

# **A Sunrise Review: Mandated Healthcare Coverage for Banked Human Milk**

Kara Preas Huertas

May 29, 2015

## Table of Contents

Executive Summary.....	3
Applicant .....	4
Keywords And Definitions.....	5
Patient Story .....	6
Introduction .....	7
The Problem.....	7
Human Milk Banking Background.....	8
Human Milk Banking Process And Safety .....	9
Role Of Milk Sharing In Human Milk Banking .....	10
Professional Statements / Endorsements On The Use Of Banked Human Milk.....	12
Health Benefits And Cost Savings Of Using Banked Human Milk .....	14
Healthcare Coverage Of Banked Human Milk .....	16
Current Landscape In Washington.....	18
Usage Of Banked Human Milk.....	18
Projected Usage Of Banked Human Milk .....	19
Sunrise Review Criteria .....	21
Social Impact: .....	21
The Financial Impact:.....	26
Evidence Of Healthcare Service Efficacy: .....	30
Detailed Recommendations.....	31
Conclusion.....	32
References .....	33

## EXECUTIVE SUMMARY

It is well documented that breastfeeding and the use of banked human milk provides optimal nutrition for infants. One-in-nine infants born in the United States is premature. Preterm and other medically fragile infants are particularly vulnerable and when mother's milk is not available or supply is inadequate. The use of banked human milk improves feeding tolerance and reduces serious infections and other life-threatening prematurity-related complications including long-term disability. The economic benefits of providing human milk feedings in this population are substantial. Hospital stays are shortened, the likelihood of surgical intervention is reduced, and overall incremental costs associated with these complications are decreased. For every \$1 spent on donor milk, \$11 is estimated to be saved in health care costs.

Currently, health insurance benefits do not include coverage of donor human milk. Hospitals using banked human milk have minimal budgets to allocate for its purchase. Insurance global diagnostic reimbursement rates do not account for the cost of banked human milk since these rates were established before it was considered the standard of care for preterm and other critically ill infants. In the outpatient population, families in need of safe pasteurized donor human milk pay the cost, which averages \$4.50 an ounce. Thus the cost of donor milk is often out of reach for many families creating inequitable access to this important therapy that is life saving for pre-term, low birth weight and medically fragile babies.

This proposal recommends mandated healthcare coverage of banked human milk for preterm and other medically fragile or at risk infants when a provider with prescriptive authority considers it to be medically necessary. The social and financial impacts of this benefit are outlined and evidence of healthcare service efficacy is addressed throughout this paper. Based on improved health outcomes and the demonstrated favorable cost benefit ratio, healthcare coverage for banked human milk should be a covered benefit of Medicaid plans, private insurance, and public employee health plans.

## APPLICANT

This Sunrise Review Application is submitted by ***Kara Preas Huertas*** of Seattle, Washington. Kara is a proponent of mandated health care coverage of pasteurized human donor milk for preterm and other at risk babies when it is considered medically necessary for the health and well-being of the infant.

Kara is a MPA candidate at Seattle University graduating in June 2015. She was introduced to the topic of banked human milk during her first term in graduate school. She went on to intern with PATH, a Seattle-based global health organization, and contributed to the published document, *Strengthening Human Milk Banking: A Global Implementation Framework*.

In April 2014, she presented at the Human Milk Banking Association of North America's annual conference regarding her work with PATH. That same year she won the Policy Incubator competition at Seattle University with a paper addressing how to increase access to human donor milk through public policy.

Kara spent eleven years working with the non-profit, LifeCenter Northwest in the field of organ and tissue donation before making the move to Fred Hutchinson Cancer Research Center's Vaccine and Infectious Disease Division in October 2014.

Her interest in this topic is multi-faceted. As a mother of two young children, she can imagine the desperation a parent feels when their child is fighting for survival, and the desire for world-class treatment to ensure the best possible outcome.

During her work with LifeCenter Northwest, she witnessed firsthand the impact of tragedy and death not only to immediate family members, but to the hospital staff providing the highest level of clinical and compassionate care. She left her work at LifeCenter with a continued commitment to advocate for individuals and communities in need.

She believes it is a paramount duty to ensure access to evidence-based, life-saving treatments such as banked human milk; particularly, in a population as vulnerable as premature and medically fragile infants.

## KEYWORDS AND DEFINITIONS

**Banked Human Milk / Pasteurized Human Milk / Donor Human Milk / Donor Milk** – means expressed breast milk contributed by a lactating woman to a milk bank for use by an infant or child other than her own. This milk is screened, tested, and pasteurized by the nonprofit human milk bank and is donated without remuneration to the donor.

**Exclusive Breastfeeding** – means babies who receive no other substance except for human milk, whether its mothers own milk or a combination of mothers milk and banked human milk.

**Human Milk Bank (HMB)** – means a member in good standing of the nonprofit Human Milk Banking Association of North America focused on obtaining, collecting, processing, storing, and distributing human milk for use by those most in need including, but not limited to: medically fragile, very low birth weight (VLBW), and preterm babies, infants of new mothers with delayed lactation, and infants recovering from serious intestinal complications and/or surgery.

**Informal or Casual Milk Sharing** – means sharing of expressed milk among mothers without formal screening and without pasteurization. This may occur between women who have an in-person, close familial or community-based relationship, or between women who share over the internet.

**Informed Milk Sharing** – means an informed choice is made by examining all credible, verifiable and relevant information available and using it to carefully and objectively weigh options as well as potential consequences of using milk from another mother

**Mothers own milk (MOM)** – means breast milk expressed from a mother and provided to her biological infant.

**NEC** – means necrotizing enterocolitis, which is an acute inflammatory bowel disease that can lead to perforation and peritonitis and death, and is a common life threatening disease affecting premature infants in the NICU.

**NICU** – means Neonatal Intensive Care Unit.

**Preterm / Premature** – means babies born alive before 37 weeks of pregnancy. There are sub-categories of preterm birth, based on gestational age: moderate to late preterm (32 to <37 weeks), very preterm (28 to <32 weeks), and extremely preterm (<28 weeks).

**Total Parenteral Nutrition (TPN)** – means fluids delivered intravenously (IV) which includes a combination of protein, carbohydrates, fats, vitamins, electrolytes, and minerals to an infant's body. TPN is a commonly used treatment in newborns and premature infants who cannot absorb sufficient nutrition through the gastrointestinal (GI) tract.

**VLBW** – means infants born at very low birth weight (VLBW < 1500 grams).

## PATIENT STORY



“Joshua was born 12 weeks early and weighed only 2 1/2 pounds. After six weeks of receiving donated breast milk, his weight is climbing: He now weighs 3 pounds, 15 ounces.”

Source: [http://www.babycenter.com/101\\_donated-breast-milk-a-life-giving-journey\\_10389312.bc](http://www.babycenter.com/101_donated-breast-milk-a-life-giving-journey_10389312.bc)

## **INTRODUCTION**

The short-term and long-term health benefits of breastfeeding are well known. These benefits also translate into substantial economic savings. The results of a 2010 study indicates the U.S. could save \$13 billion and prevent 911 deaths a year from respiratory infections, diseases such as SIDS and necrotizing enterocolitis, childhood obesity, childhood leukemia, and other health issues if 90% of families fulfill the medical recommendations to breastfeed exclusively for six months (Bartick, 2010).

One-in-nine babies in the United States are born premature; a rate higher than most developed countries (March of Dimes, 2015). The health risks associated with preterm and very low birth weight (VLBW) infants make them particularly vulnerable. Due to the unparalleled immunological and anti-inflammatory properties in breast milk, these infants particularly benefit from the protection provided against a whole host of illnesses and diseases (Lawrence, 2010). Mothers of NICU babies express their milk to provide nourishment for their children. When a baby is born too soon their bodies are often not ready or unable to produce enough of their own milk to provide the exclusive human milk feedings recommended. The ability to exclusively breastfeed can also be interrupted by certain maternal medical conditions, surgery, or medications. The use of banked human milk to supplement mothers own milk has been shown to decrease prematurity related morbidities including feeding intolerance, nosocomial infections, necrotizing enterocolitis, respiratory and lung issues, and other complications due to prematurity. It also contributes to long-term outcomes, such as improved visual acuity and neurocognitive performance. (Edwards, 2012)

Necrotizing enterocolitis (NEC) is an acute inflammatory bowel disease which can lead to perforation and peritonitis and death. NEC is a common life threatening disease affecting premature infants in the NICU. Ten percent of babies born weighing less than 1500 grams will develop NEC. A baby with NEC who develops bowel perforation has a mortality risk of 30-50%. It is estimated the development of NEC in a VLBW infant who develops NEC extends his/her NICU stay by 11 to 48 days, pushing the cost of care to \$198,000 or more (Bisquera, 2002).

## **THE PROBLEM**

Healthcare benefits in Washington State do not include coverage of banked human milk, which is used most prevalently for preterm and other medically fragile babies when mothers own milk is in low supply or unavailable. Research shows a significant improvement in health outcomes when human milk is used exclusively, instead of supplementing with artificial milk formula.

In addition, substantial savings in health care costs have also been demonstrated. For every \$1 spent on donor milk, there is an estimated \$11 in healthcare cost savings (Wight, 2001). This proposal examines the social and financial impacts, as well as the evidence of health care service efficacy of mandating healthcare coverage for banked human milk.

