GBMC
NICU DONOR MILK PROGRAM
Eva Stone MSN, RN
Dec. 4, 2015
OBJECTIVES

- At the completion of this presentation, the participant will:
  1. Name four states that require state certification for agencies/organizations to purchase and use donor milk products.
  2. Identify steps in the processing of Donor Milk Product that the state regulates.
  3. Identify 3 key issues that the state required during the GBMC Donor Milk Program site review.
Who oversees milk banks in the US?

The Human Milk Banking Association of North America is the umbrella association of which most non-profit milk banks in the US are members. HMBANA has developed guidelines for the establishment and operation of human milk banks that all member milk banks are required to follow. These guidelines have been developed in consultation with representatives of the CDC, FDA, and Infectious Disease Committees of the American Academy of Pediatrics.
Determine the Department Options for Handling the Donor Milk Program

Who?
1. Lab / Blood Bank
2. NICU under the Tissue Bank License of GBMC *

Considerations
1. Day to day determination of needed Donor Milk Products, what is on hand and what will be needed.
2. Having the milk available as needed
3. Tracking the Donor Milk Product
4. Ownership (responsibility and accountability)
Once the decision is made for the NICU to manage the donor milk program

- Four states regulate milk banks (California, Maryland, New York, and Texas) and most states regulate the storage of breast milk under licensing for child care standards.

- Maryland regulates milk banks under regulations for tissue banks (COMAR 10.50.01), and requires that banks acquire necessary permits and meet standards in regards to inspections, personnel, and testing to minimize disease transmission.

Where do you begin?
  - Search agencies that set standards and regulation.
AGENCIES THAT PROVIDED RELEVANT INFORMATION

- MD Department of Health and Mental Hygiene DHMH
- American Dietetic Association ADA
- HMBANA
- CDC
- FDA
- foodsafety.gov
HOW WE REALIZED OUR VISION

- Establish Donor Milk Bank Committee members and charter Collect, evaluate federal and state standards related to tissue banking
- Determine if the NICU Donor Milk Bank can come under the GBMC surgical tissue bank license for the state of MD Submit application and fee to MD Tissue Bank for Milk Bank addition
- Identify location possibilities for Breast Milk Bank / Nutrition area in the NICU
- Produce a layout of allocated space for fixture and appliances
- Investigate refrigerators, freezers, SS counters for space and workflow
- Arrange Evaluation of Medela thawing and warming device
- Update the Woman’s Board on program development progress
- Develop budget for renovation of space and purchase of fixtures and appliances
- Write a guideline for ordering, receiving, processing, storing, tracking and administering PDHM
- Identify Electronic Scanning Needs and Meditech capacity for Donor Milk Tracking options in Meditech EMR. Develop a Donor Milk Tracking pathway using the Meditech EMR if possible to streamline workload. Explore nurse work process and tracking
- Develop medical protocol for determining use and for ordering Donor Milk Bank and Human based fortifiers
- Review and update related policies for MOM Breast Milk Develop program brochure to include: target audience, cost & payment modality, brief overview, objectives
- Develop & Submit Program Description for brochure to Community Relations for mailing Submit Program brochure to Community Relations for formatting
- Send brochure to print
- Notify the Department of Clinical Education & Professional Development in NICU for ED Meetings held: 6/27, 7/10, 8/21
RESOURCES NEEDED FOR THE NICU BASED DONOR MILK PROGRAM

- **Time**
  1. Standard Work and Guideline Development
  2. Two hours of education per staff member
  3. Competency measurements

- **Committed Staff**
  1. Staff input for realistic operations
  2. Staff for education
GUIDELINE DEVELOPMENT

- Identify Standards from the MD DMHM and the ADA
- Identify process
- Develop standard work for each step of processing
- Develop forms for ease of access
- Develop downtime paperwork
- Develop standard work for entering patient information and other data into Horizon, the Tissue Bank Data Base at GBMC
HOW THE DONOR MILK PROGRAM WORKS

