

IMPLEMENTATION OF A GOLDEN HOUR PROTOCOL FOR EXTREMELY
PREMATURE INFANTS

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ABSTRACT

Sarah E. W. Croop: Implementation of a Golden Hour Protocol for Extremely Premature Infants
(Under the direction of Suzanne Thoyre)

Extremely premature (EP) infants are fragile, susceptible to rapidly developing hypothermia and hypoglycemia, and face substantial risk of long-term morbidity and mortality. Golden Hour protocols (GHP) bundle and standardize evidence-based practices for care of these vulnerable infants during the first 60 minutes of life and are reported to decrease short-term and potentially decrease long-term morbidity and mortality. The purpose of the study was to examine short- and long-term outcomes in EP infants following implementation of a GHP in one neonatal intensive care unit.

Cyclical plan-do-study-act quality improvement (QI) methodology was utilized. Data were collected on inborn infants < 27 weeks' gestation (2012-2017) over 3 phases; pre-GHP ($n = 80$), Phase I ($n = 42$), and Phase II ($n = 92$). There were no statistically significant differences in infant characteristics.

A systematic approach to care of EP infants in the first hour of life resulted in improved short-term outcomes. Significant differences were observed in minutes to completion of GHP care [median (Q1,Q3) 110 (89,138) vs 111 (94,135) vs 92(74,129) respectively $p = 0.0035$], abnormal temperature (59% vs 26% vs 38%; $p = 0.001$) and hypoglycemia (18% vs 7% vs 4%; $p = 0.012$).

Evaluation of long-term morbidity and mortality did not reveal significant differences. However, there was an increase in the number of infants resuscitated and admitted at the cusp of viability (22 and 23 weeks gestation) over the three phases of the study (16%, 16%, 29%), similar to national trends of providing more aggressive care at earlier gestational ages. Although significant improvements in long-term outcomes were not observed, the lack of significant differences may represent a protective effect of GHP as the highest risks of morbidity and mortality are associated with the most premature infants.

Additional studies, larger sample sizes, and consistent analysis of long-term morbidities would provide greater insight into the impact of GHP. Ongoing QI should focus on sustaining achieved improvements, continuing to improve time to completion of care, and seeking additional, meaningful short-term outcome measures.

Keywords: extremely premature, infant, golden hour, neonatal intensive care unit, quality improvement

TABLE OF CONTENTS

LIST OF TABLES.....	viii
LIST OF FIGURES.....	ix
LIST OF ABBREVIATIONS.....	x
CHAPTER 1: IMPLEMENTATION OF A GOLDEN HOUR PROTOCOL FOR EXTREMELY PREMATURE INFANTS	1
Introduction.....	1
Local Problem.....	2
Significance to Healthcare	3
Literature Review.....	5
Search Strategy	6
Quality Assessment.....	6
Outcome Measures.....	7
Temperature	8
Glucose	8
Intraventricular hemorrhage.....	9
Chronic lung disease	9
Retinopathy of prematurity	10
Additional themes	10
Summary	10
Theoretical Framework.....	12

Purpose of Project	14
Methods.....	14
Setting	15
Population and Study Sample	15
Ethical Considerations	15
Project Implementation	15
Key Personnel and Stakeholders.....	16
Barriers to Implementation and Sustainability	16
Resources and budget	17
Preparation of Equipment and Supplies.....	18
Respiratory management	18
Thermoregulation.....	20
Fluid, Electrolyte, and Nutritional Management	22
Intravascular Access and Cardiovascular Stability	22
Infection Control.....	23
Efficiency	24
Effective Teamwork and Communication	25
Study of the Interventions.....	28
Measures	28
Short-term	28
Temperature	28
Glucose	29
Time to completion of Golden Hour care	29

Long-term	30
Severe intraventricular hemorrhage	30
Severe chronic lung disease	31
Retinopathy requiring treatment	31
Gastrostomy tube placement	32
Length of stay	32
Mortality/survival	32
Procedures.....	32
Data Analysis	33
Results.....	33
Discussion	34
Strengths of the Project.....	36
Limitations of the Project.....	37
Conclusion	39
Usefulness	39
Suggested next steps and sustainability	39
Potential spread to other contexts	39
Implications.....	40
Conflict of Interest and Funding	40
REFERENCES	56

LIST OF TABLES

Table

1.	Summary of the Evidence: Quality Improvement Projects to Implement a Golden Hour Protocol	41
2.	Quality Assessment of the Studies Included in the Review of Literature	42
3.	Patient Characteristics.....	43
4.	Resuscitation Demographics.....	44
5.	Golden Hour Quality Improvement Study Outcomes	45

LIST OF FIGURES

Figure 1	Search results in the format of a PRISMA flow diagram.....	46
Figure 2	Golden Hour timeline of quality improvement interventions	47
Figure 3	Golden Hour Algorithm	48
Figure 4	Golden Hour Role Assignments.....	49
Figure 5	Golden Hour Role Assignments Cue Cards	50
Figure 6	Golden Hour Delivery Room Positioning Map.....	51
Figure 7	Box plot of gestational ages across the study phases	52
Figure 8	Control chart of the changes in admission temperatures over time.....	53
Figure 9	Run chart of the changes in serum glucose concentration on admission over time	54
Figure 10	Control chart demonstrating the change in time to completion of Golden Hour care	55

LIST OF ABBREVIATIONS

CINAHL	Cumulative index to nursing and allied health literature
CLD	Chronic lung disease
CPAP	Continuous positive airway pressure
DNP	Doctorate of nursing practice
ELBW	Extremely low birth weight
ELGAN	Extremely low gestational age neonate
EMR	Electronic medical record
EP	Extremely premature
GH	Golden hour
GHP	Golden hour protocol
GIR	Glucose infusion rate
G-tube	Gastrostomy tube
IRB	Institutional review board
IV	Intravascular
IVH	Intraventricular hemorrhage
L&D	Labor and delivery
LOS	Length of stay
NICU	Neonatal intensive care unit
NRP	Neonatal Resuscitation Program
PDSA	Plan do study act
PIV	peripheral intravenous

PMA	Postmenstrual age
PRISMA	Preferred reporting items for systematic review and meta-analyses
PubMed	Publisher MEDLINE
QI	Quality improvement
ROP	Retinopathy of prematurity
STAT	Latin: statim
VLBW	Very low birth weight
VON	Vermont Oxford Network

CHAPTER 1: IMPLEMENTATION OF A GOLDEN HOUR PROTOCOL FOR EXTREMELY PREMATURE INFANTS

Introduction

During the first few minutes of life, premature, low birth weight infants are susceptible to rapidly developing hypothermia, hypoglycemia, hypotension, and respiratory failure and they face substantial risks of morbidity and mortality (Glass et al., 2015). Resuscitation of these infants in the delivery room and stabilization during admission to the neonatal intensive care unit (NICU) involves a complex set of tasks and procedures, which must be performed proficiently within a short time period. These interventions are critical to maintaining the infant's stability and minimizing the potential for the aforementioned adverse sequelae of premature birth which contribute considerably to the risk of long-term morbidity and mortality (Annibale & Bissinger, 2010; Glass et al., 2015; Doyle & Bradshaw, 2012; Vento, Cheung, & Aguar, 2009; Wyckoff, 2014). Not only must care be provided quickly and proficiently, but because of the interdependence of interventions required for stabilization, they must also be performed in a systematic and sequential manner (Annibale & Bissinger, 2010; Reuter, Messier & Steven, 2014; Taylor, Kiger, Finch, & Bizal, 2010; Vergales et al., 2015). Due to the vulnerability of these infants and the complexity of the care required at birth, introduction of Golden Hour protocols that bundle evidence-based clinical practices and standardize their application within the first hour of life have become increasingly integral to providing consistent care in the NICU (Ashmeade, 2014; Castrodale & Rinehart, 2014; Lambeth, Rojas, Holmes, & Dail, 2016; Reuter,

Messier & Steven, 2014; Reynolds, Pilcher, Ring, Johnson, & McKinley, 2009; Vergales et al., 2015; Wallingford, Rubarth, Abbott, & Miers, 2012).

The term “Golden Hour” was originally used to refer to an approach to resuscitation that aimed to improve outcomes in adult trauma and emergency medicine. As a result of the potential to influence immediate survival as well as long-term outcomes during the first few minutes of life, the term Golden Hour (GH) is now also used to describe the hour following birth for premature, low birth weight infants (Annibale & Bissinger, 2010; Doyle & Bradshaw, 2012; McGrath, 2012; Vento, Cheung, & Aguar, 2009). The main objectives of GH protocols are to avoid short-term sequelae including hypothermia, hypoglycemia, hypotension, and respiratory compromise which the literature suggests may reduce the long-term morbidities of intraventricular hemorrhage (IVH), periventricular leukomalacia, chronic lung disease (CLD) and retinopathy of prematurity (ROP) and potentially decrease length of stay (LOS) and mortality (Glass et al., 2015; Doyle & Bradshaw, 2012; Vento, Cheung, & Aguar, 2009).

Local Problem

In the study unit, clinical care guidelines are revised biennially based on the most current literature. The author participated in the evaluation of the guidelines for extremely premature, extremely low birth weight (ELBW) infants in November of 2012. At that time, reports for the unit obtained from the Vermont Oxford Network’s (VON) databases revealed that several outcome measures for this population, including admission temperatures and serum glucose concentrations fell below the unit standards and VON databases’ reported ranges for similar type NICUs. A quality improvement (QI) initiative to implement a GH protocol for the initial management of these infants was recommended. The initial goal was to improve these outcome measures by standardizing evidence-based clinical practices thereby improving efficiency and

reducing inter-provider variance and other inconsistencies in care. Prior to initiation of the QI project, retrospective baseline data were collected on a cohort of infants meeting the planned sampling criteria. As the data were collected, the team discovered that the time from birth to obtaining vascular access, initiating intravascular (IV) fluids and antibiotics, as well as overall length of time for the admission to be completed was lengthier than the 60 minutes suggested in the GH literature. The conclusive purpose of the GH QI project was to design and implement a systematic, evidence-based approach to the care of extremely premature, ELBW infants within the first hour of life and to increase the consistency and efficiency of care in an effort to improve both short- and long-term outcomes for this population in the study unit.

Significance to Healthcare

Prematurity is the leading cause of neonatal mortality and contributes to approximately 50% of childhood disabilities in the United States; it is also the second leading cause of death in children under five years of age worldwide, making it a global health issue of substantial importance (Glass et al., 2015; U.S. Department of Health and Human Services, 2014). The highest risks of morbidity and mortality are associated with the most premature and lowest birth weight infants (U.S. Department of Health and Human Services, 2014). Infants born very prematurely (< 32 weeks' gestation) or at a very low birth weight (< 1,500 grams) have respectively 89 and 110 times the risk of death in the first year of life as their full-term and non-low birth weight counterparts (U.S. Department of Health and Human Services, 2014). Extremely premature (< 28 weeks' gestation), extremely low birth weight (< 1000 grams) infants face substantially higher risks of death and disability, with Glass et al. (2015) reporting mortality rates of 30-50% and a further morbidity risk of 20-50% for survivors. In a single-center, retrospective analysis of infants delivered at the edge of viability, 22-23 weeks' gestation, only 1

in 4 infants receiving active care survived the neonatal period without severe complications (Mehler, et al., 2016). These complications are often predictors of neurodevelopmental and sensorial disabilities including epilepsy, cerebral palsy, cognitive delay, hearing loss and visual impairment (Glass et al., 2015). In the aforementioned retrospective analysis of neonates delivered at 22-23 weeks' gestation, nearly one-third of surviving infants were severely neurologically impaired (Mehler, et al., 2016). In addition, there is emerging evidence that even for extremely premature, ELBW infants without severe disabilities there is an increased risk of symptoms of mental health issues such as autism, inattentiveness, anxiety and obsessive-compulsive disorder (Fevang, Hysing, Markestad, & Sommerfelt, 2016). Severe impairments and disabilities such as these not only decrease the infant's quality of life but also negatively affect the family (Behrman & Butler, 2007).

In 2005, the annual costs related to prematurity and low birth weight were estimated to exceed \$26 billion (Behrman & Butler, 2007; U.S. Department of Health and Human Services, 2014). This estimate represents the cost of intensive care, early intervention, special education and lost productivity due to disability (Behrman & Butler, 2007; U.S. Department of Health and Human Services, 2014). Although extremely premature, ELBW infants make up only 6% of premature births, the cost of their care represents more than one-third of the total costs related to prematurity (Allen, Smith, Iliev, Evans, & Werthammer, 2017; Glass et al., 2015). In one retrospective analysis of the medical records and financial data of infants 23-25 weeks' gestation demonstrated that the total costs for initial hospitalization in the neonatal intensive care unit increase with decreasing gestational age; ranging from $\$694,000 \pm 200,293$ at 25 weeks' to $\$895,000 \pm 101,758$ at 23 weeks' (Allen, Smith, Iliev, Evans, & Werthammer, 2017). The average cost for any infant in the NICU is around \$3,000 per day regardless of gestational age

(Kornhauser & Schneiderman, 2010). While the average LOS for a term infant in the NICU is about 6 days, the average LOS for infants < 32 weeks' gestation is about 46 days and in one evaluation of 2,012 ELBW infants from the California Quality Care Collaborative the median LOS was 79 days (range 23–219 days) (Lee, Bennett, Schulman, & Gould, 2013; March of Dimes Perinatal Data Center, 2011).

