



# The Golden Hour: a quality improvement initiative for extremely premature infants in the neonatal intensive care unit

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## Abstract

**Background** Following delivery, extremely premature infants are vulnerable to rapid development of hypothermia and hypoglycemia. To reduce local rates of these morbidities, a multidisciplinary team developed a protocol standardizing evidence-based care practices during the first hour after birth.

**Methods** Using quality improvement methodology, the Golden Hour protocol was implemented for all inborn infants <27 weeks' gestation. Data were collected (2012–2017) over three phases; pre-protocol ( $n = 80$ ), Phase I ( $n = 42$ ), and Phase II ( $n = 92$ ).

**Results** There were no significant differences in infant characteristics. Improvements in hypothermia (59% vs 26% vs 38%;  $p = 0.001$ ), hypoglycemia (18% vs 7% vs 4%;  $p = 0.012$ ), and minutes to completion of stabilization [median (Q1,Q3) 110 (89,138) vs 111 (94,135) vs 92 (74,129);  $p = 0.0035$ ] were observed.

**Conclusions** Implementation of an evidence-based, Golden Hour protocol is an effective intervention for reducing hypothermia and hypoglycemia in extremely premature infants.

## Introduction

Prematurity is the leading cause of neonatal death and contributes to ~50% of childhood disabilities in the United States [1, 2]. The highest risks of morbidity and mortality are seen with the most premature infants [1]. Extremely premature (<27 weeks' gestation), extremely low birth weight (<1000 g) (EP-ELBW) infants' mortality rates are 30–50% [1]. Survivors face substantial risk of morbidities including intraventricular hemorrhage (IVH), chronic lung disease (CLD), and retinopathy of prematurity (ROP) [1]. These morbidities are predictors of long-term neurodevelopmental, sensorial, and psychiatric disabilities, which affect quality of life and can negatively impact the family [1, 3–5].

Following birth, EP-ELBW infants are susceptible to rapid development of hypothermia, hypoglycemia, hypotension,

and respiratory failure [1, 6–24]. Resuscitation in the delivery room (DR) and stabilization during admission to the neonatal intensive care unit (NICU) involves a series of interdependent tasks and procedures. These interventions must be performed quickly, proficiently, and systematically to minimize the short-term sequelae of prematurity, which contribute to the risk of long-term morbidity and mortality [1, 6–18].

The hour immediately following the birth of an EP-ELBW infant is referred to as the “Golden Hour” (GH) [6–8, 10–18]. This term denotes the period of time in which medical care to prevent irreversible damage is most effective and represents the inverse relationship between elapsing minutes and likelihood of survival. Due to the complexity of the care required at birth, protocols that bundle evidence-based practices and standardize their application to the first few minutes after birth have been used to improve the quality and consistency of care for EP-ELBW infants during the GH [6–8, 10–18].

## Problem

In 2012, Vermont Oxford Network database reports for the NICU at the University of North Carolina (UNC) Children's Hospital revealed admission temperatures for EP-ELBW infants fell below the unit's goal range (36.5–37.5 °C), and the network's reported ranges for similar type NICUs. In our unit, 25% of infants <24 weeks' gestation and 41% of infants

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24–26 weeks' gestation were eutermic compared to 34 and 46% of similar type NICUs in Vermont Oxford Network.

A propensity for early hypoglycemia (glucose < 45 mg/dL) was also noted. At baseline, 18% of EP-ELBW infants were hypoglycemic on admission. In addition, retrospective chart review demonstrated the time from birth to obtaining intravascular (IV) access, subsequent administration of IV fluids and antibiotics, and overall time to completion of admission stabilization was prolonged, increasing the risk for hypothermia and hypoglycemia.

### Available knowledge

In a review of the literature, nine quality improvement (QI) studies were identified presenting outcomes following implementation of a GH protocol in the NICU [8, 10, 12–18]. Admission temperature was reported as a short-term outcome measure and improvements in temperatures to goal range were described in eight of the studies [10, 12–18]. One study provided statistical analysis of improvement in admission serum glucose concentration to >50 mg/dL following protocol implementation [13]. Another described “stable” glucoses throughout the QI project [14]. The only other study that discussed glycemic control reported an increase in the rate of hypoglycemia which was attributed to increased physiologic stress [18]. Although long-term outcomes were not consistently evaluated in the studies, several authors described improvements in the incidence of IVH, ROP, CLD, late-onset sepsis, and/or length of stay in their units [8, 10, 12, 16, 18].

