

# HUMAN MILK BANKING ASSOCIATION OF NORTH AMERICA

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# HMBANA

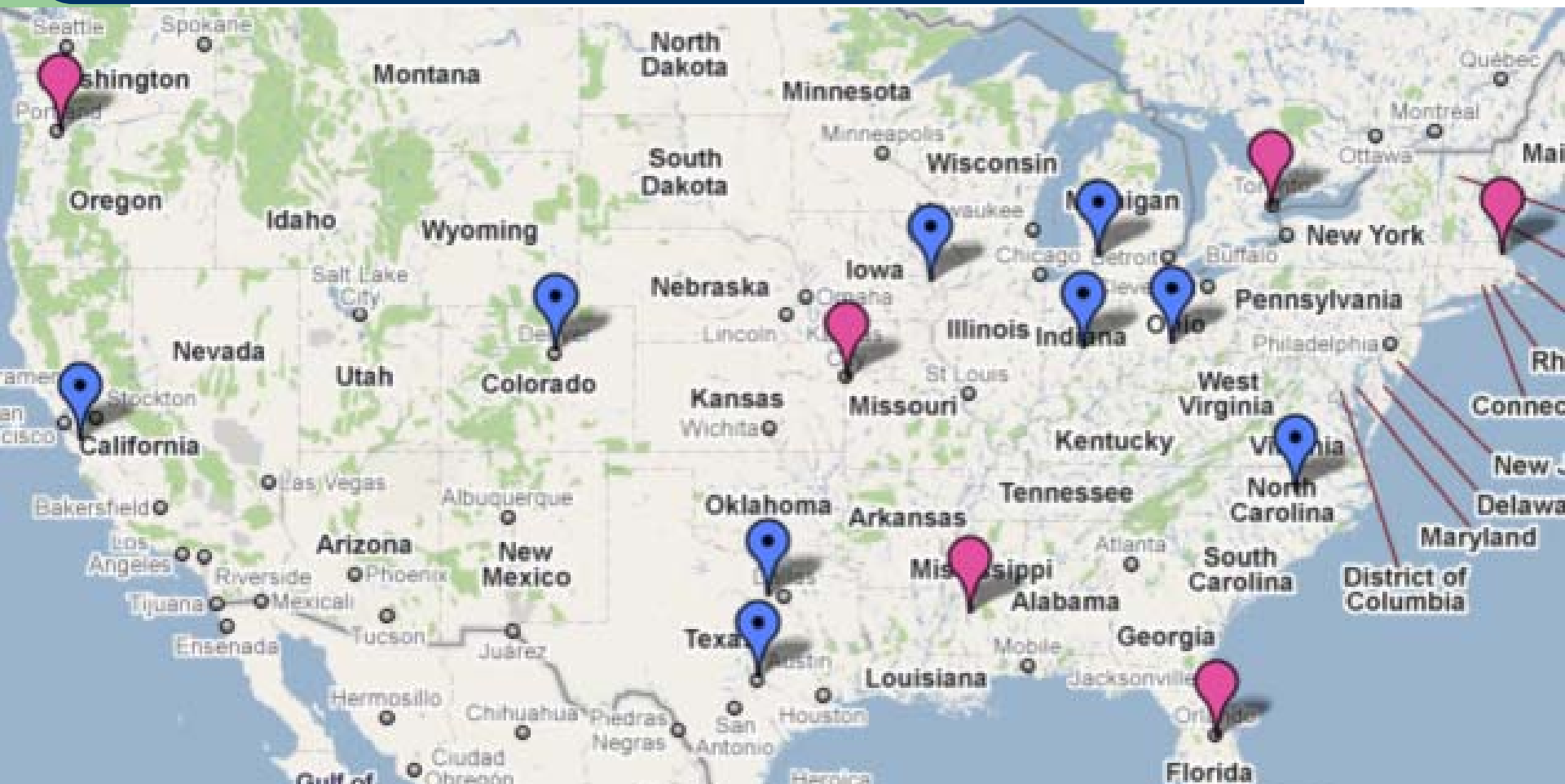


- The Human Milk Banking 10 milk banks and 6 developing milk banks in Canada and the US.
- Developed in 1985 to respond to the potential threat of disease transmission in the casual sharing of human milk and organize current operating milk banks to develop standards for the assurance of safe practices in processing human milk.