Cost analysis emphasizes the financial benefit a reduction in LOS might have on hospital expenses during the infant's initial hospitalization and suggests a long-term economic advantage to improving outcomes in this population. In one study of the relationships between LOS, cost, and clinical outcomes it was proposed that reducing LOS may not uniformly reduce hospital resource utilization (DeRienzo, Kohler, Lada, Meanor, & Tanaka, 2016). The findings in this relationship evaluation suggest that interventions should not simply be aimed at reducing LOS without aiming to improve clinical outcomes as well, a dual goal consistent with the aims of this project (DeRienzo, Kohler, Lada, Meanor, & Tanaka, 2016). Premature, low birth weight infants also have an increased risk of re-hospitalization during the first year of life and disproportionate length of stay for those hospitalizations (Behrman & Butler, 2007). An improvement in the incidence of morbidities has the potential for a positive effect not only by reducing the initial LOS in the intensive care unit but also by reducing the risk for re-hospitalization in this vulnerable patient population.

Literature Review

The purpose of the following review is to evaluate the existing body of literature to answer the question, does implementation of a GH protocol improve short- and long-term outcomes for premature, low birth weight infants in neonatal intensive care. A search of the existing body of evidence was performed with the purpose of identifying published outcomes of

QI projects relating to implementation of a GH protocol in the NICU. An appraisal of the quality of the studies obtained was performed and the outcome measures reported by each of the study units were evaluated. A summary of the evidence is presented in Table 1.

Search Strategy

The author conducted a review of the literature, not limited by year of publication, with articles retrieved from PubMed and CINAHL databases using the search terms (“golden hour” OR “golden hours” OR “golden minutes”) and (birth OR newborn OR infant* OR infanc* OR postnatal OR neonat* OR preterm OR prematur* OR preemie OR periviable OR gestation* OR “low-birth-weight” OR “low birth weight” OR “low birthweight” OR “extremely low gestational age” OR NICU OR ELBW OR VLBW OR ELGAN). This search resulted in 47 articles; 27 articles from PubMed and 20 articles from CINAHL. Following removal of duplicates, 34 articles remained. Inclusion criteria were English language, population: premature infants (defined as < 37 weeks’ gestation), articles related to implementation of a GH protocol; setting, neonatal intensive care units. A total of 15 articles were excluded based on the above inclusion and exclusion criteria and 19 articles remained. Of the remaining articles, there were seven primary sources; research-based articles presenting outcomes following implementation of a GH protocol in the NICU. Figure 1 displays the PRISMA flow diagram of the systematic review.

Quality Assessment

Retrospective data collected on a defined cohort of infants prior to project implementation were compared to prospective data following the change in practice in each article. All study populations were well defined and at the same point (birth) in the disease process (prematurity). However, there was inter-study variance in the inclusion criteria for infants standardized to protocol care. The birth weight inclusion criteria were either < 1500

grams or < 1000 grams while gestational age inclusion criteria varied from < 33 weeks' gestation to < 27 weeks' gestation across the studies.

The outcomes evaluated in these studies and reported in this review include objective measures of axillary temperature and serum glucose concentration and clinical diagnoses of IVH, ROP and CLD. Only one of the studies adjusted for confounding variables when calculating odds ratios (Ashmeade, 2014). The statistical methods used were not discussed in two of the studies (Reynolds et al., 2009; Wallingford et al., 2012). In the remaining studies, inferential statistics were used to determine differences between the groups with *p* values of 0.05 or less used to determine significance (Ashmeade, 2014; Castrodale & Rinehart, 2014; Reuter, Messier & Steven, 2014; Lambeth, Rojas, Holmes and Dail, 2016; Vergales et al., 2016). An assessment of the quality of each study in the review is provided in Table 2. using the Quality Improvement Minimum Quality Criteria Set; a tool for the critical appraisal of QI intervention publications (Hempel et al., 2015).

Outcome Measures

Each of the review studies was conducted in a single-center facility as a QI project. The sample sizes ranged from 32 to 173 infants in the pre-protocol cohorts, and from 17 to 1,091 infants in the post-protocol cohorts. Several studies demonstrated statistically significant improvements in outcome measures including admission temperature, serum glucose concentration, IVH, ROP, LOS and mean arterial blood pressure. Although several of the studies with smaller sample sizes were limited in their ability to demonstrate statistical significance in outcome differences between pre- and post-protocol cohorts, most revealed improving trends in the outcome measures evaluated.

Temperature.

Six of the studies reviewed reported outcomes related to temperature and revealed improvements in infants' temperatures. Four of the studies demonstrated statistically significant results. Reynolds et al. (2009) report a statistically significant improvement in mean admission temperatures (36.68 ± 0.65 degrees Celsius versus 36.04 ± 0.81 ; $p = 0.0001$) in the seven years following implementation of a GH protocol and a revision of that protocol. Wallingford et al. (2012) also demonstrated improvement in admission temperatures to within a "euthermic range" (31.1% versus 10.8%) as reported in the VON data for their institution over a 2-year period following initiation of a GH protocol. However, no statistical analysis of the data was provided. Similarly, Vergales et al. (2015) demonstrated improvement in admission temperatures to within a "euthermic range" (71.3% versus 54.8%; $p = 0.056$). Statistically significant improvements in admission temperatures were presented by Ashmeade et al. (2016); $\geq 97.6^{\circ}\text{F}$ in the post-GH protocol group (57%) versus the pre-protocol group (40%); ($p = 0.005$). Castrodale and Rinehart (2014) also reported statistically significant improvements in admission temperatures falling within goal range after implementation of a GH protocol (49.6% versus 28%; $p = 0.002$). Lambeth, Rojas, Holmes and Dail (2016) reported a slight increase in their mean admission temperatures initially after implementation of the GH protocol and although the mean returned to baseline as the project progressed, they reported less variability around that mean.

Glucose.

Castrodale and Rinehart (2014) provide the only statistical analysis in this review on serum glucose concentration. They report improvements in achieving admission glucoses greater than 50mg/dL following implementation of a GH protocol (72.3% versus 55.7%; $p = 0.012$).

Although Lambeth, Rojas, Holmes and Dail (2016) discuss glycemic control, they simply report stable glucose concentrations throughout their QI project without statistical analysis.

Intraventricular hemorrhage.

Three of the studies report outcomes related to IVH. All three studies described improving trends in the incidence of IVH; however, only one of the studies reached statistical significance. A statistically significant improvement in the number of infants who developed IVH following implementation of a GH protocol (18% versus 46%; $p = 0.03$) was demonstrated by Reuter, Messier and Steven (2014). Vergales et al. (2015) were able to show a decreasing trend in the incidence of grade 3 or 4 IVH (10.6% versus 13%; $p = 0.42$); however, it did not reach statistical significance. Ashmeade et al. (2016) also demonstrated a decreasing trend in the rates of IVH (13% versus 21%; $p = 0.477$).

Chronic lung disease.

CLD is reported as an outcome measure in only three of the seven studies in the review and the results were mixed. Ashmeade et al. (2016) demonstrated an improving trend in the incidence of CLD (24% versus 35%; $p = 0.06$). After adjustment for baseline variables the odds ratio demonstrated a statistically significant reduction (64%) in the odds of developing CLD (OR = 0.36; 95% CI [0.17-0.74]; $p = 0.005$). Improving trends in the incidence of CLD were revealed in the data from the VON database for one institution over a 2-year period following initiation of a GH protocol (31.1% versus 52.5%); however, no statistical analysis of the data was provided (Wallingford et al., 2012). The incidence of CLD was unchanged for the unit in the study by Vergales et al. (2015).

Retinopathy of prematurity.

Only one study included ROP as an outcome measure. Ashmeade et al. (2016) reported an improving trend in the incidence of ROP (13% versus 63%; $p = 0.097$). In addition, following adjustment for baseline variables, the odds ratios demonstrated a 48% reduction in the odds of developing ROP (OR = 0.52; 95% CI [0.28-0.98]; $p = 0.043$).

Additional themes.

Vergales et al. (2015) reported on the outcome measures of mean arterial pressure as an indicator of stability and LOS. In this study, arterial blood pressure demonstrated greater stability, defined as a mean \geq gestational age, in the post-GH protocol implementation group (76% versus 57%; $p = 0.02$). Neonatal LOS was also significantly decreased for infants in the post-protocol group, with discharge home occurring at a lower mean postmenstrual age; 39 weeks' gestation versus 40 weeks' gestation ($p = 0.04$).

Summary

There are only a few published studies on outcomes following implementation of a GH protocol in the NICU. Based on the findings in the seven studies that were reviewed, it is suggested that implementation of a GH protocol to guide application of evidence-based practices positively influences both short- and long-term outcomes in neonatal intensive care. Application to the population of interest, premature, low birth weight infants is clearly supported by the inclusion criteria of the studies reviewed.

The effect across the studies is strong. Six out of the seven studies reported admission temperature as a short-term outcome measure and all of these studies described improvements in temperatures to within goal range following implementation of a GH protocol (Ashmeade, 2014; Castrodale & Rinehart, 2014; Lambeth, Rojas, Holmes, & Dail, 2016; Reynolds et al., 2009;

Vergales et al., 2015; Wallingford, Rubarth, Abbott, & Miers, 2012). Improvement in temperatures to within a eutermic range has substantial implications for the premature, low birth weight infant as numerous studies have demonstrated hypothermia to be associated with hypoglycemia, hypoxemia, metabolic acidosis, increased incidence of CLD, late-onset sepsis and IVH as well as increased rates of mortality (Laptook & Watkinson, 2008; Miller, Lee, & Gould, 2011).

Although long-term outcomes were not reported in a consistent manner across the studies, those that were reported suggested tendencies towards improvements in the incidence of IVH, ROP and CLD following implementation of a GH protocol (Ashmeade et al., 2016; Reuter, Messier & Steven, 2014; Vergales et al., 2015; Wallingford et al., 2012). These morbidities are predictors of neurodevelopmental and sensorial disabilities for premature, low birth weight infants including epilepsy, cerebral palsy, cognitive delay and visual impairment (Glass et al., 2015). Any improvement in the incidence of morbidities such as these has the potential for a positive effect not only by reducing the need for associated diagnostic, therapeutic and surgical interventions but also by reducing the length of stay, risk for re-hospitalization and improving long-term neurodevelopmental outcomes (Horbar, 2012). Additional studies with consistent analysis of long-term outcome measures across multiple centers would provide greater insight into the impact of GH protocols on long-term morbidities and neurodevelopmental outcomes.

Furthermore, the inclusion criteria of the studies relating to gestational age varied from < 33 weeks' gestation to < 27 weeks' gestation across the studies reviewed and inclusion criteria relating to birth weight was either not evaluated or varied from < 1500 grams to < 1000 grams. Breakdown of outcomes across birth weight and gestational age would allow for evaluation and

comparison of the impact of GH protocols on defined subgroups of premature, low birth weight infants such as the VLBW (< 1500 grams) and ELBW (< 1000 grams) populations.

Theoretical Framework

The Donabedian Model, a theory which focuses on evaluating the quality of healthcare, provides a framework for this QI project. This structure-process-outcomes framework for assessing quality in healthcare is the work of Avedis Donabedian, a physician from Beirut, Lebanon with a master's degree in public health from Harvard University (Anderson, 2015). The model Dr. Donabedian presents in his writings is both descriptive, identifying the components of quality assessment, and prescriptive in that it guides QI endeavors. In his initial work in 1966 Dr. Donabedian concentrated on the quality of medical care, specifically at the level of patient-physician interactions (Donabedian, 2005). A review of Dr. Donabedian's writings reveals that he began to focus on quality assessment of nursing care in the late 60s and over the following 30 years his writings encompassed quality assessment in all aspects of healthcare from epidemiology to informational technology.

According to the Donabedian Model, the major components of measuring and improving quality in healthcare are structure, process and outcomes (Berwick & Fox, 2016). Structure refers to the environment in which services are provided and could include the facility, equipment, qualifications of the staff or the administrative structure (Anderson, 2015; Ayanian & Markel, 2016). In the NICU, critical structure features include the physical space; for instance, some hospitals have a neonatal stabilization room in the labor and delivery unit (L&D) while others move the infant directly into their bed space in the NICU following delivery. Critical structures in the NICU would also include equipment such as the radiant warmer, isolette, ventilator, etc. as

well as various care providers: neonatologists, neonatal nurse practitioners, neonatal fellows, neonatal nurses, and respiratory therapists.

Process involves the series of steps and actions by which medical care is provided to the patient (Ayanian & Markel, 2016). For the GH project, the process begins with preparing for the delivery of the infant, in the NICU and in L&D once the team has received notification of an impending birth. Following the infant's delivery, the process continues with resuscitation and stabilization through completion of the admission and initiation of an environment of minimal stimulation. The goal for the GH project is to have all these processes completed within the first hour of life.