- Processing
  1. Ordering the product
  2. Monitoring the purchase from delivery to storage
  3. Removing the product from storage
  4. Mixing
  5. Administer/Transplant
  6. Scanning the labeled product into the infant’s MAR
  7. Donor Milk Database / Tissue Bank Database
  8. Education
  9. Monitoring for Quality and Safety
STATE CERTIFICATION

- GBMC Donor Milk Program underwent a 3hr review
- Reviewed the GBMC Guideline and policy
- The state reviewer conducted a very detailed review of the process using the guideline
- Observations (mixing, processing)
- Staff interview (Chose a product used on an infant and competed a tracer into the Tissue Database (*Horizon*) to determine if practice mirrored the policy and guideline.
**Findings**

- Approximately 1 month later, we received a provisional list of process improvement recommendations.
- GBMC was given 2 weeks to answer and submit a written plan to address the items.
- Implementation date for plan completion established for Sept 2014
- Certification continued as the program awaited the “letter or site visit”
- Incidental requests were made to GBMC to produce education and the list of staff who have been signed off on the standard work competencies
Getting it right!

1. A key factor is a clear Guideline
2. Policy Components
3. Standard Work…*Do we do what we say we are suppose to do?*
4. On observation…*Did we do it?*
5. *Did we do it right?* (Right is what we say we are suppose to do)
Staff Education that Mirrors Standard Work
Ordering Donor Milk Products

Standard Work

- Monitor PDHM/DMDP inventory twice a week.
- Review all current feeding orders requesting the use of PDHM/DMDP.
- Determine the weekly ordering needs against the current inventory and orders.
- Order any needed PDHM/DMDP using the appropriate GBMC supply order form from one of the following:
  - Fax or hand deliver the GBMC supply order form to the GBMC Purchasing Dept
  - Stamp the request and/or GBMC supply order form with the date and time of fax stamp.
- Place a copy of the GBMC PDHM/DMDP order form(s) in the Donor Milk Program binder under the “Order” section.

Education Competency

- Determine the inventory based on infant’s need by inspecting all the orders, counting the inventory and determining the variance from the par level
- Complete the order paperwork and fax to HMBNA (San Jose, Wake and/or Boiscience)
- Complete the GBMC purchase order and fax to purchasing
- Stamp the request with the date and time faxed stamp
**Guideline**

- Review new feeding order in the electronic medical record, and print a copy of the order and place a copy in the Donor Milk Bank Program binder.
- Remove the ordered products from the freezer and apply a white patient label. Write the date and time of thawing on top of the container with sharpie marker.
- Document the PDHM/DMDP identification number and/or Lot number on the Donor Product Administration/Tracking Log for that infant located in the Donor Milk Bank Program binder. RN will sign the entry on the Donor Product Administration/Tracking Log. Information will be entered into tissue bank data base.
- Dry thaw the MOM/PHDM/DMDP using the breast milk warmer according to the instructions on the warmer.

**Education Competency**

- Review the current order in the Breast Milk Binder
- Identify the Donor Milk Product needed
- Remove the correct product for the baby
- Affix the infant label to the Donor Milk Product
- Document the information from the bottle onto the Product Administration/Tracking Log
- Place the Donor Milk Product into the Breast Milk warmer and set to volume for thaw.
ONGOING RESOURCES NEEDED

- Key staff to enter the implant at all stages
- Trained and competency validated NICU Nursing Staff
- Donor Milk Program resource coordinator who validates the Donor Milk Product and accounts for the “implant” and waste in the Tissue Bank Database
- Yearly competency validated education for nursing staff
FROM PROGRAM START TO FINISH?

- 18 months June 2012 to January 2014
- 6-8 months for project construction
- Jan 2014 received MD State certification to use Donor Milk Products
- June 2014 MD State Review on site
- Sept 2014 Implementation of response to findings completed
UNEXPECTED DELAYS

- Space allocation
- Design
- Construction
- Equipment
- Preparation Surfaces
- Infection Control
- Information Technology
CURRENT STATUS

- State satisfaction with the GBMC Response to COMAR findings
- Possible site visit from the state at any time
- We are prepared!
DONOR MILK PRODUCTS
THE BEST FOR OUR PREEMIES