Maintaining Safety with Baby Friendly Practices

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"Health care systems should ensure that maternity care practices provide education and counseling on breastfeeding. Hospitals should become more “baby–friendly,” by taking steps like those recommended by the UNICEF/WHO’s Baby–Friendly Hospital Initiative."

Regina A. Benjamin, MD, MBA
US Surgeon General, 2009–2013
An Oregon woman who says she accidentally suffocated her newborn baby after falling asleep with him in her hospital bed has filed an $8.6 million lawsuit against the institution, Portland Adventist Medical Center, and a nurse there, according to court documents.

The mother, Monica Thompson, filed the suit last week at Multnomah County Circuit Court. She cited negligence in causing "foreseeable harm" to her son Jacob Daniel Thompson and "negligent infliction of emotional distress" to her over the child's death on August 12, 2012. He was 10 days old. Thompson is asking for a jury trial.
3410 gm AGA term male born by SVD at 1546 hours to 30 y.o. g7 p1 mother in Level 1 hospital
Mother had balanced translocation of chromosome 15 and multiple losses
PROM x 3 days → pitocin induction
Apgars 6/9
Allowed to breast feed in LDRP in first hour
Case

- Assessed by RN x2 during “bonding period,” the last time at 1647 (born at 1546)
- 1655: found by RN to be gray, apneic, bradycardic in mother’s arms
- Rushed to nursery and CPR started
- MD arrived at 1700 and successfully intubated
- Unable to place peripheral iv
- First gasp and HR at 1729
- Neonatologist at 1737
Case

- Successful resuscitation and baby moved to Level 3 for cooling
- Now has significant developmental delays and CP
- Litigation claims inadequate monitoring during “bonding period” and resuscitation beneath the standard of care
The Problem

- Skin-to-skin care, rooming in; promotion of breastfeeding in hospitals
- WHO Ten Steps to Successful Breastfeeding
- SSC and RI have evidence of enhanced outcomes

**BUT**

- Safety concerns
  - SUPC
  - Falls
  - Unrecognized medical problems
Definitions

- **Skin-to-skin Care**
  - Placing naked infant in direct contact with mother with the ventral skin of the baby touching the ventral skin of the caregiver
  - Recommended immediately following birth for 1 hour; also later in infancy
  - Delay painful procedures (Vit K, eye treatment)
  - Provided for all “well” term and newborns (c-sections)
  - Late preterm may also “benefit”, but are at increased risk of early morbidities
Definitions

- **Rooming-in**
  - Mothers and infants to remain together 24 hours/day while in hospital
  - Applies to term and late preterm (>35 weeks)
  - Procedures performed at the bedside
  - Mothers may nap, shower or leave the room with the expectation that staff will monitor the newborn at “routine intervals”
  - Mothers encouraged to use call bell for assistance
Extensive research on SSC: Baby

- Immediately after birth stabilizes newborn temp, prevents hypothermia
- Earlier (<5 min) stabilizes HR faster
- Stabilizes blood glucose, decreases crying, better CR stability
- Decreases pain from procedures
- Longer SSC (>60 minutes) results in lower salivary cortisol levels
- In preterms, improves neurobehavioral maturation, gi adaptation, better sleep patterns, better growth
- Improves breastfeeding (reduced formula use)

Moore ER. Cochrane Database Syst Rev 2012:5
Evidence Supporting SSC & RI

- Extensive research on SSC: Mother
  - Decreases maternal stress and improves paternal perception of stress in the relationship with baby
  - Decreases postpartum hemorrhage
  - Depression scores and salivary cortisol levels lower over first month among postpartum mothers providing STS care
  - Enhances opportunity for early first breastfeed, leading to more readiness to breastfeed, organized suckling pattern and more success in exclusive and overall breastfeeding

Moore ER. Cochrane Database Syst Rev 2012:5
<table>
<thead>
<tr>
<th>Variable</th>
<th>STS≤60 min</th>
<th>STS&gt;60 min</th>
<th>P value</th>
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<td>81.0±14.9</td>
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<td>Adjusted mean salivary cortisol (ug/Dl)</td>
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<td>60 min</td>
<td>5.03±0.46</td>
<td>3.94±0.24</td>
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<td>120 min</td>
<td>2.71±0.40</td>
<td>2.08±0.21</td>
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Takahashi Y et al. Early Hum Devel. 2011
Research on RI
- Improves patient satisfaction
- Better outcomes including dyads with NAS
- Provides better security against abduction
- Leads to decreased infant abandonment
- Supports cue based feeding
- Decreases hyperbilirubinemia
- Increases likelihood of breastfeeding to 6 months
Breastfeeding and the Use of Human Milk

