New York State Perinatal Quality Collaborative (NYSPQC) Enteral Nutrition Improvement Project

Donor Milk Webinar Series: Part 1

Thursday, October 17, 2019
Welcome!

Thank you for joining the call!
Before we begin, a few notes:

• All participants will be muted upon entry to the call.
• You **DO have the ability** to unmute yourself.
• We encourage participants to remain muted to reduce background noise.
• If you are in a room with others, only one of you should connect to audio (see next slide).
• **A recording of the webinar will be shared after the call!**
Connecting to Audio

• An audio conference box will appear.
  • If you do not see the box click the ‘Join Audio’ button

• From the audio conference box: Select to “Phone Call” or “Computer Audio”

• If using the phone:
  • Dial the number next to “Dial”
  • You will be prompted to enter the “Meeting ID”
  • Then you will be prompted to enter the “Participant ID”
Click on the images at the bottom of the Zoom window to open the participant list and chat box!
Questions or Comments?

• Use the Chat Box to the right of your screen for questions or comments.

• Please chat to **everyone**, so that we can all see your questions or comments!

• If you need assistance at anytime during the call please raise your hand.

(Mute/Unmute to participate in discussions!
Click here to raise your hand!
Chat here to everyone!)
Welcome & Introductions

Kristen Lawless
Program Director
Division of Family Health
NYSDOH
# Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
</table>
| 12:00 PM – 12:05 PM | Welcome & Introductions | Kristen Lawless  
Program Director  
New York State Department of Health |
| 12:05 PM – 12:25 PM | Donor Human Milk Program | Timothy Stevens, MD, MPH  
Professor of Pediatrics  
Chief Clinical Officer  
UR Medicine Golisano Children’s Hospital |
| 12:25 PM – 12:55 PM | Implementing a Human Donor Milk Program in the NICU | New-York Presbyterian Morgan Stanley Children’s Hospital Team  
Marianne Garland  
Neonatologist  
Medical Director, NICU Lactation and Donor Milk Programs  
Christine Scheinman  
NICU Lactation Consultant  
Manager, NICU Donor Milk Program  
Betina Grigoroff-Aponte  
NICU Lactation Consultant  
Monique Woodley  
NICU Lactation Consultant  
Alix Anand  
NICU Dietician |
| 12:55 PM – 1:00 PM | Next Steps | Katie Potestio, MPH, RD  
Program Coordinator, Division of Family Health  
New York State Department of Health |
Nov. 2017 NYSDOH Medicaid Update

The Medicaid Update details criteria for coverage, and the process for fee-for-service (FFS) and Medicaid Managed Care (MMC) plan billing for Pasteurized Donor Human Milk (PDHM).

• The current policy and billing guidance for NYS Medicaid reimbursement for PDHM is available here: https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-11.htm#donormilk

• The full issue of the Medicaid Update as a PDF (Portable Document Format) is available to download from: https://www.health.ny.gov/health_care/medicaid/program/update/2017/nov17_mu.pdf.
Donor Human Milk Program

Timothy Stevens, MD, MPH
Professor of Pediatrics
Chief Clinical Officer
UR Medicine Golisano Children’s Hospital
Donor Human Milk Program

10/17/19

Timothy P. Stevens, MD, MPH
University of Rochester
Agenda

- Background
  - NYSPQC Nutrition Project
  - NYS Donor Milk Legislation

- NYSPQC NICU Survey – Prevalence of a Pasteurized Donor Human Milk (PDHM) Program Among NYS NICUs

- Introduction of a Donor Milk Program
  - Univ of Rochester

- Outcomes
Background

• Growth prior to NICU discharge is directly related to neurodevelopmental outcome and risk of cerebral palsy in preterm infants. *Belfort MB et al. 2011*