### Specific aims

Our goal was to design and implement a systematic, evidence-based approach to the care of EP-ELBW infants during the GH. The primary aims were to increase the percentage of temperatures within eutermic range, reduce the incidence of hypoglycemia, and decrease the time to completion of admission stabilization to less than 60 min after birth.

## Methods

### Design

A retrospective-prospective study design was used for comparison of data from a preprotocol cohort with postprotocol cohorts. Retrospective data were collected January, 2012 through March, 2014 from electronic medical records. Prospective data collection began with project implementation in April, 2014 and continued through February, 2015 for Phase I and March, 2015 through March, 2017 for Phase II (Table 1). The effectiveness of interventions was evaluated using plan-

do-study-act (PDSA) cycles in accordance with institutional use of Lean Six Sigma QI methodology [25, 26].

### Setting and population

This single-center, QI study was conducted in the 58-bed level IV NICU at UNC Children's Hospital, in Chapel Hill, NC. The NICU is part of a large academic medical center and serves as a regional referral center for the state. Nearly two-thirds of the 800–1000 infants admitted to the unit each year are inborn. The study population included all inborn infants <27 weeks' gestation who survived resuscitation in the DR and were admitted to the NICU. Exclusion criteria were major congenital anomalies resulting in death within the first 24 h after birth and/or parental decision to provide palliative care on admission.

### Context

A multidisciplinary team of NICU providers including neonatologists, neonatal nurse practitioners, neonatal fellows, nurses, and respiratory therapists designed the evidence-based bundles included in the protocol. Representatives from each of these groups of key stakeholders were chosen to lead the proposed culture change. Prior to implementation, presentations demonstrating baseline variation in practices were given to increase awareness of the need for improvement. Disciplinary-specific education sessions were provided with each phase. To promote sustainability, GH care was incorporated into the nurses' yearly competencies and new fellows' bootcamp. Updates were provided throughout the project to maintain stakeholder engagement.

## Interventions

### Thermoregulation

To minimize heat loss, the DR temperature was increased (74–76 °F) prior to delivery and the radiant warmer was prepared in collaboration with the obstetrical team. In the NICU, the isolette and all supplies were warmed. Radiant heat, plastic wrap, and stocking-knit caps were used at delivery in the baseline cohort. With project implementation, a warming mattress was added and the technique for wrapping the infant in plastic was modified to improve integrity during resuscitation. One corner of the plastic was folded over the infant's head and secured with a stocking-knit cap, as plastic head-coverings have been shown to be more effective at preventing heat loss than use of stocking-knit caps alone [27]. In Phase II, the