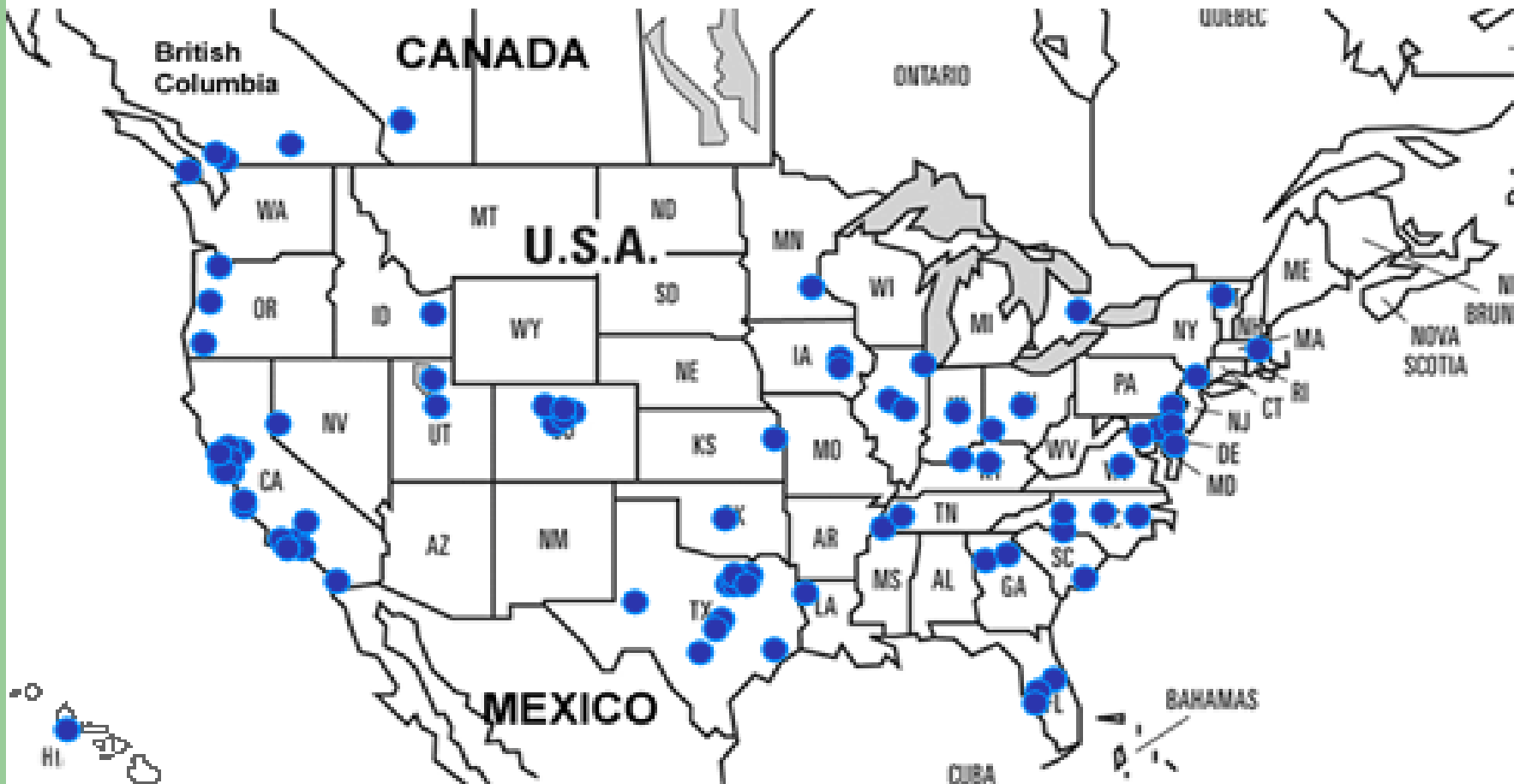
# Historical Regulation and oversight of Milk Banking

- 1943 The AAP developed formal guidelines regarding the operation of milk banks
- 1953 AABB Guidelines
- 1985 HMBANA's Guidelines
- CDC/ FDA and Advisory Board provides current data and resources for specific screening and procedural advice