## **HUMAN MILK BANKING BACKGROUND**

Human milk banking has a long history in many countries. Presently, there are more than 37 countries with developed milk bank systems employing robust quality control methods to offer safe donor milk in order to meet local needs (PATH, 2012). “In North America, milk banking is responding to an increasing demand from the medical profession and families for human milk, particularly for preterm and sick babies, when mothers own milk is unavailable. This demand is driven by unequivocal data demonstrating positive outcomes for human milk-fed babies and by growing understanding of the critical importance of collecting, storing, processing, and dispensing donor milk under strictly-controlled conditions.” (HMBANA, Guidelines for the establishment and operation of a donor human milk bank , 2011)

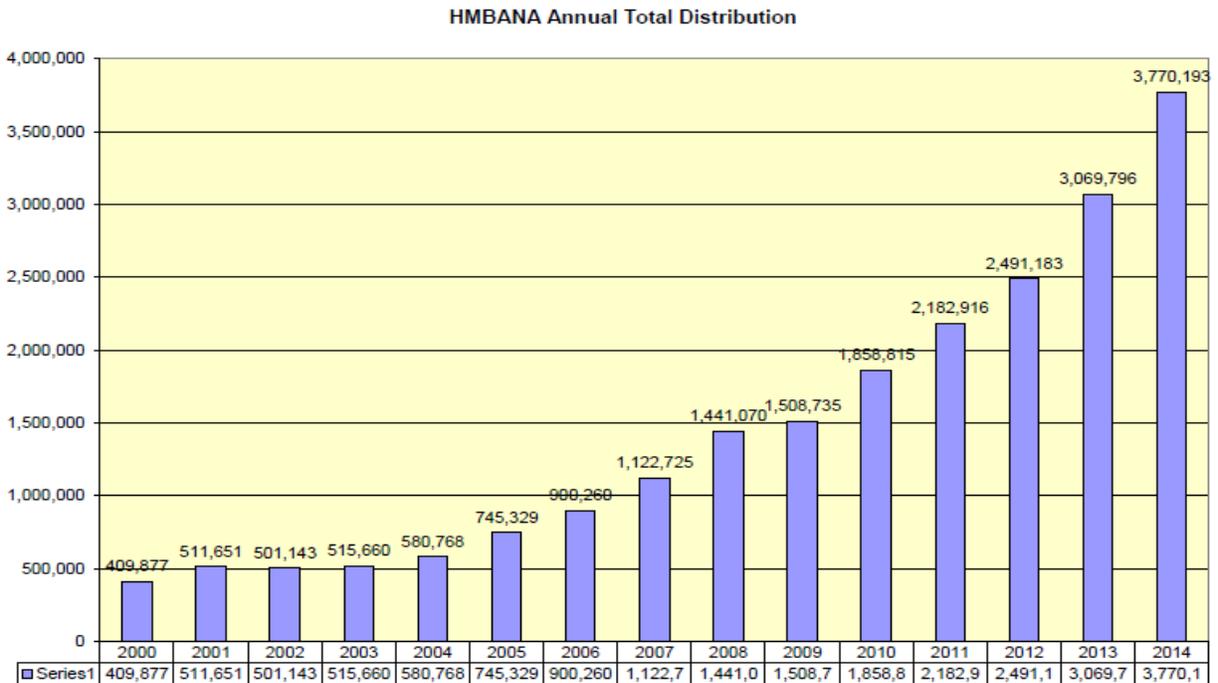
The Human Milk Banking Association of North America (HMBANA) originated in 1985 and is the accrediting organization for 18 non-profit milk banks, 15 of which operate in the U.S. and three located in Canada. **Graph 1** shows the progressive use of banked human milk by HMBANA milk banks. In 2014, 3.7 million ounces were dispensed, 77% for inpatients and 23% for outpatient use.

In 1990, HMBANA published its “Guidelines for the Establishment and Operation of a Donor Human Milk Bank”. Each HMBANA member milk bank is assessed yearly and required to show adherence to the most recent edition of the evidence based guidelines. This ensures the highest level of safety and quality assurance. In addition to being a long-established and highly respected authority on human milk banking in North America, HMBANA works in collaboration with the European Milk Banking Association (EMBA) to coordinate on issues affecting human milk as a public health imperative worldwide (Sakamoto, 2013).

**Table 1** provides links to additional information about human milk banking.

Table 1 - Human Milk Banking	
• Human Milk Banking Association of North America (HMBANA)	<a href="http://www.hmbana.org">www.hmbana.org</a>
• European Milk Banking Association (EMBA)	<a href="http://www.europeanmilkbanking.com/">http://www.europeanmilkbanking.com/</a>
• Northwest Mothers Milk Bank (NWMMB)	<a href="http://www.nwmb.org/">http://www.nwmb.org/</a>
• Strengthening Human Milk Banking: A Global Implementation Framework, PATH, 2011	<a href="http://www.path.org/publications/files/MCHN_strengthen_hmb_frame_April2015.pdf">http://www.path.org/publications/files/MCHN_strengthen_hmb_frame_April2015.pdf</a>
• The Ethics of Donor Human Milk Banking, Lois Arnold, 2006	<a href="http://www.dors.it/latte/docum/the%20ethics%20of%20donor%20human%20milk%20banking.pdf">http://www.dors.it/latte/docum/the%20ethics%20of%20donor%20human%20milk%20banking.pdf</a>

**Graph 1** (provided by HMBANA)



### HUMAN MILK BANKING PROCESS AND SAFETY

HMBANA milk banks collect, process, and distribute human milk. Donors give milk on a voluntary basis. Every potential donor is systematically screened and specific exclusion criteria based on HMBANA standards are followed. Comprehensive interviews are completed with potential donors to determine overall general health such as medication, drug and alcohol use or other possible risks or exposures. A statement of health by the donors’ child’s physician is required, and blood tests are

ordered to screen for infectious diseases including HIV, human T-lymphotropic virus (HTLV), syphilis, and Hepatitis B and C (Ransom, 2015).

The milk is then pooled and processed using the holder pasteurization method which gently heats the milk in a shaking water bath to 62.5° Celsius for 30 minutes, then immediately cools it to 4 C. Samples are taken during the pasteurization process and cultured to check for bacterial growth. If milk is found to be contaminated, it is immediately discarded. The rest of the milk is safely packaged and frozen for shipping (HMBANA, Milk Processing, 2015). Research shows that pasteurization is effective in eliminating bacteria and viruses while retaining the majority of the milk's beneficial components (Ewaschuk, 2011).

Every bottle is tracked so that donors and recipients can be traced in the event of an adverse outcome. Any contamination is reported to state licensing boards or health departments. There has never been a documented case of disease transmission or death due to banked human milk distributed from HMBANA certified milk banks (Sakamoto, 2013).

Currently, the FDA does not undertake the regulation of human milk; however they do provide HMBANA with current data and resources for specific screening and procedural advice. In 2010, the FDA formed a pediatric advisory committee workgroup to better understand human milk banking practices and disease risks. According to meeting notes, the group concluded that development of federal regulations for a more controlled collection process than already in place may decrease milk donation. The work group report acknowledged the value of banked human milk and recommended continued research on the cost effectiveness of banked human milk (FDA, 2010).

## **ROLE OF MILK SHARING IN HUMAN MILK BANKING**

Milk sharing occurs when a breastfeeding mother produces more milk than her baby needs and shares this breast milk with another mother for the purpose of feeding and nourishing an infant that is not biologically hers. Women around the world have shared milk for millennia. This practice has been considered life-saving for infants without access to their mothers own milk; nevertheless milk sharing is not without risk. The CDC and FDA recommend against informal milk sharing due to the threat of disease transmission (Arnold, 2000). With that said, it is the culture and spirit of milk sharing which make it possible for milk banks to attract donors who provide this biological resource and fill the critical need for pasteurized donor human milk.

In a society where a developed system of human milk banks exists, there is an opportunity to encourage this spirit of sharing while guaranteeing quality and safety. Women who wish to share milk can do so knowing it is being delivered to the neediest infant population. Mothers of infants receiving milk from a milk bank can be assured their babies are receiving the safest product.

The key to increasing access of pasteurized human milk is to include it as a covered healthcare benefit-- one that can be ordered by a provider with prescriptive authority for premature babies and in other situations when it is medically indicated. This increased access has potential to cut health care costs, improve health outcomes for babies that have medical need and curb informal milk sharing which could have unintended harmful consequences for public health. Improving the availability and affordability of safe, pasteurized human milk is the most effective evidence based method of providing nourishment and protective properties to infants when mother’s own milk is not available.

**Table 2** provides additional sources for information about human milk sharing.

<b>Table 2 - Informal Milk Sharing</b>	
• Breastfeeding USA	<a href="https://breastfeedingusa.org/content/article/milk-sharing-formal-and-informal">https://breastfeedingusa.org/content/article/milk-sharing-formal-and-informal</a>
• La Leche League International (LLLl)	<a href="http://www.lalecheleague.org/release/milksharing.html">http://www.lalecheleague.org/release/milksharing.html</a>
• HMBANA / EMBA joint statement on milk sharing	<a href="https://www.hmbana.org/sites/default/files/EMBA%20HMBANA%20Milk%20Sharing%20Statement%20FINAL%20January%202015.pdf">https://www.hmbana.org/sites/default/files/EMBA%20HMBANA%20Milk%20Sharing%20Statement%20FINAL%20January%202015.pdf</a>

## PROFESSIONAL STATEMENTS / ENDORSEMENTS ON THE USE OF BANKED HUMAN MILK

Exclusive breastfeeding should always be the goal; however situations exist where it is medically contraindicated or when mothers' milk is in short supply. In these cases, the use of donor milk instead of artificial milk formula is recommended.