**Table 1** Timeline of the Golden Hour

	Quality improvement interventions
Baseline	
Phase I (4/2014–2/2015)	<p>Followed existing guidelines for initial resuscitation and stabilization of ELBW infants</p> <p>Introduced concept of the Golden Hour and quality improvement objectives</p> <p>Updated ELBW guidelines to reflect GH goals and planned interventions</p> <p>A cleaned, stocked isolette was reserved and ready for GH admissions at all times</p> <p>With notification of imminent delivery advanced preparation occurred:</p> <ul style="list-style-type: none"> <li>Admission bed space was prepared</li> <li>Prepared isolette was moved into the bed space and warmed</li> <li>Respiratory therapist set up a ventilator and bubble CPAP at the admission bed space</li> <li>Provider gathered supplies for umbilical line insertion</li> <li>Nurses warmed IV fluids and primed all IV tubing (peripheral &amp; central)</li> <li>Created a “stork kit” with ELBW-specific equipment to be taken to each delivery</li> <li>Initiated delayed cord clamping at GH deliveries</li> <li>Introduced use of chemical warming mattress</li> <li>Initiated peripheral IV placement in delivery room</li> <li>Modified the plastic wrapping technique</li> <li>EMR ELBW admission order set was created</li> <li>Concluded Six Sigma “Purple Belt” project as a multidisciplinary team</li> <li>Created the ELBW GH care algorithm</li> <li>Updated the unit ELBW guidelines</li> <li>Added an additional <i>experienced</i> nurse (total of two nurses) to GH team</li> <li>Changed practice to only <i>experienced</i> providers intubating and placing umbilical lines</li> <li>Required respiratory therapist attendance at all GH deliveries</li> <li>Required availability of surfactant at all GH deliveries (not only &lt;25 weeks’ gestation)</li> <li>Collaborated with radiology to expedite confirmation of umbilical line placement</li> <li>Collaborated with pharmacy to expedite antibiotic delivery to bedside</li> <li>Education provided to <i>ALL</i> nurses via yearly required competency training</li> <li>Created role assignments and positioning in the delivery room</li> <li>Initiated “just-in-time” ELBW simulation training for multidisciplinary staff</li> <li>Implemented cardiorespiratory leads in the DR</li> <li>Decreased initial supplemental oxygen to 0.21</li> <li>Increased positive end expiratory pressure during resuscitation to +6 cm</li> <li>Standardized ordering of caffeine and vitamin A on admission</li> <li>Thermoregulation suits integrated into care</li> </ul>
(5/2016)	
	CPAP continuous positive airway pressure, EMR electronic medical record, IV intravenous

plastic wrap and stocking-knit cap were replaced by a polyethylene, heat loss prevention suit with a hood. The suit could be opened for central umbilical line placement without full removal, thus avoiding loss of heat and moisture during the procedure.

### **Glycemic control**

To achieve early initiation of glucose infusion, peripheral IV access was established in the DR with a maximum of two attempts at placement. On admission to the NICU, a 10% dextrose infusion was administered peripherally while central umbilical access was being established. Following radiographic confirmation of placement, the peripheral infusion was discontinued, and central infusions were initiated using 10% dextrose, 2.5% amino acid solution via the umbilical venous catheter and 3.6% isotonic amino acid solution via the umbilical arterial catheter. A NICU-specific system for ordering umbilical line placement films was developed in collaboration with the radiology department to reduce time to confirmation of central placement.

### **Infection control**

Establishing vascular access was also vital to treating potential sepsis. When indicated, antibiotics were started on admission to the NICU. All lab work including the blood culture was collected as soon as blood return was obtained during central umbilical line placement. Once the blood culture was collected, antibiotics could be administered peripherally before central line placement had been completed or confirmed. Collaboration with the pediatric pharmacy department improved timing of delivery of antibiotics to the bedside.

### **Respiratory management**

A respiratory management plan for DR resuscitation was implemented, based on gestational age and risk factors for respiratory compromise (Fig. 1). This plan was used throughout the project in complement with the Neonatal Resuscitation Program (NRP) guidelines. Following publication of the 7th edition NRP guidelines, cardiopulmonary monitoring in the DR was implemented and initiation of supplemental oxygen was reduced from 0.3 to 0.21 (Table 1) [28]. Administration of intramuscular Vitamin A and intravenous caffeine was routine for the first two study cohorts. However, there were some inconsistencies with the timing of initiation. In an effort to improve outcomes, the initiation of these medications was standardized (Table 1) [29, 30]. During Phase II, both medications were added to the admission order set in the

EMR and ordered within the first hour after birth for all EP-ELBW infants.

