Introduction And Use Of Pasteurized Donor Human Milk On The Mother/Baby Unit

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UC San Diego Health
We know that Pasteurized Donor Human Milk (PDHM) benefits VLBW infants

- Infection
- Necrotizing enterocolitis
- Poor growth (brain & body)
- Feeding intolerance
- Poor developmental outcomes
- Long hospital stay
- Failure to breastfeed
- Readmission after going home
But what is the role of PDHM for healthy term and late preterm infants?
Objectives

• Primer on PDHM
• What is role for PDHM for healthy term infants in hospital?
  o Physiologic
  o Practical
• National metrics re: exclusive breastfeeding
• Current trends in PDHM use in mother/baby units
• Challenges regarding supplementation
• Implementation of PDHM use
• Early outcomes, use & cost data
Non-profit milk banking

- Regulated by HMBANA
- CDPH requires a tissue bank license
- FDA site visit
- Good Manufacturing Processes
- Food safety rules
- Milk donation is voluntary
- Donor mothers are screened and tested
- Donated milk is frozen (not fresh)
- Milk less than 12 months old (varies)
- Milk heat pasteurized
- May be donated to research if not used for clinical purposes
Maternal screening for donation

- Detailed questionnaire regarding health habits and risks for infection
- Medication query
- No tobacco, cannabis, little alcohol, no street drugs
- No living in Europe during prion outbreak
- Lab testing (Syphilis, Hep B, Hep C, HIV, HTLV 1&2)
- Approval by mother and baby physician
Donated milk is:

- Shipped/delivered to bank frozen
- Thawed
- Analyzed for nutrients (varies)
- Pooled with 1-5 mothers’ milks
- Bottled and capped
- Pasteurized (30-minute Holder method)
- Cultured
- Re-frozen
- Shipped to hospitals
- Price varies (approx $4-5/ounce)
HUMAN MILK BANKING
ASSOCIATION OF NORTH AMERICA

Mobilizing the Healing Power of Donor Milk

HMBANA's 29 Member Milk Banks

Map data ©2020 Google, INEGI. Terms. 200 mi.
Challenges for Mother/Baby units regarding supplementation

• Maternal issues:
  o Many women do not make milk on a normal timetable
  o Women who cannot BF (HIV, mastectomy, ill, multiple medications, cancer patients)

• Infant issues:
  o At UC San Diego 25% of infants meet criteria for medical supplementation (BF rates >95%)
  o Attention to high risk newborns (NAS, LPI or IUGR) and delayed discharge will lead to early supplementation but discharge home exclusively BF.

• Practical issues:
  o Meeting national metrics for Ex BF rates that are imperfect
  o Hospitals want to improve their BF message
  o Families are refusing formula and/or bringing in shared milk
  o Hospitals are reluctant to expand PDHM out of the NICU
  o Milk handling on mother/baby units different than NICU
The use of donor human milk is increasing for high-risk infants, primarily for infants born weighing <1500 g or those who have severe intestinal disorders. Pasteurized donor milk may be considered in situations in which the supply of maternal milk is insufficient. The use of pasteurized donor milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established human milk banks. The use of nonpasteurized donor milk and other forms of direct, Internet-based, or informal human milk sharing does not involve this level of safety and is not recommended. It is important that health care providers counsel families considering milk sharing about the risks of bacterial or viral contamination of nonpasteurized human milk and about the possibilities of exposure to medications, drugs, or herbs in human milk. Currently, the use of pasteurized donor milk is limited by its availability and affordability. The development of public policy to improve and expand access to pasteurized donor milk, including policies that support improved governmental and private financial support for donor milk banks and the use of donor milk, is important.

INTRODUCTION

Human milk provides health benefits for all newborn infants but is of particular importance for high-risk infants, especially those born with very low birth weight (<1500 g). Donor human milk also can be beneficial to supplement the mother’s own milk when necessary. The evidence to support the use of donor human milk has been reviewed 1–6 and recent studies 7–9 support health benefits for its use in infants with a birth weight <1500 g, especially in decreasing rates of necrotizing enterocolitis.

Donor milk banks represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in NICUs and other settings. However, accessibility to donor milk in the United States is limited by its availability and affordability. The development of public policy to improve and expand access to pasteurized donor milk, including policies that support improved governmental and private financial support for donor milk banks and the use of donor milk, is important.
American Academy of Pediatrics position (2019)

- Although a mother’s own milk is always preferred, donor human milk may be used for high-risk infants when the mother’s milk is not available or the mother cannot provide milk.
- **Priority should be given to providing donor human milk to infants <1500 g birth weight.**
- Health care providers should discourage families from direct human milk sharing
- **Other AAP resources:**
  - AAP Pediatric Nutrition Book 2019 endorses the option of using PDHM for supplement of breastfeeding outside of the NICU
  - AAP Breastfeeding and the use of human milk is in the process of being updated (stay tuned)
Trends in PDHM use in mother/baby units

<table>
<thead>
<tr>
<th>Table 1. Birth Hospital Characteristics</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td><strong>All hospitals</strong></td>
</tr>
<tr>
<td>(n = 71)</td>
</tr>
<tr>
<td>Donor milk used for healthy newborns</td>
</tr>
<tr>
<td>Any donor milk use</td>
</tr>
<tr>
<td>Highest level of care</td>
</tr>
<tr>
<td>Level III or IV</td>
</tr>
<tr>
<td>Level II</td>
</tr>
<tr>
<td>Level I</td>
</tr>
<tr>
<td>Baby-Friendly Hospital Initiative-designated or on pathway</td>
</tr>
<tr>
<td>Exclusive breastfeeding percent, median (range)</td>
</tr>
</tbody>
</table>

