

Increasing the Global Supply and Affordability of Donor Milk

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HUMAN MILK BANKING was virtually discontinued at the start of the human immunodeficiency virus era amid fears that the virus might be transmitted to preterm infants receiving donor milk. However, the demand for donor breastmilk has continued to be driven by decades of research that have increasingly demonstrated the benefits of breastmilk in neonatal care regarding the reduction of life-threatening necrotizing enterocolitis (NEC) and infection, as well as improving long-term outcomes, notably neurodevelopment and bone health. Despite the progressive return of milk banking during the past two decades, the demand for breastmilk has not been met. Now, this problem has been greatly compounded by a recent, radical increase in demand for human donor milk resulting from compelling new research that is changing the standards for how preterm infants are fed.^{1,2}

This new research is rooted in the concept of “lactoengineering,” using human milk components to produce formulations and fortifiers designed to meet the special nutritional needs of preterm infants. This concept was introduced by Lucas et al.³ in 1980 and more recently commercialized to produce a human milk-based fortifier designed for use in the neonatal intensive care unit. The production and use of such “lactoengineered” products in the United States have facilitated randomized clinical trial comparisons to be made between extremely premature infants fed on human milk plus cows’ milk-based fortifier or cows’ milk-based products alone, compared with a diet that is solely based on human milk, completely excluding exposure to cows’ milk. Published clinical trial evidence has shown that such an exclusively human milk-based diet results in a major reduction in NEC, a dramatic reduction in surgical NEC, a significant reduction in mortality, and a reduction in the duration of potentially hazardous parenteral nutrition. Apart from the demonstration of such important health benefits of an exclusively human milk-based diet, the estimated health economic benefits are large, with potential savings of billions of dollars in the United States each year. But, these benefits are only possible if the supply of donor milk increases to the level required to provide a higher protein density that forms the basis for the new lactoengineered products.

The availability of donor milk has diminished to the point that milk banks cannot even serve the demands of the small percentage of hospitals using donor milk.⁴ Lack of awareness, low breastfeeding rates, and the diversion of donor milk to informal milk sharing programs have been cited as the root

cause of the donor milk shortage. It has also been suggested that the responsibility for increasing the supply of donor milk rests with healthcare professionals who should compel their patients to donate breastmilk.⁵ No credible evidence has been presented to support that case, and, surprisingly, there seems to be no clear plan to solve the current shortage. General statements about encouraging breastfeeding, increasing breastfeeding rates, and the societal responsibility to ensure that nursing mothers donate milk have been put forth as a solution for years, yet the current milk banking systems continue to provide only a small percentage of the donor milk needed for the most vulnerable infants.

It is time for a radically different approach if we are to see this problem solved in our lifetimes. More importantly, how many lives must be lost in neonatal units before a different approach is supported? A global perspective on the availability of donor milk is even more sobering. A recent report on global prematurity states that there are 15 million preterm infants born each year.⁶ If we can’t provide an adequate supply of donor milk in the United States for a mere 67,000 preterm babies, how can we expect countries with significant constraints on resources to do so?

The Unmet Need for Donor Milk

A model for calculating this requirement was presented by Audelio Rivera, MD, at a conference in 2007. He calculated the volume needed by a baby born less than 1,500 g at 10,560 mL or 357 ounces during the average stay of 44 days it takes for the infant to reach 2,000 g. His model also assumed that mothers would supply half of the volume needed by their infants. Dr. Rivera estimated that 9 million ounces or 70,000 gallons would be needed to serve 51,000 preterm infants with half of their donor milk requirements.⁷ However, at the time these calculations were made, the major clinical value of a 100% human milk diet for the smallest preterm infants was yet unknown.

This additional factor has now driven the demand far above earlier estimates because processing human milk-based fortifier requires a dramatically increased volume of raw milk in order to achieve the desired protein density. Assuming that all of the 51,000 preterm babies like the ones referenced by the 2007 model were to be given the benefit of mother’s milk to meet just half of their required volume supplemented by donor milk and combined with human milk-based fortifier, up to 54 million ounces or 422,000 gallons are needed

in addition to the 9 million ounces or 70,000 gallons referenced by the 2007 model. This brings the total requirement to 63 million ounces or a half million gallons.

The nonprofit milk banking system provides just over 2 million ounces or 16,795 gallons of donor milk per year in the United States. Based on the old model, this constitutes 20% of the requirement for very low birth weight (VLBW) babies if mothers provide half the milk and if no human milk-based fortifier is used. But in today's environment, with the knowledge that a 100% human milk fed diet is optimal, it is a fact that 80–97% of VLBW infants will not be given that advantage.