### **Teamwork and communication**

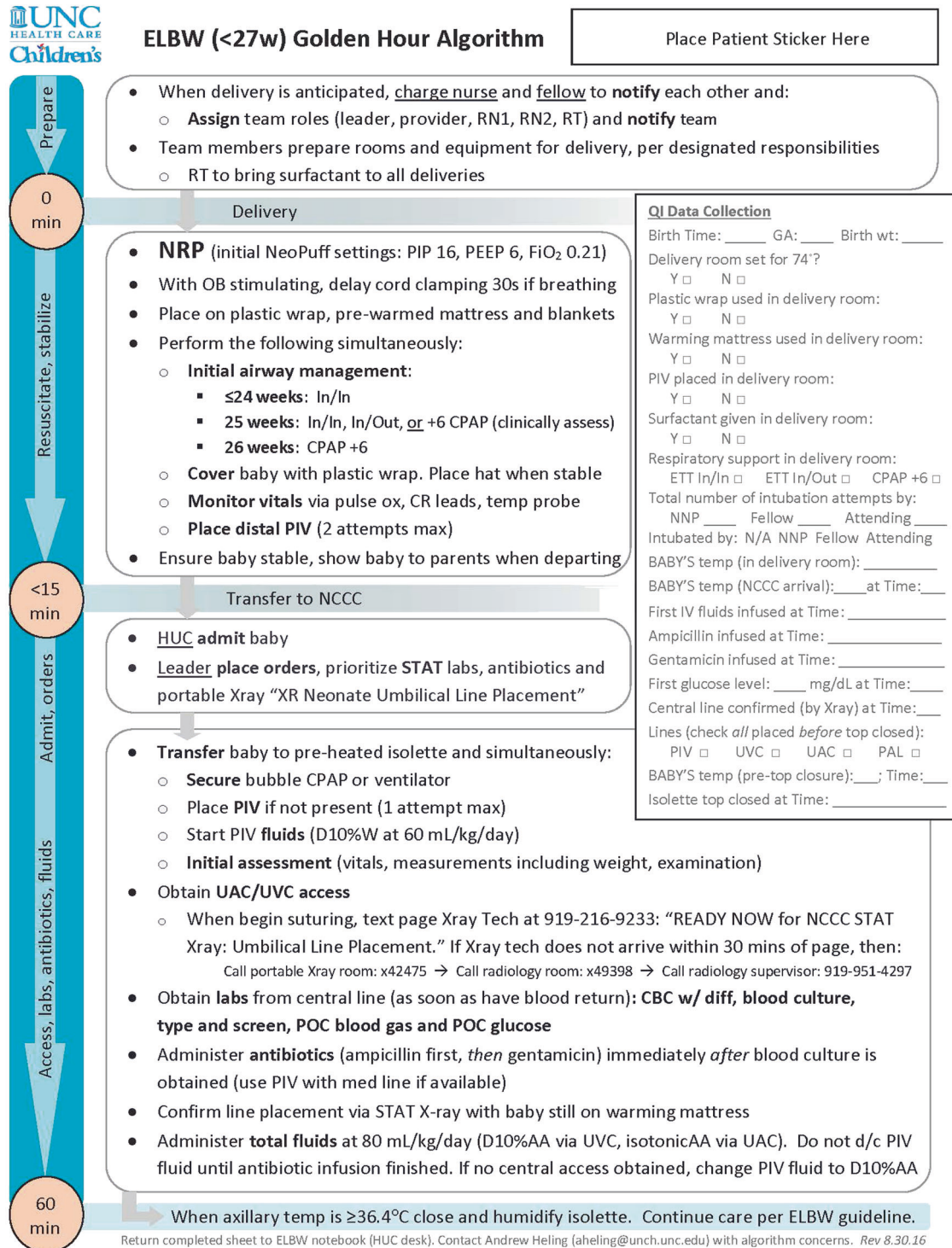
Many of the interventions implemented with Phase II of the project were focused on improving teamwork and communication. A detailed process flowchart was developed to guide the team through the GH (Fig. 1). At baseline, respiratory therapy presence at EP-ELBW deliveries was inconsistent. For implementation of Phase II, a respiratory therapist was assigned to attend every GH delivery. An additional, experienced nurse, and an additional, experienced provider were also added to the team. Previously, one provider assumed responsibility for establishing the airway and leading the team. With implementation of Phase II, two providers, physician or neonatal nurse practitioner, attended the delivery and divided these roles. The leader was responsible for supervising the resuscitation and stabilization of the infant from birth to completion of the GH as well as communicating with the obstetrical team and the family. The second provider focused on establishing an airway in the DR and inserting umbilical lines in the NICU. At this time, each team member was also assigned specific tasks and positions around the radiant warmer in the DR to improve team dynamics and communication [10].