The following professional organizations recommend exclusive breastfeeding for the first six months of life and promote the use of banked human milk from an approved milk bank, such as one associated with HMBANA, when mothers own milk is unavailable:

- [World Health Organization \(WHO\)](#)
- [Food and Drug Administration \(FDA\)](#)
- [Surgeon General of the United States](#)
- [American Academy of Pediatrics \(AAP\)](#)
- [American College of Obstetricians & Gynecologists \(ACOG\)](#)
- [American Academy of Family Physicians \(AAFP\)](#)
- [National Association of Neonatal Nurses](#)
- [United States Breastfeeding Committee \(USBC\)](#)
- [La Leche League International \(LLL\)](#)
- [Academy of Breastfeeding Medicine](#)

The American Academy of Pediatrics (AAP) policy statement on breastfeeding and the use of human donor milk conclude there is sufficient analysis and systematic reviews of published research to reinforce the use of banked human milk as a normative standard for infant feeding and nutrition when mothers own milk is not available (Eidelman, 2012).

 <b>The AAP policy statement lists the following outcomes for infants receiving human milk exclusively, including the use of donor milk, for the first six months. Reduction of :</b> <a href="http://pediatrics.aappublications.org/content/early/2012/2/22/peds.2011-3552">http://pediatrics.aappublications.org/content/early/2012/2/22/peds.2011-3552</a>	
Risk of hospitalization for lower respiratory tract infections	72%
Nonspecific gastrointestinal tract infections	64%
Necrotizing Enterocolitis (NEC)	77%
Asthma, atopic dermatitis, and eczema	27%
The risk of developing celiac disease	52%
The risk for childhood inflammatory bowel disease	31%
Incidence of Sudden Infant Death Syndrome (SIDS)	38%

The 2011 *Surgeon General's "Call to Action to Support Breastfeeding"* states, "For nearly all infants, breastfeeding is the best source of infant nutrition and immunologic protection" and recommends the following step to reduce inherent risks associated with prematurity: Identify and address obstacles to greater availability of safe banked donor milk for fragile infants. It is critical from a

public health perspective that safe banked human milk be available for hospitalized premature infants whose mothers are unable to provide enough of their own milk for their child (The Surgeon General's Call to Action, 2011).

The Baby Friendly Initiative, developed by the WHO and UNICEF in 1991, recognizes hospitals and birthing centers that implement “*The 10 Steps to Successful Breastfeeding*”. The use of banked human milk supports step 6, which instructs, “Give infants no food or drink other than breast-milk, unless medically indicated” (Baby-Friendly USA, 2015).

The Joint Commission is the accrediting body for most hospitals in Washington. As part of the accreditation process hospitals collect and submit data on patient outcomes. The Perinatal Care Core Measure Set collects data specific to five areas. One of these key accountability measures is exclusive breastfeeding. This measurement criterion is considered to be met when mothers own milk is the sole source of infant feeding or when banked human milk is used to support and supplement mothers milk when it is not available (Joint Commission, 2015).

**Table 3** provides additional sources for information about the recommended use of banked human milk.

Table 3 - Recommended use of banked human milk	
<ul style="list-style-type: none"> <li>• AAP Policy on Breastfeeding and the use of Human Milk</li> </ul>	<a href="http://pediatrics.aappublications.org/content/early/2012/2/22/peds.2011-3552">http://pediatrics.aappublications.org/content/early/2012/2/22/peds.2011-3552</a>
<ul style="list-style-type: none"> <li>• Within Reach Washington Newsletter – Donor milk in the NICU becomes the Standard of Care at UWMC</li> </ul>	<a href="http://www.withinreachwa.org/wp-content/uploads/2013/07/Winter-2013.pdf">http://www.withinreachwa.org/wp-content/uploads/2013/07/Winter-2013.pdf</a>
<ul style="list-style-type: none"> <li>• WHO Guidelines on Optimal Feeding of Low Birthweight Infants in Low-to-Middle Income Countries</li> </ul>	<a href="http://www.who.int/maternal_child_adolescent/documents/9789241548366.pdf?ua=1">http://www.who.int/maternal_child_adolescent/documents/9789241548366.pdf?ua=1</a>

## HEALTH BENEFITS AND COST SAVINGS OF USING BANKED HUMAN MILK

There is overwhelming support by the medical community for a system in which exclusive breastfeeding for the first six months of life is achievable. Banked human milk plays a central role supporting cases when women are not producing a sufficient supply of breast milk or when medical contraindications to breastfeeding exist. “Research, taken altogether, suggests that although mothers’ own milk is the gold standard, donor milk is the next best alternative when an adequate supply of mothers’ own milk is unavailable.” (Ewaschuk, 2011)

The improved health outcomes from using banked human milk instead of artificial milk formula are many-fold, and these in turn translate into significant healthcare cost savings. Preterm and VLBW infants are at high risk of complications which require expensive treatments and extended hospital stays, making them among the most expensive patients in a hospital (Johnson, 2014).

A meta-analysis review of direct hospital costs associated with VLBW infants determined the baseline NICU hospitalization for this population, with no additional prematurity related co-morbidity, is \$40,227. When infants acquire one or more co-morbidity, adjusted incremental costs range from \$9,729 to \$205,299, depending on the complexity and if surgical intervention is required (Johnson, 2014).

Extensive research and meta-analysis reviews conclude human milk feedings in VLBW infants provide a protective effect for sepsis (Hylander et al, 1998; Schanler et al, 1999; Furman et al, 2003). One particular study reports the economic impact of using human milk exclusively in the first 28 days attributing to it a decrease in the odds of sepsis, thus reducing hospital costs in the preterm population. Depending on the doses of human milk provided, average hospital costs are \$20,384-\$31,515 lower than infants given formula and bovine human milk fortifiers (Patel, 2013).

Another research study found premature infants fed solely on human milk, including mothers own milk and human donor milk, are discharged from the hospital approximately 14 days earlier than infants fed formula and human milk or just formula (Bisquera, 2002).

In the case of the intestinal disease NEC, evidence from meta-analysis and systematic reviews of 11 studies (5 of which were randomized control trials), suggest the use of human milk instead of formula reduces NEC by up to 79% (Edwards, 2012). Conversely, a Cochrane review comparing formula to banked human milk for feeding preterm or VLBW infants concludes that feeding with formula is associated with a higher risk of developing NEC (Quigley, 2007).

Pasteurized human milk has been shown to be effective for nutritional uses, post-surgical treatment and provision of immunological benefits. Additionally, patients with the following conditions have responded well to the use of banked human milk: bowel surgery, failure to thrive, formula intolerance, suppressed IgA levels, post liver transplant, formula intolerance, allergies, chronic renal failure, leukemia, intractable pneumonia, and HIV (HMBANA, Guidelines for the establishment and operation of a donor human milk bank , 2011).

**Table 4** provides additional sources for information about the health and economic benefits of banked human milk.

<b>Table 4 - Evidence of health &amp; economic benefits of human milk</b>	
• Donor Human Milk for Preterm Infants – Wight, N Cost benefit analysis	<a href="http://www.nature.com/jp/journal/v21/n4/pdf/7200533a.pdf">http://www.nature.com/jp/journal/v21/n4/pdf/7200533a.pdf</a>
• Donor Human Milk v. Formula for preventing necrotizing enterocolitis in preterm infants: systematic review - McGuire, W; Anthony, M	<a href="http://fn.bmj.com/content/88/1/F11.full.pdf+html">http://fn.bmj.com/content/88/1/F11.full.pdf+html</a>
• Benefits of Maternal and donor human milk for premature infants – Heiman, H; Schanler, R	<a href="http://www.sciencedirect.com/science/article/pii/S0378378206002325">http://www.sciencedirect.com/science/article/pii/S0378378206002325</a>
• Randomized Trial of Donor Human Milk Versus Preterm Formula as Substitutes for Mothers' Own Milk in the Feeding of Extremely Premature Infants – Schanler, R et al	<a href="http://pediatrics.aappublications.org/content/116/2/400.short">http://pediatrics.aappublications.org/content/116/2/400.short</a> <a href="#">Abstract only</a>
• Donor breast milk v. infant formula for preterm infants: systematic review and meta-analysis – Boyd, C; Quigley, M; Brocklehurst, P	<a href="http://fn.bmj.com/content/92/3/F169.full.pdf+html">http://fn.bmj.com/content/92/3/F169.full.pdf+html</a>
• Human Milk for premature infants: An important health issue – Lois Arnold	<a href="http://jhl.sagepub.com/content/9/2/121.short">http://jhl.sagepub.com/content/9/2/121.short</a>
• Use of donor milk in the treatment of metabolic disorders: glycolytic pathway defects – Arnold, L	<a href="http://jhl.sagepub.com/content/11/1/51.short">http://jhl.sagepub.com/content/11/1/51.short</a>
• Treatment of IgA deficiency in liver transplant recipients with human breast milk – Merhav, J. et al	<a href="http://onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.1995.tb01530.x/abstract">http://onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.1995.tb01530.x/abstract</a>
• Human Milk and the Preterm Infant – Bhatia, J.	<a href="https://www.nestlenutrition-institute.org/country/id/resources/Library/Free/Annales/Annales_71_2/Documents/Human%20Milk%20and%20the%20Premature%20Infant.pdf">https://www.nestlenutrition-institute.org/country/id/resources/Library/Free/Annales/Annales_71_2/Documents/Human%20Milk%20and%20the%20Premature%20Infant.pdf</a>

## HEALTHCARE COVERAGE OF BANKED HUMAN MILK

Several States recognize the value of healthcare coverage for donor milk and have passed legislation for coverage of banked human milk when medically indicated or for high risk infants.