Physiologic reasons to use PDHM for term newborns

Milk biology

Infant microbiome

Minimize formula exposure

Transient neonatal ileus
Biology of human milk—much more than nutrition

- Antimicrobial factors
- Anti-inflammatory factors
- Hormones
- Growth factors
- Regulatory peptides
- Transporters
- HMO (human milk oligosaccharides)
- Probiotic Bacteria
- Living cells

HMO’s courtesy of Dr. Lars Bode
Table 4. In-Hospital Mortality and Major Morbidities<sup>a</sup>

<table>
<thead>
<tr>
<th></th>
<th>Donor Milk (n = 181)</th>
<th>Preterm Formula (n = 182)</th>
<th>Risk Difference, % (95% CI)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality and morbidity index&lt;sup&gt;c&lt;/sup&gt;</td>
<td>78/181 (43.1)</td>
<td>73/182 (40.1)</td>
<td>5.0 (-2.7 to 12.7)</td>
<td>.20</td>
</tr>
<tr>
<td>Death</td>
<td>17/181 (9.4)</td>
<td>20/182 (11.0)</td>
<td>-1.0 (-9.7 to 7.6)</td>
<td>.82</td>
</tr>
<tr>
<td>Late-onset sepsis</td>
<td>44/181 (24.3)</td>
<td>35/182 (19.2)</td>
<td>3.8 (-2.6 to 10.2)</td>
<td>.24</td>
</tr>
</tbody>
</table>

| Necrotizing enterocolitis   |                      |                           |                                          |         |
| All stages                  | 7/181 (3.9)           | 20/182 (11.0)             | -7.1 (-12.5 to -1.8)                     | .01     |
| Stage ≥ II                  | 3/181 (1.7)           | 12/182 (6.6)              | -4.9 (-9.0 to -0.9)                      | .02     |
| Oxygen support at 36 wk postconception | 44/175 (25.1)          | 37/179 (20.7)             | 4.2 (-4.9 to 13.4)                       | .36     |
| Severe retinopathy of prematurity | 7/181 (3.9)           | 8/182 (4.4)               | -0.5 (-4.6 to 3.6)                       | .80     |
| Severe brain injury         | 38/181 (21.0)          | 37/182 (20.3)             | 4.5 (-3.7 to 12.8)                       | .28     |
From: Association of Exposure to Formula in the Hospital and Subsequent Infant Feeding Practices With Gut Microbiota and Risk of Overweight in the First Year of Life

Neonatal Ileus

- Almost universal that infants have a mild to moderate ileus at birth
- Formula, even with small volumes, often leads to vomiting and abdominal distention during first feeds
- Our observation is early PDHM feeds are very well tolerated, and on day 2-3-4 formula is better tolerated
- (Providing PDHM for infants of mothers who have a medical contraindication is a much-appreciated kindness)
Practical reasons to use PDHM on Mother/Baby units

- **Reduce raw milk sharing**
- **Reduce conflict for supplement**
- **Improve ExBF rates**
- **Support for milk donation**

<table>
<thead>
<tr>
<th>Period</th>
<th>UC San Diego</th>
<th>San Diego County</th>
<th>UC Systemwide</th>
<th>PRIME Hospitals</th>
<th>Level IV NICUS: CA, OR, WA</th>
<th>NICU Level III/IV - CA MDC</th>
<th>Delivery Volume: 2500-2999 - All MDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2019</td>
<td>67.8% (118/174)</td>
<td>69.6%</td>
<td>77.7% (1,880/2,420)</td>
<td>71.0% (4,910/6,911)</td>
<td>74.7% (2,508/3,356)</td>
<td>70.5% (4,336/6,154)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Feb 2019</td>
<td>59.0% (95/161)</td>
<td>67.2%</td>
<td>65.3% (113/173)</td>
<td>70.5% (4,910/6,911)</td>
<td>69.5% (115/166)</td>
<td>66.7% (104/156)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Mar 2019</td>
<td>74.7% (140/185)</td>
<td>72.1%</td>
<td>74.7% (142/190)</td>
<td>67.2% (4,910/6,911)</td>
<td>72.0% (121/192)</td>
<td>70.2% (104/156)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Apr 2019</td>
<td>75.7% (140/185)</td>
<td>70.4%</td>
<td>73.0% (141/190)</td>
<td>67.2% (4,910/6,911)</td>
<td>72.1% (132/183)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>May 2019</td>
<td>83.1% (177/213)</td>
<td>79.8%</td>
<td>78.5% (179/228)</td>
<td>70.5% (4,910/6,911)</td>
<td>72.9% (115/166)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Jun 2019</td>
<td>78.4% (160/204)</td>
<td>N/A</td>
<td>70% (2508/3356)</td>
<td>71.0% (4,910/6,911)</td>
<td>N/A (115/166)</td>
<td>N/A (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Jul 2018</td>
<td>69.3% (115/166)</td>
<td>72.9%</td>
<td>73.0% (141/190)</td>
<td>69.5% (4,910/6,911)</td>
<td>72.1% (132/183)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Aug 2018</td>
<td>62.7% (96/153)</td>
<td>69.5%</td>
<td>65.9% (113/173)</td>
<td>70.5% (4,910/6,911)</td>
<td>69.3% (115/166)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Sep 2018</td>
<td>72.1% (132/183)</td>
<td>70.0%</td>
<td>70.2% (104/156)</td>
<td>70.5% (4,910/6,911)</td>
<td>72.9% (115/166)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
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<tr>
<td>Oct 2018</td>
<td>63.0% (121/192)</td>
<td>68.0%</td>
<td>72.1% (132/183)</td>
<td>71.0% (4,910/6,911)</td>
<td>72.9% (115/166)</td>
<td>70.0% (121/192)</td>
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<tr>
<td>Nov 2018</td>
<td>66.7% (104/156)</td>
<td>70.2%</td>
<td>69.5% (4,910/6,911)</td>
<td>70.5% (4,910/6,911)</td>
<td>72.1% (132/183)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>Dec 2018</td>
<td>65.3% (113/173)</td>
<td>65.9%</td>
<td>65.9% (113/173)</td>
<td>70.5% (4,910/6,911)</td>
<td>72.9% (115/166)</td>
<td>70.0% (121/192)</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
</tbody>
</table>