Pediatrics, March 2012

- Policy Statement (Section on Breastfeeding)
- Reaffirmed recommendation of *exclusive* breastfeeding for first 6 months of life
- Protective effect of breastfeeding against:
  - Asthma, eczema, atopic dermatitis, gi infections, lower respiratory tract infections, O.M.
Breastfeeding and the Use of Human Milk

- SIDS reduced by >1/3 in breastfed babies
- 15–30% decrease in adolescent and adult obesity in breastfed vs. non-breastfed infants
- Pediatricians encouraged to promote breastfeeding to mothers and for hospitals to accommodate and stimulate breastfeeding during the birth hospitalization.
Mary Cassatt, 1906
Hospital Routines: AAP Recommendations

- AAP Sample Hospital Breastfeeding Policy
- Adopts WHO/UNICEF principles on breastfeeding (BFHI, 1991)
- Revise hospital policies that interfere with early skin-to-skin contact or limit time infant can spend with mother, eliminate human milk substitutes and pacifier use
- AAP endorsed Ten Steps Program (2009)
The Ten Steps to Successful Breastfeeding are:

- Have a written breastfeeding policy that is routinely communicated to all health care staff.
- Train all health care staff in the skills necessary to implement this policy.
- Inform all pregnant women about the benefits and management of breastfeeding.
- Help mothers initiate breastfeeding within one hour of birth.
- Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
- Give infants no food or drink other than breast-milk, unless medically indicated.
- Practice rooming in – allow mothers and infants to remain together 24 hours a day.
- Encourage breastfeeding on demand.
- Give no pacifiers or artificial nipples to breastfeeding infants.
- Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.
Ten Steps Program

- Adherence to program demonstrated to:
  - Increase rates of breastfeeding initiation, duration and exclusivity

- Implementation of 5 postpartum practices have been shown to:
  - Increase breastfeeding duration (regardless of SE status)
  - Increase breastfeeding in 1st hour after birth
  - Increase exclusive breastfeeding
  - Increase avoidance of pacifiers
“Baby Friendly” Hospitals

- Baby Friendly Hospital Initiative (BFHI) launched in 1991
- Based on WHO/UNICEF Ten Steps Program (1991) and Innocenti Declaration (1990)
- “Baby Friendly USA”, certifying body (the “Golden Bow”)
- First hospital certified in 1996
- May 2017: 434 certified hospitals (represents 21% of all US births)
Safety Concerns re: immediate STS care

- Contraindications to immediate STS care
  - Baby requiring positive pressure ventilation in DR
  - Low Apgar scores (< 7 at 5 minutes)
  - Cord pH < 7.0 or BD > -12
  - Baby < 37 weeks gestation

- Concerns re: lack of standardization in care
  - Lapses of observation by staff
  - Lack of education of staff in potential dangers
Unintended Consequences of Current Breastfeeding Initiatives

- Concerns re: SUPC, co-sleeping, leaving mother-baby unattended in first hours of life, falls
- Advocates against “overly rigid insistence” on following 10 STEPS
- Concerns regarding advice against pacifiers which have protective effect against SIDS

Definition of SUPC

- Potentially fatal event in otherwise healthy-appearing term newborn
  - British definition:
    - >35 weeks gestation
    - Well at birth (normal 5 minute Apgar: >8)
    - Collapses unexpectedly requiring CPR
    - Dies, goes to NICU or develops encephalopathy
    - Other medical conditions (sepsis, cardiac, etc.) ruled out
Incidence of SUPC

- Depends on definition used
  - If brief resolved unexplained event (BRUE) included, low risk and probably benign
  - Then incidence much higher
- Serious SUPC requiring medical CPR
  - 2.6 to 133 cases/100,000 live births
  - Comparison: Kernicterus estimated at 1–2/100,000 live births
SUPC of Newborn Infants: A Review of Cases, Definitions, Risks and Preventive Measures

- Reviewed all published reports of SUPC in first postnatal week (398)
- Wide ranging estimates of incidence: 2.6 to 133/100,000 births
- ½ died; ½ CNS sequelae
- No etiology found in 153 of 233 deaths
- 1/3 of cases in first 2 hours; 1/3 between 2 and 24 hours and 1/3 between 1 and 7 days