Just-in-time training simulations were employed to solidify these interventions. When delivery of an infant <27 weeks' gestation was imminent, the team members assigned to attend reviewed their roles, responsibilities, and positions around the radiant warmer and performed a quick, just-in-time simulation. Consistent exposure to each team member's role created a shared mental model of what needed to be accomplished and who was responsible for each task throughout the GH. Consequently, the team was able to assume and divide additional responsibilities on the rare occasion one role was unfulfilled.

### **Study of the interventions**

Initially, a basic handout reminded providers of the goals of the GH and served as the data collection tool. Subsequently, a detailed process flowchart with corresponding questions for data collection replaced the initial handout (Fig. 1). All information gathered from the data collection tools was confirmed in the medical record prior to analysis.

Each phase of the project corresponded to changes in the bundles of interventions (Table 1). Changes in interventions were determined using PDSA cycles, taking into consideration trends in outcomes, stakeholder feedback, and availability of new products and evidence-based practices. Evaluation of short-term outcomes and other process



**Fig. 1** Golden Hour algorithm initial airway management was based on the infant's gestational age and assessment of risk factors for respiratory failure. Choices included intubation with surfactant administration (In/In), intubation for surfactant administration with immediate extubation to CPAP (In/Out), or CPAP without surfactant administration. AA amino acid, CBC w/diff complete blood count with differential, CPAP continuous positive airway pressure, CR cardiorespiratory, D10%W dextrose 10% in water; ETT endotracheal

tube, FiO<sub>2</sub> fraction of inspired oxygen, HUC hospital unit coordinator; NCCC Newborn Critical Care Center, NNP neonatal nurse practitioner, OB obstetrician, PAL peripheral arterial line, PEEP positive end expiratory pressure, PIP positive inspiratory pressure, PIV peripheral intravenous line, POC point-of-care, RN registered nurse, RT respiratory therapist, STAT immediately, UAC/UVC umbilical arterial and venous catheters

measures including time to achieving various GH goals provided benchmarks for determining the effectiveness of interventions. To ensure internal validity, implementation fidelity was evaluated based on the consistency of adherence to protocol interventions.

## Measures

Primary, short-term outcome measures were those obtained during admission stabilization. Axillary temperatures were measured on admission to the NICU (goal range 36.5–37.5 °C). Serum glucose concentration was obtained during central line placement and measured using point-of-care testing (goal  $\geq 45$  mg/dL). Completion of admission stabilization included DR resuscitation, initiation of IV fluids and antibiotics (when indicated), establishing central access, closing the top of the isolette, initiating humidity, and providing decreased environmental stimulation to approximate the intrauterine environment.

Process measures that directly contributed to thermoregulation, glycemic control, and time to completion of GH stabilization were tracked. These measures included the percentage of time plastic wrap or thermoregulation suit, warming mattresses, and peripheral IV insertion were utilized in the DR and minutes from birth to admission temperature, initiation of IV fluids, initiation of antibiotics, central line confirmation, and closure of the isolette.

Long-term outcomes including severe IVH (Grade III or IV hemorrhages), severe CLD defined as the need for supplemental oxygen  $\geq 30\%$  or positive pressure at 36 weeks' post menstrual age (PMA) or discharge [31], ROP requiring treatment, PMA on the day of discharge home, and mortality served as balancing measures to ensure changes in interventions were not having unintended, negative impacts.

## Analysis

Statistical process control charts were created in QI Macros for Excel. Outcomes were compared with Chi-Square or Fisher's exact test for categorical data and one-way ANOVA or Kruskal–Wallis for continuous data using Stata statistical software. Median values with interquartile ranges are presented due to non-normal distribution of data. Statistical significance was set at  $p$  values of  $\leq 0.05$ .

## Results

The study included 214 inborn infants  $< 27$  weeks' gestation. Three infants were excluded due to severe congenital anomalies resulting in death shortly after admission. Data

were collected over three phases; pre-protocol ( $n = 80$ ), Phase I ( $n = 42$ ), and Phase II ( $n = 92$ ) (Table 1). There were no significant differences in infant characteristics (Table 2).