# Map of US Milk Banks of HMBANA

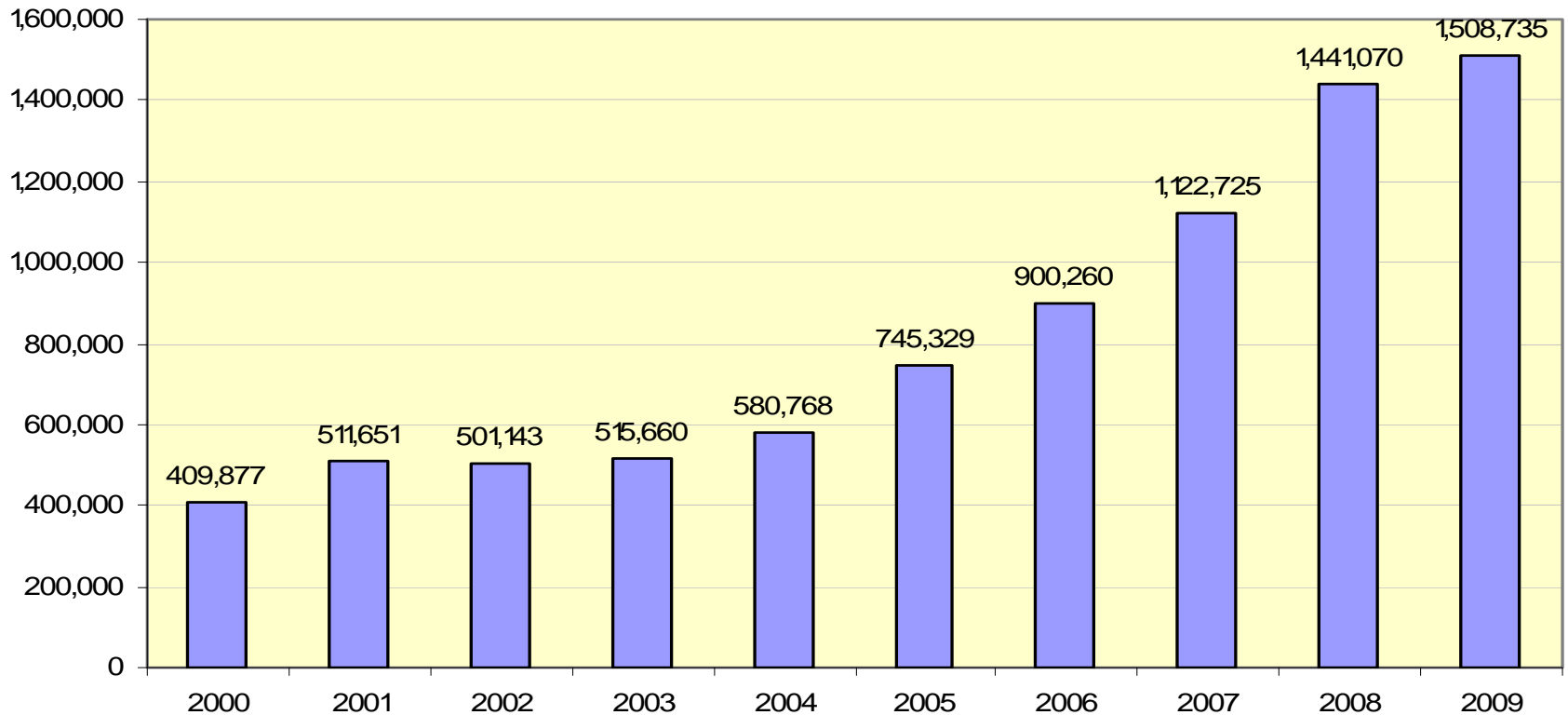


# Cities where hospitals are served with donor milk by HMBANA in 2006

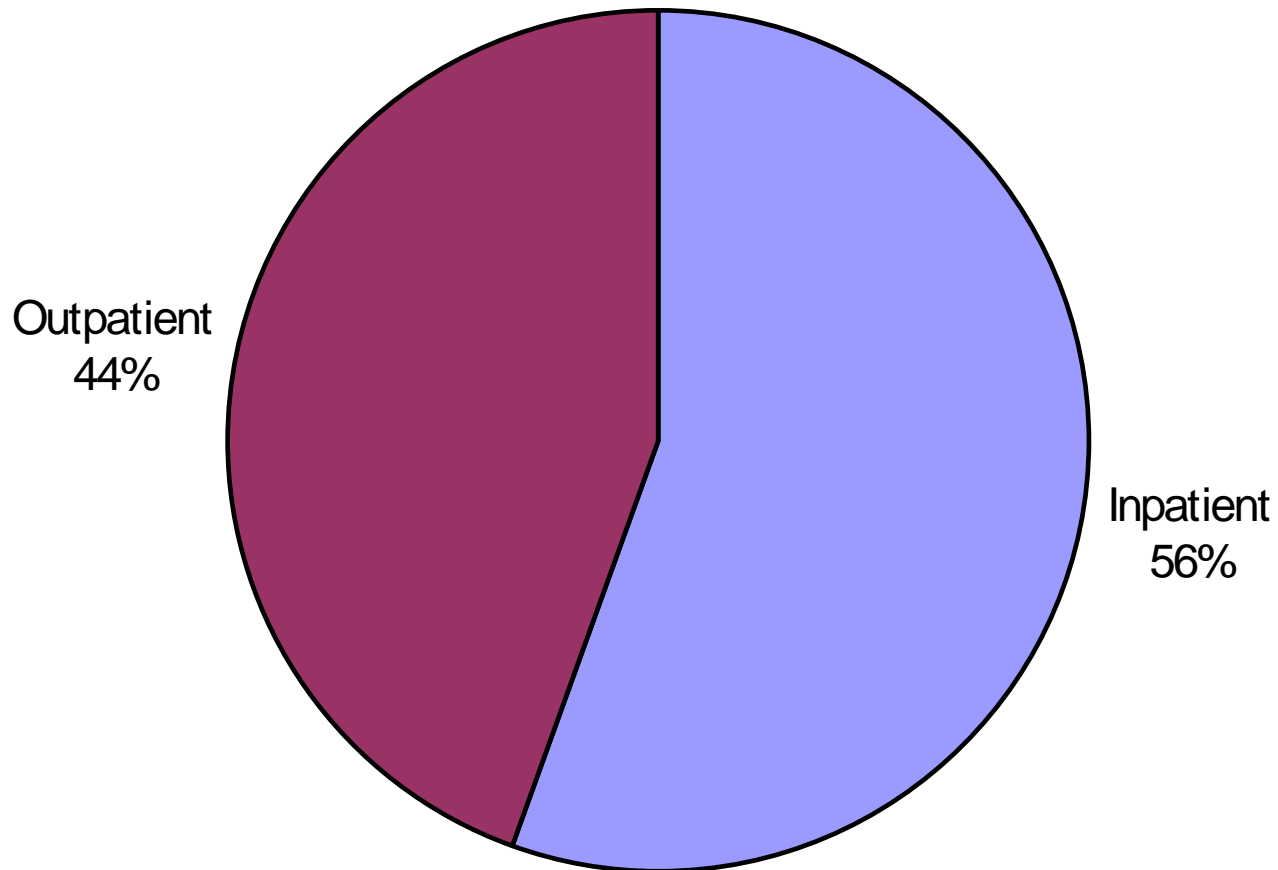


# HMBANA Annual Total

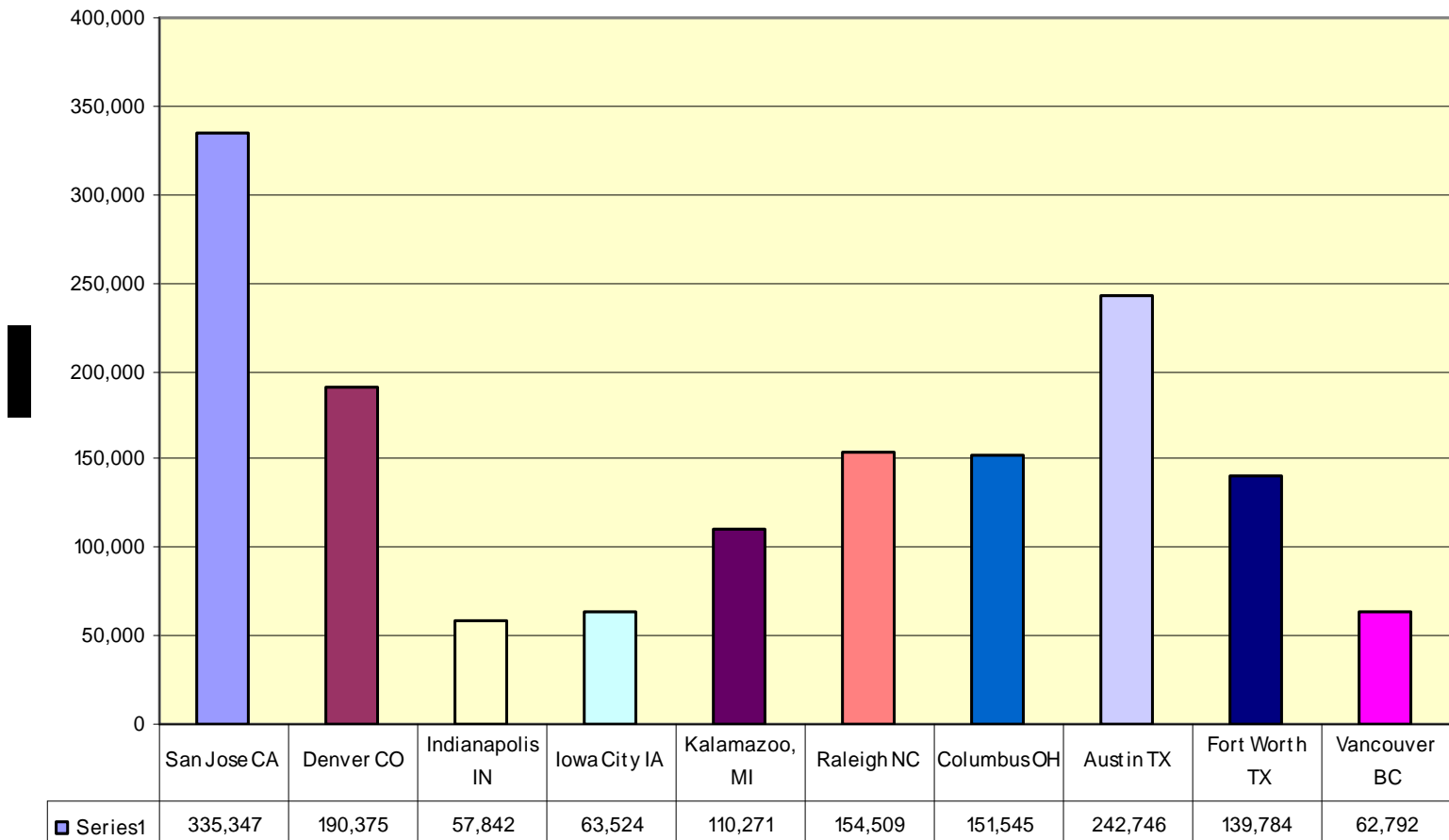
HMBANA Annual Total Distribution Rates 2000-2009



# HMBANA Total Inpatient and Outpatient Recipients



# Distribution by HMBANA Milk Bank 2009





# Purpose of HMBANA

- Develop guidelines for milk banking in North America
- Provide a forum for information sharing among those in the field of donor milk banking
- Provide information to the medical community regarding the use of donor milk
- Encourage research into the unique therapeutics and nutritive properties of human milk
- Act as a liaison between member banks and governmental agencies
- Facilitate communication among member banks
- Facilitate the establishment of new donor milk banks