Herlenius E, Kuhn P: Trans Stroke Res, 2013
Apparent life-threatening events in presumably healthy newborns during early STS contact


- 6 cases of ALTEs in DR during 1st 2 hours of life
- All healthy infants, on mother during early STS contact
- Mother and infant not observed
- Suggested surveillance during early STS
Sudden deaths and severe ALTEs in term infants within 24 hours of birth


- Report of cases in Germany in 2009 of unexplained SUD after 10 min Apgar ≥ 8
- 43 cases reported, 17 met entry criteria
- Incidence 2.6/100,000 live births
- 7 deaths, 6 abnormal CNS at discharge
- 9 events in first 2 hours of life; 12 babies lying on mother’s chest and abdomen
- 7 noticed by HP while mother was awake!!
Sudden Unexpected Perinatal Collapse in UK

- 0.5 cases per 1000 births
- ≥37 weeks gestation; 5 min Apgar ≥8
- 45 cases; 12 deaths
- 73% in first 2 hours
- Associations: primips, breastfeeding, prone positioning, unattended by staff

Becher JC et al. Arch Dis Child Fetal neo Ed, 2012; 97: F30–4
Sudden unexplained early neonatal death (SUEND) or collapse: a national surveillance study

- National 3 year surveillance study: Australia
- SUEND or ALTEs reported at 0.05–0.38/1000 live births; identified 48 cases
- 26 babies who collapsed found on carer’s chest
- “First postnatal day is a vulnerable period”
- Development and implementation of safe sleep guidelines needed

Lutz et al. 2016 Pediatr Res
Deaths and near deaths of healthy newborn infants while bed sharing on maternity wards


- Evaluate bed sharing programs on maternity wards
- Survey MEs for deaths of healthy newborns while bed sharing
- 15 deaths, 3 near deaths reported
- Accidental suffocation deemed most likely cause of incidents
- Suggests education of mothers and more efficient monitoring during STS contact
Reports of deaths and ALTEs in early neonatal period associated with STS contact

- Unexpected postnatal collapse of presumably healthy newborns
- Etiology of arrests unknown
- Are these events consistent with “Triple Risk Model”?
  - Intrinsic vulnerability of infant (blunted CO2 response)
  - Critical developmental period (e.g. post-delivery stress or sedation)
  - Exogenous stressor (e.g. prone position, nose in breast, covers over face, hyperthermia, etc.)
Falls

- Mothers (or fathers) may become dizzy, faint or unable to hold infant
- Maternal fatigue, drug administration may increase risk
- Mother with baby in bed may fall asleep and baby roll to floor
Oregon Patient Safety Review

- 7 hospitals part of one health system
- 22,866 births: 9 cases of infant falls
- Incidence of 3.94 falls per 10,000 births (2006–2007)
- Increase from previous review (1.6/100,000 births) for unknown reasons
AAP Policies in place

- Discourage bed-sharing (Task Force 0n SIDS, *Pediatrics*, 2011)

Neonatal Resuscitation Algorithm – 2016 Update

- **HR below 100, gasping, or apnea?**
  - Yes: **PPV, SpO₂ monitoring**
  - No: **HR below 100?**
    - Yes: **Take ventilation corrective steps**
    - No: **Postresuscitation care**

- **Labored breathing or persistent cyanosis?**
  - Yes: **Clear airway SpO₂ monitoring Consider CPAP**
  - No: **Postresuscitation care**
“Babies who required supplemental oxygen or PPV after delivery will need close assessment. They…..should be evaluated frequently during the immediate newborn period…Many will require admission to a nursery environment where continuous cardio–respiratory monitoring is available and vital signs can be measured frequently.”
Developed protocol to:
- Promote safe mother–infant bonding
- Establish successful early breastfeeding
- Correct risk factors for SUPC

Protocol concentrates on maternal education, frequent assessments, discouraging bed-sharing, STS only when mother awake, not leaving mother alone in first hours after birth.
Infant Safety

- Mother post delivery exhaustion
- Mother may have had opioids, MgSO4, other depressant/sedating medications
- Monitoring by hospital personnel (who?) or family (untrained, father also fatigued)
- Danger of SUPC or fall
Balance safe sleep and skin-to-skin care/breastfeeding initiation