• Postnatal growth restriction (PGR, weight below the 10th percentile for postmenstrual age) is common at NICU discharge. *Ehrenkranz RA et al. 2006*
To reduce statewide the percentage of newborns < 31 weeks gestational age who are discharged from the NICU below the tenth percentile for post menstrual age
Incidence of PGR Decreased Among Infants < 31 wks GA During NYSPQC Nutrition Project

14 of 18 NYS RPCs showed decrease in PGR
NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups (P = .05), *P = .04 vs BOV, **P = .09 vs BOV, ***P = .02 vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups (P = .02), †P = .03 vs BOV, ††P = .007 vs BOV. [ ] refers to number of infants.
### Donor Breast Milk and Incidence of NEC

#### 1.25.1 Term formula versus unfortified DBM

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Favours formula milk</th>
<th>Donor breast milk</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
</tr>
<tr>
<td>Gross 1983</td>
<td>3</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>26</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect Z = 1.38 (P = 0.17)</strong></td>
<td></td>
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</tr>
</tbody>
</table>

#### 1.25.2 Preterm formula versus unfortified DBM

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
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<th>Risk Ratio</th>
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</thead>
<tbody>
<tr>
<td>Tyson 1983</td>
<td>1</td>
<td>34</td>
<td>37</td>
</tr>
<tr>
<td>Lucas 1984a</td>
<td>4</td>
<td>75</td>
<td>1</td>
</tr>
<tr>
<td>Lucas 1984b</td>
<td>5</td>
<td>173</td>
<td>2</td>
</tr>
<tr>
<td>Costa 2018</td>
<td>0</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>328</td>
<td>325</td>
<td></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>10</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Chi² = 0.13, df = 2 (P = 0.61); I² = 0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect Z = 1.60 (P = 0.07)</strong></td>
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</tbody>
</table>

#### 1.25.3 Preterm formula versus fortified DBM

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<tr>
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<th>Donor breast milk</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schanier 2006</td>
<td>10</td>
<td>83</td>
<td>70</td>
</tr>
<tr>
<td>Cristodola 2013</td>
<td>5</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>Cropwell 2016</td>
<td>17</td>
<td>193</td>
<td>17</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>484</td>
<td>471</td>
<td></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>44</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Chi² = 6.12, df = 3 (P = 0.11); I² = 61%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect Z = 2.09 (P = 0.04)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Total (95% CI)

<table>
<thead>
<tr>
<th>Favours formula milk</th>
<th>Donor breast milk</th>
<th>Risk Ratio</th>
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</thead>
<tbody>
<tr>
<td>838</td>
<td>837</td>
<td><strong>1.87 [1.23, 2.85]</strong></td>
</tr>
<tr>
<td>57</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong> Chi² = 8.17, df = 7 (P = 0.32); I² = 14%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect Z = 2.52 (P = 0.012)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for subgroup differences:</strong> Chi² = 1.57, df = 2 (P = 0.46); I² = 0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding (performance bias and detection bias)
- (D) Incomplete outcome data (attrition bias)
- (E) Selective reporting (reporting bias)
- (F) Other bias

Cochrane Review, Quigley M, Embleton ND, McGuire W, 19 July 2019
Donor Breast Milk and Growth (g/kg/day)

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Formula milk</th>
<th>Donor breast milk</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>1.2.1 Term formula versus unfortified DBM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Davies 1977</td>
<td>14.7</td>
<td>4.7</td>
<td>34</td>
</tr>
<tr>
<td>Gross 1993</td>
<td>20.4</td>
<td>2.7</td>
<td>20</td>
</tr>
<tr>
<td>Raiha 1976</td>
<td>13.8</td>
<td>2.5</td>
<td>84</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>138</td>
<td>96</td>
<td>53.4%</td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 32.04, df = 2 (P < 0.00001); I² = 94%
Test for overall effect: Z = 4.33 (P < 0.00001)