# HMBANA Publications

- Best Practice for Expressing, Storing and Handling Human Milk in Hospitals, Homes and Child Care Settings ©
- Guidelines for the Establishment and Operation of a Donor Human Milk Bank ©
- Starting a Donor Human Milk Bank: A Practical Guide © [www.hmbana.org](http://www.hmbana.org)

# Donor Selection and Safety

- Each regional HMBANA Milk Bank is responsible to procure enough donor milk to service clients. Screening donors requires
  - Verbal Screening
  - Questionnaire with OB and Pediatrician acknowledgement
  - Blood Screening: HIV 1, 2 and 0, HTLV 1 and 2, Hepatitis B and C, Syphilis

# Safety

- Staff is trained to develop and build honest relationships with the donor through screening questions regarding physical status, social behavior and prior medical history.
- OB-GYN and Pediatrician have the opportunity to state mother's acceptability as donor
- The double blind questionnaire elicits responses that might suggest temporary or permanent disqualification

# Disqualifications

- Include
  - Documented and reported medication use
  - Chronic diseases
  - Travel restrictions
  - Presence of transmittable disease in household
  - Herbal use
  - Positive Blood tests : reported to donor and health care provider
  - Positive bacterial counts after pasteurization

# DONOR SAFETY

- Studies have shown that milk bank donors voluntarily provide milk for altruistic reasons
- There is no monetary or financial gain or benefit to donate milk or collect milk as a depot for the HMBANA milk banks
- Common characteristics of donors: working mothers, married, young, financially secure, well educated and healthy (Osbaldiston R. et al 2007) (Lindemann PC, et al 2003)

# Expectations of Donors

General expectations include

- Blood testing done at a qualified lab
- Commitment to minimum volume and healthy lifestyle for their own infant as well as donation

