

PI: [REDACTED]	Title: Strategies to Maintain Infant Temperature Following Delivery: Impact on Outcome	
Received: 09/19/2011	FOA: [REDACTED]	Council: 05/2012
Competition ID: ADOBE-FORMS-B1	FOA Title: STUDIES IN NEONATAL RESUSCITATION (R03)	
[REDACTED]	Dual:	Accession Number: 3421121
IPF: [REDACTED]	Organization: [REDACTED]	
Former Number:	Department: Pediatrics	
IRG/SRG: [REDACTED]	AIDS: N	Expedited: N
<u>Subtotal Direct Costs</u> (excludes consortium F&A) Year 1: 50,000 Year 2: 50,000	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:		
[REDACTED]	Organization: [REDACTED] [REDACTED]	Role Category: PD/PI

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE [redacted] State Application Identifier [redacted]

1. * TYPE OF SUBMISSION
 Pre-application Application Changed/Corrected Application

4. a. Federal Identifier [redacted]
b. Agency Routing Identifier [redacted]

2. DATE SUBMITTED [redacted] Applicant Identifier [redacted]

5. APPLICANT INFORMATION * Organizational DUNS: [redacted]
* Legal Name: [redacted]
Department: [redacted] Division: [redacted]
* Street1: [redacted]
Street2: [redacted]
* City: [redacted] County / Parish: [redacted]
* State: [redacted] Province: [redacted]
* Country: [redacted] * ZIP / Postal Code: [redacted]

Person to be contacted on matters involving this application
Prefix: [redacted] * First Name: [redacted] Middle Name: [redacted]
* Last Name: [redacted] Suffix: [redacted]
* Phone Number: [redacted] Fax Number: [redacted]
Email: [redacted]

6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): [redacted]

7. * TYPE OF APPLICANT: [redacted]
Other (Specify): [redacted]
Small Business Organization Type Women Owned Socially and Economically Disadvantaged

8. * TYPE OF APPLICATION: New Resubmission Renewal Continuation Revision
If Revision, mark appropriate box(es).
 A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration
 E. Other (specify): [redacted]

* Is this application being submitted to other agencies? Yes No What other Agencies? [redacted]

9. * NAME OF FEDERAL AGENCY: [redacted]

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 93.865
TITLE: [redacted]

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
Strategies to Maintain Infant Temperature Following Delivery: Impact on Outcome

12. PROPOSED PROJECT:
* Start Date 07/01/2012 * Ending Date 06/30/2014

* 13. CONGRESSIONAL DISTRICT OF APPLICANT [redacted]

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: [redacted] * First Name: [redacted] Middle Name: [redacted]
* Last Name: [redacted] Suffix: [redacted]
Position/Title: [redacted]
* Organization Name: [redacted]
Department: [redacted] Division: [redacted]
* Street1: [redacted]
Street2: [redacted]
* City: [redacted] County / Parish: [redacted]
* State: [redacted] Province: [redacted]
* Country: [redacted] * ZIP / Postal Code: [redacted]
* Phone Number: [redacted] Fax Number: [redacted]
* Email: [redacted]

<p>15. ESTIMATED PROJECT FUNDING</p> <p>a. Total Federal Funds Requested <input style="width:150px;" type="text" value="169,000.00"/></p> <p>b. Total Non-Federal Funds <input style="width:150px;" type="text" value="0.00"/></p> <p>c. Total Federal & Non-Federal Funds <input style="width:150px;" type="text" value="169,000.00"/></p> <p>d. Estimated Program Income <input style="width:150px;" type="text" value="0.00"/></p>	<p>16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</p> <p>a. YES <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: <input style="width:100px;" type="text"/></p> <p>b. NO <input checked="" type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR <input type="checkbox"/> PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</p>
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17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

* I agree

* The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

18. SFLLL or other Explanatory Documentation

19. Authorized Representative

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

* Position/Title:

* Organization:

Department: Division:

* Street1:

Street2:

* City: County / Parish:

* State: Province:

* Country: * ZIP / Postal Code:

* Phone Number: Fax Number:

* Email:

* Signature of Authorized Representative
* Date Signed

20. Pre-application

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Project/Performance Site Location(s)

Project/Performance Site Primary Location I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [REDACTED]
DUNS Number: [REDACTED]
* Street1: [REDACTED]
Street2: [REDACTED]
* City: [REDACTED] County: [REDACTED]
* State: [REDACTED]
Province: [REDACTED]
* Country: [REDACTED]
* ZIP / Postal Code: [REDACTED] * Project/ Performance Site Congressional District: [REDACTED]

Project/Performance Site Location 1 I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [REDACTED]
DUNS Number: [REDACTED]
* Street1: [REDACTED]
Street2: [REDACTED]
* City: [REDACTED] County: [REDACTED]
* State: [REDACTED]
Province: [REDACTED]
* Country: USA: UNITED STATES
* ZIP / Postal Code: [REDACTED] * Project/ Performance Site Congressional District: [REDACTED]

Additional Location(s) [REDACTED] [Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? Yes No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If yes, check appropriate exemption number. 1 2 3 4 5 6

If no, is the IRB review Pending? Yes No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? Yes No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? Yes No

IACUC Approval Date:

Animal Welfare Assurance Number

3. * Is proprietary/privileged information included in the application? Yes No

4.a. * Does this project have an actual or potential impact on the environment? Yes No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place? Yes No

5.a. If yes, please explain:

6. * Does this project involve activities outside of the United States or partnerships with international collaborators? Yes No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract

8. * Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

Management strategies to maintain infant temperature in the optimal range following delivery i.e. $36.5 \pm 0.5^{\circ}\text{C}$ is of critical importance with regard to neonatal mortality and morbidity. Recommended strategies to minimize rapid heat loss include occlusive wrapping of very low birth weight infants (VLBW) infants at birth \pm the use of an exothermic mattress. The former has been shown to raise the admission temperature of infants < 28 weeks by 1.9°C . Yet approximately 50% of VLBW infants have an admitting temperature $< 36.0^{\circ}\text{C}$. For each 1°C decrease in temperature below 36.5°C , the odds of dying increases by 28 percent. There are no recommended treatment strategies for larger infants except for placing under a radiant warmer or skin to skin contact and drying off well. Delivery room (DR) temperatures are never monitored.