*Data Source: Patient Discharge Data (ICD-9/-10 Codes) submitted by hospital to the CMQCC Maternal Data Center linked to Birth Certificate Data. Customize the time periods and comparison groups within this report by logging into the CMDC and using the drop down menus above the graphs.*
WAIVER OF LIABILITY, ASSUMPTION OF RISKS OF SHARING BREAST MILK

Waiver: In consideration of being permitted to use breast milk from a source other than yourself or a dedicated human milk bank while your child is an inpatient at the UC San Diego Health (hereinafter referred to as “Milk Sharing”), I, for myself, my heirs, personal representatives or assigns, as well on behalf of my baby as parent and/or guardian, do hereby release, waive, discharge, and covenant not to sue The Regents of the University of California, its officers, employees, and agents (collectively “The Regents”) from liability from any and all claims including the negligence of The Regents, resulting in personal injury, accidents or illnesses (including death), arising from, but not limited to, Milk Sharing.

Assumption of Risks: Milk Sharing carries with it certain inherent risks that cannot be eliminated regardless of the care taken to avoid injuries. The specific risks include, but are not limited to, exposure to infectious diseases (including HIV, Hepatitis B and other viruses or bacteria), chemical contaminants, herbs, illegal drugs, and to a limited number of prescription drugs that might be in the human milk. In addition, if human milk is not handled and stored properly, it could, like any type of milk, become contaminated and unsafe to drink.

I have read the previous paragraphs and I know, understand, and appreciate:

1. These and other risks inherent in milk sharing;
2. That there are alternatives to milk sharing (e.g., artificial formula, intravenous fluids, milk banks); and
3. That UC San Diego Health does not recommend Milk Sharing.

I hereby assert that my election to Milk Share is voluntary and that I knowingly assume all such risks on behalf of myself and my minor child.

Indemnification and Hold Harmless: I also agree to INDEMNIFY AND HOLD The Regents HARMLESS from any and all claims, actions, suits, procedures, costs, expenses, damages and liabilities, including attorney’s fees brought as a result of Milk Sharing while my child is an inpatient and to reimburse them for any such expenses incurred.

Severability: The undersigned further expressly agrees that the foregoing waiver and assumption of risks agreement is intended to be as broad and inclusive as is permitted by the law of the State of California and that if any portion thereof is held invalid, it is agreed that the balance shall, notwithstanding, continue in full legal force and effect.

Acknowledgment of Understanding: I have read this waiver of liability, assumption of risk, and indemnity agreement, fully understand its terms, and understand that I am giving up substantial rights on behalf of myself and my minor child, including my/his/her right to sue. I acknowledge that I am signing the agreement freely and voluntarily, and intend by my signature to be a complete and unconditional release of all liability to the greatest extent allowed by law.

Signature of Parent on Infant’s Behalf and also as Parent/Guardian of Minor Child

Name of Child: ___________________________  Child’s Date of Birth: __________

If Interpreted: [ ] Telephonic  [ ] Video  [ ] Interpreter OR ID#: ___________________________  Language ___________________________  Date: ____________  Time: ____________ AM / PM

If Consent Provided by Proxy Parent or Guardian: [ ]

Date: ____________  Time: ____________ AM / PM

UC San Diego Health
**NQF-ENDORSED VOLUNTARY CONSENSUS STANDARDS FOR HOSPITAL CARE**

Measure Information Form

**Measure Set:** Perinatal Care (PC)

**Set Measure ID:** PC-05

**Performance Measure Name:** Exclusive Breast Milk Feeding

**Description:** Exclusive breast milk feeding during the newborn's entire hospitalization

The measure is reported as an overall rate which includes all newborns that were exclusively fed breast milk during the entire hospitalization.

**Rationale:** Exclusive breast milk feeding for the first 6 months of neonatal life has long been the expressed goal of World Health Organization (WHO), Department of Health and Human Services (DHHS), American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG). ACOG has recently reiterated its position (ACOG, 2007). A recent Cochrane review substantiates the benefits (Kramer et al., 2002). Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) BF (Centers for Disease Control and Prevention [CDC], 2007; Petrova et al., 2007; Shealy et al., 2005; Taveras et al., 2004). Exclusive breast milk feeding rate during birth hospital stay has been calculated by the California Department of Public Health for the last several years using newborn genetic disease testing data. Healthy People 2010 and the CDC have also been active in promoting this goal.

