



The Use of Banked Donor Milk in WIC

As the nation's premier public health nutrition program, WIC is a cost-effective, sound investment—ensuring the health of our children.

NWA'S MISSION

NWA provides its members with tools and leadership to expand and sustain effective nutrition services for mothers and young children.

Why Use Donor Human Milk* Over Infant Formula?

Human milk is the normal food for infants and young children including premature and sick newborns, except in rare circumstances.^{1,2} Human milk provides optimal nutrition, promotes normal growth and development, and reduces the risk of many childhood illnesses and diseases. The unique composition of human milk includes nutrients, enzymes, growth factors, hormones, and immunological and anti-inflammatory properties that are not found in infant formulas.³ In fact, the 2011 Surgeon General's Call to Action to Support Breastfeeding states that, for vulnerable preterm infants, formula feeding is associated with a 138% excess risk for developing necrotizing enterocolitis, an inflammatory state that attacks the blood supply to the intestinal tract causing tissue death, and requiring surgery to repair or remove the intestines. Action 12 states, "Identify and address obstacles to greater availability of safe banked donor milk for fragile infants."⁴

Human milk fights infection while providing ideal nutrition for the infant. Exclusive breastfeeding for six months is recommended with introduction of complementary nutritionally adequate foods at about this time. In situations where mother's own milk is not available, provision of pasteurized, screened donor milk* is the next best option particularly for ill, or high-risk infants.^{5,6} In 2012, the American Academy of Pediatrics (AAP) released a policy statement recommending that all preterm infants receive mother's milk,

or pasteurized donor milk if mother's milk is unavailable or contraindicated. It also recommends the use of donor milk as an alternative to breastfeeding or expressed mother's milk for healthy term infants.⁷

In a recent survey of donor milk use, 42% of medical directors in 302 level 3 neonatal intensive care units (NICUs) across the country are using donor milk.⁸ Some states offer reimbursement through Medicaid for infants with a medical need after hospital discharge. These level 3 NICUs and Medicaid programs have recognized the safety and benefit of utilizing donor human milk to improve health outcomes of their patients. Donor milk can be life-saving when threatening out-patient conditions are present. As the premier public health nutrition program, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) should authorize donor human milk to ensure medically fragile infants who continue to need it after discharge from the hospital are not denied access to safe, effective, optimal nutrition.

Who Receives Donor Milk?

Donor human milk should only be used when the biological mother's own milk is not available, such as due to a maternal illness and treatment or the mother's physical inability to produce breast milk. While most women can adequately produce milk for their infants, mothers with children in the NICU face incredible challenges to establish milk supply during the most critical period following birth.

Common reasons for prescribing banked donor milk may include:

- » Preterm birth
- » Failure to thrive
- » Malabsorption syndromes
- » Allergies
- » Feeding/formula intolerance
- » Immunologic deficiencies
- » Post-operative nutrition

Banked donor milk has been reported to be effective for infants of preterm birth, post-operative treatment, and provision of immunological benefits. Patients with varied conditions including bowel surgery, failure to thrive, formula intolerance, malabsorption syndromes, suppressed IgA levels, allergies, chronic renal failure, leukemia, intractable pneumonia, and HIV have responded positively to the use of donor milk.^{7, 9, 10}

Banked donor milk should only be provided by a physician's prescription for the critical needs of fragile WIC infants, with a specific diagnosis warranting donor human milk after hospital discharge. All situations should be evaluated based on priority, and donor milk availability.

Is Donor Human Milk Safe?

Human Milk Banking Association of North America (HMBANA) is an association of non-profit milk bank members and a multidisciplinary group of healthcare providers that promotes, protects, and supports donor milk banking. HMBANA promotes the collection and distribution of donor human milk in a safe, ethical and cost effective manner. It is the only professional membership association for non-profit milk banks in Canada, Mexico, and the United States, and sets the standards and guidelines for donor milk banking in those areas.

Non-profit milk bank members of HMBANA comply with mandatory guidelines for operation as published in the Guidelines for the Establishment and Operation of Donor Human Milk Banks, 2013.¹¹ These evidence-based guidelines are informed by multiple advisory groups including AABB, US Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). Member milk banks are evaluated for compliance to the guidelines annually by a peer milk bank director.

