infants warm include raising the ambient temperature, preheating the radiant warmers, drying infants immediately after birth and wrapping them in warm blankets, transferring them to a warm bed and placing them in a warm bed for transfer to the NICU.

The study population included all infants born at the hospitals with a birth weight of less than 1500 g and a gestational age less than 32 weeks who were admitted to the NICUs. Infants who were born outside the participating hospitals and had congenital anomalies, or died in the delivery room and those whose mothers had a fever during delivery (temperature $\geq 38^\circ\text{C}$) were excluded. These three hospitals are teaching hospitals located in Shandong, China; each hospital has an adjacent level III regional NICU with an average of 40 beds. The NICUs of the three hospitals receive an average of approximately 1623 newborns per year, of which approximately 500 are VLBW infants (30.7%). The average ratios of nurses to beds and physicians to nurses are 1:2.2 and 1:1.9, respectively.

Interventions

The SNN was formed in January 2018 to collect neonatal data. Data on admission body temperature were prospectively collected. According to a data analysis performed in 2018, the incidence of hypothermia in our participating units was generally high, with an average of 88.2%.³ Our team identified the opportunity to decrease AH. A retrospective analysis of infants born between January 2017 and December 2017 was conducted to determine key drivers of change. Pareto charts were used to identify and prioritise the factors contributing to AH (figure 1). Based on these findings, keeping the infants warm and improving team training and education were identified as key drivers of change. To meet these two objectives, temperature bundle management was designed with 11 key elements. The specific elements are as follows: (1) keep warm: ambient temperature of 25°C²⁰; (2) switch on radiant warmers and set them to maximum heat output; (3) infant is wrapped in a polyethylene wrap immediately after birth, without drying; (4) infant is quickly weighed after being placed in a prewarmed blanket; (5) a prewarmed hat is placed on the infant's head; (6) thermal mattresses are used; (7) infant is transported in a heated transport incubator; improve team training and education: (8) document temperature (10 min after birth, on arrival at the NICU, every 30 min thereafter); (9) standardise the temperature measurement; (10) provide training on and assessments of temperature measurement for nurses; and (11) monthly chart reporting on

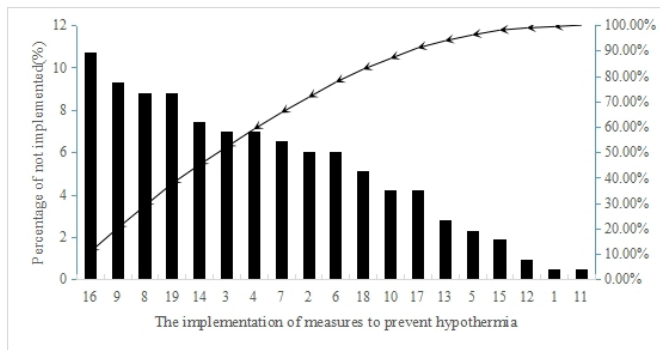


Figure 1 Pareto charts were used to identify and prioritise the factors contributing to admission hypothermia. (1) Ambient temperature of 25°C and the resuscitation bed on manual control with maximum heat output; (2) prewarmed hat and blanket prepared; (3) polyethylene wrap prepared; (4) infant immediately wrapped in a polyethylene wrap without being dried; (5) infant wrapped in a prewarmed blanket wrap after the umbilical cord is cut; (6) infant quickly weighed after being placed in a prewarmed blanket; (7) placement of a prewarmed hat on the infant's head; (8) body temperature measured and recorded 10 min after birth; (9) infant transported in a heated transport incubator; (10) all surfaces that the infant will contact are prewarmed; (11) infant immediately placed in the admission bed (eg, a Giraffe OmniBed); (12) infant's body temperature measured within 1 hour after birth; (13) infant receives hypothermic rewarming; (14) the time at which the temperature reaches $\geq 36.5^\circ\text{C}$ is recorded; (15) both nursing and medical operations are implemented; (16) monthly chart reporting on hypothermia in preterm infants on admission to the NICU; (17) standardised temperature measurement; (18) training on temperature measurement for nurses and assessments; (19) implementation of quality improvement projects to reduce hypothermia in preterm infants on admission to the NICU. Based on these findings, keeping the infants warm and improving team training and education were identified as key drivers of change. To meet these two objectives, temperature bundle management was designed with 11 key elements. NICU, neonatal intensive care unit.

hypothermia in preterm infants on admission to the NICU. Our primary goal was to prevent AH in VLBW infants by preventing excessive heat loss in the delivery room and during the transportation process. To achieve this goal, we standardised delivery room management and NICU admission processes for all VLBW infants. Briefly, the components of the bundle were the use of radiant warmers, plastic wrap, thermal mattresses, transport incubators, an increased room temperature, and prewarmed hats and blankets. The bundle also emphasised accurate documentation of temperature at designated time points. The bundles were implemented using the plan–do–study–act (PDSA) framework.