Outcomes are the measurable phenomenon that allow for QI and ongoing monitoring (Ayanian & Markel, 2016; Donabedian, 1981). For premature, low birth weight infants, survival without neurologic impairment is one of the most important outcome measures. The GH project uses several short-term outcome measures, including admission temperature, serum glucose concentration, and calculation of length of time to various short-term goals, as a means for ongoing monitoring and evaluation of QI. The goal of this Doctorate of Nursing Practice (DNP) project is to also evaluate long-term outcome measures related to IVH, CLD, ROP, and LOS following implementation of a GH protocol. These long-term outcome measures directly affect the likelihood of survival without neurologic impairment.

The Donabedian Model has been used by healthcare organizations for a wide range of QI endeavors; as a tool to shift organizational culture and nursing engagement while working toward magnet designation, as a framework for bariatric surgery accreditation and as a method for evaluating safety and quality in trauma care (Moore, Lavoie, Bourgeois, & Lapointe, 2015; Naranjo & Kaimal, 2011; Upenieks & Abelew, 2006). As a theoretical framework for quality

assurance and QI, the Donabedian Model has strong applicability to the GH project, which is focused on assessing structure in the NICU and altering the processes surrounding care during delivery and admission of extremely premature, ELBW infants in order to improve outcomes in neonatal intensive care.

Purpose of Project

The goals for the QI project were to design and implement a systematic, evidence-based approach to the care of extremely premature, ELBW infants within the first hour of life and to increase the consistency and efficiency of care in an effort to improve both short- and long-term outcomes for this population in the study unit. The purpose of the DNP project is to describe the QI project in the study unit and the process of its implementation and to present statistical analysis of outcome measures over the first three years following project implementation.

For the purposes of this project, short-term outcome measures are those obtained and recorded during the first hour of life: admission temperature, serum glucose concentration, and those measurements related to efficiency of care such as time from birth to initiation of IV fluids and nutrition, antibiotic administration, central line placement, and completion of GH care. Long-term outcome measures include the incidence of morbidities such as IVH, CLD, ROP and evaluation of the effect on LOS and mortality.

Methods

The GH QI project was a unit-specific QI project. It utilized a retrospective prospective study design for comparison of baseline data from a pre-GH protocol implementation cohort with data from a post-GH implementation cohort. Retrospective baseline data were collected from the electronic medical record (EMR) for all inborn infants < 27 weeks' gestation from January, 2012 through February, 2014. Prospective data collection began with implementation of the GH

protocol in April, 2014 and continued through March, 2017. For ongoing evaluation of the effectiveness of interventions, plan-do-study-act (PDSA) cycles were used in accordance with the study unit's institutional use of Lean Six Sigma methodology for QI. Changes in interventions over two PDSA cycles; Phase I and Phase II were compared with the baseline or pre-GH protocol data (Figure 2).

Setting

The study unit is a 58-bed level IV NICU in a teaching hospital. During the day there are usually three neonatologists, four neonatal nurse practitioners, and two neonatal fellows on service, any combination of which attend the deliveries of extremely premature, ELBW infants with residents and nurse practitioner students in the role of observing learners. At night, one fellow and one nurse practitioner provide delivery coverage with the support of a senior resident and the on-call neonatologist.

Population and Study Sample

The study population was defined as all inborn infants < 27 weeks' gestation who survived initial resuscitation in the delivery room and were admitted to the NICU. Approximately 40-50 infants per year meet this criteria in the study unit. As a QI project, all infants meeting these criteria were provided the same care.

Ethical Considerations

In accordance with ethics and human subject permissions, IRB exemption was obtained from the Institutional Review Board of the University of North Carolina at Chapel Hill.

Project Implementation

An interdisciplinary team of neonatal intensive care providers assembled in November, 2012, for biennial updating of the unit's guidelines for the care of extremely premature, ELBW

infants, determined a need for further standardization of care practices to improve unit outcomes. A GH protocol was designed in order to achieve a consistent, sequential approach to implementation of the unit's evidence-based clinical guidelines during the first hour of life. The existing unit guidelines were updated prior to implementation and with each subsequent phase of the project. The project phases correspond with specific changes in GH QI interventions (Figure 2). These changes were determined by PDSA cycles, during which trends in short-term outcomes, stakeholder feedback, and the availability of new products and new evidence-based interventions were all taken into consideration. Interdisciplinary education and reinforcement were provided with each phase to promote implementation and sustainability. Data analysis and the interpretation of study results were reported in light of these project phases.

Key Personnel and Stakeholders

Key personnel for the GH project encompassed a wide range of interdisciplinary team members responsible for the success of each infant's GH. These personnel included physicians, nurse practitioners, nurses, respiratory therapists, and ancillary staff in the NICU, as well as the departments of pediatric pharmacy and radiology. The stakeholders in the project encompass not only the key personnel but also nursing leadership, hospital administration, department of pediatrics and division of neonatology faculty members, as well as the infants' families.

Barriers to Implementation and Sustainability

The main barrier to implementation and sustainability anticipated prior to beginning the study was acceptance and support of the project from the key personnel. The initial step in addressing this barrier was dissemination of the problem. A series of presentations outlining the study unit's suboptimal short-term outcomes and the QI goals of the project were made to groups of physicians and nurse practitioners, the nursing staff, and respiratory therapists.

The next step was to include representatives from all the interdisciplinary groups of key personnel in the project planning. The unit's GH QI team was initially comprised of two nurse practitioners and an attending physician. The team added additional nurse practitioners, a neonatal fellow, several staff nurses, members of nursing leadership, and a respiratory therapist to ensure full investment of key personnel in the project.

Resources and budget

Prior to the initiation of the project, the team anticipated the need for allocation of additional non-clinical staff time for project presentations, teaching and leading team meetings. As a result of previously ensuring full investment of key stakeholders from the division of neonatology, the GH QI team was able to have this time provided to key personnel as needed to support the success of the project in the study unit.

The need for new equipment and supplies including shorter peripheral intravenous (PIV) catheters, supply kits, chemical thermal mattresses, polyethylene thermoregulation suits, respiratory devices, etc. was also anticipated. Nursing leadership presented the team's requests for new products during budget meetings. If money was approved for the product, that particular intervention could be implemented; otherwise, less expensive alternatives were explored.

During the second phase of the project, the QI team was able to draw on a concurrent hospital-wide QI initiative to assist in meeting GH goals. This project was related to early detection and treatment for patients at risk for sepsis. The shared goals of both initiatives were to improve the expediency of obtaining antibiotics and radiographic confirmation of central line placement from the pediatric pharmacy and radiology departments.

Preparation of Equipment and Supplies

Planning during the first phase of the QI project was focused on establishing a culture of advanced preparation for GH deliveries and admissions. The nurses kept a cleaned and stocked isolette reserved for extremely premature, ELBW admissions available at all times. Upon notification of an imminent delivery, all necessary equipment in the delivery room and in the unit was set up in advance. The respiratory therapist set up a ventilator and bubble continuous positive airway pressure (CPAP) at the assigned admission bed space. The previously prepared isolette was moved into the bed space and warmed at this time. Nurse practitioners gathered the necessary items for umbilical line insertion, placed them on the procedure cart, and moved the cart adjacent to the admission bed space. The admitting nurses obtained IV pumps, warmed the IV fluids and then primed all IV tubing. In addition, “stork-kits” were placed within easy reach for delivery attendance. These kits contained items specific to the resuscitation and care of extremely premature, ELBW infants and were created to ensure easy access to necessary tools in the delivery room.

Respiratory management

All infants in the study unit were resuscitated according to The Neonatal Resuscitation Program (NRP) guidelines. Prior to implementation of the GH protocol a respiratory management plan was devised based on the available literature and taking into consideration the infant’s gestational age and their risk factors for respiratory instability. Immediate intubation with prophylactic surfactant administration was performed for infants < 25 weeks’ gestation. Based on assessment of risk factors for infants 25 weeks’ gestation, the provider chose between in-and-out surfactant administration (defined as intubating, administering surfactant and immediately extubating) with transition to CPAP or immediate application of CPAP for

respiratory support. The plan for all infants 26 weeks' gestation or greater was immediate application of CPAP for respiratory support, with a low threshold to administer in-and-out surfactant. Intubation was provided for infants of any gestational age requiring prolonged positive pressure ventilation per NRP guidelines. Early extubation to bubble CPAP was encouraged for infants who required intubation during the GH.

During the second phase of the project, several new interventions were implemented related to establishing and maintaining respiratory stability. In the delivery room, attendance of a respiratory therapist and availability of surfactant at every extremely premature, ELBW delivery regardless of gestational age was made mandatory. This ensured surfactant could be administered immediately to all infants who required intubation. It also meant there was a provider dedicated to assisting with securing the airway who could take over management of the airway once the airway had been secured.

The 7th edition NRP guidelines were published during Phase II of the project (Weiner, Zaichkin, & Kattwinkel, 2016). This resulted in changes for resuscitation and respiratory management of extremely premature, ELBW infants. The use of cardiorespiratory monitoring leads became standard in the delivery room instead of sole reliance on pulse oximetry monitoring. Prior to this edition of NRP, supplemental oxygen administration had been routinely initiated at 30% for premature infants requiring positive pressure ventilation (PPV) or CPAP during resuscitation in the study unit. After the release of the new edition, positive pressure was provided with an initial supplemental oxygen concentration of 21%. The unit previously used 30%. In addition, the pressure used to initiate positive end expiratory pressure was increased from 5cm to 6cm for infants requiring PPV or CPAP.

Two pharmacological therapies, vitamin A and caffeine, are known to reduce the risk of CLD and improve outcomes in premature, LBW infants (Darlow, Graham, & Rojas-Reyes, 2016; Schmidt et al., 2006). These medications had been used routinely in the study unit prior to implementation of the GH, although vitamin A was periodically unavailable during the study due to national shortages. Although they were routinely used, there were some inconsistencies with their ordering and timing of use. In an effort to improve consistency with use and further reduce the incidence and severity of CLD in the study unit, the last respiratory interventions implemented during this phase were immediate initiation of both caffeine and vitamin A therapy on admission. Both medications became standard parts of the admission orders for extremely premature, ELBW infants in the study unit.

Thermoregulation

Hypothermia in the first few minutes of life has a substantial impact on the extremely premature, ELBW infant's stability. Their body temperatures can fall as quickly as 0.5-1 degree Celsius per minute following delivery resulting in cold stress which rapidly leads to decreased cardiac output, hypotension, and metabolic acidosis (Bissinger, 2014). Literature suggests that admission temperature is inversely related to mortality with a 28% increase in the risk for mortality with each decrease in admission temperature by one degree Celsius (Laptook, Salhab, Bhaskar, & the Neonatal Research Network, 2007).

One of the goals of the GH is to maintain euthermia throughout the admission and stabilization process, from birth to closure of the isolette and initiation of humidity. To minimize heat loss and maintain goal admission temperatures between 36.5-37.5 degrees Celsius several interventions were implemented with the first phase of the GH protocol. In the delivery room, the temperature was increased to 74-76 degrees Fahrenheit upon arrival of the NICU team to

decrease convective heat loss. The radiant warmer and all supplies were preheated to reduce conductive heat loss. Following delivery, during the initial phase of the project, the infant was placed on a chemical warming mattress under radiant heat and covered with a clear, plastic wrap to minimize radiant and evaporative losses. Radiant heat and plastic wrap had been used at baseline for infants in the pre-protocol cohort. With implementation of the GH protocol the technique used for wrapping the infant in plastic was changed due to observations that it was difficult to keep the plastic in contact with the infant during resuscitation. One corner of the plastic wrap was folded over the infant's head and a stocking knit cap was placed over the plastic wrap. This technique was used as plastic covering is more effective at preventing heat loss than our previous use of the stocking knit cap alone (Trevisanuto et al., 2010). Use of chemical warming mattresses beginning in the delivery room and continuing through central line placement was also implemented during Phase I and continued through Phase II.

During Phase II of the project, the plastic wrap and stocking cap were replaced by a polyethylene, heat loss prevention suit with an adjustable hood. The suit closed vertically along the infant's midline with a Velcro fastener that allowed for easy exit of monitoring device cords and IV catheters. The Velcro could be opened for line placement without removing the infant from the polyethylene covering and thus avoided loss of heat during central line placement and radiographic confirmation.

In the NICU, further heat loss prevention measures were employed. The isolette and its contents were warmed prior to the infant's arrival. All IV fluids including flushes were also pre-warmed. In addition, cuffs were placed on the isolette ports for the first 72 hours of life to minimize heat loss with opening of ports for infant care.