- **California** (1988) requires its Medicaid program to reimburse donor milk from Mothers Milk Banks. This bill was declared to take effect immediately as an urgency statute (Medical Care Standards Division, 1979).
- **Texas** (2008) Medicaid Children's Services Comprehensive Care Program (CCP) identifies donor human milk as a benefit for clients who are born through 11 months of age when a physician deems it medically necessary (Texas Medicaid & Healthcare Partnership, 2008).
- **Missouri** (2014) requires its state Medicaid program to reimburse a hospital for prescribed medically necessary donor human milk for babies 0-3 months old (Missouri Legislature, 2014).
- **Kansas** (2015) recently passed legislation requires Medicaid reimbursement of donor human milk (Kansas Division of the Budget, 2015).
- **Utah** (2015) requires reimbursement for donor human milk from a human milk bank enrolled as a Utah Medicaid provider and certified by HMBANA, or meets such standards as may be adopted by the Utah Medicaid program (Utah Dept of Health Medicaid, 2015).

A brief by Centers for Medicare and Medicaid services highlights the value of Medicaid coverage for lactation services to reduce preventable causes of poor health and improve both short and long term infant and maternal health. It specifically calls out the recommendation by countless professional organizations, such as WHO, UNICEF, and CMS, for exclusive breastfeeding during the first six months of life. The brief goes on to list Medicaid coverage for banked human milk as an alternative step to promote breastfeeding (Department of Health and Human Services, 2012).

Washington should lead the way and be the first state to require insurance coverage of banked human milk by private insurers. Healthcare coverage of banked human milk meets the criteria for preventive care services as required by the Affordable Care Act. The law requires most insurance plans to provide breastfeeding support, counseling, and equipment for pregnant and nursing women. This includes a doctor's recommendations concerning what is medically appropriate (HealthCare.gov, 2015). Banked human milk is medically indicated, particularly for preterm and other critically ill infants, and is a supportive service for women who are not producing enough milk or are unable to breastfeed for medical reasons. In fact, the U.S. Breastfeeding Committee, along with the National Breastfeeding

Center developed the *Model Policy: Payer Coverage of Breastfeeding Support and Counseling Services, Pumps and Supplies* which includes a section outlining coverage of banked donor human milk.

**Table 5** provides additional sources for information about healthcare coverage of banked human milk.

<b>Table 5 – Healthcare coverage of banked human milk</b>	
• Texas Medicaid coverage human milk	<a href="http://www.tmhp.com/HTMLmanuals/TMPPM/2012/Vol2_Children's_Services_Handbook.17.053.html">http://www.tmhp.com/HTMLmanuals/TMPPM/2012/Vol2_Children's_Services_Handbook.17.053.html</a>
• Missouri Medicaid coverage human milk	<a href="http://www.moga.mo.gov/mostatutes/stathtml/20800001411.html">http://www.moga.mo.gov/mostatutes/stathtml/20800001411.html</a>
• Kansas Medicaid coverage human milk	<a href="http://kslegislature.org/li/b2015_16/measures/documents/hb_2149_enrolled.pdf">http://kslegislature.org/li/b2015_16/measures/documents/hb_2149_enrolled.pdf</a>
• Utah Medicaid coverage human milk	<a href="http://www.rules.utah.gov/publicat/bulletin/2015/20150415/39248.htm">http://www.rules.utah.gov/publicat/bulletin/2015/20150415/39248.htm</a>
• CMS Medicaid Coverage of Lactation Services brief	<a href="http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/Lactation_Services_IssueBrief_01102012.pdf">http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/Lactation_Services_IssueBrief_01102012.pdf</a>
• Model Policy: Payer Coverage of Breastfeeding Support & Counseling Services, Pumps & Supplies	<a href="http://www.usbreastfeeding.org/model-payer-policy">http://www.usbreastfeeding.org/model-payer-policy</a>

## CURRENT LANDSCAPE IN WASHINGTON

In Washington, access to banked human milk is limited. Thirteen NICUs order human milk from the Northwest Mothers Milk Bank in Portland; however health providers report that due to lack of insurance coverage human milk is underutilized in the NICU and on an outpatient basis (NICU providers, Seattle area hospitals, personal communication, May 2015). Without reimbursement, providers may limit use of more effective treatments. Many NICUs have restricted budgets and policies with narrow criteria for the use of donor human milk. The health and economic benefits will not be fully realized until all infants who have a medical need receive human milk exclusively for as long as it is medically indicated.

Families are responsible to pay for banked human milk if their infant is outside of the NICU's policy criteria and when it's ordered in outpatient situations. This places a heavy financial burden on families who are struggling to balance work, finances, and caring for a sick or hospitalized infant.

### Usage of Banked Human Milk

Northwest Mother's Milk Bank (NWMMB), a HMBANA accredited non-profit milk bank located in Portland, Oregon, was established in July 2013. NWMMB serves both Oregon and Washington. Eighty-six percent of milk is supplied for inpatient use, while 14% is dispensed to outpatients.

NWMMB charges a processing fee of \$4.50 per ounce of human milk. Nationally, the cost of human milk per ounce ranges from \$3.50-\$4.75 an ounce. Some HMBANA milk banks charge differently for preterm milk or colostrum, while others price all donor milk the same (Ransom, 2015).

While NWMMB provides the majority of banked human milk to Washington State, Mother's Milk Bank of San Jose has historically supplied much of the state prior to NWMMB opening its doors, and still sends some donor milk to Washington State.

The total ounces dispensed in Washington State January – April of 2015:

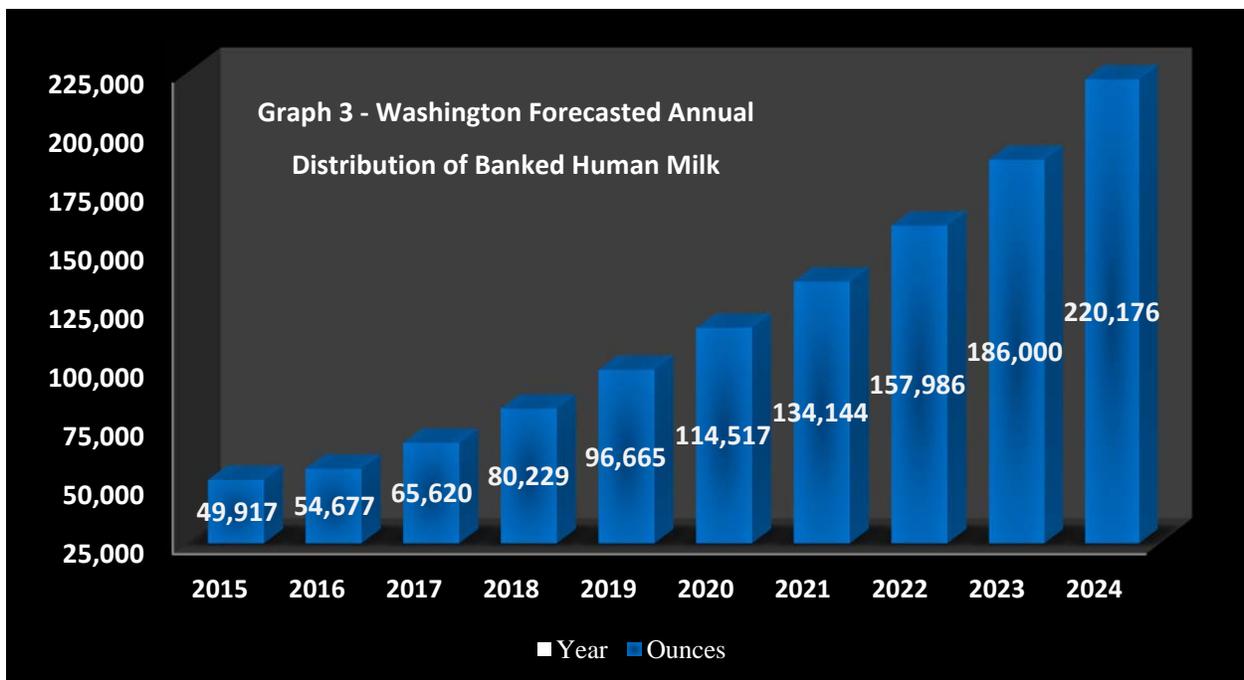
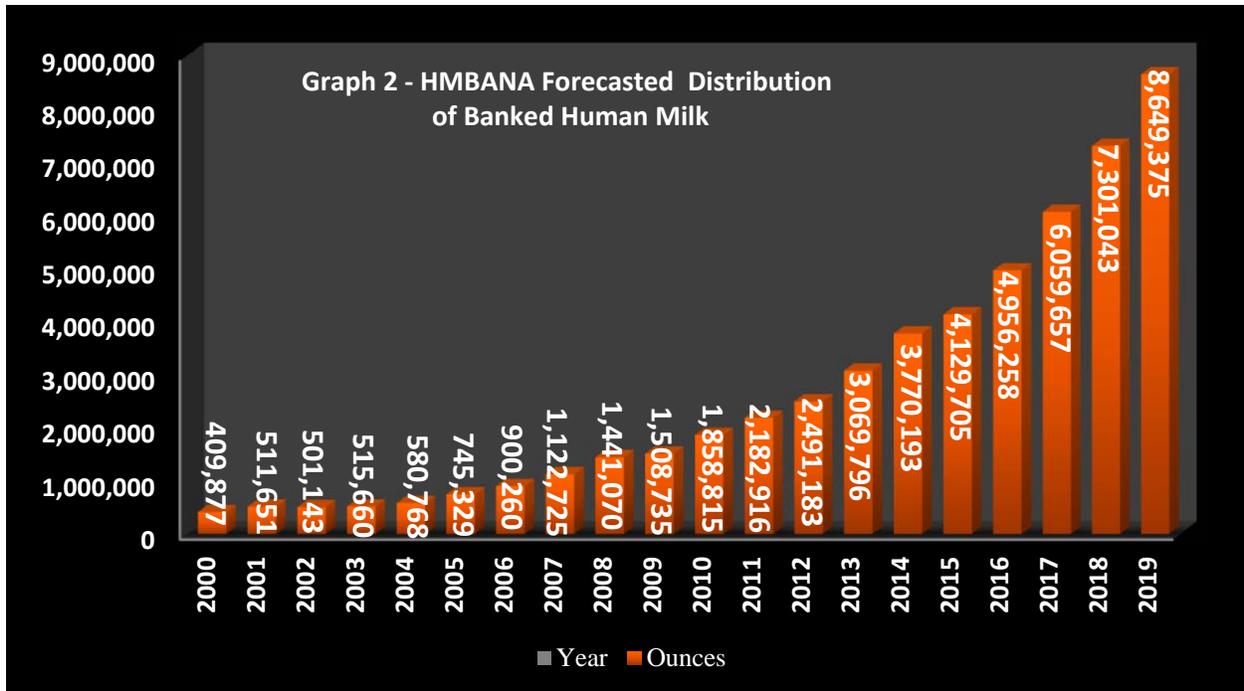
- 11,281 oz. (NWMMB) + 5,358 oz. (Mother's Milk Bank, San Jose) = **16,639 oz.**