We set up the Shandong Multicentre Study Coordination for Admission Hypothermia. For convenience of communication, the team members exchanged contact information, such as telephone numbers, QQ numbers, email addresses, and WeChat IDs, and set up a WeChat group. The team was responsible for reviewing

recommendations and initiating a preventive hypothermia programme. The team was composed of the department director, medical team leader, neonatologist, unit clinical nurse specialist and charge nurse at each centre. The department director was responsible for the research design, the discussion and development of the diagnostic criteria and the quality control plan. The medical team leader and the neonatologist were responsible for implementing the test plan, collecting data, recording temperatures and verifying the implementation of various measures. The charge nurse was responsible for temperature measurements at all time points and for quality control during the temperature measurement process. We had weekly department staff meetings and monthly online meetings. The medical team leader prepared power point presentations to report to the team on the causes of hypothermia.

Study of the interventions

Infants born between January 2018 and December 2018 constituted the pre-QI group, and infants born between January 2019 and December 2019 were classified as the post-QI group. All data were obtained from the SNN database. We developed a standard worksheet to document temperature. The worksheet mainly contained information on the time point of the temperature measurement (10 min after birth, on arrival at the NICU or every 30 min until the temperature reached 36.5°C), the value and the measurement time. All measures for preventing hypothermia were available at the centres and did not require additional resources.

The first PDSA bundle occurred in January 2019. The implementation contents are as follows: (1) maintenance of an ambient temperature of 25°C, (2) use of the heating mode of the air conditioner with the temperature set to above 25°C, (3) placement of prewarmed hats (stockinette or woollen) on the infant's head and (4) rapid determination of the infant's weight after placement in a prewarmed blanket. The incidence of AH decreased from 92.3% kept in each NICU/baseline to 70%. The ambient temperature at birth did not reach 25°C, and the temperatures of the hats and blankets were too low in the study period. After discussion, our team decided to increase the ambient temperature and warm up the hat and blanket half an hour before birth. The PDSA cycle was adopted and continued.

The second PDSA bundle was performed between April and June 2019. After repeated training, we moved on to the second stage. All infants were wrapped immediately after birth, without being dried, in a polyethylene wrap measuring 30 cm×40 cm with a T-shirt-type opening and a border that allowed closure at the other end without drying. We chose to use a thermal mattress. Hypothermia decreased from 70.0% to 61.6%. In this research phase, the polyethylene wrap was improperly used. Also, due to material limitations, suitable thermal mattresses were out of stock for a period. We decided to conduct weekly

trainings on how to quickly wrap a baby in a polyethylene wrap. The PDSA cycle was adopted and continued.

The third PDSA bundle was performed between July and December 2019. The temperature of the transport incubator was maintained at 35°C~36°C. A debriefing checklist was created for infants with AH, and auditing with weekly feedback was performed. Control charts for hypothermia were reviewed every month. Hypothermia decreased from 61.6% to 58.6%. In this research phase, the temperature of the transport incubator temperature does not meet the standard. our team decided to open the transport incubator 1 hour before the baby was born and to maintain the temperature at 35°C~36°C.

To ensure the implementation of these measures, our team developed a manual list, an implementation list and a verification list. At the monthly online meetings, the department directors followed up on unfinished work so that medical team leaders could be encouraged to complete these measures. In addition, our team leader conducted monthly supervision and site visits to each centre to solve various problems in the QI process in a face-to-face manner. In general, communication among multiple disciplines (obstetrics, operating room/delivery room and neonatal department) was strengthened; regular training for each discipline was organised; and each medical staff member was encouraged to rigorously implement QI measures.

