Best Evidence Statement (BESt)

Date: April 30, 2013

Title: Skin to Skin Care in a Level III-IV NICU

Clinical Question:

P (Population/Problem) Among neonates in a *Level III-IV neonatal intensive care unit (NICU),

I (Intervention) does receiving Skin to Skin Care (SSC)C (Comparison) compared to those not receiving SSC

O (Outcome) improve outcomes of decreased mortality, *infection, *length of hospital stay

*days on non-invasive respiratory support or *days on a ventilator?

<u>**Definitions**</u> for terms marked with * may be found in the Supporting Information section.

Target Population:

Inclusion Criteria: Neonates in a Level III-IV NICU in a high income country

Exclusion Criteria: Neonates in the low acuity setting (such as a newborn nursery) or in a resource limited setting (low income country).

Recommendations:

- 1. There is insufficient evidence and lack of consensus to make a recommendation on the use of SSC to decrease the number of days on non-invasive respiratory support or number of days on ventilation in a Level III-IV NICU in a high income country.
- 2. There is insufficient evidence and lack of consensus to make a recommendation on the use of SSC to decrease infection in a Level III-IV NICU in a high income country.
- 3. It is not recommended that SSC be used to reduce mortality or length of stay in a Level III-IV NICU in a high income country (Conde-Agudelo, 2011, [1a]; Moore, 2012, [1a]).

Note: Randomized control trials in high income countries reported lower mean duration in hours/day of intermittent SSC (Conde-Agudelo, 2011, [1a]).

Discussion/Summary of Evidence related to the recommendations:

There are many outcomes related to SSC that have been described in the literature. The purpose of this document is to describe the outcomes as they relate to the neonatal experience in a Level III-IV Neonatal Intensive Care Unit (NICU) in a high income country. Five outcomes were chosen as significant measurable outcomes in this setting:

- length of hospital stay (LOS)
- decreased mortality
- infection
- days on non-invasive respiratory support
- days on ventilator

Literature was found related to 3 of the 5 measures (LOS, mortality and infection). LOS was 0.9 days shorter when comparing early (beginning <24 hours after delivery) continuous SSC with *late (beginning between 24 hours and 10 days after delivery) continuous SSC (Conde-Agudelo, 2011, [1a]). However, no difference was seen in LOS in high income countries (Conde-Agudelo, 2011, [1a]; Moore, 2012, [1a]).

The second measure selected was mortality. The beneficial effects of SSC on mortality were also not seen in high income countries; nor were they seen with intermittent SSC nor *very late (beginning >10 after delivery) SSC (Conde-Agudelo, 2011, [1a]).

Evidence was equivocal, with regard to infection. The meta-analysis by Conde-Agudelo (2011 [1a]) found mixed results. While both intermittent and continuous SSC were reported to contribute to a reduced risk of nosocomial infection in low birth weight infants at discharge or 40-41 weeks (one randomized control trial each), only intermittent SSC and not continuous SSC was reported to reduce risk of sepsis at follow up. While risk of sepsis at follow up was seen in one of the five randomized control trials analyzed, it was not seen in the one randomized control trial done in a high income country. Additionally, there was no difference seen in the risk of moderate infection or illness at latest follow up (Conde-Agudelo, 2011, [1a]).

There was insufficient evidence regarding days on ventilator and non-invasive respiratory support as outcomes (studies generally excluded infants on respiratory support). Multiple recent meta-analyses state further research is needed with regard to safety and neurodevelopmental outcomes, demonstrating insufficient evidence and/or lack of consensus regarding these outcomes.