Donors Choosing Other Options

We live in a nation where more than 3 million women initiate breastfeeding each year and more than 1.5 million are still breastfeeding after 6 months. The number of babies breastfed in the hospital rose from 71% to 77%, according to the U.S. Centers for Disease Control and Prevention; between 2000 and 2010, the number of babies who were breastfeeding at 6 months rose from 35% to 49%, and the number of babies still breastfeeding at the age of 1 year rose from 16% to 27%.⁸ We have no shortage of healthy nursing mothers to supply the milk we need. The popularity of mother-to-mother sharing and the sale of unprocessed donor milk online provide compelling evidence for the willingness of women to provide milk to others in need as there seems to be abundance of stockpiled breastmilk in home freezers.

Why are women willing to share with one another on a large scale but not with established milk banks? Milk sharing participants claim they want control over their breastmilk; they want to choose who they give it to and how it's given. Milk donors are driving a growing movement to assert control over a precious, valuable resource that they produce and own. Beyond that, because of the growing economic value of human milk driven by medical research and the public knowledge of the superiority of breastmilk over infant formula, milk donors are seeking to leverage an asset they own for the betterment of their children and families.

New directives are required in light of this growing movement. But instead, a divisive element has emerged in milk banking as the milk banking establishment has labeled milk sharing as human milk trafficking, a term that only serves to diminish the altruism and intent of the donors. Conversely, milk donors should be respected, and milk banking programs should preserve and respect women's ownership and control over their own breastmilk. To be successful, milk banks must provide meaningful options in how donors can participate, and they must enable donors to leverage the value of their milk to the benefit of their babies and families if they so choose. Without a compelling donor program that encompasses these attributes, the supply of donor milk will continue to dwindle and be diverted to more informal programs that may pose substantial health and safety risks to both donors and recipients.

How Economics Impact Milk Banking

The law of supply

Without donors, there will continue to be a shortage of donor milk. The economic law of supply dictates that for any

raw material, supply increases as the price for the supply increases. If we expect nursing mothers to devote the time and effort required to pump extra milk without any compensation, we clearly should not expect high volumes of donor milk as a result. Conversely, if we want to increase the supply of donor milk, we must provide meaningful incentives for qualified nursing women to provide that increased supply.

A long-held belief that donors in the United States cannot be paid for their milk has no substance. In hearings held by the Pediatric Advisory Committee of the U.S. Food and Drug Administration in December 2010, a lengthy discussion was held regarding this subject, and participants drew the conclusion that no law of the land or regulatory statute barred compensation to qualified donors for their surplus milk as long as all other laws, including state tissue banking laws where applicable, were followed.⁹

A cascade of economic benefits results when greater volumes of raw milk are available for processing. A safe and effective incentive program could be designed to compel qualified nursing mothers to nurse their own babies longer, delay their return to work, and provide their surplus milk, increasing the volume of raw milk to the estimated half million gallons needed annually for VLBW babies in the United States. It is without doubt that the cost of donor milk would suddenly drop as a result of the resulting economies of scale.

Economies of scale

In an industry where volume is measured in ounces instead of gallons, small-volume processing lots result in very high processing cost. With modern processing techniques applied to donor milk, economies of scale will rapidly be reached. In most industries, cost drops as quantity output increases until the "long run average cost curve" (LRAC) is reached. At that point, for any given product/process, no further reductions in cost or efficiencies can be achieved, and beyond that point looms a potential dis-economy of scale where the cost actually increases. Determining the LRAC for the milk banking business is essential in meeting the volume requirements in a cost-effective way. With higher volumes, efficiencies can be achieved for every step of the process, from the costs for testing donors, shipping raw milk to a processing facility, testing the milk for quality and safety, processing, and shipping the final product, as these costs are spread over a larger number of units of donor milk. With these increased economies of scale, substantial improvements can be made to the product, making it possible to overcome objections to the current products. A larger operation is able to negotiate lower prices and more favorable terms, creating a reduced cost of goods. The increased supply of raw donor milk will certainly drive improved economies of scale, making it realistic to expect a ready supply of superior products at affordable prices.

The law of demand

For many hospitals, the expense of donor milk is preventing widespread use. The law of demand demonstrates that if the price of a product drops, the demand for that product will increase. In the case of donor milk, medical evidence is driving a shift in feeding protocols to the exclusive use of human milk. If the price barrier is removed, usage will increase. If economies of scale enable the development of meaningful

improvements, such as safety, quality, and ease of use, the increased demand will be significant.