Annualized through 2015:

- 16,639 x 3 = **49,917 oz.**

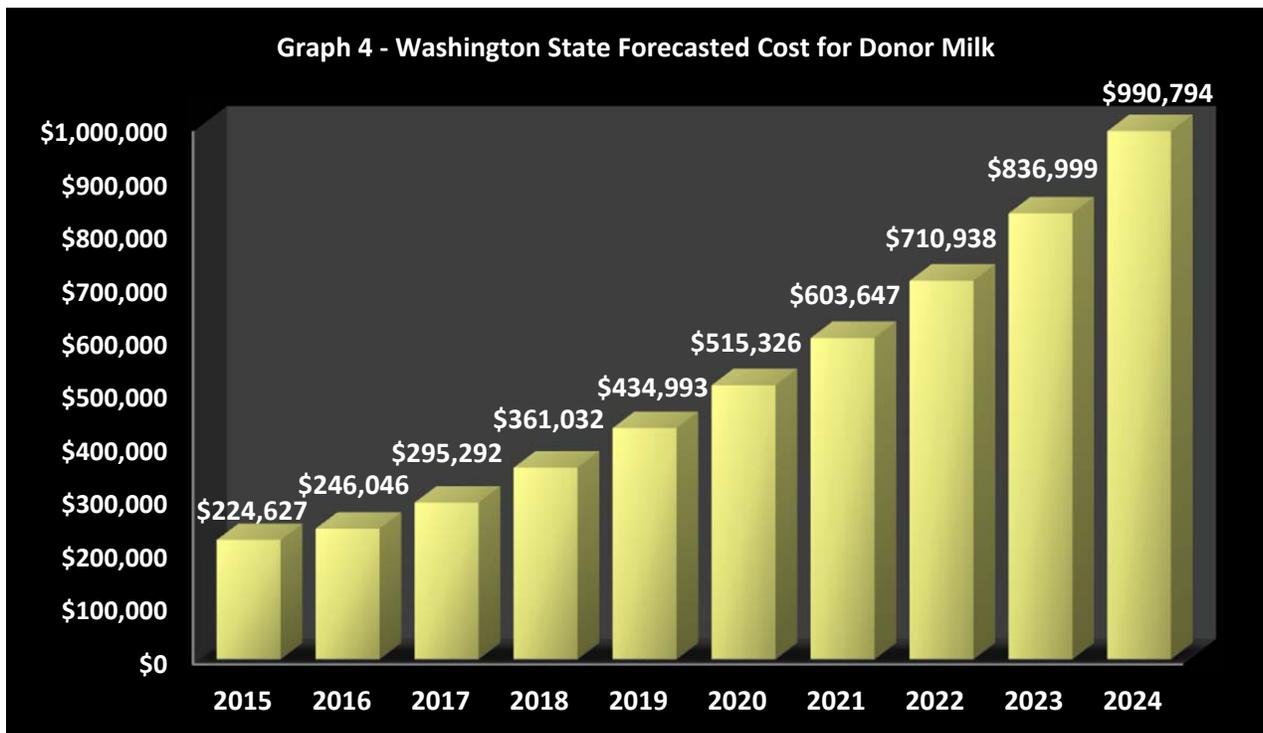
## Projected Usage of Banked Human Milk

HMBANA data ranging from 2000 – 2014 was utilized to determine a forecasted annual distribution rate of banked human milk over the next five years (graph 2). Using this information along with the annualized 2015 data from Washington, a 10-year projected growth rate in annual distribution of banked human milk can be seen (graph 3). A growth rate of 9.5% is expected from 2015 to 2016. The growth rate from 2016 through 2024 is expected to stay between about 18%-20% per year.



A calculation of the annual forecasted distribution rate in Washington State with the current cost of banked human milk from NWMMB, at \$4.50 an ounce, demonstrates the expected cost of donor milk over the next 10 years (graph 4).

There are significant cost savings on a smaller scale that add up when donor human milk is used in the NICU. Examples include reduction in the need for Total Parenteral Nutrition (TPN), an IV fluid and nutrition treatment often ordered for preterm babies and reduced infection rates which translate in to decrease costs for lab tests, antibiotics, and other medical treatments. On a larger scale, preventing one case of NEC needing surgical intervention, estimated well over \$200,000, neutralizes the cost of banked human milk for an entire year.



## SUNRISE REVIEW CRITERIA

### Social Impact:

#### (i) To what extent is the benefit generally utilized by a significant portion of the population?

Healthcare coverage of banked human milk will be considered a new benefit. The Insurance Commissioner's Office and the Health Care Authority confirms that human milk is not currently a covered benefit by private insurance, Public Employee Benefits plans, or Medicaid health plans in Washington State, either as a global billing practice or individually reimbursed item. Although human milk is not explicitly included as a benefit, it is also not explicitly excluded (Insurance Commissioner's Office of Washington, personal communication, 2015; Health Care Authority of Washington, personal communication, 2015).

Evidence reveals babies born to African American and Native American mothers have 2-3 times more incidence of preterm birth and infant mortality in the first year of life, these populations are also more likely to receive Medicaid (USDHHS, Office of Minority Health, 2010).

Isabella Knox, MD is a neonatologist with over 30 years of experience serving high risk and premature babies. A provider at multiple hospitals throughout the Seattle area, Dr. Knox gave insight into the billing of human milk from a NICU perspective. It is often charged as a food even though it is utilized as a medication and nutritional therapy, in addition to being a food. Any potential reimbursement to the NICU results from the global daily charge, however human milk has never been figured into the cost of this reimbursement rate (personal communication, May, 2015).

Kim Updegrave, Clinical and Executive Director at Mothers Milk Bank of Austin, states healthcare coverage for human milk is often based on global diagnostic code rates and is not reimbursed as a line item. Most of those rates were determined before banked human milk was widely used as part of the standard care for preterm and other sick infants. Ultimately, a hospital may only receive a small portion, if any reimbursement, for human milk (personal communication, May, 2015).

In addition to hospitalized medically fragile infants, a need exists for human milk in a small group of outpatients. Ultimately, preterm infants are discharged and sent home on artificial milk formula when their mothers' supply remains inadequate. However, the standard of care is to order banked human milk instead of relying on formula for nutrition. These infants remain at high risk of

complications or re-hospitalization. Given the evidence, human milk reduces risk of further complications and additional healthcare costs will be avoided. Other outpatient uses considered medically necessary include, but are not limited to: babies with gastroschisis, congenital heart disease, feeding intolerance, post-NEC, or post-surgery (Isabella Knox, personal communication, May, 2015)

**(ii) To what extent is the benefit already generally available?**

As referenced in the previous question, healthcare coverage is not available. In some cases, families report contacting their insurance provider and have obtained coverage for donor human milk on a limited basis. This is not known to be the common experience.