Fluid, Electrolyte, and Nutritional Management

At delivery, infants are disconnected from placental circulation and therefore, their source of nutrition is interrupted. Extremely premature, ELBW infants quickly become hypoglycemic and within hours begin to develop a negative nitrogen balance and enter a catabolic state. Therefore, initiation of glucose and protein administration during the first hours of life are essential components of the GH (Taylor, Kiger, Finch, & Bizal, 2010). To this end, with implementation of the GH, peripheral IV access was to be established in the delivery room during stabilization with a maximum of two attempts. If not obtained in the delivery room, peripheral IV access was established on admission to the NICU. Upon admission, a 10% dextrose infusion was initiated at 60 mL/kg/day to provide a continuous glucose infusion rate (GIR) while central access was being established. Umbilical arterial and venous catheters were inserted immediately after admission. Following radiographic confirmation of central placement, the 10% dextrose infusion was replaced with a 10% dextrose, 2.5% amino acid solution via the venous catheter and a 3.6% isotonic amino acid solution via the arterial catheter for a total fluid goal of 80 mL/kg/day. In the study unit, fluids infusing through a peripheral line cannot be subsequently primed and infused through a central line. The plain dextrose solution was used peripherally and then replaced with the dextrose and amino acid solution centrally. This allowed for the provision of a continuous, stable GIR after delivery and the early initiation of protein without wasting an entire bag of the costly dextrose and amino acid solution to provide the GIR until central access could be confirmed.

Intravascular Access and Cardiovascular Stability

Establishing IV access was made a priority for the study unit's GH. This goal was vital to accomplishing most of the other goals of the GH including preventing hypoglycemia, providing

early administration of nutrition, monitoring central blood pressure, and effectively treating potential sepsis. First peripheral and then central access were established. The GH QI team collaborated with the radiology department to expedite obtaining radiographic confirmation of central umbilical line placement. A designated order was created in the EMR “XR Neonate Umbilical Line Placement” to be placed immediately on admission. This would alert the radiology technician to the imminent need for an x-ray. Once the provider was suturing the umbilical lines in place, a page was sent to the radiology technician’s STAT pager that the infant was ready for the x-ray to be performed.

Establishing arterial access permitted central blood pressure monitoring to be initiated within the first hour of life which was vital for determination of the infant’s cardiovascular stability. One other GH QI study, Vergales et al. (2015), reported mean arterial blood pressure as an outcome measure and found improved hemodynamic stability in the post-GH protocol implementation group. Although our study did not report data on arterial blood pressure, we did utilize an evidence-based, unit-specific guideline for the management of hypotension in the extremely premature, ELBW infant.

Concurrently with Phase I of the GH QI project, delayed cord clamping was implemented for the study population. This practice is aimed at reducing some of the same long-term morbidities as the GH. Delayed cord clamping is associated with a reduction in the incidence of IVH and the need for early red blood cell transfusions and may also reduce LOS (Chiruvolu et al., 2015; Mercer, et al., 2006).

Infection Control

Most extremely premature, ELBW infants are at high risk for sepsis. This is a result of the same indications for which they were delivered prematurely and due to the complications

associated with prematurity. When indicated, antibiotics were ordered on admission to NICU. All admission lab work including the blood culture was sent to the lab as soon as arterial blood return was obtained during central line placement. Once the blood culture had been obtained, antibiotics could be administered through the PIV even before central line placement had been completed and confirmed. As previously discussed, during Phase II of the project, a separate hospital wide QI project aimed at improving the initial response to pediatric sepsis allowed for improved expediency of delivery of the antibiotics to the infant's bedside.

Efficiency

Efficiency is the fundamental theme of any GH protocol and supports each of the goals previously discussed. According to Merriam-Webster, the focus of the word efficient is on how little is wasted or lost in the process of achieving the desired results (Efficient, *n.d.*). Efficiency within the GH refers to the capacity to achieve completion of the protocol goals without wasting precious minutes of the infant's first hour of life and risking compromises in stability that lead to long-term morbidity and mortality. The GH interventions previously described were implemented to improve efficiency towards achieving the essential GH goals. Below are a few efficiencies which were implemented to improve staff productivity in support of the GH goals.

Phase I of the project was designed to coincide with hospital-wide implementation of a new EMR. Within the new EMR the GH QI team was able to customize a new set of orders specifically for the admission of extremely premature, ELBW infants. This "order-set" allowed the team to standardize care and minimize inter-provider variance in orders and ensured ongoing compliance. During Phase II, a shorter, "STAT order-set" was added to the EMR separately so that the most urgent orders could be signed first before starting the longer set of full admission orders.

A set of documents were added to the hospital intranet with the other unit guidelines which could be easily accessed and referenced or printed for use during the GH. These documents included the GH Algorithm (Figure 3), a nursing-specific worksheet for the GH admission process in the unit, a GH role assignments document with provider-specific assigned tasks (Figure 3), simulation training resources based on gestational age, role assignment cue cards for simulation training (Figure 4), a map of recommended positioning during delivery room resuscitation based on role assignments for simulation training (Figure 5) and a resource on management of hypotension in the extremely premature, ELBW infant.

Effective Teamwork and Communication

Consistent application of effective teamwork and communication throughout the GH process is essential to achieving efficiency. Interventions aimed at effective teamwork and communication began with extensive education and training of staff prior to the initial implementation of the GH QI project. This included instructional presentations for nurse practitioners and physicians, presentations at nursing staff meetings with hands on demonstration of various protocol techniques, and presentations at respiratory therapy meetings. Golden Hour training was also incorporated into the required yearly competencies for the unit nursing staff the month of initial project implementation. Only “stork nurses,” nurses who had passed in-depth training and attended a specified number of deliveries with another “stork nurse,” attended the deliveries of extremely premature, ELBW infants.

Phase II began with a Lean Six Sigma “Purple Belt” project.” The study institution combines Lean, a method for minimizing waste without sacrificing productivity, with Six Sigma, a method for process improvement, into a single methodology for healthcare QI. According to the study institution, Lean focuses on speed, elimination of waste, standardization, and flexibility or

responsiveness while Six Sigma seeks to determine root causes of performance and eliminate variation (UNC School of Medicine, 2015). “Purple Belt” projects focus on the Lean aspect of QI and utilize a technique called “value stream mapping,” a process of diagramming the people, resources, activities, and information required to deliver a product or service (Schweikhart & Dembe, 2009). “Value stream mapping” is used to identify ways to reduce waste and improve efficiency (Schweikhart & Dembe, 2009). This particular “Purple Belt” project revealed significant room for improvement with teamwork and communication in order facilitate more efficient care. One of the most important means of accomplishing this goal was the development of a process algorithm, the ELBW GH Algorithm, to guide team members through the steps of the GH (Figure 3). The document served as a reference and a tool for QI data collection.

Based on the results of the “Purple Belt” project, changes were made to the allocation of providers during the GH. An additional experienced nurse was added to the team, so that two “stork nurses” attended the delivery and stayed at the bedside to assist the admitting nurse until completion of the GH. Instead of one provider performing the role of establishing the airway as well as leading the entire team, two experienced providers, physicians or nurse practitioners, were to attend each delivery and divide the two roles. A designated team leader was responsible for communicating with the family, the obstetrical team, and supervising the resuscitation. The goal of designating a team leader was to avoid the tunnel vision that can occur for the provider who is attempting to establish the airway in a high stress situation. At this time, the expectation was set that all providers in these roles be experienced with resuscitation and stabilization of extremely premature, ELBW infants. Providers, nurses, and respiratory therapist learners were to remain in the role of observer only. This was particularly emphasized for the providers who were responsible for intubating and inserting umbilical lines.

As suggested by Vergales et al. (2015) each team member was assigned specific tasks and positions around the radiant warmer in the delivery room to improve team dynamics and communication during the resuscitation (Figures 5, 6). To support staff education, interprofessional teamwork, and communication, simulation training was incorporated to help solidify these roles and responsibilities. During actual resuscitations of extremely premature, ELBW infants video recording without patient identification was utilized. This provided another means of evaluation for ongoing QI efforts and provided a tool for debriefing and staff training purposes. The recordings were erased following evaluation per established legal guidelines. A day of high-fidelity training was held on a quarterly basis for the team members who happened to be in the unit at that time. In addition, the study unit implemented abbreviated, just-in-time GH delivery training simulations to be held any time an infant < 27 weeks' gestation was to imminently deliver. For these sessions, the members of the team assigned to the potential delivery for that day met and assigned roles, responsibilities, and position around the radiant warmer. Simulation cue cards were used to remind each team member of their tasks and positions (Figures 4, 5). First, the specific circumstances related to that particular delivery were established. The assigned team discussed the indications for delivery, mode and location of delivery, whether the infant had received antenatal steroids, the presence of fetal anomalies and any other complicating factors. Then the team leader, and second provider made a preliminary determination about whether or not to immediately intubate for those infants who were 25 weeks' gestation (based on the previously discussed risk factors). After establishing the likely scenario, the team performed a quick, just-in-time simulation of the delivery.

Ongoing communication and support from nursing management and nursing peer project champions was helpful in maintaining nursing interest in project success and sustainability

throughout the phases. The author, who was also the primary investigator (PI), gave project updates and compliance reminders at physician and nurse practitioner staff meetings. In addition, the PI regularly spoke to or sent email reminders to the team members involved in a study delivery who did not fill out and submit the data collection sheet.

Study of the Interventions

Interventions were evaluated as a component of the PDSA cycle. The short-term outcomes and trends in data following interventions were studied in combination with feedback from key personnel and stakeholders. Assessment of multiple process measures including time to achieving various GH goals provided a way to determine the overall effect of interventions on short-term outcomes and identify the processes that were unsuccessful and required change.

Measures

The study sample was described using the information in Table 4. Short- and long-term study outcome measures are listed below. The definition of each measure is provided along with the rationale for choosing it, the validity and reliability of the method of measurement, and the plan for analysis.

Short-term

Temperature.

Measurement of the infant's axillary temperature was recorded in degrees Celsius in the EMR on admission to the NICU. This provided a relatively accurate and reliable measurement of the success of interventions aimed at maintaining thermoregulation. Temperatures outside the goal range (36.5-37.5°C) were evaluated using control charts and by calculation of the percent of study patients with abnormal temperatures.

Glucose.

Measurement of the infant's serum glucose concentration was performed using either point-of-care or laboratory testing. This value was reported in milligrams per deciliter (mg/dL) in the infant's EMR. Measurement of the serum glucose concentration using either method is a valid and reliable method of determining whether interventions aimed at preventing hypoglycemia are effective. Hypoglycemia in this study was defined as a glucose less than 45mg/dL. Rates of hypoglycemia were evaluated using run charts and by calculation of the percent of the sample that were hypoglycemic.

Time to completion of Golden Hour care.

Time to completion of GH care was defined by the study unit as closing the top of the isolette, initiating humidity, and providing decreased environmental stimulation to approximate the condition of the infant in the womb. The goal was to accomplish complete stabilization within the first 60 minutes of life. This is a measurement of the efficiency of the team in meeting the goals of the GH without compromising the infant's stability or wasting time. There is no dedicated location in the infant's EMR to document this time and real-time documentation on the data collection sheet was inconsistent. Therefore, time to confirmation of central access was used as a surrogate for completion of GH care as this should be the last goal achieved in the process.

The time at which central access is confirmed is consistently and reliably captured in the EMR on the x-ray time stamp. In the very few cases where a central line was not placed, a surrogate time measure was used. If use of a surrogate time measure was indicated, the time of completion of GH care was utilized if available, otherwise, the time was approximated based on the charting indicating the time to achieving all other goals of the GH. The median time to

completion of GH care in minutes with interquartile ranges was calculated for each infant in the study and this information was also analyzed using control charts.

For the purposes of this study time to IV fluid administration and antibiotic administration were collected but statistical analysis was not performed. These measures should both occur prior to confirmation of central line placement and thus evaluation is useful for root cause analysis during PDSA cycles but not necessarily as a measure of the success of the project.

Long-term

The rationale for choosing the long-term outcomes measures of IVH, CLD, ROP, and LOS is that they are all indicators both of stability in the first few weeks of life and of the potential for long-term neurodevelopmental impairment and sensorial disabilities. The need for gastrostomy tube (G-tube) placement is an indicator of the infant's lack of ability to feed safely by mouth which may be directly related to the severity of lung disease and/or the degree of neurologic impairment. Due to the rate of mortality inherent in this population, evaluation of outcomes for CLD, ROP requiring treatment, G-tube placement, and LOS were calculated either for survivors only or as combined outcomes of "long-term measure or death."

Severe intraventricular hemorrhage.

Every infant in the study unit delivered at < 27 weeks' gestation received at least one screening cranial ultrasound at 7-10 days of life. Infants who were clinically unstable may have received the screening as early as a few hours of life. These ultrasounds were interpreted by pediatric radiologists and the interpretation was attached to the imaging in the infant's EMR.

Severe IVH was defined as a reading of grade III or IV hemorrhages on the final report for the cranial ultrasound. The clinical definition of IVH leaves the diagnosis open to some degree of subjectivity. The degree of interrater reliability is significantly improved for diagnosis

of severe IVH due to the more objective criteria of ventricular dilatation and parenchymal involvement. The rates of severe IVH were evaluated by calculating the percent of the sample with a clinical diagnosis of grade III or IV IVH on cranial ultrasound.

Severe chronic lung disease.

The study unit defined severe CLD, using the diagnostic criteria of the National Institute of Child Health and Human Development; the need for supplemental oxygen of 30% or greater and or positive pressure (PPV or CPAP) at 36 weeks PMA or discharge, whichever comes first (Jobe & Bancalari, 2001). Each infant's EMR was searched and the respiratory requirements at the time of discharge for those survivors who were discharged home were documented. This is an easily reproducible means of evaluating the rate of CLD. However, it should be noted that variability exists between units regarding how CLD is treated and the infant's "oxygen requirement" is defined. The percent of infants surviving to discharge home without severe CLD and a composite outcome of the percent of infants with severe CLD or death were calculated.