**Type of Measure:** Process

**Improvement Noted As:** Increase in the rate
TJC PC-05

Excluded Populations:

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization
- Galactosemia
- Received parenteral nutrition
- Experienced death
- Length of Stay >120 days
- Enrolled in clinical trials
- Patients transferred to another hospital
- Patients who are not term or with < 37 weeks gestation completed

But what about…

- Moms with one breast
-Multiples
- Foster care, adoption, surrogacy
- Mother in ICU
- Hospitals that care for high risk newborns in couplet care (rather than NICU)
- Hospitals that encourage mothers try to breastmilk feed even if they don’t do it exclusively
California PRIME quality measures: ExBF

**Project Name:** Exclusive Breast Milk Feeding (2.1.2)
**Executive Sponsor:** Marie Webber

**Gap:** Capture of exclusive breast feeding in Epic. Donor milk availability and access (refrigerators requested). Supplementation for medical indications or maternal insistence after education.

<table>
<thead>
<tr>
<th>Numerator</th>
<th>Denominator</th>
<th>Rate</th>
<th>PRIME Threshold</th>
<th>Steering Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1349</td>
<td>2048</td>
<td>65.87%</td>
<td>&gt; 67.32%</td>
<td>&gt; 69.00%</td>
</tr>
</tbody>
</table>

Despite QI work on standardizing weight loss and jaundice assessment, introduction of glucose gel for hypoglycemia, and extensive RN education, we are still not meeting the state target and continues to trend down.

**Exclusive Breast Milk Feeding Rate Trend**

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</tr>
</thead>
<tbody>
<tr>
<td>Rate</td>
<td>66.76</td>
<td>69.91</td>
<td>69.62</td>
<td>69.62</td>
<td>67.74</td>
<td>68.71</td>
<td>66.87</td>
<td>68.71</td>
<td>66.87</td>
</tr>
</tbody>
</table>

**Clinical Leads:** Lisa Stellwagen
**Event Locations:** In-patient

**Recommended Tactics:**
1. PDHM consent process to be obtained prenatally by OB and Midwife providers, and in hospital by pediatric team.
2. The EPIC build complete for documentation, and consent confirmation, and milk orders.
3. The 24 hour milk technician staff that PRIME facilitated last summer has been a key part of making this work.
4. W&J Quality Team plan to start without waiting for the fridges in mothers rooms and our tentative start date is March 18th.
5. We have verified that Mothers’ Milk Bank at Austin has sufficient stores of PDHM to supply our term neonatal needs.
6. Our outstanding needs for optimal implementation are:
   a. Funds to purchase the individual refrigerators for all Postpartum rooms which we believe will improve the safety, convenience, and nursing impact of this project.
   b. The cost of the additional donor milk is currently unknown. We plan to track it carefully and circle back when we have better data.

**Update:**
1. UC lactation teams met last month. The other UC hospitals are not doing this in an organized fashion.
2. Consent implemented 3 weeks ago, almost all families supporting. Tracking milk donor usage and metric rates.
3. Donor refrigerators are still being requested to support program.

**Event Dates:** FY 2019
**Last Updated:** April 25th, 2019

**KEY:**
- **Orange Arrow:** Plan with defined workflow and ownership
- **Seal Team:** TOC Care Management, PHSO, Pharmacy, Care Navigation Hub or IS
Donor Milk policies at UC San Diego Health

- 2008: UCSD took part in the Prolacta Trial & developed SPIN Program
- 2009: NICU offered PDHM after consent to all babies under 1500 grams until reach 34 weeks, or bowel injury, or physician discretion
- 2015: Expanded PDHM in NICU to birth weight of 2000 grams
- 2019: Extended PDHM:
  - BW < 2000 grams until reach 34 weeks
  - Infants with medical indication for supplement for 72-96 hours
  - Mothers with HIV, mastectomy, adoption/surrogacy

PDHM implementation

1. Task force created using multidisciplinary approach
2. Tissue Bank license
3. Considerations for PDHM use in infants > 34 weeks including supplementation guidelines
4. Consent process
5. EPIC orders/MOMS system
6. Clear designation of consent
7. Milk technicians
8. PDHM workflow for nursing
9. Policies and Guidelines updated
It took a village… and 2 years!

- **Key players:**
  - Newborn Medicine team took the lead
  - Lactation Consultant team
  - RN staff
  - Registered Dietician and milk techs
  - Nursing and hospital leadership were on board

- **Key challenges:**
  - Regulatory concerns
  - Consent
  - EPIC orders
  - Diet tech issues
  - Feeding process in mothers’ room
Tissue Bank License

- Tissue Bank license covers all units in Women & Infants Services
  - NICU
  - Pospartum
  - L&D
### Consideration for PDHM use in infants > 34 weeks

<table>
<thead>
<tr>
<th>Considerations for Pasteurized Donor Breastmilk Use in Infants &gt;34 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Donor breastmilk (DBM) should be considered when mother intends to exclusively breastfeed, is pumping regularly but has insufficient supply or breastfeeding is medically contraindicated (HIV+, mastectomy, etc)- compassionate milk use</td>
</tr>
<tr>
<td>• If mother available, attempt to get expressed breastmilk (EBM) by breastfeeding, hand expression or pump; mother needs to continue expression to stimulate milk production and supply breastmilk.</td>
</tr>
</tbody>
</table>

