HMBANA Standards for Donor Human Milk Banking: An Overview

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HMBANA Guidelines Committee

Kim Updegrove, MSN, MPH, APRN, CNM*; Chairperson

Jannette Festival, BN, RN, IBCLC*

Raechel Hackney, BSN, RN, IBCLC

Frances Jones, MSN, RN, IBCLC

Summer Kelly, MS, RN, IBCLC*

Pauline Sakamoto, MS, RN, PHN*

Amy Vickers, MSN, RN, IBCLC, ASQ-CQA*

*PCQI certified

HMBANA
4455 CAMP BOWIE BLVD,
SUITE 114-88
FORT WORTH, TX 76107
PHONE (817) 810-9984; FAX (817) 810-0087
www.hmbana.org info@hmbana.org

HMBANA

The Human Milk Banking Association of North America (HMBANA) mobilizes the healing power of donor milk by accrediting nonprofit milk banks in the United States and Canada and setting international guidelines for milk banking.

Mission

HMBANA advances the field of nonprofit milk banking through member accreditation, development of evidence-based best practices, and advocacy of breastfeeding and human lactation to ensure an ethically sourced and equitably distributed supply of donor human milk.

Vision

HMBANA believes in a world where all infants have access to human milk through support of breastfeeding and use of donor human milk.

Section I: Introduction

This overview of *HMBANA Standards for Donor Human Milk Banking,* previously known as the *Guidelines for the Establishment and Operation of a Donor Human Milk Bank*, summarizes the safety measures that HMBANA Accredited milk banks utilize to ensure the safety and quality of donor human milk. This public document provides useful background for clinicians, healthcare organizations, and public health agencies that are interested in learning more about HMBANA milk banking procedures.

The complete version of *HMBANA Standards for Donor Human Milk Banking* are proprietary and are provided to each HMBANA Accredited member milk bank, along with accreditation documents and other tools. HMBANA Accreditation provides evidence that a milk bank is compliant with HMBANA's *Standards* and maintains a comprehensive system of preventive controls, safety checks, verifications, validations, and corrective actions. HMBANA Accreditation audits are comprised of onsite inspections, plant walkthroughs, record audits, standard operating procedure (SOP) and Food Safety Plan review, sanitation assessments, staff training evaluations, mock recalls, critical control point audits, staff interviews, and additional rigorous safety evaluations. HMBANA Auditors are certified Preventive Controls Qualified Individuals (PCQIs) through the Food Safety Preventive Controls Alliance (FSPCA) and receive additional auditor training on an annual basis.

Please note that adherence to the donor screening *Standards* contained in this brief overview does not provide assurance that informally shared or sold milk is safe or that HMBANA approved donors are qualified to provide milk to others outside of milk banking. Pasteurization is required to safeguard donor milk from biological hazards, like viral and bacterial contaminants. Organizations that identify as milk banks, but lack HMBANA Accreditation, do not have access to the proprietary version of HMBANA Standards and shall not make claims that they adhere to HMBANA Standards.

Section II: Helpful Definitions

Donor human milk bank — a nonprofit organization established for the purpose of collecting, screening, processing, pasteurizing, storing, and distributing donated milk.

Donor human milk — milk expressed and donated by lactating women, pasteurized via the Holder Pasteurization method, and dispensed for use by a recipient who is not the donor's own baby.

Food Safety Plan (FSP) — a written plan to significantly minimize or prevent biological, chemical, and physical hazards. An FSP must include a hazard analysis, preventive controls, monitoring actions, corrective actions, verifications and validations, supply-chain management programs, a recall plan and records of actions to support the food safety plan.

Milk donor — a healthy lactating woman who voluntarily donates milk and does not receive remuneration.

Milk-processing centers – for-profit entities that collect human milk and produce human milk–based products.

Processing — use of evidence-based methodologies, including pasteurization, to prepare safe milk for recipients.

Processing fees — fees assessed by the milk bank to offset the cost of donor screening and serological testing, milk processing, supplies and equipment, storage and distribution, record-keeping and other compliance activities.

Section III. Administrative Structure

HMBANA Accredited member milk banks maintain procedures and protocols that meet HMBANA *Standards* and follow federal/state/province licensure requirements and regulations, where required. HMBANA member banks are nonprofit organizations.

HMBANA Accredited Milk Banks are comprised of:

- Qualified executive director/milk bank coordinator to oversee business, clinical, and laboratory operations.
- Medical director who provides clinical guidance and policy review.
- Qualified staff that includes health care professionals, donor screeners, and lab technicians.
- A board of directors and a medical advisory committee with a wide representation of relevant experience and skills.

Milk Bank staff must have:

- Knowledge of food safety, food processing, PCQI training content, HMBANA *Standards*, and state, province and federal regulations.

Definition: PCQI refers to Preventive Controls Qualified Individual as defined by the FDA. A PCQI has completed a formal certification program through the Food Safety Preventive Controls Alliance (FSPCA).

- Documented on-going education and training critical to the safe provision of donor human milk.