Hypothesis: An admitting temperature in a normal range i.e. $36.5 \pm 0.5^{\circ}\text{C}$ upon arrival to neonatal intensive care will lessen the requirement for respiratory support and reduce the length of hospital stay (LOS).

Specific Aims 1. To determine whether a consistent treatment approach (practice plan) for maintaining body temperature following delivery for all infants regardless of birth weight or gestational age will be associated with less neonatal morbidity and a shorter LOS; 2. To determine whether there is a temperature cutoff below which neonatal morbidity and LOS is affected. 3. To determine whether ambient temperature in the delivery or operating room modulates the admitting temperature. 4. To determine factors/events that predispose to increased LOS with decreasing temperature 5. To determine the financial impact of maintaining temperature a temperature $> 36^{\circ}\text{C}$ secondary to potential reduction in LOS.

Preliminary pertinent findings include the following: For the years 2009 to 2010 the initial temperature for all infants admitted to neonatal intensive care ($n=1040$) was $36.1 \pm 0.7^{\circ}\text{C}$ and the mean LOS 19.6 ± 2.6 days (median 10 days). For the cohort the LOS with an admitting temperature ≤ 36.1 vs $> 36.1^{\circ}\text{C}$ was longer i.e. $24.2 \pm 30.8\text{d}$ vs. $16.3 \pm 22\text{d}$ ($p=0.0001$) as well as for infants $< 1500\text{g}$ i.e. $72 \pm 45\text{d}$ vs $63 \pm 40\text{d}$ ($p=0.005$) and $> 2500\text{g}$ i.e. $8.5 \pm 8.9\text{d}$ vs $5.9 \pm 6.9\text{d}$ ($p=0.0001$). For gestational age (GA) the LOS was longer only for infants ≥ 34 wks i.e. $10.6 \pm 8.4\text{d}$ vs $6.68 \pm 7.1\text{d}$ ($p=0.0001$). By linear regression analysis the impact of LOS was greater for BW ($t=6.9$, $p=0.00001$) than GA ($t=3.3$, $p=0.001$). More recent analysis indicates that infants admitted with temperature one standard deviation below the mean are significantly more likely to exhibit respiratory problems requiring intubation and surfactant administration. Moreover infants of GA ≤ 28 vs > 28 weeks had a higher admitting temperature of approximately 0.4°C ((this likely reflects a consistent approach to temperature management in the smallest infants). The DR temperature was always slightly higher than the admitting temperature i.e. 0.3°C - this stresses the critical importance of maintaining an infant DR temperature in a normal range. We propose to extend the standard practice plan for maintaining temperature in infants < 28 weeks to include all infants < 34 weeks GA, ensure that standard basic stabilization steps are practiced in near term and term infants and facilitate the ability to continuously monitor and regulate DR temperature to achieve a recommended goal range. This should promote maintenance of infant body temperature in the DR enhance transitional adaptation; reduce neonatal morbidity and LOS.

Maintaining the delivery room temperature of infants in a normal range $36.5 \pm 0.5^{\circ}\text{C}$ is highly relevant to reduce neonatal mortality and morbidity as well as reduce length of stay. The latter effect has significant economic implications.

Clinical:

[REDACTED] It specializes in care of extremely premature neonates and newborn infants requiring medical or surgical intervention. The neonatal intensive care specialists have expertise in delivery room resuscitation and the major neonatal neurologic disorders. The labor and delivery service is located immediately above the neonatal intensive care unit and there are approximately 5500 deliveries. There is a very active high risk service providing comprehensive care to a variety of complex cases.

Office: The Newborn Medicine academic offices are located one floor below the Neonatal Intensive Care Unit. The suite includes the office of PI. All offices have network connected computers, printers and fax machines. In addition, the investigators have access to a full-time secretary who is located in the academic suite as the PI.

Database: The Newborn Medicine division maintains a continuous comprehensive database on all admissions to the neonatal intensive care. The database is in part supervised by the PI.

Laboratory: Not applicable.

Animal: Not applicable.

Major Equipment: Not applicable.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator			
Prefix:	* First Name:	Middle Name:	
* Last Name:		Suffix:	
Position/Title:	Department:		
Organization Name:	Division:		
* Street1:			
Street2:			
* City:	County/ Parish:		
* State:	Province:		
* Country:	* Zip / Postal Code:		
* Phone Number:	Fax Number:		
* E-Mail:			
Credential, e.g., agency login:			
* Project Role:	Other Project Role Category:		
Degree Type:			
Degree Year:			
*Attach Biographical Sketch	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Attach Current & Pending Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

PROFILE - Senior/Key Person 1			
Prefix:	* First Name:	Middle Name:	
* Last Name:		Suffix:	
Position/Title:	Department:		
Organization Name:	Division:		
* Street1:			
Street2:			
* City:	County/ Parish:		
* State:	Province:		
* Country:	* Zip / Postal Code:		
* Phone Number:	Fax Number:		
* E-Mail:			
Credential, e.g., agency login:			
* Project Role:	Other Project Role Category:		
Degree Type:			
Degree Year:			
*Attach Biographical Sketch	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Attach Current & Pending Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

ADDITIONAL SENIOR/KEY PERSON PROFILE(S)		Add Attachment	Delete Attachment	View Attachment
Additional Biographical Sketch(es) (Senior/Key Person)		Add Attachment	Delete Attachment	View Attachment
Additional Current and Pending Support(s)		Add Attachment	Delete Attachment	View Attachment

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME [REDACTED]		POSITION TITLE [REDACTED]	
eRA COMMONS USER NAME (credential, e.g., agency login) [REDACTED]			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
[REDACTED]		[REDACTED]	[REDACTED]

A. Personal Statement

The goals of my research are to improve our understanding of the mechanisms contributing to neonatal morbidity and in particular brain injury. Of particular relevance to this proposal is my interest in the importance temperature at the time of delivery. Thus I initially demonstrated that maternal fever was an important cause of respiratory depression at birth. Furthermore we demonstrated that a substantial number of babies born to mother with chorioamnionitis have an elevated temperature in the delivery room and that the temperature decreases spontaneously within the first postnatal hour of life. [REDACTED]

[REDACTED] In my role as [REDACTED] I facilitated the review and guidelines for maintaining the temperature in very low birth weight babies following delivery through admission to neonatal intensive care. It was very apparent that failure to maintain temperature is associated with significant neurologic morbidity and mortality. In the term infant I have focused my clinical research on the role of therapeutic hypothermia as a neuroprotective strategy. The preliminary observations in this proposal describing a prolonged length of stay with decreasing admitting temperature is exciting because it suggests that simple interventions in the delivery room may have the potential to positively impact the neonate.