- **Medical Indication (infant) for Supplementation:**
  - "Bridge Milk" for infant of mother whose milk supply does not meet infant’s nutritional needs:
    - Late preterm/small for gestational age
    - Excessive weight loss not improving with exclusive breastfeeding/EBM
    - Hyperbilirubinemia judged to be secondary to poor intake
    - Hypoglycemia unresponsive to breastfeeding
    - Maternal/Infant separation (ie mom in PACU or long C/S and can't pump/express milk)

- **Duration of DBM/Transition to Formula:**
  - Evaluate at 72 hours
    - If mother’s milk supply increasing and getting close to infant’s nutritional needs (getting > ½ EBM), continue DBM and re-evaluate @ 96 hours
    - If mother’s milk supply low and not increasing, transition to formula
    - If BF contraindicated, transition to formula
  - Re-evaluate at 96 hours
    - If mother’s milk supply increasing and most likely to be able to have full supply in next 24 hours (infant only getting small volume of DBM), continue DBM
    - If mother’s supply still insufficient and not nearing infant’s nutritional needs, transition to formula
  - Transition to formula for all babies at 120 hours
Supplementation or Bottle Feeding Volumes

DOL 1: ~5-10 ml/feed
DOL 2: ~10-20 ml/feed
DOL 3: ~20-30 ml/feed
DOL 4: ~30-40 ml/feed
DOL 5: ~40-50 ml/feed
DOL 6: 50-60 ml/feed
1 week-1 st month: ~60-90 ml/feed

Possible Indications for Supplementation in Healthy, Term Infants

**Infant**

1. Hypoglycemia that is persistent or recurrent despite appropriate, frequent breastfeeding.
2. Signs or symptoms that may indicate inadequate milk intake:
   a. Clinical or laboratory evidence of dehydration that is not improved after skilled assessment and proper management of breastfeeding.
   b. Weight loss >10% from birth weight and/or >75% weight loss/age (Newborn Weight Tool).
   c. Continued meconium stools DOL 5.
      i. Even though there is a wide variation between infants, urine and stool patterns after 2-3 days of life may be useful in determining adequacy of breastfeeding.
   d. Hyperbilirubinemia due to suboptimal intake despite appropriate feeding interventions.
   e. Excessive fussiness or crying not attributed to pain or other medical cause.
3. Late preterm, SGA or IUGR infant that is not effectively breastfeeding despite early intervention and education.

**Maternal**

1. Delayed lactogenesis with inadequate intake of infant.
2. Primary glandular insufficiency as evidenced by abnormal breast shape, poor breast growth during pregnancy or minimal indication of secretory activation.
3. Breast pathology or prior surgery resulting in poor milk production.
4. Temporary cessation of breastfeeding due to certain medications or temporary separation of mother and infant without EBM available.
5. Intolerable pain during feedings unrelieved by interventions.
Infant Hypoglycemia Management Algorithm: ASYMPTOMATIC INFANT <24 HOL*

**FIRST HYPOGLYCEMIC EPISODE**
- Place S2S, administer glucose gel AND breastfeed immediately
  - If breastfeeding poorly, initiate hand expression & feed EBM while S2S
  - If feeding method is formula only, give 10-15 mL formula while S2S
  - Check BG 30 min after feeding completed
- If repeat BG <45, give 2nd dose of glucose gel AND breastfeed again, supplementing with 10-15 mL EBM/DBM/formula
  - Check BG 30 min after feeding completed
- After 2nd glucose gel dose:
  - If BG 30-44, feed 20-30 mL of EBM/DBM/formula
  - If BG remains <45, obtain blood gas or STAT lab glucose. If BG confirmed <45, notify provider, transfer to NICU, place PIV & start IV glucose with goal BG ≥50
  - If infant has received a total of 4 doses of glucose gel & then has BG <45, notify provider, transfer to NICU, place PIV & start IV glucose with goal BG ≥50

**SUBSEQUENT HYPOGLYCEMIC EPISODES**
- Place S2S, administer glucose gel AND breastfeed immediately, supplementing with 10-15 mL EBM/DBM/formula
  - If feeding method is formula only, give 10-15 mL formula while S2S
  - Check BG 30 min after feeding completed
- If repeat BG remains <45, give 2nd dose of glucose gel AND breastfeed again, supplementing with 10-15 mL EBM/DBM/formula
  - Check BG 30 min after feeding completed
- After 2nd glucose gel dose:
  - If BG <45, notify provider & transfer to NICU. Obtain blood gas or STAT lab glucose. If confirmed <45, place PIV & begin IV glucose with goal BG ≥50

**REMINDERS**
- Follow responses below
- If symptoms develop, switch to Symptomatic Infant algorithm
- Once BG < 45, infant needs 3 consecutive AC BG ≥ 45 before stopping screening. If IV glucose given, infant needs 3 consecutive AC BG ≥ 50 off IVF before stopping screening
- Check another AC BG at 24-48 HOL; BG should be ≥ 50
- Do not give more than 2 doses of glucose gel per hypoglycemic episode
- New gel tube per dose
- An infant may receive up to 4 doses of glucose gel total
- If radiant heat necessary, finger or bottle feed

### Hypoglycemic Infant

**GLUCOSE GEL DOSING**

<table>
<thead>
<tr>
<th>WT (KG)</th>
<th>Total Dose (mL)</th>
<th>% Dose (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3.4 kg</td>
<td>1.5</td>
<td>~0.375</td>
</tr>
<tr>
<td>&gt;3.5 kg</td>
<td>2</td>
<td>~0.5</td>
</tr>
</tbody>
</table>

**On Fenton growth chart until 39w6d; WHO for ≥40w0d**

* Between 24-48 HOL, BG should be ≥50. After 48 HOL, BG should be ≥60.