1.2.2 Preterm formula versus unfortified DBM

<table>
<thead>
<tr>
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<th>Donor breast milk</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>Lucas 1984a</td>
<td>18</td>
<td>6</td>
<td>30</td>
</tr>
<tr>
<td>Lucas 1984b</td>
<td>16.3</td>
<td>4.5</td>
<td>56</td>
</tr>
<tr>
<td>Tyson 1983</td>
<td>24.3</td>
<td>8.2</td>
<td>42</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>128</td>
<td>121</td>
<td>26.3%</td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 35.94, df = 2 (P < 0.00001); I² = 94%
Test for overall effect: Z = 7.25 (P < 0.00001)

1.2.3 Preterm formula versus fortified DBM

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Formula milk</th>
<th>Donor breast milk</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>Cristofalo 2013</td>
<td>17</td>
<td>7.1</td>
<td>24</td>
</tr>
<tr>
<td>O'Connor 2016</td>
<td>25.5</td>
<td>9.7</td>
<td>162</td>
</tr>
<tr>
<td>Schanler 2005</td>
<td>20.1</td>
<td>6.7</td>
<td>88</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>274</td>
<td>271</td>
<td>20.3%</td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 1.02, df = 2 (P = 0.60); I² = 0%
Test for overall effect: Z = 3.63 (P = 0.0003)

Total (95% CI) 540 100.0% 2.51 [1.93, 3.08]

Heterogeneity: Chi² = 80.95, df = 8 (P < 0.00001); I² = 90%
Test for overall effect: Z = 8.52 (P < 0.00001)
Test for subgroup differences: Chi² = 11.95, df = 2 (P = 0.003), I² = 83.3%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Incomplete outcome data (attrition bias)
(E) Selective reporting (reporting bias)
(F) Other bias

Cochrane Review, Quigley M, Embleton ND, McGuire W, 19 July 2019
Benefits of BM for premature infants

• Protection from:
  o Infection (eg, urinary tract infection and sepsis)
  o Necrotizing enterocolitis (NEC)
  o Retinopathy of prematurity (ROP)
  o Bronchopulmonary dysplasia (BPD)

• More rapid attainment of full enteral feeds and shorter duration of hospital stay

• Possible beneficial effects on neurodevelopmental outcome

*Up to date 2019, Schanler et al*
AAP Recommendations on Breastfeeding Management of Preterm Infants (Ped 2012)

• The potent benefits of human milk are such that all preterm infants should receive human milk

  • Mother’s Own Milk, fresh or frozen, should be the primary diet, and it should be fortified “appropriately” for the infant born < 1500g.

  • If mother’s milk is unavailable despite significant lactation support, pasteurized donor milk should be used
New York State Medicaid Reimbursement for Pasteurized Donor Human Milk

- The July 2017 Medicaid Update advised providers that in accordance with the 2017-2018 state budget, pasteurized donor human milk (PDHM) is a covered Medicaid benefit for inpatient use.

- PDHM is covered for infants who:
  - Birth weight < 1500 grams (3.3 pounds); or
  - Have a congenital or acquired condition that places the infant at a high risk of NEC
Pasteurized Donor Human Milk (DHM)

- DHM Products (NYS Reimbursement $0.17/ml)
  - Human Milk Banking Association of North America (HMBANA) ($0.12-$0.17 per ml)
    - Medolac
  - Prolacta
    - 20 cal (30 cent / ml)
    - 24 cal ($1.27/ml)

- Protein Sources (fortifiers not reimbursed via NYS Medicaid)
  - 2 Bovine derived fortifiers
  - 1 Human milk-derived fortifier
    - +4 fortifier ($1.14/ml)
NYSPQC Survey of Feeding Practices 2018

• Survey Methods

• A survey concerning neonatal feeding policies, protocols, and practices was distributed to all RPC and Level III NICUs in July 2018.