Section IV. Donor Screening

Donor qualifications are based on best practices and clinical data and are updated continuously to reflect emerging diseases, new pharmaceutical agents, and new health risks.

All information pertaining to donor screening, including written and verbal communication with donors must be HIPAA or PIPEDA compliant (*HIPAA refers to the US Health Insurance Portability and Accountability Act. PIPEDA refers to Canadian laws protecting the collection, use and disclosure of personal information).*

Donor screeners should meet the following qualifications:

- Comprehensive knowledge of and proficiency in applying the latest *HMBANA Standards for Donor Milk Banking*.
- Documented training and continuing education of HMBANA's donor screening process.

Donor Screening Standards Summary

- Initial screening includes verbal communication and is never limited to electronic communication.
- Donors are screened verbally as well as in writing and provided educational materials that meet HMBANA's minimal donor education requirements.
- Accommodations for non-English speaking donors are made, when possible.
- Milk banks establish and maintain a personal, trusting relationship with each donor. Milk Banks communicate with the donor at least every two months during the donation period to update changes in donor's health, medical status, medications, and lifestyle status.
- Potential donors are screened serologically for HIV-1 and -2, HTLV-1 and -2, hepatitis C, hepatitis B, and syphilis.
- Donors are instructed about situations in which they must temporarily or permanently discontinue donation and are instructed to report such situations to the milk bank.

Temporary deferral periods or a permanent donor exclusion may apply in the following situations:

- Smoking or use of tobacco products
- Use of illegal recreational drugs
- Risk of Creutzfeldt-Jakob disease (CJD)
- Positive serological test results for HIV, HTLV, Hepatitis B or C, or syphilis
- Medication use (non-approved medications)

- Recent history of blood transfusion
- Risk of blood borne illnesses
- Body piercing, tattoos, or permanent makeup
- Organ or tissue transplant
- Vegans not supplementing with B12
- At risk sexual partner
- Travel deferrals related to CJD risk
- Alcohol consumption (requires a deferral)

Milk Handling Restrictions

- Milk may not be donated if it has been heat-treated in any way by the donor.
- Milk may be temporarily stored in the refrigerator for a maximum of 96 hours before being moved to the freezer for long-term storage.
- Milk expires one year from the date of collection.

Section V. Donor Education and Procedures

To ensure the highest level of safety and quality of donated milk, milk donors are instructed both verbally and in writing about potential risks and deferrals [such as medication/botanical dietary supplement (herbal) use, illnesses, life style choices, etc.] and appropriate methods for clean expression, handling, storage and transportation of human milk. Donors are instructed to contact the milk bank to report household illness and any changes in health status or medication use.

Donors are given written instructions covering:

- Clean technique for milk collection, including:
    - Hand washing
    - Washing pump parts and containers
    - Appropriate containers for storing donor milk
    - Handling of milk containers, both while storing milk and during transit to the milk bank
- Those times when the donor should refrain from donating and lifestyle choices that may affect her eligibility as a donor.
- Labeling of donated milk, which includes donor identification and date of collection.
- Optimal freezing and storage of milk.
- Transporting milk safely to the milk bank or depot.

To ensure that donors are fully informed of their rights and responsibilities, donors are provided with the following written information:

- A statement regarding confidentiality of records.
- A statement that approval as a milk donor does not indicate that a donor's milk is safe to share or sell informally.
- An explanation of the required serology tests and what actions are taken when positive tests are received, according to a plan developed by each milk bank, and in accordance with state or provincial regulations.

Section VI. Milk Bank Standard Operations, Safety, Quality, and Processing

Definitions

Current Good Manufacturing Practice (cGMP) – FDA Title 21, Part 117, Subpart B outlines minimum standards for safe and sanitary food manufacturing. Current cGMPs include staff training, staff hygiene and illness reporting, plant layout, sanitation procedures, and pest control.

Food and Drug Administration (FDA) – a US governmental agency that is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of America's food supply, cosmetics, and products that emit radiation.

Food Safety Modernization Act (FSMA) – enacted in 2015 by the US FDA, FSMA shifted the focus from responding to foodborne illnesses to preventing them. FSMA rules are designed to identify specific actions that must be taken at each processing step to prevent contamination. One key FSMA requirement is verification or validation with scientific evidence that a preventive control is capable of effectively controlling an identified hazard. Controls include verification of instrument function, record keeping that includes monitoring and corrective actions, product testing, and environmental monitoring. Canada's equivalent to FSMA is the Safe Food for Canadian's Act.

Food Safety Plan – a written plan to significantly minimize or prevent hazards. It must include hazard analysis, preventive controls, monitoring, corrective actions, verification, supply-chain management programs, recall plan, and records of actions to support the food safety plan.

Good Laboratory Practices – a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health (including pharmaceuticals).

Hazard Analysis Critical Control Points – (HACCP) plan is a safety monitoring system that is used to identify and control biological, chemical, and physical hazards with the storage, transport, use, preparation, and distribution of donor milk. It identifies critical control points (CCPs).