**If first feeding delayed >1 HOL due to maternal issue, check BG before giving supplement. If BG ≥45, first feeding may wait another 30-60 min as long as infant remains asymptomatic**
Late Preterm, SGA, IUGR Infant

Breastfeeding Management: Early Term/Late Preterm/SGA/IUGR Infant (Little Baby Bundle)

**Assist with early feedings/milk production**
1. Skin to skin (S2S) after delivery if mom and baby stable, increase temperature in room.
2. Assist with breastfeeding within 1 hour of delivery, if baby unable to feed, help mother express milk/stimulate milk production.
3. Hand expression/breast compressions during breastfeeding will facilitate milk transfer.
4. If baby not latching or sustaining suck, express milk and give EBM.
5. Limit feeds to <30 minutes to assist with metabolic stability.

**Support ongoing breastfeeding/breast milk feedings**
1. Encourage skin to skin and increase temperature in room to assist with metabolic stability.
2. Baby to breastfeed on demand but should be woken at least every 3 hours to feed.
3. Mother to hand express/pump after every feed unless infant breastfeeding well to help stimulate milk production.
4. Use feeding method that allows infant to take adequate volume in <30 minutes.
5. Daily Lactation consult/follow up with updated feeding plan. Occupational Therapy consult if baby bottle feeding or other concerns.
6. Excessive weight loss is concern for inadequate milk production/transfer.
7. Provider to document feeding order and plan daily.

Skin to skin, attempt breastfeed.

**Does baby latch and sustain suck?**

- NO
  - Help mom express breastmilk and feed baby. OK to bottle feed.
  - Can baby take volume in <30 minutes?

- YES
  - Notify provider for further orders/plan.

- NO
  - Help mom express milk and give by bottle. OT consult needed.
  - Can baby take adequate volume in <30 minutes?

-YES
  - Daily weight
  - Frequent feeding assessment
  - Increase volume daily
  - Milk production assessment each shift, encourage frequent milk expression
  - Daily Lactation consult
  - OT consult as needed
  - Update feeding plan daily
  - No discharge until infant feeding well with stable weight.

UC San Diego Health
Parent Requests Formula (no medical indication)

Breastfeeding Management: Mother Requesting Formula

Mother Requests Formula
Ensure feeding preference is an informed decision including benefits of breastfeeding and provide tailored education. If family decides to formula feed after education, document feeding preference and provide safe formula preparation education.

1. Ask more questions to understand her concerns.
2. Re-state and validate concerns.
3. Review normal feeding patterns and milk production.
4. Document appropriate education points.

Assess a feed and provide assistance:
1. Assist with positioning and latch.
2. Demonstrate hand expression and breast compression with feeds.
3. Notify lactation/provider if baby still unable to latch or sustain sucking.
4. Offer mechanical pump to supply EBM to baby.

Indications for supplementation present?
- Hypoglycemia unresponsive to breastfeeding
- Clinical or laboratory evidence of dehydration not improving with breastfeeding
- Excessive weight loss (≤10% from BW or >75% for age)
- Delayed bowel movement (>48 hours) or continued meconium on DOL5
- Excessive crying or fussiness not due to pain or other medical cause
- Failure to latch or sustain sucking
- Maternal insufficient milk supply

YES or family still prefers to offer infant formula
1. Educate family on potential risks of supplementation with formula.
2. Help mom preserve breastfeeding:
   - Frequent skin to skin
   - Breastfeed with feeding cues
   - Breast compression and hand expression with feeds
   - Pump every time baby receives formula and offer EBM to baby first followed by limited amount of formula, preferably avoiding bottle feeding initially.

NO

- Provide reassurance and education to the family
- Evaluate at least every 12 hours for changes in clinical status.
Consent process

• Initial plan to have consent done by OB/CNM prenatally; difficult to enforce across multiple clinics and providers

• 2nd plan was to have inpatient provider or Lactation obtain consent if needed

• Ultimately consent primarily done by nursing staff in anticipation of need for supplementation

Parent handout for information on PDHM
PDHM consent by RN, LC or provider

UC San Diego Health

USE OF PASTEURIZED DONOR HUMAN MILK
CONSENT OR REFUSAL

Breast milk provides the best nutrition, helps with normal growth and development, and reduces the risk of your baby getting sick. Cow's milk formula does not have any of the unique immune or infection fighting ingredients of breast milk. When mother's own milk is not available or there is not enough, pasteurized donor human milk from a donor milk bank is often the next best choice. Pasteurized donor human milk has many of the unique properties that protect your baby from infection and is easier to digest than infant formula.

UC San Diego Health (UCSDH) provides donor human milk from an approved Human Milk Banking Association of North America (HMBANA) donor milk bank. This milk bank follows guidelines to make sure the safest milk possible is provided. Women who donate milk have blood tests similar to when blood is donated. The breast milk that is donated by healthy mothers is carefully tested. It is heat treated – pasteurized – to kill any germs that could cause disease. This process destroys all human cells and most bacteria and viruses in the milk. The milk is tested after heating to check again for any bacteria. There is a very small chance that your baby could become sick from germs in the donor human milk. Please discuss any questions or concerns with your baby’s health care team.