Non-profit milk banks are required to register as food facilities with the FDA as required by 21 CFR Part 1, Subpart H, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2001. They are subject to random unscheduled visits from FDA Consumer Safety Officers as well as from their state Department of Health Services. These visits are inspections to ensure that regulations for food manufacturers are followed.

Potential milk donors provide complete medical and lifestyle histories, and undergo blood tests, similar to the screening process used at blood banks. The donor's healthcare provider submits medical information on both the donor and her child as well. Donated milk is then tested for bacteria and levels of nutrients, and pasteurized. Before the pasteurized milk is dispensed, bacteriological testing is conducted to ensure its safety; dispensing milk depends on seeing zero growth on a 48 hour agar plate culture. Any bacterial growth post pasteurization leads the milk to be discarded.

Non-profit donor human milk banking has a long safety record in North America where processed human milk from screened donors

has been provided to patients in selected neonatal intensive care units since 1943. To ensure a safe product, HMBANA Guidelines, under which all member banks must operate, establish best practice based on current published clinical evidence. Just as with other donor tissue banking, the milk banks rely on extensive testing and processing procedures as well as self-reported health information. HMBANA also requires a health statement from both the donor's healthcare provider and her infant's healthcare provider. HMBANA Guidelines, which were first published in 1990, are used globally as a standard for donor milk banking.^{11, 12, 13, 14} There have been no documented cases of disease transmission from donor milk provided by a HMBANA-member milk bank since 1985 when HMBANA was founded. Banked human milk should not be confused with informal milk sharing. The National WIC Association (NWA) and the WIC Program should only support using milk obtained through HMBANA milk banks. WIC can educate mothers on the risks of informal milk sharing in order to properly protect their babies.¹⁵

On June 9, 2014, the FDA published its final rule to set standards for infant formula manufacturers. Effective September 8, 2014, this rule will set in place, federally enforceable requirements for the safety and quality of infant formula. In announcing the final rule to the public, FDA noted that many manufacturers were already voluntarily applying the practices and quality control procedures outlined in the new requirements. Nonetheless, despite the lack of required federal safety standards, WIC has authorized infant formula since the inception of the program forty years ago. The US Department of Agriculture (USDA) continues to authorize infant formula

to infants who may have a medical need for donor human milk. Infant formula safety standards are no more stringent than those for donor human milk. It is inconceivable that the premier public health nutrition program would deny an infant access to donor milk on the grounds of safety concerns. The safety standards of human milk are rigorous enough for level 3 NICUs to use it with the most fragile infants they serve.

Why Support Banked Human Milk for WIC Mothers?

Human milk is best for human babies. Babies that fail to receive human milk are at greater risk for illness and obesity.¹⁶ The Surgeon General stated that the United States would save 13 billion dollars if babies were exclusively breastfed until six months as recommended by the American Academy of Pediatrics.⁴ For some babies, however, human milk is life-saving; these are the babies born vulnerable because of prematurity, congenital defects, or other medical complications.

WIC babies are the most vulnerable infants in the United States. WIC mothers want to give their babies the best nutrition even when they cannot provide their own breast milk; however, it is frustrating to them that banked human milk is beyond their financial means when needed. Additionally, donor human milk is a scarce resource requiring gatekeeping to ensure that the most fragile receive it before the general population. And when the milk is not readily available, mothers turn to formula as an alternative. Meanwhile, powdered formulas, which are not sterile, are most commonly used. This can introduce additional health risks for a vulnerable infant.

When WIC supports breastfeeding and banked human milk, mothers become more aware of the value of their own milk. Many WIC moms who have donated their breast milk reported the rewarding experience they felt to have helped other mothers and babies.¹⁷ Additionally, the presence of donor human milk in the NICU has been found to be associated with increased breastfeeding rates.¹⁸

The WIC Program strives to provide families with the resources for a healthy start and long term positive health outcomes. Allowing banked human milk for ill and at-risk mother infant dyads would distinguish WIC among all other public health nutrition programs and set a new level of excellence in infant nutrition care.

***In this paper, “donor human milk,” “donor milk,” “banked donor milk,” and “banked human milk” are used interchangeably.**

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