Retinopathy of prematurity requiring treatment.

The study unit defined ROP requiring treatment as a degree of retinopathy, diagnosed by the pediatric ophthalmologist in the study unit, requiring treatment with either intraocular injection of bevacizumab or laser ablation. EMR confirmation of the surviving infants requiring treatment for ROP was obtained and a composite outcome of ROP requiring treatment or death was calculated. Although obtaining these results via the EMR is reliable, the validity of the diagnosis is somewhat subjective to a degree of interrater disagreement as there are several pediatric ophthalmologists who see patients in the study unit.

Gastrostomy tube placement.

The EMR was used to evaluate the number of infants surviving to discharge who required placement of a G-tube for enteral nutrition. The percent of surviving infants with a G-tube in place at discharge was calculated. This is both a reliable and a valid method of measurement.

Length of stay.

Length of stay was defined as the PMA on the day of discharge to home. The validity and reliability of LOS as an indicator of early stability and reduction in morbidity is complicated in the study unit. As the unit is a Level IV regional referral center in a tertiary care facility, many of the most stable infants in the study were transported to outlying centers with lower level intensive care nurseries closer to the infants' homes. Evaluation of PMA at discharge as opposed to the day of life at discharge is a more accurate measurement of LOS across a wide range of gestational ages in the study (22-26 weeks). The PMA at the time of discharge home were obtained from the infants' EMR and the median was calculated. These numbers excluded those infants who died or were transferred to another facility prior to discharge home.

Mortality/survival.

The percentages of infants who died prior to transfer or discharge home were calculated. In addition, as previously discussed, the percentages of infants with the composite scores of "death or ROP" and "death or CLD" were calculated.

Procedures

Prior to Phase I of the project, a handout with the goals and basic steps of the GH protocol was created with fill-in blanks which also served as a data collection sheet. Following the Six Sigma "Purple Belt" project, which marked the beginning of the second phase of the

project, a more in-depth process algorithm was created which replaced the initial handout and also served as a data collection sheet (Figure 3).

Deliveries of infants < 27 weeks' gestation and completion of the data collection sheet were tracked by the PI. Some of the QI data used for evaluation of interventions in the PDSA cycles could only be obtained in real-time. For example, the infant's temperature in the delivery room is not charted anywhere in the EMR and neither is the time of completion of GH care. All verifiable information on the data collection sheet was confirmed by the PI using the infant's EMR. If a data collection sheet had not been filled out in real-time during the GH the PI filled it out using the infant's EMR. For the purposes of this study, only outcomes based on verifiable information were presented. De-identified data were entered into a Microsoft Excel spreadsheet by the PI. Data collection sheets were then stored in a locked cabinet inside a locked office within the study unit.

Data Analysis

Statistical process control or run charts were created using QI Macros for Excel to display patterns over time in admission temperature, serum glucose concentration, and time to completion of GH care. Clinical outcomes across the three phases of the project were compared with Chi-Square or Fisher's exact for categorical data and one-way ANOVA/Kruskal-Wallis for continuous data using STATA software. Statistical significance was set at *p* values of 0.05 or less.

Results

Data were collected on all inborn infants < 27 weeks' gestation from January, 2012 through March, 2017. There were 214 extremely premature, ELBW infants in the cohort divided over the 3 phases; pre-GH protocol (*n* = 80), Phase I (*n* = 42), and Phase II (*n* = 92). Three infants < 27

weeks' gestation who survived resuscitation in the delivery room and were admitted to the NICU were excluded from Phase II due to severe congenital anomalies which resulted in death shortly after birth.

The study unit's designation as a regional referral center results in a more medically fragile patient population. Infants with complicated hospital courses and those requiring more medical intervention due to morbidities of prematurity remain in the unit. The more stable infants are transferred out to lower level nurseries closer to their homes to facilitate bonding and preparation for discharge home. This phenomenon resulted in missing data for a small portion of the sample. There was a loss of 7% of the data for CLD due to transfer out prior to 36 weeks PMA, and 4% of the data related to ROP for survivors who were transferred early was dropped.

There were no significant differences in gestational age, birth weight, sex, administration of any antenatal steroids, or delivery method (cesarean vs vaginal) across the phases (Table 3) nor were significant differences noted in resuscitation measures including 5-minute Apgar scores and surfactant administration (Table 4). Significant differences were observed in short-term outcomes between the phases. There was a significant reduction in the incidence of abnormal admission temperatures, hypoglycemia, and minutes to complete admission (Table 5). These improvements in short-term outcome measures were also illustrated by the statistical process control and run charts (Figures 8, 9, 10). Evaluation of long-term morbidity and mortality did not reveal significant differences (Table 5).

Discussion

The aim of this project was to implement a systematic, evidence-based approach to the care of extremely premature, ELBW infants within the first hour of life in order to increase the consistency and efficiency of the care provided in an effort to improve both short- and long-term

outcomes in the study unit. The primary areas of focus during the first two phases of the project were on maintaining euthermia and preventing hypoglycemia. Therefore, most of the interventions implemented during the study were aimed at improving these two short-term outcome measures for which data analysis revealed the most significant improvements. Although we did not consistently meet the goal of completion of GH care within the first 60 minutes of life, we were able to make statistically significant improvements towards this goal. Our findings were similar to the findings of the studies in the review which demonstrated improvements in temperature, glucose, and/or time to completion of the GH (Ashmeade, 2014; Castrodale & Rinehart, 2014; Lambeth, Rojas, Holmes, & Dail, 2016; Reynolds, Pilcher, Ring, Johnson, & McKinley, 2009; Vergales et al., 2015; Wallingford, Rubarth, Abbott, & Miers, 2012).

We did not find significant differences in long-term morbidity and mortality across the study phases. However, in the study unit there has been a trend, similar to trends in NICUs across the nation of providing more aggressive resuscitation to infants on the cusp of viability. As a result of this gradual change in practice our unit has experienced an increase in the rate of survival among this group of infants. Although not statistically significant, resuscitation of infants at 22-23 weeks' gestation across the phases of the project reflects this phenomenon. The percentage of infants delivered at 22-23 weeks' gestation remained stable across the first two cohorts and then almost doubled in the third cohort (16%, 16%, and 29% respectively). The box plot for gestational age displays that at the beginning of the study (pre-GH and Phase I) 75% of the babies were 24-26 weeks gestation at the time of birth (Figure 6). However, in Phase II 75% of the babies are 23-26 weeks gestation at time of birth (Figure 6). Only one infant delivered at 22 weeks' gestation in the first two cohorts of infants (pre-GH and Phase I) and there were 4 infants delivered at 22 weeks' gestation in the third cohort (Phase II).

As a slightly more vulnerable population, periviable infants born at 22 and 23 weeks gestation are less resilient and more susceptible to the negative effects of cold stress and hypoglycemia (Wyckoff, 2014). But despite this higher risk, and a higher proportion of these infants in the Phase II cohort, there were no significant differences in their long-term outcomes or in the PMA at discharge. We hypothesize that these results may indicate a positive effect of the GH protocol which may be stronger at lower gestational ages. Stratification of results by gestational age across studies could provide further insight into this effect.

An improvement in short-term outcomes corresponds to an improvement in population health for extremely premature, ELBW infants in the study unit. There is a potential for a reduction in healthcare expenditures associated with diagnostic, therapeutic and surgical interventions for complications related to hypoglycemia and hypothermia. There is also potential for a decreased burden on the healthcare system after discharge related to re-hospitalization and the provision of care for long-term morbidities if the GH does in fact offer a protective effect in this population (Behrman & Butler, 2007; Horbar, 2012). Future studies could examine costs associated with outcome measures more closely.

Strengths of the Project

One of the main strengths of the study is the focus on an extremely premature population of infants, those < 27 weeks' gestation. In contrast, some of the other studies in the review included more mature infants, up to 32 and 33 weeks' gestation (Reynolds, Pilcher, Ring, Johnson, & McKinley, 2009; Wallingford, Rubarth, Abbott, & Miers, 2012). As the project progressed, the study population included a higher percentage of even more premature infants (22 and 23 weeks gestation), related to the national trend of providing more aggressive resuscitation to infants delivered at the limits of viability. Despite this trend, our study

demonstrated results with a similar or higher level of significance and outcomes that measured tighter within goal ranges than some of the other NICUs in the review with less fragile, less premature populations.

Additionally, through the phases of the project, several tools were developed to support achievement of the GH goals. These tools included “stork kits” of materials needed for delivery room care, laminated lists of supplies needed for umbilical line placement, laminated cue cards for role assignment and positioning in the delivery room, guidelines for GH simulation training, a worksheet for nurses admitting the extremely premature, ELBW infant, and two EMR “order-sets.” Many of these resources could be easily adapted and used by other NICUs looking to implement a successful, evidence-based GH protocol.

Limitations of the Project

One limitation of the study was the potential for reduced availability of physicians and nurse practitioners for nighttime delivery attendance. Similar to most NICUs across the nation, the study unit staffs with fewer providers at night than during the day. There were always enough experienced providers at night to fill both the roles of team leader and the second provider responsible for establishing the airway. However, on the rare occasion that another emergency occurred during the GH, both providers may not have been available to attend the delivery and the role of team leader may have been unfilled. This was largely addressed by the simulation training which included role assignment for all staff attending the delivery of extremely premature, ELBW infants. As a result of all staff members being exposed to the assigned roles of each provider the team had a shared knowledge of exactly what needed to be accomplished during the GH and who was responsible for each task and procedure. Thus, they were better able

to assume and share additional responsibilities in the rare occasion the role of team leader was unfulfilled.

Although the project has an excellent design for examination of outcomes related to QI, the retrospective-prospective study design presents a limitation to traditional research design and examination of long-term outcomes. With this type of design there is poor control over the exposure variable, covariates and potential confounding factors. The retrospective/prospective cohort design and the 5-year time span of this QI project introduce the risk of historical threat to the validity of the study in regards to examination of long-term outcome measures. Changes in practice over time and other confounding variables, not related to the interventions of the GH might contribute to variations in outcomes and in some instances and could provide an alternative explanation of the study findings.

In addition, other NICUs may not have been exposed to the same changes in practice or confounding factors. Therefore, these threats to the internal validity of the study also limit the generalizability of the work. For this reason, and as a result of differences in available resources, staffing, and physical space, GH protocols are unit-specific. Although the generalizability to other units is limited, the transferability is relatively high because these protocols can be adapted and modified to fit the unique requirements of any NICU.

There were also limitations to examining long-term outcomes in this patient population for our study unit. The sample was a convenience sample of all infants admitted and since no power analysis was done it may be that the sample size was not large enough to demonstrate differences in long-term outcome measures. We also encountered a small amount of missing data related to the long-term outcomes of CLD and ROP for a few of the healthiest, most stable

infants. This was due to transfers to other facilities which complicates or prevents collection of long-term outcome measures. However, this was true across all three phases of the project.

Conclusion

Usefulness

Golden Hour protocols promote efficient care delivery and prioritize the stability of the most vulnerable population in the NICU through the first, most tenuous minutes of resuscitation and stabilization. They also provide a way to incorporate tools for building effective teamwork and communication within interdisciplinary groups in the NICU.

Suggested next steps and sustainability

Prolonged exposure to the study interventions is evidence of the sustainability of this GH protocol and of the capacity for internal monitoring of ongoing compliance. The study unit's GH QI team is already considering the next steps in sustaining the goals already achieved. Although portable radiography has been standard in the study unit for some time, the recent acquisition of a system that now allows for real-time, bedside viewing of the films may be an important avenue for continuing improvements in the time to central line confirmation and completion of GH care. Maintaining "just-in-time" simulation training and utilizing information from delivery room video recording will allow the team to continue fostering teamwork, communication, and efficiency. Furthermore, identifying additional, meaningful short-term outcome measures such as blood pressure, blood flow, serum cortisol levels, etc. might provide better indicators of the effectiveness of the GH interventions.

Potential spread to other contexts

The findings of this QI study and their consistency with the findings of the other studies in the review suggest two conclusions. (1) The simple extension of the application of an

evidence-based GH protocol is relevant to any NICU. (2) The extension of the GH protocol to include very premature, VLBW infants is beneficial.

Implications

A systematic, evidence-based approach to care of extremely premature, ELBW infants in the first hour of life resulted in improved short-term outcomes. Although significant differences in long-term outcomes were not observed in this study, the results may represent a protective effect of GH protocols as the highest risks of morbidity and mortality are associated with the most premature infants. Additional studies with larger sample sizes and consistent analysis of long-term morbidities would provide greater insight into the long-term impact of GH protocols. Stratification of results by gestational age across studies could possibly provide further understanding of any potential protective effect. Ongoing QI should focus on sustaining achieved improvements, continuing to improve time to completion of care, and seeking additional, meaningful short-term outcome measures.

Conflict of Interest and Funding

The author declared no potential conflicts of interest and received no financial support for the research or authorship related to this study and dissertation.