During the review of the literature, the following were noted:

- Evidence indicates increased exclusivity, duration and likelihood of any breastfeeding in healthy newborns with the use of SSC (Ahmed, 2010, [1a]; Moore, 2012, [1a]).
- SSC reduced pain in preterm infants but was ineffective in reducing pain in neonates (Pillai Riddell, 2012, [1a]).
- Evidence supports use of SSC in low birth weight (LBW) infants as an alternative to conventional care in resource limited settings (Conde-Agudelo, 2011, [1a]; Mori, 2010, [1a]).
- Further information is required concerning effectiveness and safety of early onset SSC in unstabilized LBW infants and long term neurodevelopmental outcomes (Conde-Agudelo, 2011, [1a]).
- A meta-analysis on the physiologic effects of SSC found evidence of a decrease in oxygen saturations during SSC but stated the evidence was equivocal that such an effect remained after SSC and this needed further investigation (Mori, 2010, [1a]).

Definitions:

<u>Days on non-invasive respiratory support (DNRS):</u> Number of days a patient receives continuous positive airway pressure (CPAP); high flow nasal cannula (HFNC); or nasal cannula (NC) respiratory support (oxygen supplementation without mechanical ventilation).

<u>Days on ventilator (DOV)</u>: Number of days a patient receives mechanical ventilation (regardless of oxygen supplementation).

<u>Infection:</u> Treatment with antibiotics for greater than 48 hours.

<u>Length of hospital stay (LOS):</u> Number of days patient remains in hospital prior to discharge home.

<u>Level III NICU</u>: Equipped to medically and/or surgically treat and support extremely high risk or critically ill newborns regardless of birth weight or gestational age. Available services include; the full range of pediatric subspecialties, advanced imaging, assisted ventilation and transport (AAP, 2012, [5a]).

<u>Level IV NICU</u>: Offering the capabilities of a Level III NICU as well as on-site surgical repair of serious congenital or acquired malformations, facilitation of transport systems and outreach education (AAP, 2012, [5a]).

Late Skin to skin care (LSSC): Late skin to skin care, initiated between 24 hours and 10 days after birth.

Very late skin to skin care (VLSSC): Very late skin to skin care, initiated >10 days after birth.

Reference List:

- Ahmed, A. H. & Sands, L. P. (2010). Effect of Pre- and Postdischarge Interventions on Breastfeeding Outcomes and Weight Gain Among Premature Infants. *Journal of Obstetric, Gynecologic, and Neonatal Nursing.* 39, 53-63. [1a]
- American Academy of Pediatrics: COMMITTEE ON FETUS AND NEWBORN. 2012. Policy Statement: Levels of Neonatal Care. Pediatrics 2012; 130:3 587-597; DOI:10.1542/peds.2012-1999 [5a]
- Conde-Agudelo, A., Belizán, J.M., & Diaz-Rossello, J. (2011). Kangaroo mother care to reduce morbidity and mortality in low birth weight infants. *Cochrane Database of Systematic Reviews*, 2011(3), 1-116. DOI: 10.1002/14651858.CD002771.pub2. [1a]
- Moore, E., Anderson, G.C., Bergman, N., & Dowswell, T. (2012). Early Skin-To-Skin Contact for Mothers and Their Healthy Newborn Infants. *Cochrane Database of Systematic Reviews*, 2012(5), 1-104. DOI: 10.1002/14651858.CD003519.pub3. [1a]
- Mori, R., Khanna, R., Pledge, D. & Nakayama, T. (2010). Meta-analysis of physiological effects of skin-to-skin contact for newborns and mothers. *Pediatrics International.* 52, 161–170. [1a]
- Pillai Riddell, R.R., Racine, N.M., Turcotte, K., Uman, L.S., Horton, R.E., Din Osmun, L., Ahola Kohut, S., Hillgrove Stuart, J., Stevens, B., Gerwitz-Stern, A. (2012). Non-pharmacological management of infant and young child procedural pain. *Cochrane Database of Systematic Reviews*, 2012(5). 1-212. DOI: 10.1002/14651858.CD006275.pub2. [1a]

IMPLEMENTATION

Applicability Issues:

Frequently, in the Level III-IV NICU environment, patients are unstable, admitted after, or stay beyond the optimal period for SSC.