# Informed Consent

In 2008, consent form minimum standards established for all HMBANA milk banks

- Each milk bank's form reflects local requirements
- For hospital consent, each hospital develops their own consent for donor use.
- HMBANA milk banks will comply with state regulations regarding tissue banking requirements



# Consent form

Reflects

- Voluntary status of human milk donation
- Obligation to notify milk banks of changes or risks of behavior or health
- Agreement to have blood tested
- Truthfulness

# Internal Milk Bank Procedures (Storage)

- Standard Freezing Temperatures/alarms
  - Freezers are locked or in a secure area
  - No higher than -20°C (-4°F)
  - Freezers are monitored by recording thermometers or temperature alarms

Temperature established to deter CMV growth and decrease bacterial replication

# Internal Milk Banking Procedures ( Milk Processing)

- Holder Pasteurization : 62.5°C for 30 minutes, then immediately cooled down to 4°C
- Small batch processing
- Cultured for bacterial growth
- Labeled with individual batch ID

Known to erradicate common skin bacteria

# Internal Milk Bank Procedures (Microbiology)

One random bottle from each batch is utilized for microbiology testing by a certified lab.

**ANY BACTERIAL GROWTH IN THE POST  
HEAT TREATMENT SAMPLE IS  
UNACCEPTABLE FOR DISTRIBUTION**

# Recall and Tracking System

- Documentation of
  - Donor application, approval and shipments
  - Milk Processing and distribution data
  - Recipient data and acceptance
  - Pool distribution data

**are maintained until the recipient reaches the age of 21.**

# Recall and Tracking

Every bottle of milk sent to a recipient can be

- Tracked to the donors in the pool
- Tracked to the other recipients who also received the same batch or donor's milk
- Immediately investigated for contamination and inventory
- Tracked for 21 years of distribution or recipient age.

# Recall And Tracking

Any Positive Outcomes are immediately reported to State Licensing Boards or regional health Departments

- **There has never been a documented case of disease transmission or death due to donor milk.**

# Accreditation and Certification Programs

- Minimum Standards for HMBANA milk banks
- Standards of job performance for milk bank technicians, includes customer service, technical skills
- Based on the HMBANA Guidelines, Good Tissue Practice Act, Food Safety Acts and recommendation from HMBANA Board of Directors
- Reviewed and updated annually



# Accreditation and Certification

- Within the HMBANA organization the first year the Directors of Milk Banks did their own review with the testing tool and refined the questionnaire
- The second year, milk bank directors appointed a member of the community to review their agency
- 2011, Mandatory Peer Assessments by HMBANA Directors

# Accreditation and Certification

- Compliance is determined by the appointed Accreditation Committee of HMBANA
- When deficiencies are found, the committee reports findings to the Executive Board
- HMBANA membership is questioned if the deficiencies are not corrected in a timely manner.

# Accreditation and Certification Program in HMBANA

- Assessment tools include
  - Organizational structure
  - Donor selection and Documentation
  - Donor Education and procedures
  - Milk Bank Procedures and Documentation
  - Equipment and Monitoring Documentation
  - Processing of Milk and Documentation
  - Recipient Selection

# Education for recipient use of donor milk

- Many milk bank directors have direct access to hospital staff who use donor milk or interested in using donor milk. Support includes educational materials, consent form development, storage questions
- All shipments of donor milk includes directions on the use of the donor milk for hospital and home use.
- California, New York and Maryland have Tissue Banking requirements for human milk.

# Priority Listing of Distribution of Donor Milk

- HMBANA Priority list to regulate a scarce resource
  - Preterm infants, inpatient
  - Preterm infants, outpatient
  - Infants, less than 12 months with medical condition likely to respond to donor milk
  - Individuals more than 12 months old with medical condition likely to respond to donor milk
  - Individuals with chronic conditions, high functioning, responding to donor milk

# Ethical Distribution of Human Milk

Similar to Organ Transplant agencies,  
HMBANA

- protects the donor identification
- provides no financial incentive to donors or organizations assisting HMBANA milk banks to educate and procure donations
- provides donor milk to the patients with high need and best outcome
- provides a service not in operation for personal gain

# In Conclusion

- American Academy of Pediatrics 2005

“Banked Human Milk may be a suitable feeding alternative for infants whose mothers are unable or unwilling to provide their own milk. Human milk banks in North America adhere to national guidelines for quality control of screening and testing of donors and pasteurize all milk before distribution.”

## American Academy of Family Physicians 2008

“Banked pasteurized donor milk has been found to be safe and nutritionally sound for babies who do not have access to their mother’s own milk.”