Your baby's UCSDH care team recommends donor human milk if your milk supply is not meeting your baby's needs. Donor milk will be provided for:
- premature babies until the baby reaches 34 weeks gestation,
- babies whose mother does not have enough milk for baby.

This benefit will depend on the donor human milk supply available. Premature and sick babies will receive donor human before healthy babies. UCSDH does not provide donor human milk upon discharge.

I have received this education about donor human milk and the UCSDH staff have answered my questions about donor human milk. If my baby needs a supplement in addition to my breastfeeding, I prefer that the following be provided:

CHECK ONE: □ I CONSENT the use of donor human milk for my child.
OR
□ I REFUSE the use of donor human milk for my child and want my child to receive cow's milk formula if additional nutrition is required.

Parent/Authorized Guardian Signature: ___________________________
Parent/Authorized Guardian Print Name: ___________________________
Date: ___________ Time: ___________

If interpreted:
□ Telephone □ Video Interpreted Sign □ Oral Language: ___________________________
Date: ___________ Time: ___________

AM / PM

UC San Diego Health
Clear designation of PDHM consent

Documentation that parent/guardian consented to use of PDHM triggers banner for easy recognition of consent
EPIC order/Timeless-MOMS system

- PDHM order is part of Standard Admission Orderset
- Interfaces with Timeless-MOMS system
Milk preparation room and milk tech program

- Hospital supported program with 24/7 milk tech coverage
- Registered Dietician oversees diet techs and distributed responsibilities among different shifts
- Changed to 18 hour coverage with cross coverage of shifts to improve work load
- Thawed milk is good for 48 hours
Unit milk handling

- Milk is prepped in milk preparation room each day
- Bar coding system to track milk and ensure correct administration
- Milk techs prepare community syringes and put in L&D and Postpartum refrigerators
- RNs assign milk to proper baby when needed by scanning baby and then milk
- Lactation consultants help with milk ordering
- Charge nurses interact with milk techs and night to ensure adequate volumes
Community syringes

• Initially had individual syringes assigned to patients as needed but found milk wasn’t always available when needed and milk was wasted (couldn’t be reassigned if not used)

• Changed to community syringes that could be scanned and assigned to baby as needed

• Par maintained by milk tech with help from Lactation Consultants and charge nurses
Struggle with milk storage

• Considered individual refrigerators for each patient room
  o Expensive
  o Bulky
  o Who is responsible for cleaning?
  o Temperature monitoring difficult

• Settled on unit milk refrigerators
  o Feedings brought to mothers’ room every feeding or every other feeding (milk okay at room temp for 4 hours)
  o Milk warmers in nutrition room to warm milk if needed
Process in mother’s room

1. Mom calls RN when ready to feed (or RN brings in room when does assessment)
2. RN brings syringe to room, scans baby and then scans syringe
3. Can warm in nutrition room or warmer in room (good at room temperature x 4 hours)
4. Family uses as would formula and reports volume to RN
5. RN records volume and feeding method in I&O flowsheet
Transition to formula

Provider assesses infant’s daily nutritional needs to determine need for continued supplementation.

Transition to formula at discharge or sooner if mom not pumping or not getting close to full milk volume by 72 hours.

Rx given if PDHM supplementation desired after discharge (may not be available).
What to do if no milk prep room or MOMs?

- 1 bottle assigned to each baby; good for 48 hours once thawed
- RN to draw up milk as needed
- 2 RN verification to ensure accurate administration
Lessons learned and unintended consequences

• RN buy in was amazing and change to workflow easier than anticipated
• More supplementation than before (sometimes easier to supplement than get a baby to breast feed)
• Mothers not pumping as consistently
• Shortage of PDHM and rationing based on need
• Families upset when unable to get PDHM at home
Next steps, upcoming projects

- Lactation working education to display on pump explaining milk production and importance of early and consistent pumping
- Additional education regarding medical indications for supplementation
- Education for staff regarding transition to formula
- Promoting milk donation for mothers who end up with an over supply
To: Our UC San Diego Mother/Baby Unit staff:

We are so excited to announce the introduction of Pasteurized Donor Human Milk (PDHM) for all neonates at UC San Diego Health! The improvements in support for breastfeeding mothers and infants at this institution started many years ago and led to the Baby Friendly Hospital Initiative, now a UNICEF/WHO program. Our continuing work to improve nutritional care in the NICU and the SPIN program led to the use of PDHM in our NICU in 2008. Over the years, we have found that other infants also benefit from having the earliest feeds be breast milk. Our new project of starting a milk bank at UC San Diego has given us the opportunity to open up the provision of donated milk to more infants at our institution.

Although the science of the benefit of PDHM is strongest for critically ill, premature, cardiac and GI babies, recent evidence supports that even a feeding or two of infant formula can change the intestinal bacterial balance for the healthy term infant for many months. We worry that these short exposures of cow’s milk protein may have other effects on the infant and there is interest in trying to avoid this exposure if possible. I believe that this offering of PDHM to all our families sends a potent message about the importance of mother’s milk for all babies. Lastly, the state has imposed some strict guidelines for exclusive breastfeeding rates that are difficult for a hospital with many complicated mother baby pairs to succeed. This has led to some extra support from the hospital for us to introduce the new policy that we have been thinking of for many years.

To address all of this we are electing to offer PDHM to supplement breastfeeding babies, if they have a medical indication, for a short period of time. This is 100% at the discretion of the family, we do not expect that everyone will want to feed their baby PDHM, nor do we want to force it on reluctant families.