[REDACTED]

[REDACTED]

[Redacted text block]

C. Selected Peer-reviewed Publications (Selected from 130 peer-reviewed publications)

- [Redacted]

[REDACTED]

Ongoing Research Support

[REDACTED]

[REDACTED]

[REDACTED]



1. Project Director / Principal Investigator (PD/PI)

Prefix: [redacted] * First Name: [redacted]
Middle Name: [redacted]
* Last Name: [redacted]
Suffix: [redacted]

2. Human Subjects

Clinical Trial? No Yes
* Agency-Defined Phase III Clinical Trial? No Yes

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: [redacted] * First Name: [redacted]
Middle Name: [redacted]
* Last Name: [redacted]
Suffix: [redacted]
* Phone Number: [redacted] Fax Number: [redacted]
Email: [redacted]

* Title: [redacted]
* Street1: [redacted]
Street2: [redacted]
* City: [redacted]
County/Parish: [redacted]
* State: [redacted]
Province: [redacted]
* Country: [redacted] * Zip / Postal Code: [redacted]

PHS 398 Modular Budget, Periods 3 and 4

Budget Period: 3	Start Date: <input style="width: 100%;" type="text"/>	End Date: <input style="width: 100%;" type="text"/>
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A. Direct Costs	* Direct Cost less Consortium F&A	* Funds Requested (\$)
	Consortium F&A	
	* Total Direct Costs	

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 100%;" type="text"/>			
2.	<input style="width: 100%;" type="text"/>			
3.	<input style="width: 100%;" type="text"/>			
4.	<input style="width: 100%;" type="text"/>			

Cognizant Agency (Agency Name, POC Name and Phone Number)	<input style="width: 100%;" type="text"/>
Indirect Cost Rate Agreement Date <input style="width: 100%;" type="text"/>	Total Indirect Costs <input style="width: 100%;" type="text"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)
	<input style="width: 100%;" type="text"/>

Budget Period: 4	Start Date: <input style="width: 100%;" type="text"/>	End Date: <input style="width: 100%;" type="text"/>
-------------------------	---	---

A. Direct Costs	* Direct Cost less Consortium F&A	* Funds Requested (\$)
	Consortium F&A	
	* Total Direct Costs	

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 100%;" type="text"/>			
2.	<input style="width: 100%;" type="text"/>			
3.	<input style="width: 100%;" type="text"/>			
4.	<input style="width: 100%;" type="text"/>			

Cognizant Agency (Agency Name, POC Name and Phone Number)	<input style="width: 100%;" type="text"/>
Indirect Cost Rate Agreement Date <input style="width: 100%;" type="text"/>	Total Indirect Costs <input style="width: 100%;" type="text"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)
	<input style="width: 100%;" type="text"/>

PHS 398 Modular Budget, Periods 5 and Cumulative

Budget Period: 5

Start Date:

End Date:

A. Direct Costs

	* Funds Requested (\$)
* Direct Cost less Consortium F&A	<input type="text"/>
Consortium F&A	<input type="text"/>
* Total Direct Costs	<input type="text"/>

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date

Total Indirect Costs

C. Total Direct and Indirect Costs (A + B)

Funds Requested (\$)

Cumulative Budget Information

1. Total Costs, Entire Project Period

*Section A, Total Direct Cost less Consortium F&A for Entire Project Period	\$	<input type="text" value="100,000.00"/>
Section A, Total Consortium F&A for Entire Project Period	\$	<input type="text" value="0.00"/>
*Section A, Total Direct Costs for Entire Project Period	\$	<input type="text" value="100,000.00"/>
*Section B, Total Indirect Costs for Entire Project Period	\$	<input type="text" value="69,000.00"/>
*Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period	\$	<input type="text" value="169,000.00"/>

2. Budget Justifications

Personnel Justification	<input type="text" value="1242-Budget_Justification.pdf"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

New Resubmission Renewal Continuation Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application (for RESUBMISSION or REVISION only)	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
2. Specific Aims	1239-SpecificAims_Final.pdf	Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy	1240-ResearchStrategy_Final	Add Attachment	Delete Attachment	View Attachment
4. Inclusion Enrollment Report	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

6. Protection of Human Subjects	1243-Protection of Human Sub	Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	1244-Inclusion Women.pdf	Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	1245-Enrollment.pdf	Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children	1246-Inclusion_Children.pdf	Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

10. Vertebrate Animals	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
11. Select Agent Research	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
12. Multiple PD/PI Leadership Plan	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
13. Consortium/Contractual Arrangements	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
14. Letters of Support	1247-LOS_Grunebaum.pdf	Add Attachment	Delete Attachment	View Attachment
15. Resource Sharing Plan(s)	1248-Data_Sharing_Plan.pdf	Add Attachment	Delete Attachment	View Attachment