NWMMB, and other HMBANA milk banks fundraise to maintain charitable care programs which can help with the cost of an ongoing prescription for banked human milk in outpatient situations; however there are limited funds and milk banks currently receive no public support and largely bootstrap their ability to cultivate donors and their capacity to continue to meet the demand for milk in a multi-state region (Lesley Mondeaux, NWMMB, personal communication, May 24, 2015).

**(iii) If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?**

NICU's incorporate individual policies for utilization of human milk after weighing the budgetary considerations. Some policies are very narrow in criteria, allowing use of banked human milk in the very sickest preterm populations and only for a limited timeframe. Other policies are broader, offering human milk to any infant who meets the definition of preterm and extending use to full term as risk infants. (Isabella Knox, MD, personal communication, April 24, 2015). Some hospitals are providing human milk when parents request it, fearful of adverse outcomes given the evidence base concerning the harmful effects of infant formula in the preterm population (Marion Rice, IBCLC, personal communication, May 28, 2015)

The main barrier to optimal usage of banked human milk in NICUs is the lack of reimbursement from insurance. It creates an inequitable system, placing patients at a disadvantage if they happen to be in a hospital with a more restrictive policy. In outpatient settings, a disparity also exists for families who cannot afford the cost of banked human milk. If donor human milk costs more, there are questions regarding equitable access, even though it has therapeutic benefit and overall increases lifelong health.

**iv) If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?**

There are three considerations, financial impact to: (1) patients and families (2) hospital (3) insurance providers.

Hospitals

As hospitals continue to expand the use of banked human milk for preterm and other at risk infants, health outcomes will improve, mortality rates will decline, and healthcare costs will drop. Although these outcomes are positive, it may result in some lost revenues for hospitals. The current system requires hospitals to absorb the cost for donor milk with little-to-no insurance reimbursement, which isn't financially sustainable. The top priority of hospitals should be to ensure the highest quality of care is allocated in an equitable manner to every patient in need.

Patients and Families

Some families are doing their own research on potential effective treatments for their sick infants. One local dietitian reports that although families may not know to ask about donor human milk, increasingly families come to the healthcare team after learning about the benefits of donor milk in the preterm population and ask for it. If their infant is outside of the hospital's policy for using banked human milk, the family is required to pay for it. This dietitian stated she has contacted health insurers on behalf of the families to obtain coverage for banked human milk was denied on numerous occasions, revealing further inequities in access to banked human milk.

To estimate the financial burden of a family with a hospitalized preterm infant, assume a baby is born at 28 weeks gestation and the mother is unable to supply milk. At one NICU in the Seattle area, the criteria for using banked human milk is a baby under 1,800 grams (Dietitian, Seattle area hospital, personal communication, May 2015). At 33 weeks a baby is approximately 1900 grams or just over 4 pounds and is no longer eligible for human donor milk under that hospital's policy. In order to continue treatment of this effective, evidence based therapy, the family would have to pay out of pocket. The average intake of breastmilk for a preterm baby weighing 4 ½ lbs. is about 15oz. per day.

- **15oz. x \$4.50 per oz. x 7 days = \$472.50 per week or \$1,890 for a month**

In this case, the family will pay \$472.50 per week. This cost will rise as the baby requires more milk. The mother may or may not be able to supply her own breastmilk. If this preterm is fed human milk exclusively from birth on, research shows hospital length of stay will be reduced, use of TPN will be reduced, and there is less likelihood of preterm complications and infections, such as sepsis or NEC.

The financial hardship in outpatient situations is also significant for families. Below is an example of the cost to provide banked human milk exclusively per week for a preterm baby discharged from the NICU. In many cases, the mother might be expressing some of her own milk, but for the purpose of this example, assume mothers milk is not available.

Consider that the average intake of breast milk for a 1-6 month old is 25 oz. per day.

- **25oz. X 7 days x \$4.50 per oz. of donor milk = \$787.50 per week**

### Insurance Providers

Initially, the fee for banked human milk seems high, at a rate of \$4.50 per ounce; however compared to other medications which can be priced in the thousands of dollars, the fee is reasonable, particularly when the cost savings are applied. Wight's cost benefit analysis of human milk estimates savings of \$11 for every \$1 spent on banked human milk for preterm infants at risk for NEC. She goes on to suggest that even assuming banked human milk is only 50% as effective as mothers' own milk, there is still a savings of \$6 for every \$1 spent on human milk. Insurers will benefit substantially by covering donor milk. The savings show in reduced number of hospital days; use of TPN; number of x-rays and lab tests; antibiotics and other medications; costs associated with surgical interventions due to NEC; and more. This doesn't even take into account the long term health benefits which translate into healthcare savings down the line and are more difficult to estimate.

### **(v) What is the level of public demand for the benefit?**

There is a limited population impacted in Washington, and therefore a low public demand for this benefit. However, the population impacted is extremely vulnerable and access to donor human milk is not only life-enhancing, but life-saving for this group.

### Prevalence of NEC in Preterm and VLBW Infants

- **90%** of infants who develop NEC are born premature; however full-term and near-term infants also develop the disease (Gephart, 2012).
- Nearly **12%** of infants born weighing less than 1500 grams will develop NEC and about **30%** of those infants will not survive (Gephart, 2012).
- The rate of NEC-associated acute mortality is greater than **10%** overall and more than **25%** for infants with NEC severe enough to require a surgical intervention (Patel B. K., 2012).
- If surgical care is required, there is an additional cost of at least \$186,200, and infants stay an additional 60 days longer than other preterm infants (Gephart, 2012).
- Infants with NEC have a higher incidence of nosocomial infections and lower levels of nutrient intake, grow more slowly, and have longer durations of intensive care and hospital stay (Patel B. K., 2012)

### 2013 Washington State Data on Birth Rates:

- **9.7%** = Preterm birth rate (March of Dimes, 2015)
- **8,276** = Number of preterm births (WA DOH Vital Statistics, 2015)
- **5,555** = Births meeting LBW criteria > 2,500 grams (WA DOH Vital Statistics, 2015)
- **920** = Births meeting VLBW criteria > 1,500 grams (WA DOH Vital Statistics, 2015)
- **50%** = Medicaid funded total deliveries

Based off the NEC prevalence data and Washington birth rates, at minimum **110** infants weighing less than 1,500 grams are expected to develop NEC annually; **33** of those infants are expected to die of complications from NEC.

- If NEC extends NICU stays by 11 to 48 days, it can be estimated these VLBW infants with NEC will have **1,210** to **5,280** extended hospital days
- A diet where donor milk is used instead of formula reduces NEC by 79% (Edwards, 2012). Looking solely at the VLBW population, if fed human milk exclusively, **87** of those 110 NEC cases in Washington of NEC could be prevented.
- If 25% of NEC cases need surgical intervention (Gephart, 2012), out of the 110 NEC cases mentioned, **28** could be prevented equating to \$5,213,600 in health care costs.

**(vi) What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?**

There is a very limited population of impacted people in Washington. About half of this population is expected to be covered under Medicaid, while the remainder is patients on Public Health Plans or private insurance. As a result, there should be no impact on collective bargaining based on this benefit.

**The financial impact:**

**(i) To what extent will the benefit increase or decrease the cost of treatment of service?**

A cost benefit analysis published by Wight, found that using formula instead of human milk increased NICU costs by \$9,669. The estimated direct costs of hospitalization are shown in **Table 6**.

Wight uses data from research by Schanler et al (1999) on the differences in (1) length of stay (2) number of cases of NEC (3) late on-set of sepsis and (4) duration of TPN in preterm infants who were given human donor milk rather than formula. (2001).

Based off this analysis, it's estimated for every dollar spent on human donor milk, \$11 in healthcare costs can be saved when donor milk is used in place of formula.

Another widely cited cost analysis by Lois Arnold (2002), presents three models which show savings to the healthcare system or individual family if donor human milk is provided as first feedings when mothers' milk is not available.

<b>Table 6 – (Wight, 2001)</b>	
<i>Estimated costs of hospitalization</i>	
NICU nursing care	\$600/day
Total parenteral nutrition (TPN)	\$160/day
Antibiotic therapy	\$50/day
Radiology	\$10/film
Lumbar puncture tray	\$9/each
Bacteriologic culture	\$15/each
Preterm formula	No cost
Human milk fortifier	No cost
<i>Estimated cost of one case of nonsurgical NEC</i>	
Antibiotic therapy x 10 days	\$500
TPN x 10 days	\$1600
Additional X-rays (10)	\$60
Bacteriologic cultures (4)	\$60
<b>Total</b>	<b>\$2260</b>
<i>Estimated cost of one case of sepsis</i>	
Antibiotic therapy x 10 days	\$500
TPN x 5 days	\$800
Additional X-rays (3)	\$30
Bacteriologic cultures (4)	\$60
<b>Total</b>	<b>\$1399</b>
<i>Estimated cost of human donor milk for VLBW infant \$3.00oz + shipping</i>	
1 month donor milk ~ 70oz	\$260
2 months donor milk ~250oz	\$850

**Model 1:** Direct Cost Model (see Wight's model above)

**Model 2:** Charge Model (cost reduction from shorter hospital stays as a result of NEC/sepsis prevention)

Takes hospital charges calculated by the March of Dimes and data from Schanler et al's research, which found the use of donor milk instead of formula reduces hospital stay by 15 days, will save \$48,150 per preterm baby.