• NICUs were asked to complete the survey questions for babies born at < 31 weeks gestation who are admitted to their NICU.
## Feeding Type Most Often Used While Waiting for Maternal Milk Availability

<table>
<thead>
<tr>
<th></th>
<th>Total N (%)</th>
<th>RPCs N (%)</th>
<th>Participating Level III S N (%)</th>
<th>Non-participating Level III S N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infants Born &lt;1500g</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor Milk</td>
<td>27/50 (54%)</td>
<td>13/17 (76%)</td>
<td>10/21 (48%)</td>
<td>4/12 (33%)</td>
</tr>
<tr>
<td>Formula</td>
<td>22/50 (44%)</td>
<td>4/17 (24%)</td>
<td>10/21 (48%)</td>
<td>8/12 (67%)</td>
</tr>
<tr>
<td>Water</td>
<td>1/50 (2%)</td>
<td>0/17 (0%)</td>
<td>1/21 (4%)</td>
<td>0/12 (0%)</td>
</tr>
<tr>
<td><strong>Infants Born ≥1500g</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor Milk</td>
<td>11/50 (22%)</td>
<td>4/17 (24%)</td>
<td>5/21 (24%)</td>
<td>2/12 (17%)</td>
</tr>
<tr>
<td>Formula</td>
<td>39/50 (78%)</td>
<td>13/17 (76%)</td>
<td>16/21 (76%)</td>
<td>10/12 (83%)</td>
</tr>
</tbody>
</table>
NYSPQC Interventions at Univ of Rochester

• NYSPQC Growth Project (2010)
  • Goal: Decrease infants < 31 wks discharged with weight < 10th percentile
  • Evidence-based practices:
    • Early, aggressive TPN (protein & lipid goals)
    • Trophic feedings
    • Earlier human milk fortification

• Nov 2017 – Donor Human Milk Program Launched
  • Prolacta DHM
  • Prolacta DHM +4 fortifier
  • Liquid protein fortifier
Nutrient Intake at 150 ml/kg/d

<table>
<thead>
<tr>
<th></th>
<th>Preterm Human Milk (Early PTHM)</th>
<th>Preterm Human Milk (Late PTHM)</th>
<th>PTHM + HM HMF (24 kcal/oz)</th>
<th>PTHM with HM HMF (24 kcal/oz) + 6 ml liq protein/dl (24 kcal/oz)</th>
<th>PTHM with HM HMF (26 kcal/oz)</th>
<th>Early PTHM with Similac HMF SHMF HP Cl* (24 kcal/oz)</th>
<th>PTHM with Enfamil Acidified LHMF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kcal</td>
<td>102</td>
<td>102</td>
<td>123</td>
<td>122</td>
<td>134</td>
<td>120</td>
<td>122</td>
</tr>
<tr>
<td>Protein (g)</td>
<td>2.1</td>
<td>1.6</td>
<td>3.4</td>
<td>4.7</td>
<td>4.2</td>
<td>4.2</td>
<td>4.8</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>5.2</td>
<td>5.2</td>
<td>7.4</td>
<td>6.9</td>
<td>8.1</td>
<td>5.4</td>
<td>7.2</td>
</tr>
<tr>
<td>CHO (g)</td>
<td>12</td>
<td>12</td>
<td>10.6</td>
<td>10</td>
<td>11.1</td>
<td>13.8</td>
<td>9.9</td>
</tr>
<tr>
<td>Ca (mg)</td>
<td>34</td>
<td>34</td>
<td>184</td>
<td>174</td>
<td>184</td>
<td>178</td>
<td>177</td>
</tr>
<tr>
<td>Phos (mg)</td>
<td>20</td>
<td>20</td>
<td>96</td>
<td>91</td>
<td>96</td>
<td>102</td>
<td>98</td>
</tr>
<tr>
<td>Ca/Phos Ratio</td>
<td>1.7</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
<td>1.9</td>
<td>1.7</td>
<td>1.8</td>
</tr>
</tbody>
</table>

- *Extensively hydrolyzed protein concentrated liquid
- Recommended Ca/Phos ration 1.5-1.7 (Up-to-Date, 2019)
- DHM has protein content similar to Late PTHM
### Nutrient Intake at 150 ml/kg/d