Table 1

Summary of the Evidence: Quality Improvement Projects to Implement a Golden Hour Protocol

Author	Design	Population	Sample	Setting	Admission Temperature	Admission Glucose	IVH	CLD	ROP	Additional
Ashmeade et al., 2014	QI project; retrospective collection of baseline data; prospective data following change in practice	Inborn infants delivered at GH < 28 weeks and/or < 1000 grams BW	Pre-protocol N = 173 Post N = 122	82-bed, Level IV NICU Tampa, FL	Improvement in admission temperatures; $\geq 97.6^{\circ}\text{F}$ 40% vs 57%; $p = 0.005$		Decreasing trend in the rates of IVH; 21% vs 13%; $p = 0.477$	Decreased odds of developing CLD by 64%; (OR = 0.36; 95% [CI] = 0.17-0.74; $p = 0.005$)	Decreased odds of developing ROP; 48% reduction (OR = 0.52; 95% [CI] = 0.28-0.98; $p = 0.043$)	
Castrodale & Rinehart, 2014	Retrospective cohort study	Inborn infants delivered at GA < 28 weeks	Pre-protocol N = 106 Post N = 119	75-bed, Level III NICU Indianapolis, IN	Improvement in admission temperatures to within goal range (36.5-37.4°C) 28% vs 49.6%; $p = 0.002$	Improvement in achieving admission glucose >50mg/dL 55.7% vs 72.3%; $p = 0.012$				
Lambeth et al., 2016	QI project; retrospective collection of baseline data; prospective data following change in practice	Inborn infants delivered at < 1500 grams BW	Pre-protocol N = 50 Post N = 105	56-bed, Level IIIB NICU Winston-Salem, NC	Increase in mean temperature from baseline (reported via control chart)	Stable glucoses; no significant improvement (reported via control chart)				
Reuter et al., 2014	Retrospective cohort study	Inborn infants delivered at GA ≤ 29 weeks or < 1000 grams BW	Pre-protocol N = 32 Post N = 40	Level III NICU Sioux Falls, SD			Decreased rates of IVH 46% vs 18%; $p = 0.03$			
Reynolds et al., 2009	QI project; retrospective collection of baseline data; prospective data following change in practice	Inborn infants delivered at GA < 32 weeks or < 1500 grams BW	Pre-protocol N = 245 Initial N = 1,091 Revised N = 103	83-bed, Level III NICU Dallas, TX	Improvement in mean admission temperatures; 36.04°C \pm 0.81 vs 36.68 \pm 0.65; $p = 0.0001$					
Vergales et al., 2016	QI project; retrospective collection of baseline data; prospective data following change in practice	Inborn infants delivered at GA < 27 weeks	Pre-protocol N = 62 Post N = 90	51-bed, Level IV NICU, Charlottesville, VA	Improvement in admission temperatures to within a defined eutermic range (36.0-37.5°C) 54.8% vs 71.3%; $p = 0.056$		Decreasing trend in incidence of grade 3 or 4 IVH 13% vs 10.6%; $p = 0.42$	No change; 69% vs 70.5%; $p = 1.0$		MAP demonstrated greater stability (MAP: mean \geq GA) 76% vs 57% $p = 0.02$ Discharge home at lower mean PMA; 40 vs 39 weeks; $p = 0.04$
Wallingford et al., 2012	QI project; retrospective collection of baseline data; prospective data following change in practice	Inborn infants delivered at GA < 33 weeks	Pre-protocol N = 32 Post N = 17	Level III NICU Omaha, NE	Improvement in admission temperatures; 10.8% vs 31.1% (per reported VON data)			Improving trends in the incidence of CLD; 52.5% vs 31.1% (per reported VON data)		

Note. Abbreviations: neonatal intensive care unit (NICU), gestational age (GA), birth weight (BW), chronic lung disease (CLD), retinopathy of prematurity (ROP), intraventricular hemorrhage (IVH), mean arterial blood pressure (MAP), length of stay (LOS)

Table 2

Quality Assessment of the Studies Included in the Review of Literature

Domain		Minimum Standard	Score						
			Ashmeade et al., 2014	Castrodale & Rinehart, 2014	Lambeth et al., 2016	Reuter et al., 2014	Reynolds et al., 2009	Vergales et al., 2016	Wallingford et al., 2012
1.	Organizational Motivation	Names or describes at least one motivation for the organization’s participation in the intervention	Met	Met	Met	Met	Met	Met	Met
2.	Intervention Rationale	Names or describes a rationale linking at least one central intervention component to intended effects	Met	Met	Met	Met	Met	Met	Met
3.	Intervention Description	Describes at least one specific change in detail including the personnel executing the intervention	Met	Met	Met	Met	Met	Met	Met
4.	Organizational Characteristics	Reports at least two organizational characteristics	Met	Met	Met	Met	Met	Met	Met
5.	Implementation	Names at least one approach used to introduce the intervention	Met	Met	Met	Met	Met	Met	Met
6.	Study Design	Names the study design	Met	Met	Met	Met	Met	Met	Met
7.	Comparator	Describes at least one key care process	Met	Met	Met	Met	Met	Met	Met
8.	Data Source	Describes the data source and defines the outcome of interest	Met	Met	Met	Met	Met	Met	Met
9.	Timing	Describes the timing of the intervention and evaluation to determine the presence of baseline data and the follow-up period after all intervention components were fully implemented	Met	Met	Met	Met	Met	Met	Met
10.	Adherence	Reports fidelity information for at least one intervention component, or describes evidence of adherence or a mechanism ensuring compliance to the intervention	Met	Met	Met	Met	Met	Met	Met
11.	Health Outcomes	Reports data on at least one health-related outcome	Met	Met	Met	Met	Met	Met	Met
12.	Organizational Readiness	Reports at least one organizational-level barrier or facilitator	Met	Met	Met	Met	Met	Met	Met
13.	Reach	Describes the proportion of all eligible units who actually participated	Met	Met	Met	Met	Met	Met	Met
14.	Sustainability	Describes the sustainability or the potential for sustainability	Met	Met	Met	Met	Met	Met	Met
15.	Spread	Describes the potential for spread, existing tools for spread, or spread attempts / largescale rollout	Met	Met	Met	Met	Met	Met	Met
16.	Limitations	Reports at least one limitation of the design / evaluation	Met	Not Met	Met	Not Met	Not Met	Met	Not Met
Total			16/16	15/16	16/16	15/16	15/16	16/16	15/16

Note. The Quality Improvement Minimum Quality Criteria Set (QI-MQCS) – Version 1.0 is from Hempel et al. (2015).

Table 3

Patient Characteristics

	Pre-protocol	Phase I	Phase II	<i>p</i> value
Characteristic	(<i>n</i> = 80)	(<i>n</i> = 42)	(<i>n</i> = 92)	
Median (25 th , 75 th)				
Gestational Age	25 (24,26)	25 (24, 26)	25 (23,26)	0.44
Birth Weight	705 (607,854)	740 (650,860)	670 (580,805)	0.13
%				
Female Sex	48%	52%	54%	0.66
Antenatal Steroids	93%	100%	96%	0.18
Delivery via C/S	66%	71%	62%	0.56

Note. Abbreviation: cesarean section (C/S). Measurements: gestational age (in weeks), birth weight (in grams), antenatal steroids (percent treated). Chi-Square or Fisher's exact for categorical data and one-way ANOVA/Kruskal/Wallis for continuous data.

Table 4

Resuscitation Demographics

	Pre-protocol	Phase I	Phase II	<i>p</i> value
Demographic	(<i>n</i> = 80)	(<i>n</i> = 42)	(<i>n</i> = 92)	
Median (25th, 75th)				
5-minute Apgar	5 (3,7)	6 (3,8)	6 (3,7)	0.556
%				
Surfactant in DR	59%	52%	55%	0.790
Surfactant by 2 hours	74%	67%	78%	0.368

Note. Abbreviations: delivery room (DR). Chi-Square or Fisher's exact for categorical data and one-way ANOVA/Kruskal/Wallis for continuous data.

Table 5

Golden Hour Quality Improvement Study Outcomes

Study Infants (<i>N</i> = 214)	Pre-protocol (<i>n</i> = 80)	Phase I (<i>n</i> = 42)	Phase II (<i>n</i> = 92)	<i>p</i> value
Abnormal Temperature	59%	26%	38%	0.001
Hypoglycemic	18%	7%	4%	0.012
Severe IVH	20%	14%	18%	0.722
Survivors without Severe CLD <i>N</i> = 156	38(58%)	19(66%)	28(45%)	0.14
Survivors without ROP treatment <i>N</i> = 162	56(84%)	27(90%)	47(72%)	0.1
Survivors with G-tube placement <i>N</i> = 148	12%	7%	17%	0.441
Death	15%	26%	25%	0.186
Death or ROP	29%	34%	47%	0.06
Death or CLD	51%	53%	67%	0.077
Median (25 th , 75 th)				
Time to completion (min)	110 (89, 138)	111 (94, 135)	92 (74,129)	0.0035
PMA (at discharge home)	40 (38,43)	41 (38,44)	41 (39,45)	0.24

Note. Abbreviations: intraventricular hemorrhage (IVH), chronic lung disease (CLD), retinopathy of prematurity (ROP), gastrostomy tube (G-tube), postmenstrual age (PMA), minutes (min). Abnormal temperature (< 36.5, >37.5). Chi-Square or Fisher's exact for categorical data and one-way ANOVA/Kruskal-Wallis for continuous data.



PRISMA 2009 Flow Diagram

For extremely premature infants, does implementation of a Golden Hour admission process improve patient outcomes in neonatal intensive care?

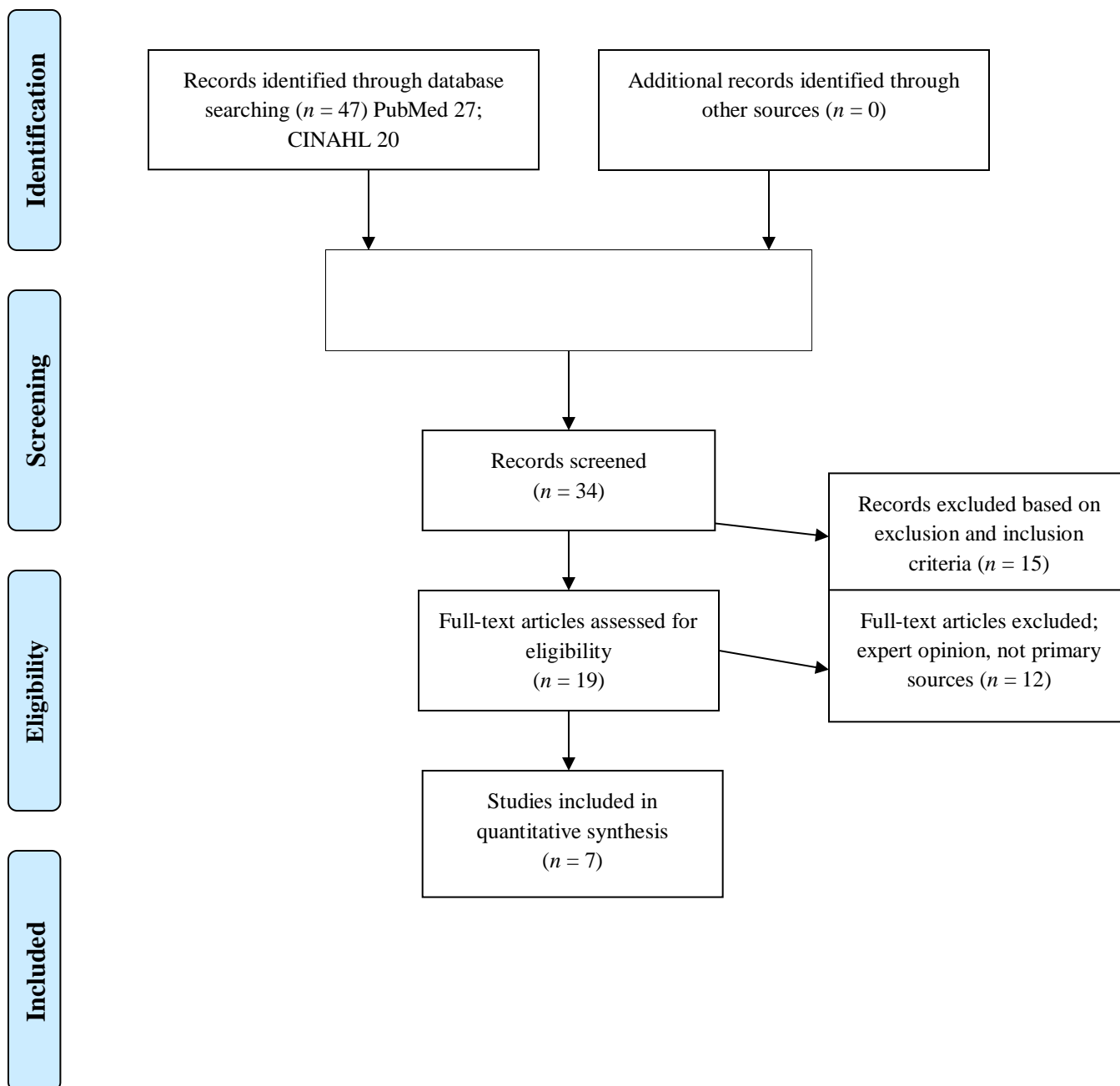


Figure 1. Search results in the format of a PRISMA flow diagram. Adapted from Moher, Liberati, Tetzlaff, & Altman, The PRISMA Group (2009).