Measures

The primary outcome was the monthly proportion of newborns with AH and the mean admission temperature. We calculated this proportion by taking the monthly number of VLBW infants who met the inclusion criteria and had a hypothermic event and dividing it by the monthly total number of VLBW infants who met the inclusion criteria. Admission temperatures were measured with a thermometer before the infants were placed in a NICU incubator. AH was defined as a rectal temperature of <36.5°C, measured with a digital thermometer (OMRON, MC-685-HP), when the newborn arrived in the NICU.

Balancing measures were the proportion of newborns with AH (defined as a rectal temperature of >37.5°C). Process measures included maintaining an ambient temperature of 25°C, documenting the infant's temperature (10 min after birth), wrapping the infant in polyethylene wrap without drying them first and warming the transport incubator. The minimum target for compliance with the process measures was ≥80%, with an ideal target of >90%.

Additionally, to ensure that the ambient temperature was maintained above 25°C, we used the same digital laser infrared thermometer for measurements and made adjustments once a month to avoid errors.

The secondary outcomes were the morbidities of severe intraventricular haemorrhage (IVH) (grades III and IV according to the Papile classification), necrotising enterocolitis (NEC) (Bell grades II and III), pulmonary

haemorrhage, severe bronchopulmonary dysplasia (BPD) (the need for supplemental oxygen or positive pressure support at 36 weeks of postmenstrual age), retinopathy of prematurity (ROP) (grades≥III) and in-hospital mortality.

Analysis

The statistical analyses were conducted using SPSS V.25.0. Demographic data are expressed as means (±SDs) or percentages. In the univariate analysis, we used t-tests, χ^2 tests or Fisher's exact tests. We then evaluated the ORs according to admission temperature using a multivariate logistic regression analysis, with adjustments for factors that had a p value of <0.1 in the univariate analysis. A two-sided level of significance of 0.05 was used for all analyses.

The monthly rate of AH was tracked by using statistical process control (SPC) methods (QI Macros). Using SPC methods, we created p-charts to evaluate the monthly percentages of hypothermic events over the 24-month study period. When the value was ≥7, subsequent data points were below the one side of the centreline average, indicating a special-cause shift in the signal.²¹ Our writing format was based on the SQUIRE V.2.0 guidelines.

The study has been registered at the Chinese Clinical Trial Registry.

RESULTS

The new thermoregulation protocol was introduced into practice in January 2019. The incidence of AH decreased dramatically in the post-QI group, with a reduction from 92.3% to 62.0% ($p<0.001$, table 1). The mean admission temperature also significantly increased to 36.0°C±0.7°C from 35.5°C±0.7°C ($p<0.001$). The rate of AH was tracked with the control chart (figure 2). The control chart revealed that the centreline shifted downward during the post-QI phase. The incidence of AH decreased gradually with each test change and decreased to 58.6% after the third test change (table 2).

We collected process measure compliance data throughout the project and shared these data at monthly meetings to understand the key practices that led to improvements. Figure 3 shows a sample chart that shows the ambient temperature in relation to the number of infants per month. The ambient temperature was within the target range 73.2% of the time on average (range: 55.9%–88.6%) throughout the study period. Throughout the study period, the average compliance with documenting the patients' temperatures at 10 min after birth was 63.1% (range: 55.2%–77.8%); compliance with wrapping the infant in a polyethylene wrap without drying them first was 75.6% (range: 57.8%–89.6%); and compliance with the use of a heated transport incubator was 78.4% (range: 56.2%–90.6%).

The baseline characteristics of the infants in the intervention group were similar to those of the historical controls in 2018 (table 1). There were no differences in the incidence of hypothermia or in neonatal outcomes among the PDSA cycles (table 2).

Table 1 Comparison of maternal and infant characteristics

	Pre-QI (n=235)	Post-QI (n=295)	P value*
GA (weeks, $\bar{X}\pm s$)	28.8 \pm 1.7	28.5 \pm 1.6	NS
BW (g, $\bar{X}\pm s$)	1138 \pm 228	1103 \pm 228	NS
Sex (male)	126 (53.6)	157 (53.2)	NS
Caesarean section	175 (74.5)	208 (70.5)	NS
Multiple birth (twins or more)	42 (17.9)	71 (24.1)	NS
Apgar score at 1 min <7	111 (47.2)	154 (52.2)	NS
Apgar score at 5 min <7	48 (20.4)	69 (23.4)	NS
Maternal hypertension	93 (39.6)	112 (38.0)	NS
GDM	25 (10.6)	39 (13.2)	NS
PROM	60 (25.5)	78 (26.4)	NS
Admission temperature ($^{\circ}$ C, $\bar{X}\pm s$)	35.5 \pm 0.7	36 \pm 0.7	<0.001
Hypothermia	217 (92.3)	183 (62.0)	<0.001
Hyperthermia	--	1 (0.3)	--

Data are presented as the mean or n (%).