<table>
<thead>
<tr>
<th></th>
<th>Preterm Human Milk (Early PTHM)</th>
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<td>96</td>
<td>91</td>
<td>96</td>
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<td>98</td>
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<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
<td>1.9</td>
<td>1.7</td>
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</tr>
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<td>Fat (g)</td>
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<td>CHO (g)</td>
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<tr>
<td>Ca (mg)</td>
<td>34</td>
<td>34</td>
<td>184</td>
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</tr>
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<td>Phos (mg)</td>
<td>20</td>
<td>20</td>
<td>96</td>
<td>91</td>
<td>96</td>
<td>102</td>
<td>98</td>
</tr>
<tr>
<td>Ca/Phos Ratio</td>
<td>1.7</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
<td>1.9</td>
<td>1.7</td>
<td>1.8</td>
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</table>

- *Extensively hydrolyzed protein concentrated liquid*
- Recommended Ca/Phos ration 1.5-1.7 (*Up-to-Date, 2019*)
- DHM has protein content similar to Late PTHM
## Nutrient Intake at 150 ml/kg/d

<table>
<thead>
<tr>
<th></th>
<th>Preterm Human Milk (Early PTHM)</th>
<th>Preterm Human Milk (Late PTHM)</th>
<th>PTHM + HM HMF (24 kcal/oz)</th>
<th>PTHM with HM HMF(24) + 6 ml liq protein/dl (24 kcal/oz)</th>
<th>PTHM with HM HMF (26 kcal/oz)</th>
<th>Early PTHM with Similac HMF SHMF HP Cl* (24 kcal/oz)</th>
<th>PTHM with Enfamil Acidified LHMF</th>
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<tr>
<td><strong>Kcal</strong></td>
<td>102</td>
<td>102</td>
<td>123</td>
<td>122</td>
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<tr>
<td><strong>Protein (g)</strong></td>
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<td>4.7</td>
<td>4.2</td>
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</table>

- *Extensively hydrolyzed protein concentrated liquid
- Recommended Ca/Phos ration 1.5-1.7 (Up-to-Date, 2019)
- DHM has protein content similar to Late PTHM
DHM Program – Watch for

• Pre-prandial Hypoglycemia on Full Feedings
  Solution -> increase feeding volume and/or duration of feedings, glucose polymer

• Hypercalcemia -> hold Vitamin D, check phosphorous, reduce fortifier

• Slow Growth -> Change to bovine fortifier, Prolacta 26, MCT oil
Univ of Rochester Feeding Protocol

1. **Goal** is to begin feeding within first 12 hrs of life, especially for preterm infants. **Advance feeding volume daily on work team rounds.**

2. Trophic feedings are indicated for minimum of 72 hrs for ALL infants < 1500 grams (Volume < 20 ml/kg/day; Frequency q4-8h)

3. BG Monitoring: **once daily** while advancing feedings/changing TPN or **one time** AC when on full feedings and off TPN/IVF

4. **FORTIFICATION** of human milk (MBM or DBM): Do not advance feeding volume on fortification days

   **Birthweight < 1250 grams**
   a. At 60 ml/kg/day add Prolact+4 and 3ml of liquid protein
   b. At 80 ml/kg/day add an additional 3 ml of liquid protein (for a total of 6 ml of liquid protein)

   **Birthweight 1250 – 1799 grams**
   a. At 60 ml/kg/day add 2 vials Enfamil HMF to make 22kcal/oz
   b. At 80 ml/kg/day add 4 vials Enfamil HMF to make 24 kcal/oz