16. Appendix [Add Attachments](#) [Remove Attachments](#) [View Attachments](#)

Body temperature is a critical modulating factor in humans, with heat loss and gain finely tuned so as to maintain temperature in the optimal range for efficient metabolism, growth and survival. The newborn and in particular the very low birth weight baby has immature thermoregulatory controls during the early neonatal period. At birth if not managed appropriately the infant's core temperature can decrease rapidly in part due to evaporative losses from a wet body, a large surface area/ body mass ratio as compared to the adult, and a cold delivery room environment. Management strategies to maintain infant temperature following delivery in the optimal range for term infants i.e. $36.5 \pm 0.5^{\circ}\text{C}$ is of particular importance with regard to neonatal mortality and morbidity. In a recent report approximately 50% of over 5000 very low birth weight infants (VLBW) < 28 weeks were shown to have an admitting temperature < 36.0°C . Importantly for each 1°C decrease in temperature of below 36.5°C the odds of dying increased by 28 percent. Clearly maintaining temperature in the desired range should be the goal in order to avoid neonatal morbidity and mortality. Management strategies to overcome this problem include occlusive wrapping of VLBW infants at birth \pm the use of an exothermic mattress. The former has been shown to raise the admission temperature of infants < 28 weeks by 1.9°C . In order to provide guidance to clinicians to maintain body temperature following birth, the most recent International Liaison Committee for Cardio-Pulmonary Resuscitation (ILCOR) treatment recommendations for neonates states "Newborn infants of < 28 weeks' gestation should be completely covered in a polythene wrap or bag up to their necks without drying immediately after birth and then placed under a radiant heater and resuscitated or stabilized in a standard fashion. Infants should be kept wrapped until admission and the temperature checked at this time. Hyperthermia should be avoided. Delivery room temperatures should be at least 26°C for infants of < 28 weeks gestation". This treatment recommendation does not provide guidance for the management of the "larger premature infant" or include the potential role of the exothermic mattress in maintaining temperature in any infant. Moreover the delivery room or operating suites temperatures are often centrally controlled, not directly monitored in delivery rooms, and independent of staff or parental preferences.

Specific Aims

1. To determine whether a consistent treatment approach (practice plan) for maintaining body temperature following delivery for all infants regardless of birth weight or gestational age will be associated with less neonatal morbidity and a shorter length of stay (LOS).
2. To determine whether there is a temperature cutoff below which neonatal morbidity and LOS is affected.
3. To determine whether ambient temperature in the delivery or operating room modulates the admitting temperature of infants to neonatal intensive care.
4. To determine factors/events that predispose to increased LOS with decreasing admitting temperature.
5. To determine the potential financial impact of maintaining temperature a temperature of $36.5 \pm 0.5^{\circ}\text{C}$ as a consequence of a potential reduction in LOS.

Research Strategy

Significance

Body temperature is a critical modulating factor in humans, with heat loss and gain finely tuned to maintain temperature in the optimal range for efficient metabolism, growth and survival. The newborn and in particular the very low birth weight (VLBW) baby has immature thermoregulatory controls during the early neonatal period. At birth the infant's core temperature can decrease rapidly in part due to evaporative losses from a wet body, a large surface area/ body mass ratio as compared to the adult, and a cold delivery room environment which can result in large radiant and convective heat losses. Management strategies to maintain infant temperature in the optimal range following delivery i.e. $36.5 \pm 0.5^{\circ}\text{C}$ is of critical importance with regard to neonatal mortality and morbidity. In a recent report of over 5000 VLBW infants < 28 weeks, approximately 50% were shown to have an admitting temperature < 36.0°C . Importantly for each 1°C decrease in temperature below 36.5°C , the odds of dying increased by 28 percent.¹ Clearly maintaining body temperature in the optimal range should be the goal in order to avoid neonatal morbidity and mortality. Management strategies to overcome this problem of rapid heat loss include occlusive wrapping of VLBW infants at birth \pm the use of an exothermic mattress. The former has been shown to raise the admission temperature of infants < 28 weeks by 1.9°C .² In order to provide guidance to clinicians for maintaining body temperature following birth, the most recent International Liaison Committee for Cardio-Pulmonary Resuscitation (ILCOR) treatment recommendations for neonates states "Newborn infants of < 28 weeks' gestation should be completely covered in a polythene wrap or bag up to their necks without drying immediately after birth and then placed under a radiant heater and resuscitated or stabilized in a standard fashion. Infants should be kept wrapped until admission and the temperature checked at this time. Hyperthermia should be avoided. Delivery room temperatures should be at least 26°C for infants of < 28 weeks gestation."³ This treatment recommendation does not provide guidance for the management of "larger premature infants" or include the potential role of the exothermic mattress in maintaining temperature in any infant. Moreover the delivery room or operating suites temperatures are often centrally controlled, not directly monitored in delivery rooms, and independent of staff or parental preferences.

Current strategies to maintain temperature in the delivery room in our institution are as follows: ≤ 28 weeks GA – infant is placed under a radiant warmer, on an exothermic mattress, a polyethylene occlusive wrapping is placed immediately on the baby without drying; 29 -34 weeks-infant is placed under a radiant warmer, dried \pm occlusive wrap-no exothermic mattress; > 34 weeks- infant is placed under a radiant warmer dried followed by stabilization/resuscitation as clinically indicated. The delivery room or operating suite temperatures are centrally modulated by bioengineering and individual room temperatures are not monitored.

The overall significance of this proposal is that by extending the standard practice plan used for maintaining temperature in infants less than 28 weeks to include all infants less than 34 weeks gestational age, ensuring that standard basic stabilization steps are practiced in near term and term infants and facilitating the ability to continuously monitor and regulate delivery room temperature to achieve a recommended goal range, should enhance the ability to maintain infant body temperature in the delivery room, enhance transitional adaptation, reduce neonatal morbidity and length of stay.

Innovation

The preliminary observations outlined below are the first to link a low admitting temperature (< 36.1 vs $> 36^{\circ}\text{C}$) to a longer length of stay of approximately eight days for infants admitted to neonatal intensive care. We also noted that the smallest infants managed with a consistent practice plan have a significantly higher admitting temperature than larger premature infants. We plan to adjust the practice strategy for maintaining temperature control in the larger premature infant to match that of the smaller premature infant. The delivery room temperature is controlled remotely by the bioengineering department, and the labor and delivery staff currently have no knowledge of what the delivery or operating room temperatures are. The future plans are to have the delivery and operating temperature readings continuously available to the labor and delivery staff thereby facilitating maintenance of temperature in the recommended range.

Approach

The rationale for our approach for maintaining the admitting temperature in the goal range of $36.5 \pm 0.5^{\circ}\text{C}$ is based on the preliminary observations outlined below.