### **Model 3: Costs to an individual State**

Calculations from Texas data on preterm infants in 1994 demonstrate the inadequate use of mothers' own milk and donor human milk cost the state \$32,682,000.

#### **(ii) To what extent will the benefit increase the appropriate use of the benefit?**

There is a limited population of patients in which banked human milk is considered medically necessary. Some expanded use should be expected because donor milk is underutilized due to lack of healthcare coverage.

**NICU preterm infants:** Some NICUs may expand policies to include a broader population. A conservative goal would be to reduce rates of NEC by 50% and eliminate infant mortality due to NEC and other prematurity related complications. This would help Washington in reaching its goal of reduced infant mortality. Expanded use of donor milk will accomplish this goal, which also means millions of dollars saved in healthcare costs.

Infant Mortality Report: <http://www.doh.wa.gov/Portals/1/Documents/5500/MCH-IM2013.pdf>

**Full term, critically ill infants:** Hospital policies will likely expand on a limited basis for use with full term infants who are critically ill. Examples of medically indicated situations include but are not limited to: pre and post organ transplant, post-surgery, GI anomalies, feeding intolerance, congenital heart disease.

**Late Pre-Term, Full term LBW, and babies with medical indication for supplementation:** Hospitals are providing donor human milk upon parental request for babies who have low blood sugar or other medical indication or at a Physician's request.

**Outpatient use:** Common diagnoses for outpatient use of banked human milk include but are not limited to: Formula intolerance, post-surgical, feeding difficulty / weight loss, maternal low milk supply, maternal illness / infection, maternal cancer, neonatal jaundice, hypoglycemia, prematurity, adoption (NWMMB, personal communication, May 2015)

**(iii) To what extent will the benefit be a substitute for a more expensive benefit?**

When mothers own milk is not available, there are two substitutes, infant formula and banked human milk. According to the top professional medical and healthcare organizations listed in Table 1 of this paper, the first choice is always mothers own milk, but when mothers own milk is not available banked human milk is recommended. The cost benefit analyses cited throughout this paper shows that although the initial fee for banked human milk may be higher than infant formula ounce for ounce, savings in healthcare costs due reductions in NEC, sepsis, feeding intolerance, TPN, use of antibiotics, lab tests, surgical interventions, and shortened hospitals stay make banked human milk the most cost effective option.

**(iv) To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?**

The administrative expenses of health carriers would not likely increase. This new benefit expands coverage to a limited group who are already enrolled in healthcare plans. In addition there is a cost savings associated with this new benefit which offsets the cost of coverage for donor milk.

Premiums will likely see little-to-no change. Based on the amount of donor milk dispensed in Washington State from January to April of this year (16,639 oz.), it is projected 49,917 oz. of banked human milk will be dispensed in 2015. At \$4.50 an ounce, this amounts to \$224,627. If one case of NEC needing surgical intervention is prevented by the use of human milk, the annual cost will be neutralized.

**(v) What will be the impact of this benefit on the total cost of healthcare services and on premiums for health coverage?**

The use of banked human milk used for preterm and other at risk infants, when it is medically indicated to supplement mothers own milk in order to meet the recommendation of exclusive breastfeeding will reduce healthcare costs significantly. All evidence points to clear reductions in expensive treatments and to shortened hospital stays for premature and other critically ill babies. The long term health benefits are not calculated here, however it is worth mentioning the healthcare system will likely see additional reductions in healthcare costs ongoing due to this early intervention.

The 2011 *AAP Policy Statement on Breastfeeding and the Use of Human Milk* states these long term outcomes when infants are exclusively breastfed for the first 6 months:

- **63%** decrease in the risk of ear infections

- **27%** decrease in the development of asthma, atopic dermatitis, and eczema (this protection increases to 42% infants with a positive family history for these allergic conditions)
- **52%** reduction in the risk of developing celiac disease if infants are being breastfed at the time of their first exposure to gluten
- **15% - 30%** decrease in adolescent and adult obesity (the longer the breastfeeding, the more the reduction in overweight)
- **Up to a 30%** decrease in type 1 diabetes and a reduction of 40% in the incidence of type 2 diabetes
- **20%** reduction in the risk of acute lymphocytic leukemia and 15% in the risk of acute myeloid leukemia

Due to the small population impacted by this benefit, premiums are likely to be minimally effected.

**(vi) What will be the impact of this benefit on costs for state-purchased healthcare?**

The State of Kansas passed a bill requiring Medicaid coverage of banked human milk in March of 2015. HB 2149 establishes a system of reimbursement to medical care facilities that provide medically necessary donor human breast milk for any recipient of medical assistance under the Kansas program of medical assistance administered by the Kansas Department of Health and Environment (KDHE). The fiscal note states the fiscal effect of the bill for KDHE would be negligible (Kansas Division of the Budget, 2015).

Due to the small population expected to utilize this benefit and the cost savings outlined in this paper, the impact of this benefit on costs for state-purchased healthcare are expected to minimal.

**(vii) What will be the impact of this benefit on affordability and access to coverage?**

As outlined in 1.iv, receiving insurance coverage would have a positive impact on affordability for patients, insurance providers, and increase access to banked human milk.

## **Evidence of healthcare service efficacy:**

**(i) If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?**

See section “Health Benefits and Cost Savings of using Banked Human Milk” for an outline of the studies indicating when human milk is used, instead of formula, showing that complications such as NEC, sepsis, and many others are significantly reduced; expensive medical interventions decline; and hospital length of stay is shortened. This section also provides links to studies available online.

**(ii) If a mandated benefit of a category of healthcare provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of healthcare provider?**

N/A

**(iii) To what extent will the mandated benefit enhance the general health status of the state residents?**

Although this benefit affects a small portion of Washington State’s population, it will enhance the general health status of what can be considered our most vulnerable population. When a baby is ill or hospitalized the entire family is greatly impacted. Healthcare coverage of banked human milk will allow patients and their providers to optimize this effective, evidence based treatment to improve overall health outcomes in a more equitable way. It will reduce time spent in the hospital, and lower overall healthcare costs.

## DETAILED RECOMMENDATIONS

Currently, banked human milk is not a covered healthcare benefit in Washington State. Based off the information and data outlined in this paper, it is recommended that banked human milk from a non-profit milk bank which follows evidence-based guidelines developed by an accrediting organization approved by the Department of Health, be an added benefit for Medicaid plans, private insurance, and public employee health plans. The covered benefit should include infants from birth to 11 months of age when a medical provider with prescriptive authority orders banked human milk as a medically necessary treatment or therapy. This benefit will improve health outcomes for our most vulnerable population and save millions of dollars in healthcare costs.

Another important step toward successfully implementing this new covered benefit is to encourage stakeholders to leverage the opportunity to develop initiatives which strengthen the breastfeeding culture, especially for those impacted by health inequity and breastfeeding disparities, engage women to consider becoming milk donors, and optimize the use of banked donor milk. This can be accomplished through workgroups. These workgroups should include milk banking experts, clinical providers, parents of premature infants, community representatives who experience breastfeeding disparities and health inequities, and other interested groups, such as child healthcare advocates, the local chapter of the American Academy of Pediatrics, the Washington State Hospital Association, and the Department of Health.

Examples of initiatives include:

- Develop a standard model hospital policy for the use of human donor milk in NICUs.
- Establish recommendations for providers who order human milk on an outpatient basis.
- Formulate strategies for community education to increase continuous breastfeeding rates and milk donation rates to non-profit human milk banks.
- Form strategies that make it easier for women to donate milk to a milk bank and men to share in support for the resource.
- Create incentives for more hospitals to attain Baby-Friendly certification.

## CONCLUSION

Banked human milk is a safe, effective, evidence based treatment for premature and other critically ill or at-risk babies. The use of pasteurized human milk is considered to be a supportive measure towards exclusive breastfeeding for the first six months of life, as recommended by the American Academy of Pediatrics, the World Health Organization, and countless other professional medical organizations.

Mothers of premature infants often have trouble producing enough milk to provide an exclusive diet of breastmilk for their babies. Other medical conditions can contribute to a delayed ability to breastfeed such as maternal surgery or medications, certain medical conditions and stress. Healthcare coverage is essential for increasing access to banked human milk in situations where mothers own milk is unavailable.

Pasteurized human milk is both life-enhancing and life-saving for premature and low birth weight and other at risk infants when mothers own milk is unavailable. Research clearly shows improved outcomes in these populations through reduced incidences of serious infections such as NEC and sepsis; decrease in feeding intolerance; reduced risk of SIDS; improved visual acuity and neurodevelopment; more efficient feedings; declines in invasive interventions such as surgery; and shortened hospital stays.

Additional infant populations who would benefit from increased access to pasteurized human milk include but are not limited to infants with issues such as gastrointestinal anomalies, congenital heart disorders, post-surgery, feeding intolerance, and post NEC.

The cost savings resulting from banked human milk as an added healthcare benefit are considerable. Two cost benefit analysis studies by Lois Arnold and Nancy Wight show significant reductions in healthcare costs when banked human milk and mothers own milk are used instead of formula in the preterm and VLBW populations. Although these studies were completed in 1998 and 2001, the models still applies today and can be calculated using current hospital costs.