Adherence to the intended interventions were as follows: the use of plastic wrap or thermoregulation suit was 100% and 98% in Phases I and II respectively and the use of warming mattresses was 95% in both phases. The number of attempts for IV insertion in the DR was limited (max of two) and overall, an IV was placed in the DR for 33% of infants in Phase I and 47% in Phase II.

Significant improvements were observed in all three primary outcome measures including the incidence of temperatures outside goal range (59% vs 26% vs 38%;  $p = 0.001$ ), the incidence of hypoglycemia (18% vs 7% vs 4%;  $p = 0.012$ ), and median time in minutes to GH stabilization (110 vs 111 vs 92 min;  $p = 0.004$ ) (Table 3). Evaluation of long-term morbidity and mortality as balancing measures to stabilize our metrics did not reveal any unintended negative effects (Table 3).

Statistical process control charts were used to analyze process performance. Changes in the center line and control limits were based on process shifts that occurred with continuous evaluation and implementation of interventions throughout the project. At baseline, both processes were stable. A few instances of a single measure above the upper control limit or below the lower control limit were noted on both control charts. These special cause variations were related to deviation from or noncompliance with the process. New control limits were calculated for both charts when clinically relevant special cause variation was identified (Fig. 2a, b). The limits were recalculated for admission temperature two months after project implementation resulting in a new center line with a eutermic temperature 36.8 °C (Fig. 2a). The limits were recalculated for time to completion during Phase II resulting in a new center line at 89 min (Fig. 2b). Both processes remained stable around the new center line.

## Discussion

### Summary

Implementation of an evidence-based GH protocol was effective at significantly improving euglycemia, euthermia, and time to completion of admission stabilization for EP-ELBW infants in our NICU. Following project implementation, admission temperatures in our unit for infants  $< 27$  weeks' gestation consistently fell within the Vermont Oxford Network's reported ranges for similar type NICUs. Although we did not consistently meet our goal of completion within the first 60 min after birth, we made significant improvements in time from baseline.

**Table 2** Golden Hour patient characteristics

Variable	Statistic	Preprotocol (N = 80)	Phase I (N = 42)	Phase II (N = 92)	P
Gestational age (weeks)	Median (IQR)	25 (24,26)	25 (24,26)	25 (23,26)	0.44
Birth weight (g)	Median (IQR)	705 (607,854)	740 (650,860)	670 (580,805)	0.13
Female sex	N (%)	38 (48)	22 (52)	50 (54)	0.66
Antenatal steroids	N (%)	74 (93)	42 (100)	88 (96)	0.18
Cesarean delivery	N (%)	53 (66)	30 (71)	57 (62)	0.56
5-min Apgar	Median (IQR)	5 (3,7)	6 (3,8)	6 (3,7)	0.56
Surfactant at delivery	N (%)	47 (59)	22 (52)	51 (55)	0.79
Surfactant by 2 h	N (%)	59 (74)	28 (67)	72 (78)	0.37

IQR interquartile range

**Table 3** Golden hour outcomes

Variable	Statistic	Preprotocol (N = 80)	Phase I (N = 42)	Phase II (N = 92)	P
Severe IVH	N (%)	16 (20)	5 (14)	16 (18)	0.722
Survivors without Severe CLD	N (%)	38 (58)	19 (66)	28 (45)	0.140
Survivors without ROP treatment	N (%)	56 (84)	27 (90)	47 (72)	0.100
Death	N (%)	12 (15)	11 (26)	23 (25)	0.186
Death or CLD	N (%)	39 (51)	21 (53)	57 (67)	0.077
PMA at discharge home (weeks)	Median (IQR)	40 (38,43)	41 (38,44)	41 (39,45)	0.240
Time to completion (minutes)	Median (IQR)	110 (89,138)	111 (94,135)	92 (74,129)	0.004
Non-eutermic temperature	N (%)	46 (59)	11 (26)	33 (38)	0.001
Hypoglycemic	N (%)	14 (18)	3 (7)	4 (4)	0.012

Eutermic range (36.5–37.5 °C). Hypoglycemia defined as glucose <45 mg/dL

CLD chronic lung disease, IQR interquartile range, IVH intraventricular hemorrhage, PMA postmenstrual age, ROP retinopathy of prematurity