We are very excited to be at the forefront of a policy of global introduction of PDHM at our institution. We know it has been a complicated and long process and we will surely encounter some bumps in the road. The implementation team has been working on this for over a year and will love to have your feedback and improvement suggestions as we progress- so please give us your comments!

Thank you for helping us all advance the care for our families at UC San Diego Health! Lisa Stellwagen

Importance of on-going education and “speaking with one voice”

- Consistent messaging important
- Buy in from leadership key
- Ongoing education for staff and providers
- Strong support from nutrition department necessary for success
- Lots of questions when project first rolled out but RNs quickly became independent
Breastfeeding and PDHM use rates 2017-2019

Breastfeeding Rates at Jacobs

- Any breastfeeding
- Exclusive breastfeeding
- Prime Target
- Donor Milk Use

Data courtesy of Dr. Michelle Leff
Impact of PDHM expansion

- Breastfeeding rates:
  - Exclusive breastmilk feeding rates increased by 23%
  - PRIME EXBF rate increased by 25%
  - Overall breastfeeding rates stayed stable at infant discharge: 96.7%

- Hospital cost/benefit:
  - MOMS training for all staff
  - Expanded milk tech program
  - Cost of PDHM
  - Meeting PRIME metric earned hospital significant funds

- Estimates of PDHM usage/cost for 12 months:
  - NICU: 10,856 ounces/year  cost: $50,000
  - Mother/Baby: 9,355 ounces/year  cost: $44,000
  - Non- NICU infants given PDHM: 536 (32% of all births)
  - Each infant received average of 8.7 ounces/ $40 per supplemented infant ($15 per day)

UC San Diego births in 2019= 3549
**Measure**  
PRIME: Exclusive Breast Milk Feeding (PC-05)†

**Definition**  
Exclusive breast milk feeding during the newborn’s entire hospitalization in the PRIME population

**Hospital and Peer Trends**

<table>
<thead>
<tr>
<th>Period</th>
<th>UC San Diego</th>
<th>CA MDC Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 2019</td>
<td>84.3% (188 / 223)</td>
<td>N/A</td>
</tr>
<tr>
<td>Sep 2019</td>
<td>85.9% (183 / 213)</td>
<td>75.1%</td>
</tr>
<tr>
<td>Aug 2019</td>
<td>89.9% (204 / 227)</td>
<td>76.2%</td>
</tr>
<tr>
<td>Jul 2019</td>
<td>83.3% (185 / 222)</td>
<td>71.2%</td>
</tr>
<tr>
<td>Jun 2019</td>
<td>78.4% (160 / 204)</td>
<td>72.7%</td>
</tr>
<tr>
<td>May 2019</td>
<td>83.1% (177 / 213)</td>
<td>73.7%</td>
</tr>
<tr>
<td>Apr 2019</td>
<td>75.7% (140 / 185)</td>
<td>70.6%</td>
</tr>
<tr>
<td>Mar 2019</td>
<td>74.7% (142 / 190)</td>
<td>71.9%</td>
</tr>
<tr>
<td>Feb 2019</td>
<td>58.6% (95 / 162)</td>
<td>66.9%</td>
</tr>
<tr>
<td>Jan 2019</td>
<td>67.4% (118 / 175)</td>
<td>70.0%</td>
</tr>
<tr>
<td>Dec 2018</td>
<td>65.3% (113 / 173)</td>
<td>66.2%</td>
</tr>
<tr>
<td>Nov 2018</td>
<td>66.7% (104 / 156)</td>
<td>70.1%</td>
</tr>
</tbody>
</table>

*Due to space constraints, only the 12 most recent data points are displayed in this table.*

**Peer Comparisons: May - Oct 2019**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC San Diego</td>
<td>84.3% (1,097 / 1,302)</td>
</tr>
<tr>
<td>San Diego County</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>UC Systemwide</td>
<td>81.8% (2,276 / 2,783)</td>
</tr>
<tr>
<td>San Diego/Imperial RPPC</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>PRIME Hospitals</td>
<td>73.7% (5,251 / 7,125)</td>
</tr>
<tr>
<td>Level IV NICUS: CA, OR, WA</td>
<td>78.9% (2,779 / 3,522)</td>
</tr>
<tr>
<td>NICU Level III/IV-CA MDC</td>
<td>73.4% (4,517 / 6,150)</td>
</tr>
<tr>
<td>Delivery Volume: 2500-2999 - All MDC</td>
<td>Insufficient hospitals reporting to calculate rate</td>
</tr>
<tr>
<td>CA MDC</td>
<td>73.7% (5,251 / 7,125)</td>
</tr>
</tbody>
</table>
Ethical issues

• Is there enough milk for us to be using PDHM for low risk infants?
• Aren’t NICUs the priority?
• Do donor mothers know their milk may not go to a sick infant?
• Are they okay with that?
Summary & Recommendations

• Get buy-in from all service lines in hospital
• Streamline the process
• Allow RN and MD to get consent
• Clear guidelines for supplementation
• Consider nurse workflow on L&D (hypoglycemia)
• Consider nurse workflow on Postpartum (frequent feeds)
• Protect mother’s milk supply… keep her pumping!
• Family education & transition home
References


4. Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States. COMMITTEE ON NUTRITION, SECTION ON BREASTFEEDING, COMMITTEE ON FETUS AND NEWBORN. Pediatrics Jan 2017, 139 (1) e20163440