*t-test or χ^2 test.

BW, birth weight; GA, gestational age; GDM, gestational diabetes mellitus; NS, not significant; PROM, premature rupture of membranes; QI, quality improvement.

There were no significant differences in other secondary outcomes, namely, severe IVH, NEC, pulmonary haemorrhage, severe BPD, LOS or ROP. However, there was a significant reduction in the incidence of in-hospital mortality in the post-QI group compared with the pre-QI group ($p=0.01$) (table 3).

A total of 636 infants with a birth weight <1500 g and a gestational age <32 weeks were enrolled in the study on their day of birth; 58 out-born infants were excluded. Ten infants with maternal fever and 27 infants with missing data were excluded, as were 11 infants whose families did not agree to participate in the study. The remaining 530 infants were included in this analysis.

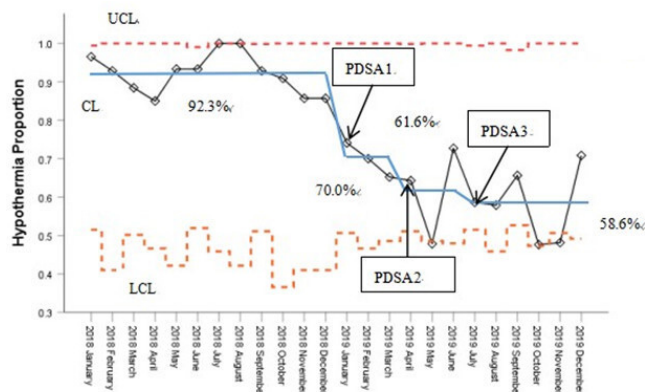


Figure 2 P-chart of the hypothermic birth rate with control limits. PDSA1: January 2019–March 2019; PDSA2: April 2019–June 2019; PDSA3: July 2019–December 2019. The incidence of admission hypothermia decreased dramatically in the postquality improvement group, with a reduction from 92.3% to 62%. CL, centreline; LCL, lower control limit; PDSA, plan-do-study-act; UCL, upper control limit.

DISCUSSION

Summary

This is a prospective, multicentre cohort study of the implementation of QI programmes to prevent AH in VLBW infants in China. We succeeded in reducing the incidence of AH in VLBW infants using standardised targeted temperature bundle management. The use of an ambient temperature of 25 $^{\circ}$ C, a polyethylene wrap,^{22–25} prewarmed hats,^{23–25} a heated transport incubator,²⁶ team training and education, temperature documentation and workflows were all relatively easy changes to implement in practice, but they dramatically improved the admission temperatures of VLBW newborns. The incidence of AH dropped from 92.3% to 62% in the post-QI group, a decrease of 30.3%.

Although warming measures are highly standardised internationally, there are differences in clinical practice and thermoregulation guidelines in China. Therefore, the incidence of hypothermia was very high in this study compared with previous studies.^{11–15} However, the extent to which the incidence of AH decreased as a result of the intervention was consistent with previous studies.^{11–15 22} Retrospective analysis has shown that body temperature maintenance is still a very weak link in neonatal resuscitation, especially for premature infants, in China.^{1 3} Although the rate of process measure implementation did not meet minimum international standards ($\geq 80\%$), the study showed an increase in the implementation of process measures from less than 50%¹ to approximately 73.2%. Communication delays, a lack of training and poor coordination among obstetric and paediatric medical staff led to the inadequate implementation of QI measures. In addition, a lack of domestic paediatric medical staff and a lack of attention from senior leaders