- Trained observer during first 1–2 hours
- Limit bonding in compromised infant
- Increased maternal education re: bedsharing
Procedure for immediate postnatal STS

- Delivery of term infant
- Dry, stimulate, assess
- If stable place STS with cord attached, clamp cord after one minute
- Cover head with cap (optional) and place prewarmed blankets over cover body, leaving face exposed
- Assess 1 and 5 minute Apgar scores
- Replace wet blankets and cap with dry warm ones
- Assist and support to breastfeed
High risk situations include:
- PPV (resuscitation)
- Low Apgar scores
- Late preterm
- Difficult delivery (operative vaginal delivery)
- Mother receiving opioids, MgSO4
- Excessively sleepy mother
Additional safety measures

- Stabilize ambient temperature
- Use of appropriate lighting
- Facilitating unobstructed view of baby’s face
- Additional support persons may augment but not replace staff monitoring
- Education of staff in SUPC including safe positioning of baby
Components of safe positioning during STS

- Infant’s face can be seen
- Head in sniffing position
- Nose and mouth are not covered
- Head turned to one side
- Neck is straight, not bent
- Shoulders and chest face mother
- Legs flexed
- Back (not face) covered with blankets
- Monitored continuously by staff in delivery area
- Infant placed in bassinet when mother wants to sleep
Safety Concerns When Rooming-In

- Similar concerns to STS
  - Mother falling asleep with baby in bed leading to SUPC or fall
- Mother may be unstable due to exhaustion, medication effects; may not be able to ambulate safely
- Relatively unstudied compared to falls of neurologically impaired, post surgical cases or elderly
British study on rooming-in safety

- 64 mother-infant dyads
- Sleep in stand alone bassinet, side-car bassinet or mother’s bed
- Breastfeeding more frequent in bed-sharing and side-car
- No adverse events, but video monitoring identified more safety issues with bed-sharing
- Authors concluded side-car provided best opportunity for breastfeeding and safest conditions

Ball et al, ADC, 2006
Randomly Allocated Postnatal Unit Bassinets

Control, standard rooming-in with a stand-alone bassinet to the bed.

Intervention, side-car bassinet attached
AWHONN: no more than 3 maternal–infant dyads to 1 RN
Nursing extenders may augment care and monitoring
Education of mothers and families on risks of bed sharing
Safe sleep practices for babies modeled and taught (firm surface, back to sleep, sleep alone)
Suggestions for rooming-in

- Use a patient safety contract
- Monitor mothers according to risk assessment
- Use fall assessment tools
- Implement maternal egress testing
- Review mother–infant equipment (bed rails, call bells, resuscitation equipment)
- Educate staff re: prevention of infant falls
- Use risk assessment tools to avoid hazards of rooming–in and STS practices
Anticipatory guidance re: breastfeeding and sleep safety
Follow AAP recommendations on smoking, pacifier introduction, use of alcohol, bed sharing, sleep positioning
Post discharge support for breastfeeding
Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns

Lori Feldman-Winter, MD, MPH, FAAP, Jay P. Goldsmith, MD, FAAP, COMMITTEE ON FETUS AND NEWBORN, TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

- Combined effort of COFN and Task Force on SIDS
- Published in *Pediatrics*, September 2016
Another “unintended consequence”? 

- Perhaps “Baby Friendly” will make hospitals more attractive and ↓ home births
- Planned Out-of-Hospital Birth and Birth Outcomes
  - Oregon 2012–2013 birth certificates reviewed
  - Revised birth certificates indicated **planned** place of birth
  - Planned out-of-hospital births:
    - 3.9 vs. 1.8 deaths/1000 deliveries
    - Higher risk of seizures and NICU admission
    - Decreased odds for obstetric procedures

Snowden JM et al, NEJM, 2015
Case Denouement

- Multiple expert depositions taken for both sides
  - Defense claimed no protocol required full time staff in mother’s room (arrest occurred after 1 hour of age)
  - Defense claimed resuscitation met standard for Level 1 hospital
- Defendant hospital settled for undisclosed amount prior to start of trial
The Human Touch

Tis the human touch
in this world that counts,
The touch of your hand and mine,
Which means far more
to the fainting heart
Than shelter and bread and wine.
For shelter is gone
when the night is o’er,
And bread lasts only a day.
But the touch of the hand
And the sound of the voice
Sing on in the soul always.

Spencer Michael Free, MD (1925)