5. Transition off Prolacta fortifiers at **33 0/7 weeks PMA**
Incidence of NEC (Univ of Rochester)

Incidence of Necrotizing Enterocolitis

<table>
<thead>
<tr>
<th>Year</th>
<th>Incidence</th>
</tr>
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<tbody>
<tr>
<td>2009</td>
<td>6.20%</td>
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<tr>
<td>2010</td>
<td>8.30%</td>
</tr>
<tr>
<td>2011</td>
<td>7.40%</td>
</tr>
<tr>
<td>2012</td>
<td>10.50%</td>
</tr>
<tr>
<td>2013</td>
<td>7.90%</td>
</tr>
<tr>
<td>2014</td>
<td>7.30%</td>
</tr>
<tr>
<td>2015</td>
<td>10.40%</td>
</tr>
<tr>
<td>2016</td>
<td>11.00%</td>
</tr>
<tr>
<td>2017</td>
<td>6.40%</td>
</tr>
<tr>
<td>2018</td>
<td>2.30%</td>
</tr>
<tr>
<td>2019</td>
<td>3.20%</td>
</tr>
</tbody>
</table>

Donor Milk Program Starts
Percent of Infants <31 Wks Discharged with Wt < 10th Percentile
(Total Discharges n = 1472)

PGF decreased by 41% and has been sustained

Donor milk

Average

NYSPQC
Nutrition bundle
Questions
New-York Presbyterian Morgan Stanley Children’s Hospital Team

Marianne Garland
Neonatologist
Medical Director, NICU Lactation and Donor Milk Programs

Christine Scheinman
NICU Lactation Consultant
Manager, NICU Donor Milk Program

Betina Grigoroff-Aponte
NICU Lactation Consultant

Monique Woodley
NICU Lactation Consultant

Alix Anand
NICU Dietician
The Labor and Delivery of H220—MS-CHONY NICU Donor Milk Journey
MS-CHONY Donor Milk Journey

- The beginnings
- Getting the license
- This is more complicated than we thought!
- Starting small
- ARRGGGHH!!! Auditing and Compliance
- Going Enterprise wide
  – Donor Milk Workshop
The Team

NICU Team
- Local Milk Bank
- Tissue Compliance
- Nutrition Management
- Parent Education
- Epidemiology
- Contract Procurement Billing
- Regulatory
- Legal Consent Forms
- IT Orders NED
- Procurement
- Billing
- Compliance
- Nutrition
- Education
- Epidemiology
The Labor and Delivery of H220

- Conceived in 2013 @ a TLC meeting
- NY State DOH Wadsworth Guidelines
- Mother’s Milk Bank Northeast
  - Sample hospital policies
  - Manual on creating a hospital policy
- Did you know?.....
  – There’s a policy on how to make a policy!!
The Tissue Resources Program oversees all tissue banking activities and services provided in New York State, from donor solicitation to clinical use. Regulations also include requirements for facilities (Non-Transplant Anatomic Banks) that recover, process, store and/or distribute nontransplant anatomic parts for medical research or health professional education.

**Tissue Bank License Application Instructions**

- Instructions
- All facilities complete the Application for Licensure-Human Tissue Bank Nontransplant Anatomic Bank DOH 2973.
- All facilities except those subject to Article 28, complete Form F, Disclosure of Ownership and Controlling Interest Statement, DOH 2973.
- If your facility is considered a corporation, also provide a copy of the certificate of incorporation
- If your facility is considered a partnership, also provide a copy of the partnership agreement
Getting a Tissue License for Donor Human Milk

- **Tissue Services** - Public Health Law Article 43-B, enacted in 1990, established the Commissioner's authority over tissue banks. [Part 52, Tissue Banks and Nontransplant Anatomic Banks](#), covers such tissues as skin, eye, semen, embryos, and stem cells. [Subpart 58-5, Hematopoietic Progenitor Cell Banks](#), regulates activities involving hematopoietic progenitor cells (precursors of blood cells found in umbilical cord blood, peripheral blood, and bone marrow). Licensure is required for all tissue banking activities in New York, including collection, processing, storage, and distribution.