Preliminary observations

Admitting Temperature as a Function of Birth weight (BW) –Impact on Length of Stay(LOS)

For the years 2009 to 2010 the initial temperature for all infants admitted to the neonatal intensive care unit ($n=1040$) was $36.1 \pm 0.7^{\circ}\text{C}$ and the mean length of stay 19.6 ± 2.6 days (median 10days). For infants $< 1500\text{g}$ ($n=173$) the temperature was $36 \pm 0.7^{\circ}\text{C}$; for infants $1501-2500\text{g}$ ($n=438$) the initial temperature was $35.8 \pm 0.65^{\circ}\text{C}$; and for infants $> 2500\text{g}$ ($n=529$) the initial temperature was $36.4 \pm 0.73^{\circ}\text{C}$. Based on these data the impact of an admitting temperature of $\leq 36.1^{\circ}\text{C}$ vs $> 36.1^{\circ}\text{C}$ on LOS for the cohort and then the LOS for the individual BW categories was evaluated. For the cohort ($n=1040$) the LOS with an admitting temperature ≤ 36.1 vs $> 36.1^{\circ}\text{C}$ was significantly longer i.e. $24.2 \pm 30.8\text{d}$ (median =

14d) vs. 16.3 ± 22 d (median 7d) ($p=0.0001$). (Table 1); for infants < 1500g, the LOS with an admitting temperature ≤ 36 vs $> 36^{\circ}\text{C}$ was significantly longer i.e. 72 ± 45 d vs 63 ± 40 d ($p=0.005$); for infants 1501-2500g with an admitting temperature ≤ 35.8 vs $> 35.8^{\circ}\text{C}$ the LOS was shorter i.e. 16.9 ± 10 vs 18.9 ± 13 d ($p=0.06$) and infants > 2500g with an admitting temperature ≤ 36 vs $> 36^{\circ}\text{C}$ the LOS was significantly longer i.e. 8.5 ± 8.9 d vs 5.9 ± 6.9 d ($p=0.0001$) (Table 1). The LOS for the group was next analyzed at one standard deviation (SD) from the mean for the entire cohort and for the specific BW categories. The LOS (1 SD) for the entire cohort with an admitting temperature ≤ 35.4 vs $> 35.4^{\circ}\text{C}$ remained significantly longer i.e. 24.3 ± 33 d vs 18.6 ± 24 d ($p=0.006$); for infants < 1500g i.e. ≤ 35.3 vs $> 35.3^{\circ}\text{C}$ the LOS remained significantly longer i.e. 83 ± 57 d vs 63 ± 40 d ($p=0.006$); for infants 1500-2500gm ≤ 35.2 vs $> 35.2^{\circ}\text{C}$ LOS was not different i.e. 19.2 ± 11.9 d vs 17.6 ± 11.6 d ($p=0.26$) and for infants > 2500g i.e. ≤ 35.3 vs $> 35.3^{\circ}\text{C}$ the LOS remained significantly longer i.e. 9.1 ± 7.9 d vs 6.45 ± 7.5 d ($p=0.02$) (Table 1).

Table 1 – Impact of an Admitting Temperature and Temperature one Standard Deviation below the Mean on Length of Stay (LOS) for all infants as a Function of BW

Temperature	All Infants	Temperature	BW \leq 1500g
$\leq 36.1^{\circ}\text{C}$	24.2 ± 30 d *	$\leq 36.0^{\circ}\text{C}$	72 ± 45d **
$> 36.1^{\circ}\text{C}$	16.3 ± 22 d	$> 36.0^{\circ}\text{C}$	55 ± 34 d
Temperature (1SD)		Temperature (1SD)	
$\leq 35.4^{\circ}\text{C}$	24 ± 33 d #	$\leq 35.3^{\circ}\text{C}$	83 ± 57d #
$> 35.4^{\circ}\text{C}$	18.6 ± 24 d	$> 35.3^{\circ}\text{C}$	63 ± 40 d

Temperature	1501-2500g	Temperature	> 2500g
$\leq 36.1^{\circ}\text{C}$	16.9 ± 10 d	$\leq 36.0^{\circ}\text{C}$	8.5 ± 8.9d *
$> 36.1^{\circ}\text{C}$	18.9 ± 13 d	$> 36.0^{\circ}\text{C}$	5.9 ± 6.9 d
Temperature (1SD)		Temperature (1SD)	
$\leq 35.2^{\circ}\text{C}$	19.2 ± 11.9 d	$\leq 35.6^{\circ}\text{C}$	9.1 ± 7.9d ##
$> 35.2^{\circ}\text{C}$	17.2 ± 11.5 d	$> 35.6^{\circ}\text{C}$	6.4 ± 7.5 d

* $p=0.0001$, ** $p=0.005$ # $p=0.006$ ## $p=0.02$

Initial Admitting Temperature as a Function of Gestational Age-Impact on LOS

For infants ≤ 28 wks ($n=83$) the admitting temperature was $35.9 \pm 0.8^{\circ}\text{C}$; for infants 29-33 weeks ($n=304$) $36.0 \pm 0.64^{\circ}\text{C}$; and for infants ≥ 34 wks ($n=769$) $36.1 \pm 0.75^{\circ}\text{C}$. Based on these data the impact of an admitting temperature on LOS for the individual GA categories was analyzed (Table 2). For infants ≤ 28 weeks GA, with an initial temperature $\leq 35.9^{\circ}\text{C}$ vs $> 35.9^{\circ}\text{C}$ the LOS was longer 96 ± 51 d vs 81 ± 39 d ($p=0.21$). For infants of GA 29-33wks, the LOS of stay with an initial temperature $\leq 36.1^{\circ}\text{C}$ vs $> 36.1^{\circ}\text{C}$ was comparable i.e. 32 ± 18 vs 33 ± 19 d ($p=0.63$). For infants ≥ 34 wks the LOS with an admitting temperature of $\leq 36.1^{\circ}\text{C}$ vs $> 36.1^{\circ}\text{C}$ was 10.6 ± 8.4 d vs 6.68 ± 7.1 d ($p=0.0001$) The LOS (1SD) for specific GA categories was then analyzed. For GA ≤ 28 wks i.e. ≤ 35.1 vs $> 35.1^{\circ}\text{C}$ the LOS was longer 103 ± 66 vs 87 ± 42 ($p=0.29$); GA 29-33 wks i.e. ≤ 35.4 vs $> 35.4^{\circ}\text{C}$ the LOS was comparable i.e. 31.6 ± 18.7 d vs 32.9 ± 19 d ($p=0.65$) and GA ≥ 34 wks i.e. ≤ 35.4 vs $> 35.4^{\circ}\text{C}$ the LOS was significantly longer 11 ± 8.4 d vs 7.5 ± 7.6 d ($p=0.0001$) (Table 2).