## Interpretation

Our GH protocol was implemented in a more premature population of infants than those of the studies in our review. Only one of the review studies focused on a population of infants <27 weeks' gestation, while inclusion criteria for the remaining studies ranged from <28 to <33 weeks' gestation [8, 10, 12–18]. However, despite a more vulnerable population, the improvements in admission glucoses and temperatures demonstrated in our study were consistent with the results reported by the studies in our review. Initially, we noted a slight increase in time which we contributed to the learning curve associated with project implementation. The significant decrease in time to GH stabilization during Phase II was associated with efforts to improve team dynamics and implementation of simulation training.

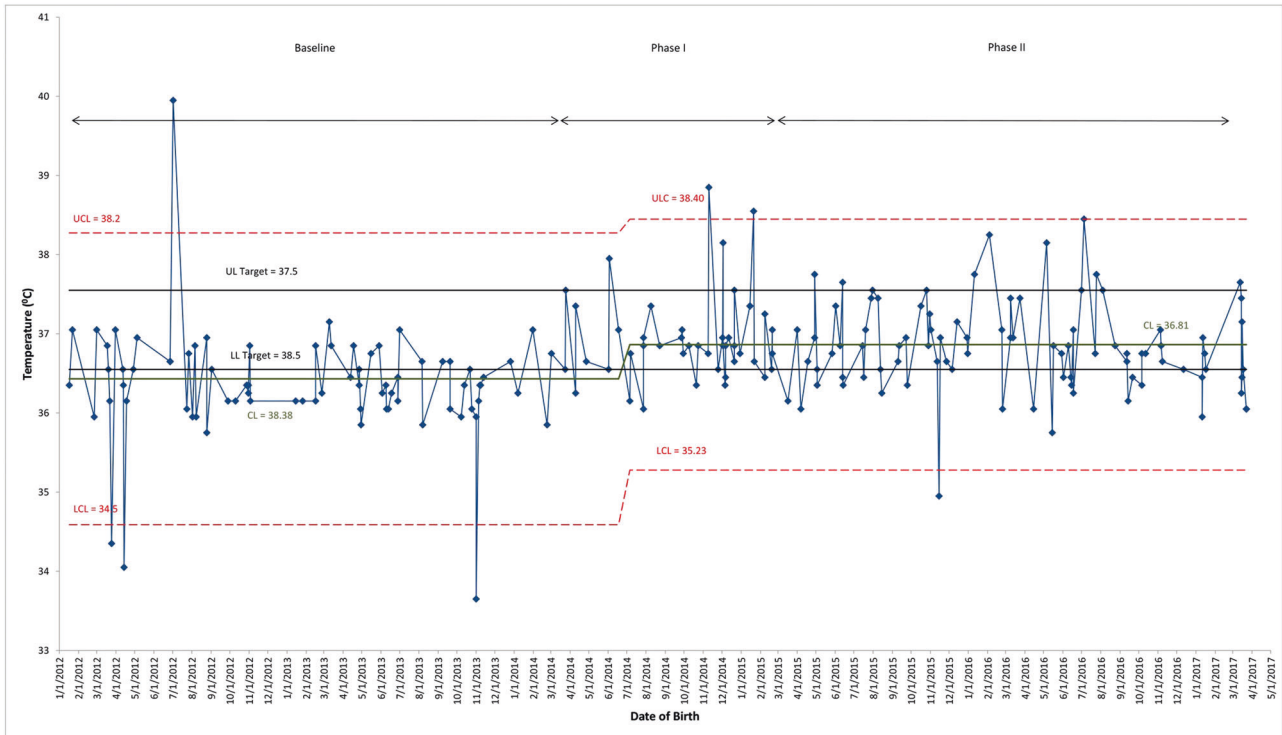
A potential confounder was the increase in the resuscitation and survival of periviable infants (22–23 weeks' gestation) during the course of our interventions, a phenomenon which was not isolated to our unit [32, 33]. We noted that the percent of periviable infants remained stable across the first two cohorts and nearly doubled in the third cohort (16%, 16%, and 29% respectively). The

inverse relationship between gestational age and survival without morbidities is well-recognized and confers a higher degree of vulnerability to those infants delivered at the “cusp of viability” [1, 34]. Periviable infants are more susceptible to hypothermia and hypoglycemia and less resilient from the ensuing morbidities [35]. Despite an increasing percentage of more immature infants, the rates of hypothermia and hypoglycemia improved without significant differences in balancing measures. This finding remained when balancing measures were evaluated separately for 22 and 23 week infants. We speculate that implementation of the interventions in our GH protocol may offer a protective effect which may be even more beneficial at lower gestational ages.