- **SubPart 52-9 – Human Milk Banks**

- Contact Office of Regulatory Planning for *any* tissue license updates

- Work with your local Tissue Compliance Officer
Local Milk Banks

- Mothers Milk Bank Northeast (MMBN)
- New York Milk Bank

- MMBN provided a wealth of information
  - sample policies, consents, and info sheets

- The ordering of donor breast milk is very easy
  - Ordermilk@nymilkbank.org
Update NYSDOH Tissue License

- Add Human Milk as Tissue Category on existing license
- Identification of a local Medical Director
- Requires submission of policy and procedure
  - Ordering and tracking mechanisms
  - Freezer requirements
  - Medical/Nursing Committee Approval
- Name of vendor/contract/vendor’s NYSDOH Tissue License
- Freezer Location
- Annual Tissue Banking Activity Report conducted by local Tissue Compliance Officer
Informed Consent

- **Consent form**
  - Structured after the blood transfusion consent
  - Approved by Legal and forms committee
  - English, Spanish, and Mandarin
  - Available through forms on demand
  - Obtained by physician, NP or PA
  - Telephone consent accepted

- **Information sheet**
  - 5th grade language and question based
  - Approved by Patient and Family Education Review Committee
  - Available on infonet in English and Spanish
The Labor And Delivery of H220

- Numerous revisions at local level
- Labor Began in the fall of 2014 – presented to Nursing Practice Council
- Active Labor when Approved by Nursing Board in Nov 2014
- Born in December 2014 after Medical Board Approval
- Admitted to the CHONY NICU in January 2016
- First Steps Taken Feb 2016
How to become operational …

Donor Human Milk Program
- Medical Director
- Tissue Compliance Officer
- Program Manager

Getting Started
- Add donor Milk to your Facilities Tissue License

Setting Up
- Local Milk Banks Contracts and Purchasing Reimbursement

Day-to-Day Operations
- Processes for eligibility, consent, documentation, procurement, and education
- Monitoring, compliance, reporting and DOH visits
- Nutrition and fortification
Infrastructure for Maintaining DHM

- Dedicated Deep Freezer for DHM
  - Must be able to maintain temp of -20C and colder
  - Cannot be household Freezer with AutoDefrost

- Freezer Monitoring
  - Daily freezer logs
  - Centralized Monitoring System
    - Notification Tree
  - Logs must be available upon DOH request
Pilot Program – started small

- Bridge program
  - Provided donor milk for up to 14 days while waiting for mom’s milk
  - Allowed exemptions particularly for ELBW infants

- Allowed time to supervise more closely and fix kinks in the system

- Medicaid approved donor milk for babies at risk for NEC around July 2017
  - Time to expand our program
  - Who’s going to pay for this?

- Expanded program in March 2018
  - All babies under 1500 g eligible for donor milk till close to discharge
  - All cardiac babies eligible for donor milk
Section 52-9.7 - Maintenance of records

- Records shall be maintained on each recipient, including, but not limited to:
  - the infant's or child's age, birth weight and/or weight history, and diagnosis indicating the medical need for human milk;
  - the dates the milk banking service began and terminated;
  - identification by donor identification number of the source of all milk given to the recipient;
  - documentation that the risks of consumption by an infant or child of donated milk have been disclosed to the person(s) legally responsible for such infant or child;
  - recipient health status at the time of discontinuation of milk banking service and reason for such discontinuation.
- Donor and recipient records shall be maintained for at least three (3) years after a recipient's age of majority (18 years) or for at least six (6) years after a recipient's death.
Donor milk requires a Prescription and Specific Documentation

- Prescription means an order in the EMR

- **Authorization of Donor Human Milk**
  - Captures required documentation
    - Name, MRN, DOB, gestational age, birth weight, current age, current weight, disclosure of risks/consent, indication, diagnosis

- **Donor Human Milk Order**
  - Diet order includes provision details
  - Generates flowsheet parameter