Further research is needed concerning effectiveness and safety of early onset SSC in unstabilized LBW infants and long term neurodevelopmental outcomes.

Relevant CCHMC Tools for Implementation:

None found

Outcome or Process Measures:

Not applicable

SUPPORTING INFORMATION

Background/Purpose of BESt Development:

SSC is the time a newborn spends in a developmentally appropriate position which allows for the greatest amount of skin to skin contact, generally chest to chest between a mother and diaper clad infant. This BESt developed out of a quality improvement project focused on SSC in the NICU. The project goal was 60 percent of eligible patients receiving SSC at least once in a 2 week period. This goal led to multiple questions regarding an appropriate rate and timing of SSC to obtain benefits and which benefits could be assigned considering the often critical nature our patient population and typical late onset of SSC in the tertiary pediatric hospital setting. While the developmental care team was able to increase rates of SSC using various methods, such as discussion of eligibility in daily rounds and implementation of a checklist, questions remained. Is one episode in a two week period a sufficient amount of SSC to produce positive outcomes? What population are we counting as eligible? Is this a medical definition of any patient that meets given criteria or does this only include appropriate patients given beneficial outcomes desired? For example, do we not include infants beyond a given age, those not planning to breastfeed, or those that have not done SSC before a certain time? All of these issues exist when considering our Level IV NICU population.

There is high level evidence that strongly supports the use of early SSC for breastfeeding success up to 6 months of age in healthy infants. While this is well documented, it is not specific to our target population and therefore not included in the PICO question. Many outcomes are measured in the literature (ex: Conde n=47, Moore n=34) related to SSC. This review describes 5 specific outcomes related to the Level III-IV setting in a high income country and Cincinnati Children's Hospital Medical Center's strategic goals (safety, flow, cost). Outcomes not discussed in the background or PICO question of this best evidence statement had insufficient evidence or lack of consensus.

While there is evidence to support SSC for pain reduction in the preterm infant, the benefits described were not seen in older infants (Pillai Riddell, 2012, [1a]). Also, it was repeatedly recommended that further research be conducted regarding unstable patients, which is common in the Level III/IV NICU. This population is often unstable, critically ill or otherwise outside the parameters described in the literature (meeting exclusion criteria of most studies). Although, pain reduction in the preterm neonate and breastfeeding up to 6 months are included in the discussion because they are seen in many NICU's, these outcomes were not included in the PICO question because the purpose of the best evidence statement was to determine the effectiveness SSC in a Level III-IV NICU setting in a high income country considering the population and implementation. Is SSC effective when implemented late or very late? What is an effective duration, rate or frequency? Is SSC effective in the unstable or critically ill patient? In other words, is it effective in our patient population?

Lastly, while ventilated patients and patients with other forms of respiratory support comprise a large portion of our population, healthy term/preterm infants comprise a very small portion, the 2 respiratory outcomes "days on a ventilator" and "days on non-invasive respiratory support" were chosen as characteristic of our population.

Search Strategy:

Databases: Cinahl, Cochrane Library, Medline

Search Terms: Skin to Skin Care, Kangaroo Care, Kangaroo Mother Care

Filters: 1999 to 2012, Human, English Search Dates: October 16, 2012

Relevant CCHMC Evidence-Based Documents:

None found

Group/Team Members:

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NIDCAP Trainer

Conflicts of Interest were declared for each team member:
No financial conflicts of interest were found.
No external funding was received for development of this BESt:
The following financial conflicts of interest were disclosed:

Note: Full tables of the <u>LEGEND evidence evaluation system</u> are available in separate documents:

- Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality (abbreviated table below)
- Grading a Body of Evidence to Answer a Clinical Question
- <u>Judging the Strength of a Recommendation</u> (dimensions table above)

Table of Evidence Levels (see note above)

Quality level	Definition
1a [†] or 1b [†]	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

[†]a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength (see note above):