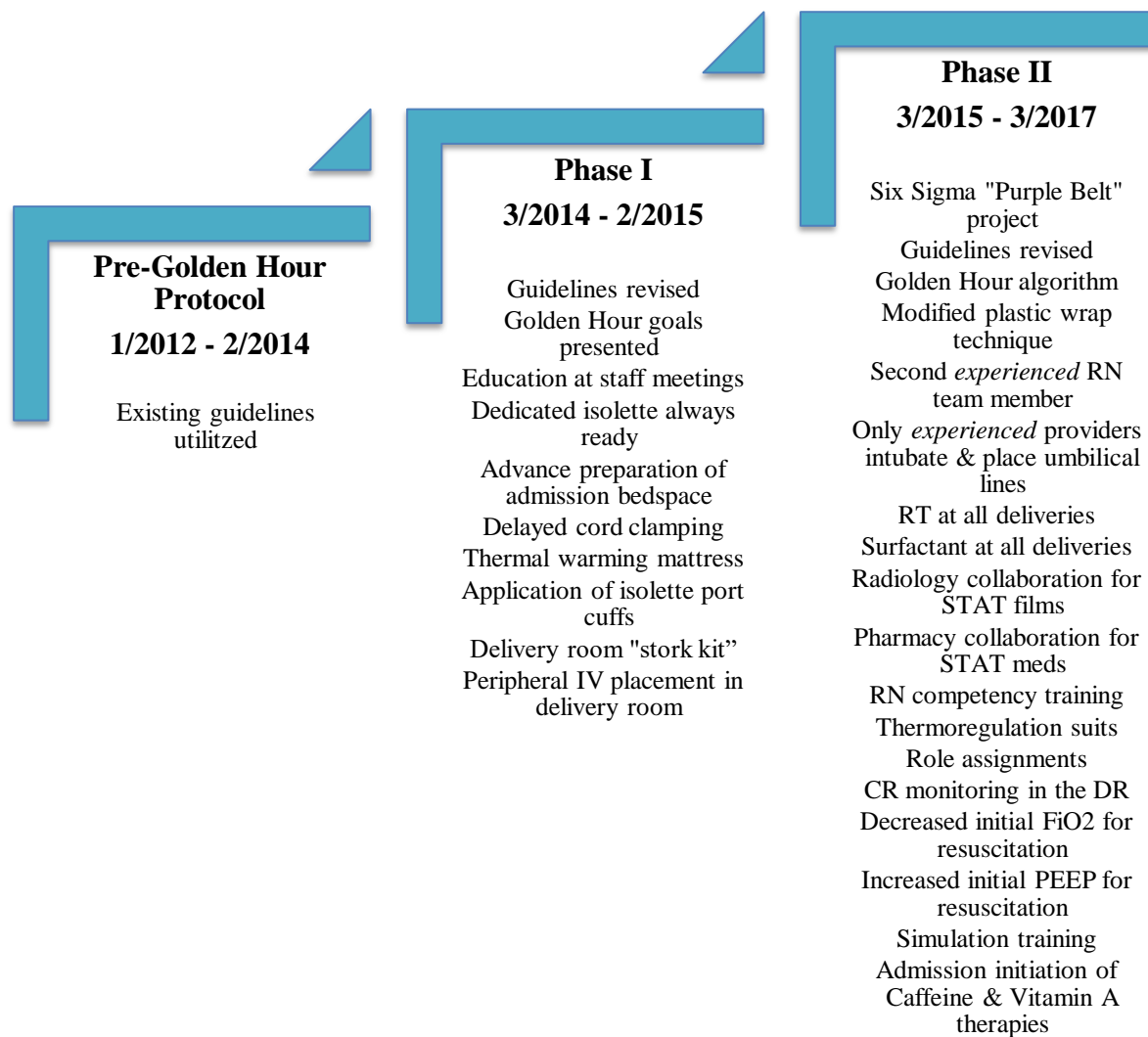


Figure 2. Golden Hour timeline of quality improvement interventions

ELBW (<27w) Golden Hour Algorithm

Place Patient Sticker Here

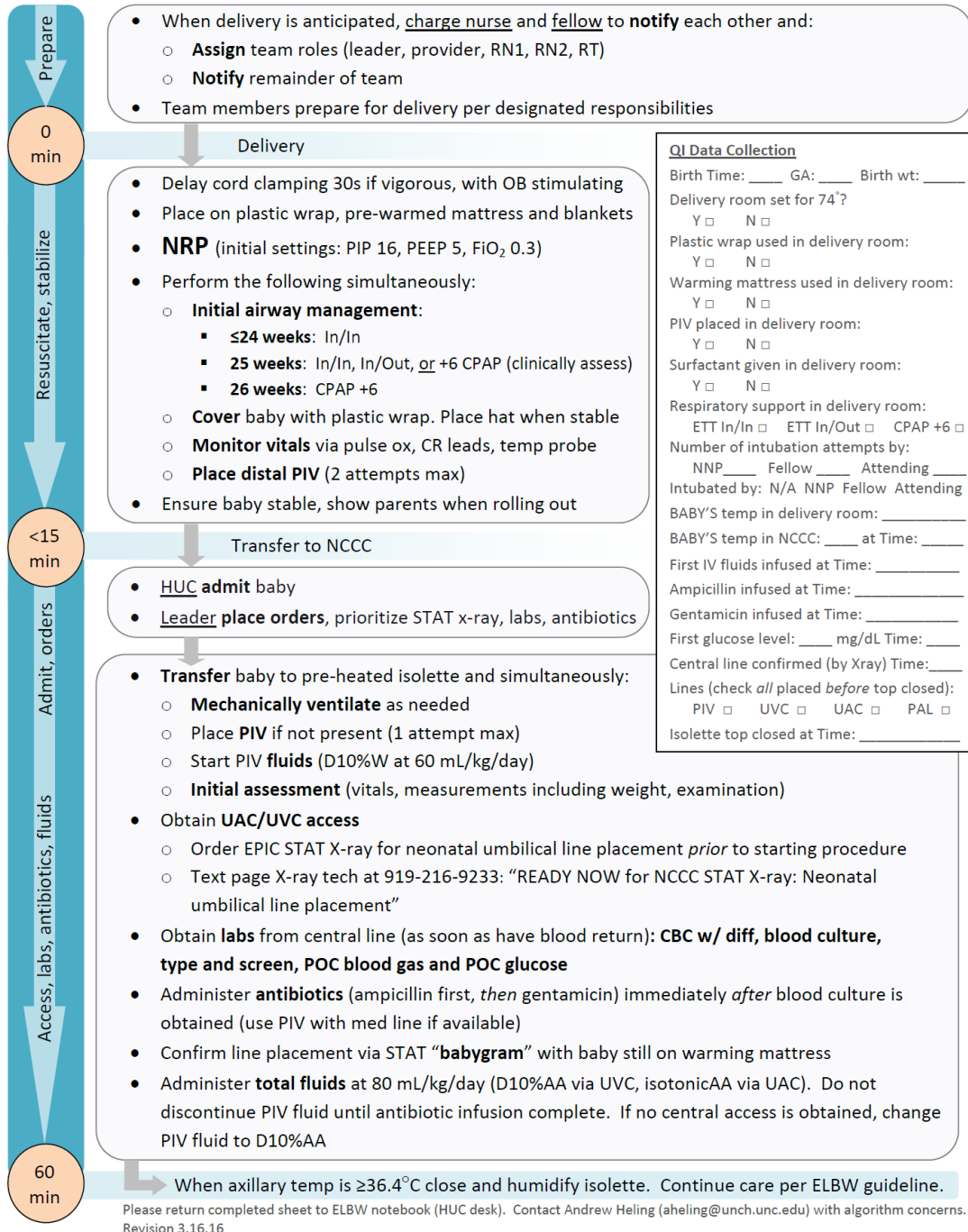


Figure 3. Golden Hour Algorithm

	Leader	Provider #2	RT	Nurse 1	Nurse 2
Pre-delivery	<ul style="list-style-type: none"> Preparation & coordination with team Discuss respiratory plan & any special considerations 	<ul style="list-style-type: none"> Set up umbilical line equipment 	<ul style="list-style-type: none"> Preparation in unit of CPAP & ventilator Bring surfactant to ALL deliveries < 27 weeks' gestation 	<ul style="list-style-type: none"> Set-up bed space including fluids 	<ul style="list-style-type: none"> Prepare and check delivery room equipment
In the DR/OR	<ul style="list-style-type: none"> Lead huddle prior to delivery "shared mental model" Encourage stimulation during delayed cord clamping Direct the team at resuscitation Back-up for intubation (switch roles) Update parents Show baby 	<ul style="list-style-type: none"> Set up camera Clear air way Provide immediate CPAP or intubation per plan Provide PPV as indicated 	<ul style="list-style-type: none"> Set oxygen at 21% Adjust oxygen Secure CPAP +6cm Maintain PEEP Place protective barrier & secure ETT if intubated Give surfactant if indicated Take over head of the bed after airway established 	<ul style="list-style-type: none"> Start/announce APGAR time Auscultation of breath sounds and heart rate Insertion of PIV Assist with lines/drugs if needed 	<ul style="list-style-type: none"> Re-check resuscitation equipment Temperature advocate Apply pulse ox & CR leads Assist with intubation if needed Measure infant's temperature
In the NCCC	<ul style="list-style-type: none"> Admitting provider performs examination (including eyes) Place STAT orders Look at x-ray/dismiss technician 	<ul style="list-style-type: none"> Admitting provider performs examination (including eyes) Line placement with assistant Adjust lines 	<ul style="list-style-type: none"> Connect to ventilator or CPAP +6cm Adjust oxygen Run POC gas and adjust ventilator per provider instructions 	<ul style="list-style-type: none"> Temperature advocate Transfer to open isolette & weigh infant Obtain measurements & admission vitals Place on monitors Connect fluid with medication line to PIV Secure infant for line placement Send STAT labs during line placement Initiate antibiotic administration after blood culture obtained STAT page x-ray technician when ready Secure umbilical lines & connect new fluids Administer erythromycin & Vitamin K 	
Completion of Golden Hour	<ul style="list-style-type: none"> Sign out to admitting provider Lead debrief after completion of Golden Hour 	<ul style="list-style-type: none"> Update family, obtain blood consent, discuss use of DBM/MBM Debrief QI form 	<ul style="list-style-type: none"> Debrief 	<ul style="list-style-type: none"> Close isolette and initiate humidity once all tasks are completed and infant's temperature is stable Debrief QI form 	

Figure 4. Golden Hour Role Assignments

LEADER

Pre-delivery	<ul style="list-style-type: none"> Preparation & coordination with team Discuss respiratory plan and any special considerations
→ In the DR/OR	<ul style="list-style-type: none"> Lead huddle prior to delivery: "shared mental model" Encourage stimulation during delayed cord clamping Direct the team at resuscitation Back-up for intubation (switch roles) Update parents Show baby to parents
In the NCCC	<ul style="list-style-type: none"> Ensure admitting provider performs examination (including eyes) Place STAT orders Look at x-ray/dismiss Tech
Completion of Golden Hour	<ul style="list-style-type: none"> Sign out to admitting provider Lead debrief after completion of Golden Hour

PROVIDER #2

Pre-delivery	<ul style="list-style-type: none"> Set up umbilical line equipment
→ In the DR/OR	<ul style="list-style-type: none"> Set up camera Clear airway Provide immediate CPAP or intubation per plan Provide PPV as indicated
In the NCCC	<ul style="list-style-type: none"> Line placement with assistant Adjust lines
Completion of Golden Hour	<ul style="list-style-type: none"> Update family, obtain blood consent, discuss DBM/MBM Debrief QI form

RN #1

Pre-delivery	<ul style="list-style-type: none"> Set-up bed space including fluids
→ In the DR/OR	<ul style="list-style-type: none"> Start/announce APGAR time Auscultation of breath sounds and heart rate Insert PIV Assist with lines/drugs if needed
In the NCCC	<ul style="list-style-type: none"> Temperature advocate Transfer to open isolette, obtain measurements and admission vitals Place on monitors Connect fluid with medication line to PIV Secure for line placement Send STAT labs during line placement Initiate antibiotic administration after blood culture obtained STAT page x-ray technician when ready Secure umbilical lines & connect new fluids Administer erythromycin & Vitamin K
Completion of Golden Hour	<ul style="list-style-type: none"> Close isolette Debrief QI form