Table 2 – Impact of an Admitting Temperature as a Function of GA

Temperature	≤ 28 wks LOS (d)	Temperature	29-33wks LOS (d)	Temperature	> 34 weeks LOS (d)
$\leq 35.9^{\circ}\text{C}$	96 ± 51	$\leq 36.0^{\circ}\text{C}$	32 ± 18	$\leq 36.1^{\circ}\text{C}$	10.6 ± 8.4 *
$> 35.9^{\circ}\text{C}$	81 ± 39	$> 36.0^{\circ}\text{C}$	33 ± 19	$> 36.1^{\circ}\text{C}$	6.68 ± 7.1
Temperature (1SD)		Temperature (1SD)		Temperature (1SD)	
$\leq 35.1^{\circ}\text{C}$	103 ± 66	$\leq 35.4^{\circ}\text{C}$	31.6 ± 18.7	$\leq 35.4^{\circ}\text{C}$	11 ± 8.4 *
$> 35.1^{\circ}\text{C}$	87 ± 42	$> 35.4^{\circ}\text{C}$	32.9 ± 19	$> 35.4^{\circ}\text{C}$	7.5 ± 7.6

* $p=0.0001$

Summary of Findings

- Over a 2 year period (n=1040) infants with an admitting temperature ≤ 36.1 vs > 36.1 °C had a significantly longer LOS of approximately 8 days.
- Infants < 1500 g BW (n=173) with an admitting temperature ≤ 36.1 vs > 36.1 °C had a significantly longer LOS of approximately 17 days which increased to approximately 20 days with a lower admitting temperature one standard deviation below the mean.
- Infants with a BW > 2500 gm (n=529) with an admitting temperature ≤ 36.1 vs > 36.1 °C had a significantly longer LOS of approximately 2.5 days which increased to 3 days with a lower admitting temperature one standard deviation below the mean.
- Infants with a GA > 34 weeks (n=769) with an admitting temperature ≤ 36.1 vs > 36.1 °C had a significantly longer LOS of approximately 4 days which was sustained with a lower admitting temperature one standard deviation below the mean.
- For infants of BW 1501 to 2500g, GA ≤ 28 weeks and GA 29-32 weeks, although the LOS was longer, the differences were not significant.
- By linear regression analysis the impact of LOS was greater for BW ($t=6.9$, $p=0.00001$) than for GA ($t=3.3$, $p=0.001$).
- These retrospective data do not provide insight into the mechanisms accounting for the increased length of stay.

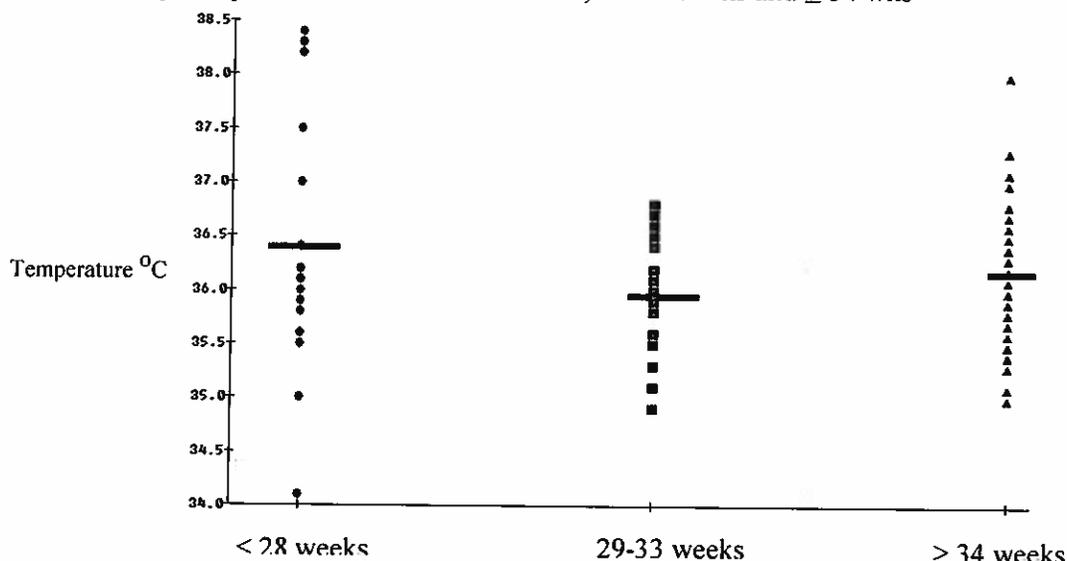
To begin to address this important issue we have reviewed data of admissions to the NICU from June through July 2011 (see below).

Admitting temperature of Infants Admitted to the NICU June - July 2011

Over a six week period the admitting temperature of 77 inborn admissions to the NICU was 36.1 ± 0.8 °C (1SD = 35.3 °C). Of these 35/77 (44%) had an admitting temperature < 36.1 °C and 9/77 (11.6%) an admitting temperature < 35.3 °C (temperature obtained within 15 minutes by protocol). These nine infants versus the 68 infants with an admitting temperature > 35.2 °C were of comparable BW 1656 ± 534 vs 1877 ± 864 g and GA 32 ± 2.2 vs 33 ± 4.2 wks. Clinical findings in the nine infants included intubation (n=5) (56%), surfactant administration (including an infant of GA 32 weeks) (n=5) (56%), continuous positive airway pressure (CPAP) (n=2) (this included one infant of GA 35 wks); hypoglycemia (n=1) (this in an infant of GA 35 wks). Of the infants with temperature > 35.2 °C, 16/68 (24%) were intubated and 13/68 (19%) were administered surfactant. Infants with a temperature < 35.3 °C vs > 35.2 °C were more likely to be intubated ($p=0.056$) and receive surfactant ($p=0.02$).