Strength	Definition						
It is strongly recommended that There is consensus that benefits clearly outweigh risks and			itweigh risks and burdens				
It is strongly recommended that not	negative recommendation	ons).					
It is recommended that There is consen		s that benefits are closel	ly balanced with risks and burd	dens.			
It is recommended that not							
There is insufficient evidence and a lack of	consensus to make	a recommendation					
Reflecting on your answers to the dimension	ons below and giver	that more answers to the	he left of the scales indicates s	upport for a stronger			
recommendation, complete one of the sen	•						
(Note that for negative recommendations,	the left/right logic i	may be reversed for one	or more dimensions.)				
1. Grade of the Body of Evidence		High	Moderate Moderate	Low			
Rationale: There was a high risk of bias due to selective outcome reporting and some studies did not report the outcomes listed in the							
Methods section. (Conde-Agudelo, 2011, [1a]). None of the 34 studies met all of the methodological quality criteria. (Moore, 2012, [1a]).							
2. Safety/Harm (Side Effects and Risks)		Minimal	Moderate	Serious			
Rationale: Moore et al. found no evidence of short- or long-term negative effects of SSC on neonates. (Moore, 2012, [1a]). However, Mori							
et al. found evidence of a decrease in oxygen saturations during SSC but stated the evidence was equivocal that such an effect remained							
after SSC but this needed further investigation (Mori, 2010, [1a]).							
3. Health benefit to patient		Significant	Moderate	Minimal			
Rationale: The evidence does not support the use of SSC for pain in the term infant (Pillai Riddell, 2012, [1a]); nor does it support the							
implementation of SSC after 10 days (Conde-Agudelo, 2011, [1a]). Additionally, there is inconclusive evidence regarding implementation							
of SSC prior to stabilization (Conde-Agudelo, 2011, [1a]).							
4. Burden on patient to adhere to recommendation		Low	Unable to determine	High			
Rationale:							
5. Cost-effectiveness to healthcare system		Cost-effective		☐ Not cost-effective			
Rationale: Cost benefit described in resource limited setting does not apply to target population.							
6. Directness of the evidence for this target		Directly relates	Some concern of	Indirectly relates			
population			directness				
Rationale: Meta-analyses describe bei	nefits to late preteri	m infants in low acuity re	esource limited settings; howe	ver these benefits have not			
been reproduced in the more acute setting or in high income countries. (Conde-Agudelo, 2011, [1a]; Moore, 2012, [1a]). Thirty of the 34							
RCT's analyzed included only healthy term infants. (Moore, 2012, [1a]). The majority of trials excluded patients with congenital							
anomalies, severe perinatal complications or parental refusal. (Conde-Agudelo, 2011, [1a]).							
7. Impact on morbidity/mortality or q		High	Medium	Low			
Rationale: Benefit on mortality and length of stay have not been seen in high income countries (Conde-Agudelo, 2011, [1a]).							

Copies of this Best Evidence Statement (BESt) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/bests/

Examples of approved uses of the BESt include the following:

- · Copies may be provided to anyone involved in the organization's process for developing and implementing evidence based care;
- · Hyperlinks to the CCHMC website may be placed on the organization's website;
- The BESt may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at EBDMinfo@cchmc.org for any BESt adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

Please cite as: Moyer, M., Cincinnati Children's Hospital Medical Center: Best Evidence Statement Skin to Skin Care in a Level III-IV NICU, http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/best.htm, BESt 161, pages 1-6, 4/30/13.

This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration. Conflict of interest declaration forms are filed with the CCHMC EBDM group.

Once the BESt has been in place for five years, the development team reconvenes to explore the continued validity of the recommendation. This phase can be initiated at any point that evidence indicates a critical change is needed. CCHMC EBDM staff performs a quarterly search for new evidence in an horizon scanning process. If new evidence arises related to this BESt, authors are contacted to evaluate and revise, if necessary.

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at EBDMinfo@cchmc.org.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.