Table 2 Infant characteristics and neonatal outcomes by plan–do–study–act cycle

	PDSA 1 (n=70)	PDSA 2 (n=73)	PDSA 3 (n=152)	P value
GA (weeks, $\bar{X}\pm s$)	28.8 \pm 1.6	28.3 \pm 1.7	28.5 \pm 1.7	NS
BW (g, $\bar{X}\pm s$)	1122 \pm 228	1101 \pm 221	1096 \pm 232	NS
Maternal hypertension	29 (41.4)	21 (28.8)	62 (40.8)	NS
Caesarean section	55 (78.6)	45 (61.6)	108 (71.1)	NS
Apgar score at 1 min <7	30 (42.9)	38 (52.1)	86 (56.6)	NS
Apgar score at 5 min <7	16 (22.9)	15 (20.5)	38 (25.0)	NS
Hypothermia	49 (70.0)	45 (61.6)	89 (58.6)	NS
Mortality	5 (7.1)	8 (11.0)	13 (8.6)	NS
Pulmonary haemorrhage	6 (8.6)	7 (9.6)	7 (4.6)	NS
BPD	8 (11.4)	5 (6.8)	15 (9.9)	NS
IVH	9 (12.8)	5 (6.8)	24 (15.8)	NS
NEC	3 (4.3)	3 (4.1)	8 (5.3)	NS
LOS	28 (40.0)	21 (28.8)	41 (26.9)	NS
ROP	3 (4.3)	3 (4.1)	13 (8.6)	NS

Data are presented as the mean or n (%).

BPD, bronchopulmonary dysplasia; BW, birth weight; GA, gestational age; IVH, intraventricular haemorrhage; LOS, late-onset neonatal sepsis; NEC, necrotising enterocolitis; NS, not significant; ROP, retinopathy of prematurity.

were responsible for the inadequate implementation of some measures. Finally, the overall duration of our study was 3 years long, and this paper describes only the intervention phase. In the QI maintenance stage, we constantly improved the process based on the problems we encountered during the implementation of various measures to further reduce the incidence of AH.

Because hypothermia has been shown to be associated with LOS, IVH and death,^{27–31} we monitored survival without serious complications as a secondary outcome.

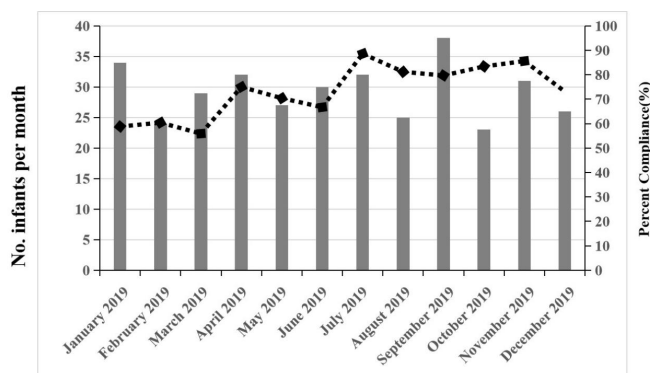


Figure 3 Compliance with the process measures of raising the ambient temperature to 25°C. The left y-axis and the dark grey bars represent the number of very-low-birth-weight infants who met the inclusion criteria per month. The right y-axis and the black boxes represent the percentage of those infants who experienced compliance with protocol measure of raising the ambient temperature to 25°C. A sample chart that shows the ambient temperature in relation to the number of infants per month is shown. The ambient temperature was within the target range 73.2% of the time on average (range: 55.9%–88.6%) throughout the study period.

Concomitant with the near elimination of moderate-to-severe hypothermia was the trend towards improved survival. This encouraging result shows that our intervention not only was effective in reducing the incidence of hypothermia but also had a potentially positive impact on the survival rate of VLBW infants.

However, we must also acknowledge undesired outcomes, such as hyperthermia, which occurred in one case after the intervention. One newborn who spent a prolonged time on the chemical mattress had a hyperthermic admission temperature. Such cases were rare; however, when staff obtain rectal temperature measurements every 30 min from the delivery room or operating room to NICU admission, they should use this information to adjust their practices removing the chemical mattress when temperatures exceed 37.0°C.