RN #2

Pre-delivery	<ul style="list-style-type: none"> Prepare and check delivery room equipment
→ In the DR/OR	<ul style="list-style-type: none"> Re-check resuscitation equipment Apply pulse ox & CR leads Assist with intubation if needed Temperature advocate and measure infant's temperature
In the NCCC	<ul style="list-style-type: none"> Temperature advocate Transfer to open isolette, obtain measurements and admission vitals Place on monitors Connect fluid with medication line to PIV Secure for line placement Send STAT labs during line placement Initiate antibiotic administration after blood culture obtained STAT page x-ray technician when ready Secure umbilical lines & connect new fluids Administer erythromycin & Vitamin K
Completion of Golden Hour	<ul style="list-style-type: none"> Close isolette Debrief QI form

Respiratory Therapist

Pre-delivery	<ul style="list-style-type: none"> Preparation in unit of bCPAP & ventilator Bring surfactant to bring to ALL < 27 weeks gestation deliveries
→ In the DR/OR	<ul style="list-style-type: none"> Set oxygen at 30% Adjust oxygen Secure CPAP Maintain PEEP Place duoderm & secure ETT if intubated Give surfactant if indicated Take over head of the bed after airway established
In the NCCC	<ul style="list-style-type: none"> Connect to vent/bCPAP Adjust oxygen Run POC gas and adjust vent
Completion of Golden Hour	<ul style="list-style-type: none"> Debrief

Figure 5. Golden Hour Role Assignments Cue Cards

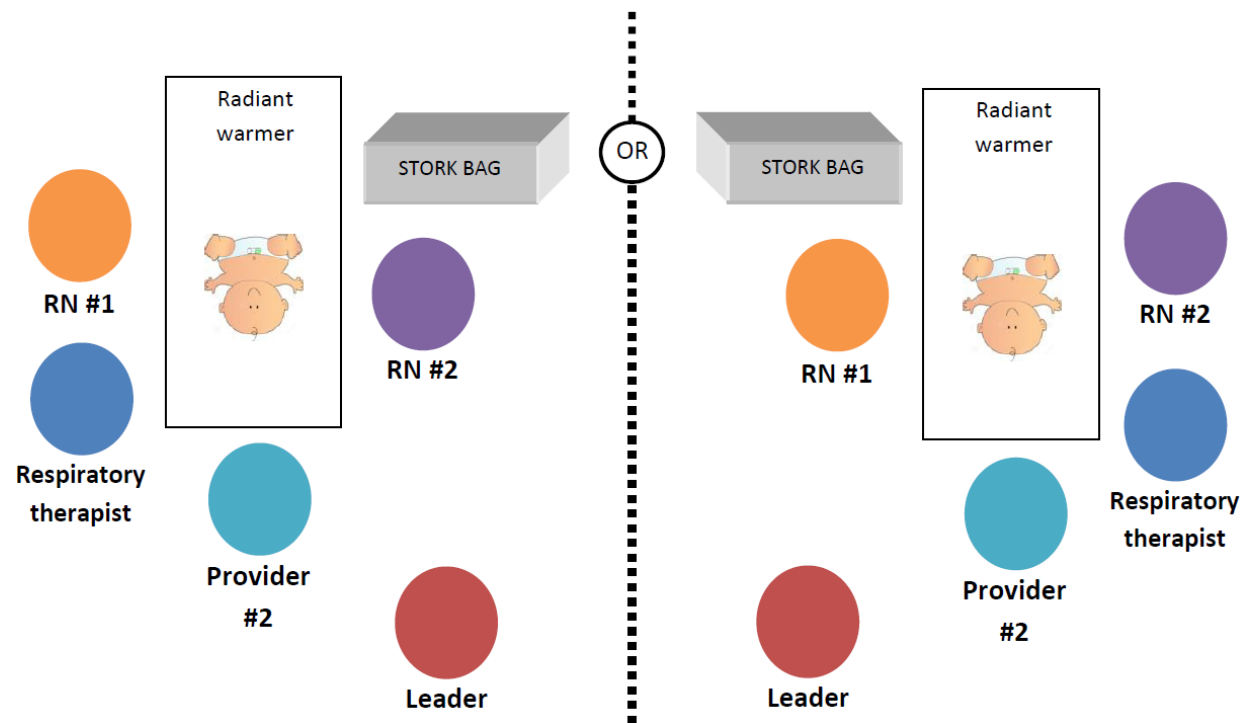


Figure 6. Golden Hour Delivery Room Positioning Map. Adapted from Vergales et al. (2015).

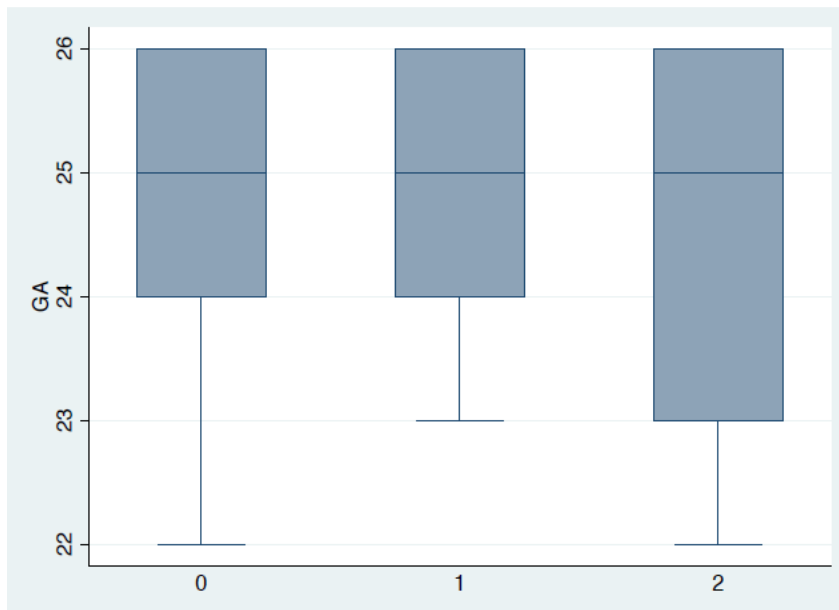


Figure 7. Box plot of gestational ages across the study phases

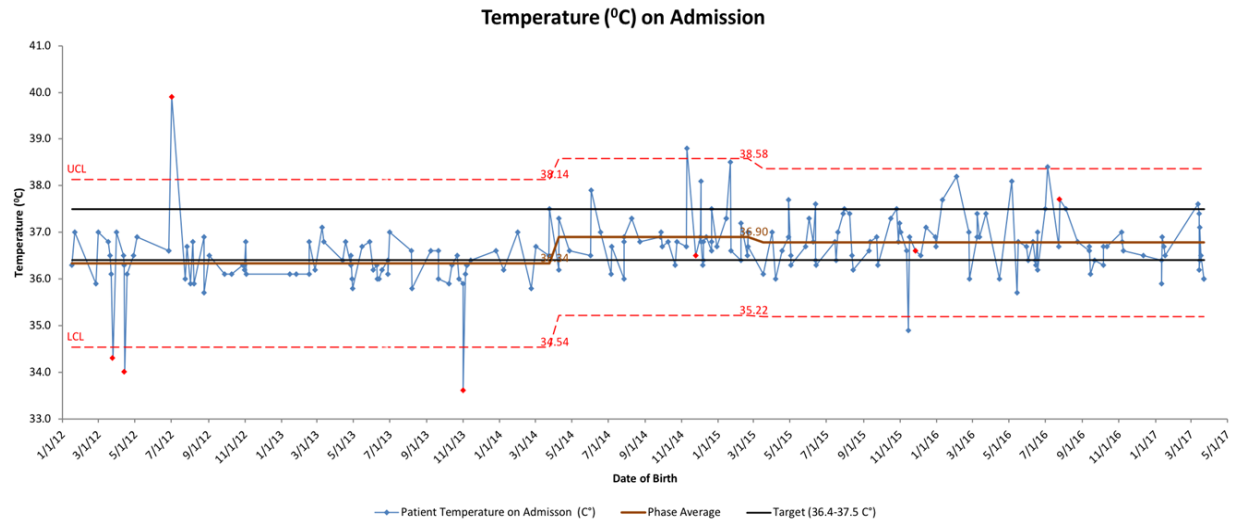


Figure 8. Control chart of the changes in admission temperatures over time. Abbreviations: upper control limit (UCL), lower control limit (LCL)

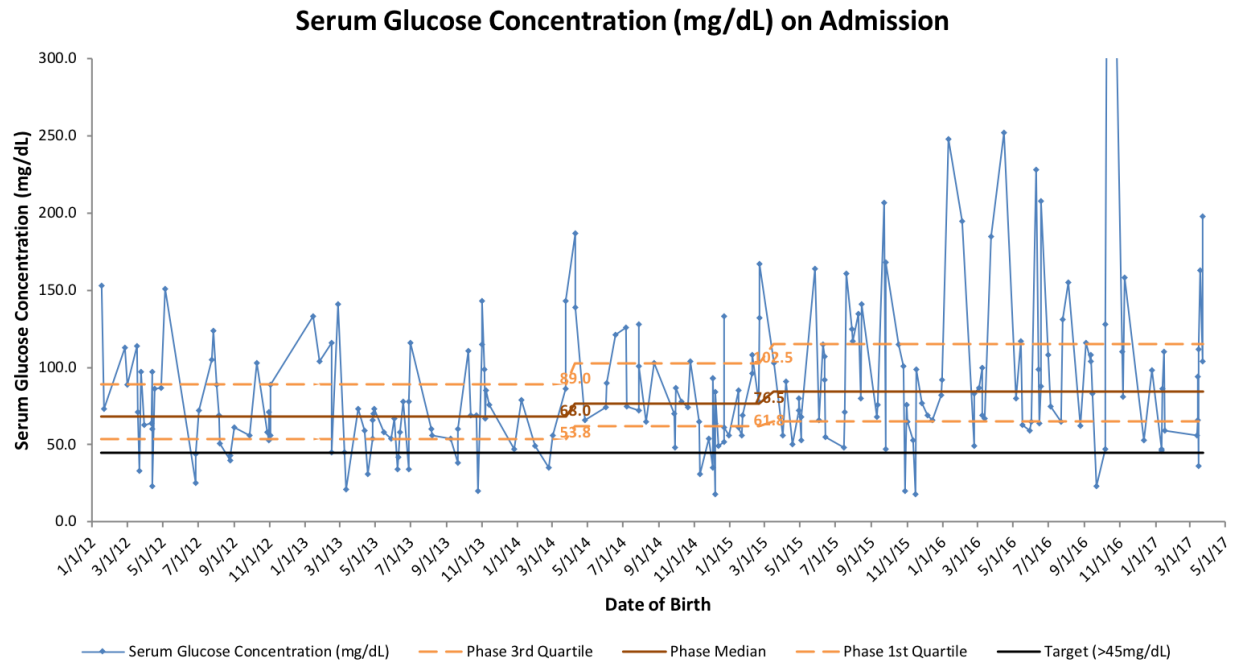


Figure 9. Run chart of the changes in serum glucose concentration on admission over time

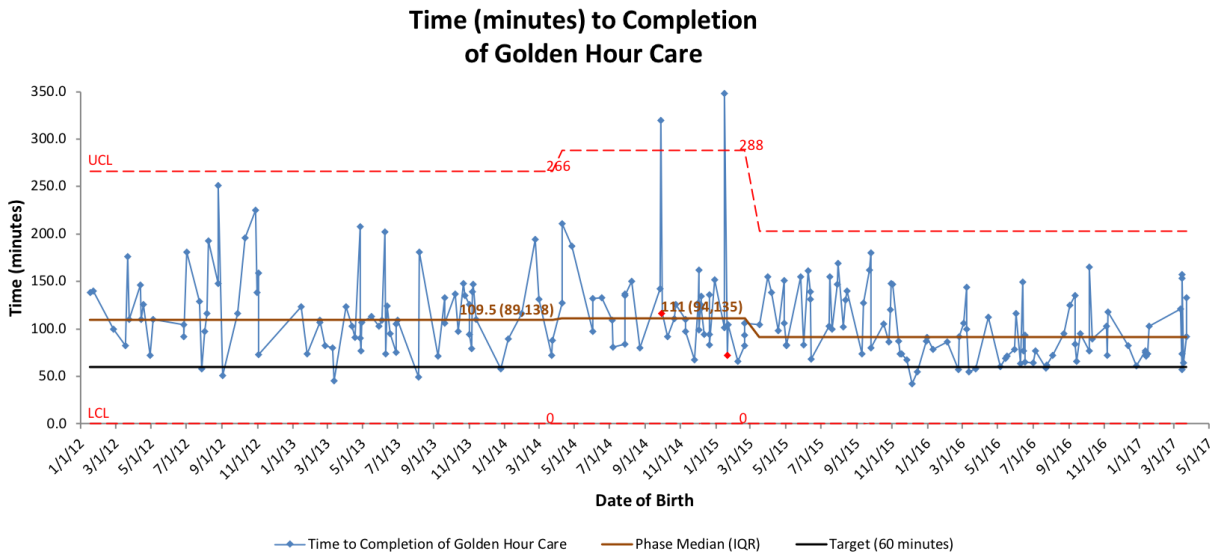


Figure 10. Control chart demonstrating the change in time to completion of Golden Hour care.

Abbreviations: upper control limit (UCL), lower control limit (LCL), interquartile range (IQR)

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