Hazard – biological, chemical, or physical agent that is reasonably likely to cause injury in the absence of its control.

Standard Operating Procedure (SOP) – instructions that document how to perform an activity and guide staff in a concise, consistent, and step-by-step manner. SOPs often include clear steps for each procedure, supplies and materials needed, rationale, and references. SOPs help to ensure that consistency, safety, and quality are maintained.

HMBANA milk banks process, pasteurize, and dispense donor human milk to vulnerable infants. American milk banks are regulated and inspected as food manufacturers by the FDA and their local health departments. All American milk banks must comply with the Food Safety Modernization Act (FSMA) and register with the FDA as a food manufacturer bi-annually. Canadian milk banks are subject to regulation and inspection by Canada Food Inspections Agency (CFIA). All HMBANA milk banks comply with current good manufacturing practices (cGMPs).

Standard Operating Procedures

Milk banks maintain detailed Standard Operating Procedures (SOPs) that are available to all staff and are updated annually. SOPs include (but are not limited to):

- Donor screening and serological testing
- Pasteurization
- Microbiological testing
- Receiving, storage, and transport of donor milk
- Sanitation and cGMPs
- Emergency preparedness
- Recall

Plant Design

- Milk processing facilities are suitable in size, construction, and design to ensure sanitary operations for milk processing activities and are compliant with all food manufacturing FDA safety requirements for food manufacturing facilities.

Equipment

General Requirements:

- Equipment intended for human milk bank processing is used only for milk banking purposes.
- Equipment is cleaned and maintained according to manufacturer's instructions.
- Equipment and utensils are designed and made from non-corrosive food grade material that can be adequately cleaned and maintained. The design, construction, and use of equipment and utensils must not result in contamination of milk.

Pasteurizers:

- Pasteurizers are calibrated and maintained to meet HMBANA time and temperature requirements.

Freezers and Refrigerators:

- Freezers are locked or located in a secured area that is inaccessible to the public.
- Freezer temperatures are held at -18 °C [or 0 °F] or less.
- Refrigerator temperatures are held between 1 °C and 4 °C [or 40 °F].

Dish Machines:

- Commercial dish machines must reach boost temperature of 180 °F with every cycle.
- Dish machine sanitizers and rinse agents are food safe and appropriate for the machine.

Thermometers:

- Thermometers are calibrated to NIST reference thermometer quarterly, or more often if dropped, damaged, or at any time the accuracy is in question.
- Milk banks follow HMBANA specification guidelines for thermometers that monitor freezers, refrigerators, pasteurizers, and pasteurization control bottles.

Milk Processing

Receiving:

- Milk banks use a robust electronic inventory system to account for every ounce received, processed, dispensed, discarded, and used for research.
- Milk is traced to a specific milk donor throughout every step in the process.
- Detailed logistics records include: incoming shipping records, receiving date, volume, and condition of milk.

Thawing:

- Milk may be gradually thawed in a manner that prevents contamination per FDA Food Code, with careful monitoring and record keeping that document adherence to time and temperature requirements.

Pooling/Mixing:

- Milk from multiple donors is pooled together to create a uniform batch of donor milk.
- Pooling is performed with aseptic technique under clean conditions.

- Milk is adequately mixed to ensure an even macronutrient distribution throughout the batch.

Bottling:

- Milk is strained with a food grade filter before bottling.
- Processed milk is stored in glass or food-grade plastic bottles that meet FDA requirements.
- Bottles are air-tight and leak proof.

Pasteurization:

- Bottled milk is heat-treated via Holder pasteurization at 62.5 °C for 30 minutes.
- Following pasteurization, milk is rapidly chilled using either the processing equipment manufactured to cool milk or ice baths.

Bacteriological Testing:

- Each batch of processed milk is cultured for bacteria.
- Post-pasteurization bacteriological testing is conducted by a third-party accredited lab. Clinical labs maintain CLIA or equivalent certification, and food testing labs meet ISO/IEC 17025 standards.
- Milk that fails bacteriological testing is not dispensed.

Quality Assurance Program

Each milk bank has a robust quality assurance program that includes:

- cGMP program monitoring and record keeping
    - Sanitation and pest control schedules and checklists
    - Staff education and training records
    - Equipment maintenance and calibration schedules and records
- Verification and validation activities
    - Dish machine temperature verification
    - Sanitizer and disinfectant chemical concentration verification
    - Donor and batch record self-audits to validate that critical limits are met
- Safety meeting and root cause analysis records
- Mock recalls
- Annual SOP and FSP review and revision

Section VII. Annual Audit and Accreditation

Accredited Milk Banks

- HMBANA milk banks are required to complete an annual HMBANA audit to demonstrate compliance to the *HMBANA Standards* for accreditation.
- Onsite audits are completed by a HMBANA appointed and trained auditor assigned by the Accreditation Committee chair.

Organizations Seeking Accreditation

- Organizations functioning outside of HMBANA who seek HMBANA accreditation must meet requirements and follow process outlined at www.HMBANA.org.

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