Interpretation

Regarding collaborative improvement processes, Paul Batalden popularised the quote, ‘Every system is perfectly designed to get the results it gets’; that is, ‘if we want different results, we must change (transform) the system’.³² Therefore, each team must evaluate its own system at the local level to identify its own challenges and the process changes that are necessary to produce improvements. Some of the participating units have delivery rooms or operating rooms that are far from the NICU; for these units, the use of chemically heated mattresses and transfer materials was considered to further enhance the benefits of thermal care. The low incidence of AH demonstrated the success of the QI measures at all process points as a result of communication among multiple disciplines (obstetrics, operating room/delivery room and neonatal

Table 3 Outcomes of infants in the QI intervention group compared with historical controls

	Pre-QI (n=235)	Post-QI (n=295)	P value*
Mortality	38 (16.1)	26 (8.8)	0.01
Pulmonary haemorrhage	22 (9.4)	20 (6.8)	NS
BPD	28 (11.9)	28 (9.5)	NS
IVH	31 (13.2)	38 (12.9)	NS
NEC	13 (5.5)	14 (4.7)	NS
LOS	87 (37.0)	90 (30.5)	NS
ROP	18 (7.7)	19 (6.4)	NS

Data are presented as the mean or n (%).

Although the numbers were small, one infant (0.3%) in the intervention group had admission hypothermia (table 1).

* χ^2 test.

BPD, bronchopulmonary dysplasia; IVH, intraventricular haemorrhage; LOS, late-onset neonatal sepsis; NEC, necrotising enterocolitis; NS, not significant; QI, quality improvement; ROP, retinopathy of prematurity.

department), regular training for each discipline and the requirement for each medical staff member to rigorously implement the QI measures. To ensure the implementation of QI measures, our team developed a manual list, an implementation list and a verification list. In monthly online meetings, department directors followed up on unfinished work to encourage medical team leaders to complete the implementation of these measures. In addition, our team leader conducted monthly supervision and site visits at each centre to address various problems in the QI process in a face-to-face manner.

By refining the temperature bundle management process, we could significantly reduce the incidence of hypothermia among VLBW infants. Although this study examined process indicators, further study is needed; furthermore, the current domestic measures for heat preservation in premature infants are inadequate; senior management's attention to this issue is minimal; and QI research is very limited. Therefore, the QI team from the centres that participated in the project described in this study not only can serve as a resource for other provinces but also can gain the attention of top leaders to formulate incentives to ensure that all QI measures are rigorously implemented by all medical personnel. This simple and practical bundle can be broadly expanded to the increasing number of NICUs affiliated with perinatal medical centres at all levels in China.

Limitations

Limitations of this study include the following: first, our study was conducted for 1 year, which was followed by a 2-year QI maintenance phase in which a target of $\geq 80\%$ compliance with process measures was set to promote ongoing reductions in the incidence of AH; second, although we did not identify any demographic shifts between the preintervention and postintervention periods, unmeasured differences, such as seasonal changes in room temperature, may have confounded the results. However, the potential value of promoting an approach in which the NICU leads the way forward will likely greatly outweigh the already minimal cost and

difficulty of implementing simple thermoregulation strategies.

CONCLUSIONS

We described a successful QI effort to reduce AH in VLBW infants in China. The results of this QI initiative indicate that relatively simple targeted interventions can dramatically reduce preventable hypothermic events and potentially improve survival without severe morbidity. The overall duration of our study was 3 years long, and this paper describes only the intervention phase. In the QI maintenance stage, we constantly improved the process based on the problems we encountered during the implementation of various measures to further reduce the incidence of AH.

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Contributors Y-hY, doctorate and professor of medicine, designed the study, trained and supervised the data collectors, interpreted the results and revised the manuscript. LW, the first author, played a role in the analysis and interpretation of the data and in preparing and drafting the manuscript. Z-JL and F-mL, the cofirst authors, designed the data collection instruments, collected the data, carried out the initial analyses, and reviewed and revised the manuscript. S-yB, BL, H-yX and C-yY conceptualised and designed the study, coordinated and supervised the data collection, and critically reviewed the manuscript for important intellectual content. All authors read and approved the manuscript. The guarantor is Y-hY.

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Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and was approved by the institutional review board of Shandong Provincial Hospital Affiliated to Shandong University (ethical approval number LCYJ: No. 2019-004). Informed consent was signed by the legal guardian of all participants. The participants gave informed consent to participate in the study before taking part, signed by their legal guardians.

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Data availability statement Data are available in a public, open access repository. Data are available upon reasonable request. Data may be obtained from a third party and are not publicly available. <http://www.ningbx.com/index/login/login.html>.



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