Infants ≤ 28 weeks (managed with occlusive wrapping, exothermic mattress) (n=16) vs infants 29-34 weeks (n=23) (managed with drying \pm occlusive wrap) had an initial admitting temperature of 36.4 ± 1.22 vs 35.8 ± 0.23 °C ($p=0.03$) respectively. Where both temperature data were available, the delivery room temperature of the infant as compared to the initial temperature in the neonatal intensive care unit was higher by 0.3 ± 0.55 °C (median difference of 0.1 °C). For twins the second twin differed in temperature from the first twin by 0.40 °C (median IQR 0.50) ($p=0.02$). The low admitting temperatures normalized within 67 ± 69 minutes (median 45 minutes)

Graph. Admitting Temperatures for Infants < 28 wks, 29 to 33 wks and ≥ 34 wks



Delivery and Operating Room Temperature

There is a central control mechanism for maintaining delivery and operating room temperatures. A snapshot of the temperature in the 12 delivery rooms (11.30AM) revealed a mean of 23 °C (range 21 to 23.8 °C) and the mean in the four operating rooms was 20.8 °C (range 20.5-21 °C). A day later the mean temperature in the operating rooms was 20 °C. These mean values on both days are below the recommended international cutoff of 26 °C³.

Summary

- An admitting temperature 1 SD below the mean i.e. ≤ 35.3 vs > 35.2 °C is associated with more respiratory problems as indicated by a higher likelihood of intubation and administration of surfactant.
- Infants of GA ≤ 28 vs > 28 weeks GA have a higher admitting temperature of approximately 0.4 °C (this may reflect a consistent approach to temperature management i.e. occlusive wrap and exothermic mattress)
- The admitting NICU temperature is lower than the delivery temperature by a mean of 0.3 °C (median 0.1 °C) - this stresses the critical importance of maintaining a delivery room temperature of the infant in a normal range.
- The lower temperatures normalize within approximately one hour following admission.
- The delivery room temperature is approximately 3 °C and the operating room temperature approximately 5 °C below the recommended goal.

Hypothesis

An admitting temperature in a normal range i.e. 36.5 ± 0.5 °C upon arrival to neonatal intensive care will lessen the requirement for respiratory support and reduce the length of hospital stay.

Specific Aims

1. To determine whether a consistent treatment approach (practice plan) for maintaining body temperature following delivery for all infants regardless of birth weight or gestational age will be associated with less neonatal morbidity and a shorter LOS.
2. To determine whether there is a temperature cutoff below which neonatal morbidity and length of stay is affected
3. To determine whether ambient temperature in the delivery or operating room modulates the admitting temperature to neonatal intensive care.
4. To determine factors/events that predispose to increased LOS with decreasing temperature
5. To determine the financial impact of maintaining temperature a temperature > 36 °C secondary to potential reduction in LOS.

Methods

Phase 1 (Duration of Six Months)

Practice plan for Temperature Management of Infants < 34 weeks GA

Following delivery and placement of the infant under the radiant warmer occlusive wrapping will be placed without drying off of the infant. Infants will be placed on an exothermic mattress. A cap will be placed on the head. An axillary temperature will be obtained prior to transport to the neonatal intensive care unit. The delivery or operating room temperature will be recorded. Maternal temperature will be recorded. Admitting axillary temperature will be recorded within 15 minutes of arrival in the NICU and then every 30 minutes until the temperature is within the normal range (as per current protocol). The infant will be weighed upon arrival in the NICU.

Practice plan for Temperature management for Infants 34 – 36 6/7 weeks GA

Following delivery and if appropriate, the infant will be placed under the radiant warmer and thoroughly dried. A cap will be placed on the head. Stabilization and/or resuscitation should proceed as per standard protocol. For those infants deemed appropriate the infant will be placed on the mother's chest/ abdomen and dried while maintaining skin to skin contact. A cap will be placed on the head. Axillary temperature will be obtained on all babies within 30 minutes of delivery and/or prior to transfer to the NICU or special care area. The delivery room temperature will be recorded. Maternal temperature will be recorded. For those infants admitted to the NICU and/or special care area for continuing observation, an admitting temperature will be obtained within 15 minutes of arrival to the NICU and then every 30 minutes until the temperature is within the normal range (as per current protocol).

Practice plan for Temperature management for Infants ≥ 37 weeks

Following delivery and if appropriate, the infant will be placed under the radiant warmer and thoroughly dried. A cap will be placed on the head. Stabilization and/or resuscitation should proceed as per standard protocol. For those infants deemed appropriate the infant will be placed on the mother's chest/ abdomen and dried while maintaining skin to skin contact. Axillary temperature will be obtained on all babies within 30 minutes of delivery and/or prior to transfer to the NICU or special care area. The delivery room or operating temperature will be recorded. Maternal temperature will be recorded. For those infants admitted to the NICU and/or special care area for continuing observation an admitting

temperature will be obtained within 15 minutes of arrival in the NICU and then every 30 minutes until the temperature is within the normal range (as per current protocol)

Monitoring of Data (Initial six months)

Any infant with an admitting axillary temperature $< 36^{\circ}\text{C}$ will have a review of the events from the time of delivery to the NICU within 48 hours of admission. For infants with an admitting axillary temperature $< 35.3^{\circ}\text{C}$ (1SD below mean), a debriefing with the care team will be conducted within 6 -12 hours of admission. Items reviewed will include adherence to the practice plan i.e. use of occlusive wrap and placement of exothermic mattress for infants < 34 weeks GA, management of near term and term babies i.e. dried, managed under a radiant warmer or on the chest/abdomen; maternal temperature, delivery or operating room temperature. Additional specifics will include BW, GA, ponderal index (to assess for growth restriction), antenatal administration of steroids within 48 hours of delivery, mode of delivery, specific resuscitative interventions in the delivery room, time from delivery to time of admission.

After six months of implementation of the practice plan, the data will be analyzed to determine potential reasons for an admitting temperature $< 36^{\circ}\text{C}$.

If adjustments to the practice plan are necessary they will be made with mutual co-operation involving the Medical and Nursing Directors of the Neonatal Intensive Care Nursery, Labor and Delivery the Bioengineering Department of the Hospital as well as the Hospital Administration.