There are two elements to donor milk pricing: the selling price and the effective price, which includes freight. Currently, all donor milk is delivered in frozen form, requiring overnight express shipping. Depending on the volume/weight of the shipment, the distance shipped, and potential discounts for freight contracts, overnight shipping adds 30–100% over and above the cost to hospitals of purchasing donor milk.

A shift in these economic factors would create a viable opportunity to meet the growing demand for donor milk with an attractive, sustainable donor program to create a larger volume of donor milk, driving costs downward and resulting in an abundant supply of safer, higher-quality donor milk.

A Word About Ethics

Is there an ethics argument here? Although some may passionately argue that women should never be paid for their milk, others will counter that it is unacceptable for preterm infants to suffer major morbidity and increased mortality because of the ongoing donor milk shortage. Some may worry that a mother will become so obsessed with selling her milk that she won't nurse her own baby or that she'll switch to infant formula entirely, but it is also plausible that the same mother could delay the return to work and nurse her own baby longer as a result. There are seemingly endless arguments to be made for and against compensating milk donors. The merit of each argument should be based on data and facts. Paying women for their milk clearly falls under health-related incentive programs, any number of which can be associated with both good and bad outcomes.

There is also the basic issue of fairness to consider. Why should women be expected to give freely of an increasingly valuable substance they independently produce, own, and control when the present system allows others to profit from their generosity? It could be seen as a paternalistic and inaccurate view that women somehow need to be protected from their own irresponsible decisions regarding their baby's well-being. Even nursing mothers are divided on the subject. Some passionately argue that they should be paid so that they would not have to return to work as early. After all, they wouldn't have to replace all of their wages if they could just make up the difference between their total paycheck and what they would actually net after deducting the costs of daycare and transportation. Other mothers find it abhorrent to think of something so crass as to sell their breastmilk.

Careful consideration must be made when designing any program involving a vulnerable population like mothers and babies. Once designed and implemented, the model should be studied, outcomes analyzed, and conclusions drawn. The prospect now emerges that paying mothers for their milk will not only increase the donor milk supply and reduce major and costly morbidity and mortality in preterm infants, but could also increase the duration of breastfeeding in donors and reduce their need to return so early to the workplace. These proposed benefits require careful research, as do the postulated downsides.

Envisioning a New Reality

There is a compelling need to solve the global donor milk shortage and to seek novel solutions that close the gap

between supply and demand. These models must address several critical factors in order to be successful. Milk banking must be democratized on a global basis, and control of the milk supply must start with the donor being given meaningful options. Processing solutions need to facilitate high-volume, professional processing, resulting in safer and more affordable donor milk. Funding agencies need to continue to explore and elaborate models in order to resolve the donor milk shortage that is impacting babies worldwide, to provide an alternative to informal milk sharing programs, and to create a reliable, sustainable answer to the current situation.

Tools to Build a Solid Milk Banking Industry

Solutions to the shortage of donor milk should focus on ensuring that donor milk is safe from contamination and disease. Raw donor milk should always be tested for the presence of drugs of abuse, prescription drugs, virus, bacteria, adulteration, and contamination. Vigilance is required to prevent potentially lethal organisms like *Bacillus cereus* from entering the donor milk supply. Additional new tests for safety and quality should be developed to keep up with risks and changing public health challenges.

Evidence-based methods must be used in the handling and processing of donor milk. Food safety standards must be at the core of every milk bank operation, and valuable immune factors must be preserved for the benefit of preterm infants receiving donor milk. Insurance reimbursement will only be realized when content labeling is clear and a universal lexicon is used to describe human milk products. Human milk is different from cow's milk regarding the nutritive and nonnutritive protein. Donor milk labeling should differentiate between total protein, which includes up to 25% of nonprotein nitrogen, and true protein, which is required for growth.

Finally, continuous improvement programs should be a required part of every operating milk bank so that safer, more effective processing and delivery methods continue to evolve. All solutions should be studied, improved, expanded, and exported globally so that women all over the world may realize social and economic benefits from breastfeeding.

Disclosure Statement

I am the Founder of Prolacta Bioscience but no longer a shareholder. I receive no income from patents issued and assigned to Prolacta Bioscience. I am a member of the Board of Directors of the Mother's Milk Cooperative and owner of North American Instruments, developer of the Calais human milk analyzer. I receive no income from breast pump patents or any other patents issued to date.

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