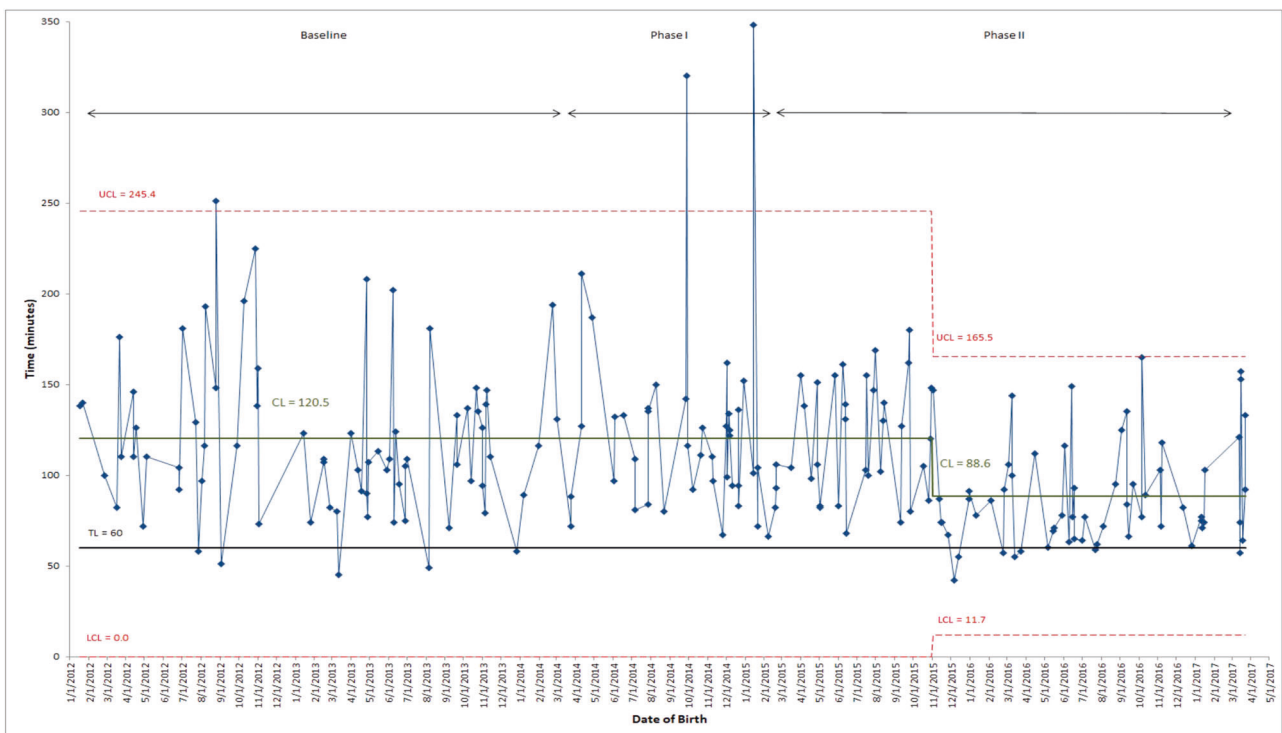
## Limitations

One limitation to the study was the transfer of stable infants to lower-level facilities. There was a loss of 7% of the data for CLD and 4% of the data related to ROP for survivors transferred prior to 36 weeks' PMA. Sample size was also a limiting factor. The sample size for Phase I of the project

a



b



**Fig. 2** Golden Hour statistical process control charts **a** Change in admission temperatures over time **b** Change in time to completion of admission stabilization over time. LCL lower control limit, UCL upper control limit





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