Phase 2 (Duration of Six Months)

Phase 2 will include potential changes to the practice plan based on the observations noted during the first phase. It is the goal during Phase 2 to implement a system whereby the temperature in an individual delivery or operating rooms can be maintained in a recommended range (to be determined). The objective is to determine whether maintaining the delivery room temperature in the desired range modulates the admitting temperature of the infant to neonatal intensive care. A secondary objective is to determine whether increasing delivery room temperatures (if indicated) modulates provider and/or maternal comfort level. During this phase any infant with an admitting axillary temperature $< 36^{\circ}\text{C}$ will have a review of the events (as described above) from the time of delivery to the NICU through 48 hours of admission. For infants with an admitting axillary temperature $< 35.3^{\circ}\text{C}$ (1SD below mean), a debriefing with the care team will be conducted within 6 -12 hours of admission.

Phase 3 (Duration of One Year) (Evaluation of a Co-Coordinated Practice Plan)

Phase 3 of the proposal will evaluate all changes to the original practice plan including a daily targeted delivery or operating room temperature. The primary outcome will be to determine whether the overall length of stay can be reduced by two days as compared to the historical data presented in this proposal.

Potential Problems

Since the delivery room and operating room temperatures are monitored centrally it is conceivable that increases in the room temperatures may cause discomfort to mothers and providers. Moreover an elevated delivery room temperature in addition to other measures in the practice plan may result in an elevated temperature i.e. $> 37^{\circ}\text{C}$ in the babies. Elevated temperatures have been associated with adverse consequences in babies. Since the changes proposed are extensions of basic principals and practice and have been agreed upon by both the obstetrical and neonatal care teams we do not anticipate having to consider alternative strategies.

Data Analysis

The overall goal following introduction of all facets of the practice plan is to reduce LOS by 2 days. Based on our current cohort in this report we can infer the following. The mean admitting temperature was $36.1 \pm 0.7^{\circ}\text{C}$ and the LOS was 19.6 ± 2.6 (median 10 days). In order to reduce the LOS by two days, it is estimated based on the current cohort that we need to increase the admitting from 36.1 to 36.3 - 36.5°C (an increase of 0.2 to 0.4°C). This represented a sample size of 371 in the current cohort. The data will be analyzed using standard analysis including logistic modeling to determine whether other factors modulate initial temperature i.e. mode of delivery, extent/duration of resuscitation, maternal temperature, birth weight, gestational age, adherence to the practice plan etc. Standard analysis and logistic modeling will be used to determine whether other factors i.e. birth weight, gestational age, degree of initial respiratory support influence LOS. Additional data will be obtained from an ongoing neonatal data base.

Data Collection Sheet

MRN _____

Birth weight ____ grams

Gestational Age ____ weeks

Sex Male Female

Singleton Twin A B

Antenatal Steroids within 48 hours prior to delivery Y N

Maternal temperature $\geq 38^{\circ}\text{C}$ Y N Clinical Chorioamnionitis Y N

Maternal Analgesia Y N Time Prior to Delivery hrs

Maternal antibiotics

Maternal Anesthesia General Epidural Spinal

Mode of Delivery Vaginal CS Emergent CS

Maternal Temperature around delivery \pm hour _____

Infant Stabilization/ Resuscitation

Under the Radiant Warmer

< 34 weeks GA

Saran Wrap Y N

Exothermic Mattress Y N

Resuscitation Interventions

CPAP Y N

Intubation Y N

CPR/Medications Y N

Under the Radiant Warmer

Maternal Abdomen

≥ 34 weeks

Dried

Dried thoroughly

Skin to Skin or wrapped

Resuscitation Interventions

Infant temperature prior to transfer to the NICU/CCN _____

Delivery Room temperature prior to transfer

Duration of time from delivery to transport to the NICU _____ minutes

NICU /CCN

Initial Axillary temperature upon admission

If $< 36^{\circ}\text{C}$ time to achieve a normal temperature _____ minutes

Respiratory support in the first 24 hours

CPAP Y N

Intubation Y N

Surfactant Y N

Blood Sugar < 40 mg/dl Y N

Protection of Human Subjects

All infants delivered at [REDACTED] will be treated in the standard manner as part of a practice plan to maintain infant temperature. Consequently no consent will be sought from parents.

The practice plan has been submitted to the Institutional Review Board for review and approval in order for us to use the data for subsequent analysis and publication.

Inclusion of Women and Minorities

Not applicable.

This is a data analysis study of newborn infants. Consent will not be obtained from the parents.

Targeted/Planned Enrollment Table

Not applicable.

Data will be collected on all infants born in the NICU during the project period which meet the inclusion criteria.

Inclusion of Children

This is a data analysis study of newborn infants. Data will be collected from the medical records of all newborns delivered in the NICU.

References

1. Lupton AR, Salhab W, Bhaskar B, et al. Admission Temperature of Low Birth Weight Infants: Predictors and Associated Morbidities. *Pediatrics*; 2007; 119: E643-E649
2. Vohra S, Frenn G, Campbell V, Abbott M, Whyte R. Effect of polyethylene occlusive skin wrapping on heat loss in very low birth weight infants at delivery: a randomized trial. *J Pediatr*. 1999; 134(5):547-551.
3. [REDACTED] Neonatal Resuscitation: International Consensus on Cardiovascular Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. *Circulation* 2010;122:S516-S538

Data Sharing Plan

The proposed study will include data collected from medical records of newborns delivered in the NICU at [REDACTED] temperature of infants at time of delivery. We will not be collecting identifying information. All information will be maintained in a secure database to maintain confidentiality. Data will be shared as part of the publication of research findings.

PHS 398 Checklist

OMB Number: 0925-0001

1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

New Resubmission Renewal Continuation Revision

Federal Identifier:

2. Change of Investigator / Change of Institution Questions

Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

* First Name:

Middle Name:

* Last Name:

Suffix:

Change of Grantee Institution

* Name of former institution:

3. Inventions and Patents (For renewal applications only)

* Inventions and Patents: Yes No

If the answer is "Yes" then please answer the following:

* Previously Reported: Yes No

4. * Program Income

Is program income anticipated during the periods for which the grant support is requested?

Yes No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount (\$)	*Source(s)
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5. * Disclosure Permission Statement

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

Yes No