- **Discontinuation of Donor Human Milk**
  - D/Cs all associated donor milk orders
  - Captures required documentation
    - reason, condition, complications, age, weight, wt:age %ile
Parameters automatically generated from diet order (O2FS)
- Volume
- Donor Milk Lot #
- Milk Bank

Alert will trigger if any *required documentation* left blank

Donor Milk parameter can not be manually added
Tracking

- EMR
  - Which batch each baby got
- ?
  - Which batch given to which babies

Oh for a scanning system!
Purchasing Donor Milk

- Setting up a contract with the supplier
  - Purchasing department assists in setting this up
  - Legal signs off on the contract

- Who pays for donor milk?
  - Good question
Auditing: Who Knew!

- Donor milk was logged in correctly
- No temperature aberrations during transport – Cold chain document
- Consent obtained on all infants receiving donor milk
- Required documentation in the chart – Authorization order
- Batch numbers recorded for all donor milk feeds
- Freezer sheets have correct expiration date
- No administration of donor milk in error
- Discontinuation documentation completed
- Report auditing results at the monthly Tissue Compliance Meeting
Going Live

▪ 80% Education of all staff at outset
  – Nurses
  – MDs, NPs, PAs

▪ New Hires
  – Included in orientation

▪ Updates
  – Read and sign
  – NICU Update board
  – Huddles and staff meetings
  – NICU Newsletter
Donor Milk Use by CHONY NICU

Quarterly Milk Usage in Liters

Number of Babies Receiving DM

- 7 Tower
- Cardiac ICU
NEC rates over past 10 years in inborn VLBW Infants

Based on Vermont Oxford Data
Mother’s Milk is Best

- Donor human milk is an alternative to preterm infant formula
  - when mother's milk is not available
- Major emphasis is on the prevention of NEC by avoiding infant formula
  - may have other benefits
- Fortification of breast milk (human and donor) is still required
  - The benefit of human over bovine based human milk fortifiers has not been demonstrated at this time
- Donor Human Milk is not a replacement for mother’s own milk
  - every NICU should have programs to support lactation
Promote Mother’s Own Milk
The more of mom’s milk you have the less donor milk you need to buy
Thank You
Q&A
Webinar Evaluation

NYSPQC Enteral Nutrition Improvement Project October 2019 Coaching Call Webinar Evaluation Survey

Survey to gather feedback from participants attending: NYSPQC Enteral Nutrition Improvement Project October 2019 Coaching Call Webinar Evaluation Survey

1. Does your facility participate in the NYSPQC Enteral Nutrition Improvement Project?

   -- Please Select --

2. Does your facility have a human donor milk program?

   -- Please Select --

3. Please indicate your level of agreement with the following statements regarding the October 17, 2019 NYSPQC Enteral Nutrition Improvement Project Coaching Call Webinar.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>n/a</th>
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</thead>
<tbody>
<tr>
<td>Timothy Steven's presentation on the Donor Human Milk Program was</td>
<td>○</td>
<td>○</td>
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<tr>
<td>informative.</td>
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<tr>
<td>The presentation by New York-Presbyterian Hospital staff on The Labor</td>
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<td>and Delivery of H220-MS-CHONY NICU Donor Milk Journey was informative.</td>
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Upcoming Events

NYSPQC Donor Milk Webinar Series: Part 2
Thursday, November 7th from 12-1PM

Topic: Management of Human Donor Milk

Speakers:

- **Adriann Combs, DNP, NNP-BC**
  Clinical Director Service Line
  Obstetrics and Gynecology
  Northwell Health

- **Martha Caprio, MD**
  Associate Professor of Pediatrics
  New York University School of Medicine
  NYU Langone Medical Center

- **Julie Bouchet-Horwitz, FNP-BC, IBCLC**
  Executive Director
  The New York Milk Bank, Inc.
Contact

New York State Perinatal Quality Collaborative
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Corning Tower, Room 984
Albany, NY 12237

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www.nyspqc.org