Based on improved health outcomes and reduced medical costs, healthcare coverage for banked human milk should be a covered benefit of Medicaid plans, private insurance, and public employee health plans.

## References

- Arnold, L. (2000). Becoming a donor to a human milk bank. *Leaven*, 36(2), 19-23.
- Ayala Maayan-Metzger, Shirli Avivi, Irit Schushan-Eisen, & Jacob Kuint. (2012). Human milk versus formula feeding among preterm infants: Short-term outcomes. *American Journal of Perinatology*, 29(2), 121-126. Retrieved from <http://search.ebscohost.com.proxy.seattleu.edu/login.aspx?direct=true&db=a9h&AN=71626091&site=ehost-live>
- Baby-Friendly USA. (2015). Ten steps to successful breastfeeding. Retrieved from <https://www.babyfriendlyusa.org/about-us/baby-friendly-hospital-initiative/the-ten-steps>
- Bartick, M., & Reinhold, A. (2010). The burden of suboptimal breastfeeding in the United States: A pediatric cost analysis. *Pediatrics*, 125, e1048-e1056. doi:doi: 10.1542/peds.2009-1616
- Bisquera, J. A., Cooper, T. R., Berseth, C. L., & MD. (2002). Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. *Pediatrics*, 109(3), 423. Retrieved from <http://search.ebscohost.com.proxy.seattleu.edu/login.aspx?direct=true&db=a9h&AN=6566485&site=ehost-live>
- Boyd, C. A., Quigley, M. A., & Brocklehurst, P. (2007). *Donor breast milk versus infant formula for preterm infants: Systematic review and meta-analysis* doi:10.1136/adc.2005.089490
- Department of Health and Human Services. (2012, January 10). Brief: Medicaid Coverage of Lactation Services. Baltimore, MD, U.S.A.
- Dietitian, Seattle Area Hospital. Personal communication May 2015. Interviewed by Kara Preas Huertas.
- Edwards, T. M., & Spatz, D. L. (October 2012). Making the case for using donor human milk in vulnerable infants. *Advances in Neonatal Care*, 12(5), 273-278. doi:10.1097/ANC.0b013e31825eb094
- Eidelman, A. I., Schanler, R. J., Johnson, M., Landers, S., Noble, L., Szucs, K., & Viehmann, L. (2012). Policy statement: Breastfeeding and the use of human milk. *Pediatrics*, 129, e827. doi:10.1542/peds.2011-3552
- Ewaschuk, J. B., Unger, S., O'Connor, D. L., Stone, D., Harvey, S., Clandinin, M. T., & Field, C. J. (2011). *Effect of pasteurization on selected immune components of donated human breast milk* Nature Publishing Group. doi:10.1038/jp.2010.209
- Food & Drug Administration [FDA]. (2010, December 6, 2010). Meeting of the pediatric advisory committee. Retrieved from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM238627.pdf>
- Furman, L., Taylor, G., Minich, N., & Hack, M. (2003). The effect of maternal milk on neonatal morbidity of very low-birth-weight infants. *Arch Pediatr Adolesc Med*, 157, 66-71.
- Gephart, S. M. (2012). Necrotizing Enterocolitis Risk: State of the Science. *Advances in Neonatal Care*, 12(2), 77-89. doi:doi:10.1097/ANC.0b013e31824cee94
- HealthCare.gov. (2015). *HealthCare.gov*. Retrieved from Breastfeeding Benefits: <https://www.healthcare.gov/coverage/breast-feeding-benefits/>
- Health Care Authority of Washington. Personal communication on April 15, 2015. Interviewed by Kara Preas Huertas.

- Human Milk Banking Association of North America [HMBANA]. (2011). *Guidelines for the establishment and operation of a donor human milk bank*. HMBANA. Fort Worth, Texas.
- HMBANA. (2015). Milk processing. Retrieved from <https://www.hmbana.org/milk-processing>
- Hylander, M. A., Strobino, D. M., & Dhanireddy, R. (1998). Human milk feedings and infection among very low birth weight infants. *Pediatrics*, *102*, e38. doi:doi: 10.1542/peds.102.3.e38
- Hylander, M. A., Strobino, D. M., Pezzullo, J. C., & Dhanireddy, R. (2001). Association of human milk feedings with a reduction in retinopathy of prematurity among very low birthweight infants. *Journal of Perinatology*, *21*(6), 356. Retrieved from <http://search.ebscohost.com.proxy.seattleu.edu/login.aspx?direct=true&db=a9h&AN=8882481&site=ehost-live>
- Insurance Commissioners Office of Washington. Personal communication on April 29, 2015. Interviewed by Kara Preas Huertas
- Johnson, T. J., Patel, A. L., Bigger, H. R., Egstrom, J. L., & Meier, P. P. (2014). Economic benefits and costs of human milk feedings: A strategy to reduce the risk of prematurity-related morbidities in very-low-birth-weight infants. *Advances in Nutrition: An International Review Journal*, *5*, 207-212. doi:10.3945/an.113.004788
- Kansas Division of the Budget. (2015, February 18). Fiscal Note for HB 2149. *Fiscal Note for House Bill 2149*. Retrieved from [http://www.kslegislature.org/li/b2015\\_16/measures/documents/supp\\_note\\_hb2149\\_00\\_0000.pdf](http://www.kslegislature.org/li/b2015_16/measures/documents/supp_note_hb2149_00_0000.pdf)
- Knox, Isabella, MD. Personal communication in May 2015. Interviewed by Kara Preas Huertas.
- Lawrence, R. A., & Landers, R. M. (Eds.). *Breastfeeding: A guide for the medical profession* (7th ed.). Philadelphia: Saunders.
- March of dimes 2014 premature birth report cards. (2015). Retrieved from <http://www.marchofdimes.org/mission/prematurity-reportcard.aspx#>
- Medicaid coverage of lactation services*. (January 10, 2012). (Brief). Baltimore, MD, U.S.A.: Department of Health and Human Services.
- Medical Care Standards Division. (1979, December 31). Policy Statement: 79-10 Human Milk Distributed by Milk Banks as Medical Program Benefit.
- Menon, G., & Williams, T. C. (2013). Human milk for preterm infants: Why, what, when and how? *Archives of Disease in Childhood -- Fetal & Neonatal Edition*, *98*(6), F559-F562. doi:10.1136/archdischild-2012-303582
- Missouri Legislature. (2014, August 28). *Missouri Revised Statutes*. Retrieved from Missouri General Assembly.
- Mondeaux, Lesley. Executive Director, Northwest Mothers Milk Bank. Personal communication in April, 2015. Interviewed by Kara Preas Huertas.
- Patel, A. L., Johnson, T. J., Engstrom, J. L., Fogg, L. F., Jegier, B. J., Bigger, H. R., & Meier, P. (2013). Impact of early human milk on sepsis and health-care costs in very low birth weight infants. *Journal of Perinatology*, *33*, 514-518. doi:10.1038/jp.2013.2
- Patel, B. K. (2012). Necrotizing Enterocolitis in Very Low Birth Weight Infants: A Systemic Review. *ISRN Gastroenterology*. doi:doi:10.5402/2012/562594

- PATH. (2013). *Strengthening human milk banking: A global implementation framework*. (Bill & Melinda Gates Foundation Grand Challenges Initiative No. version 1.1). Seattle Washington, U.S.A.: PATH. Retrieved from [http://www.path.org/publications/files/MCHN\\_strengthen\\_hmb\\_frame\\_April2015.pdf](http://www.path.org/publications/files/MCHN_strengthen_hmb_frame_April2015.pdf)
- Ransom, Joanne. Clinical Director, Northwest Mothers Milk Bank [NWMMB]. Personal communications in April and May 2015. Interviewed by Kara Preas Huertas.
- Rice, Marion. Executive Director of Breastfeeding Coalition of Oregon. Personal communication April 28, 2015. Interviewed by Kara Preas Huertas.
- Sakamoto, Pauline. Executive Director, Mothers Milk Bank San Jose; President of HMBANA. Personal communication in June of 2014 and May 2015. Interviewed by Kara Preas Huertas.
- Schanler, R. J., Shulman, R. J., & Lau, C. (1999). Feeding strategies for premature infants: Beneficial outcomes of feeding fortified human milk versus preterm formula. *Pediatrics*, *103*, 1150-1157.
- Schanler, R. J., Lau, C., Hurst, N. M., & O'Brian Smith, E. (2005). Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. *Pediatrics*, *116*(2), 400-406. doi:10.1542/peds.2004-1974
- Texas Medicaid & Healthcare Partnership. (2008). *Texas Medicaid Services*. Retrieved from <http://www.tmhp.com/HTMLmanuals/TMPPM/2008/2008%20TMPPM-46-108.html>
- U.S. Department of Health and Human Services. (2011). *The surgeon general's call to action to support breastfeeding*. Washington D.D.: U.S. Department of Health and Human Services, Office of the Surgeon General. Retrieved from <http://www.surgeongeneral.gov/library/calls/breastfeeding/calltoactiontosupportbreastfeeding.pdf>
- U.S. Department of Health and Human Services. (2010). *Infant Mortality and African Americans*. Washington D.D.: U.S. Department of Health and Human Services, Office of Minority Health. Retrieved from <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=23>
- Updegrave, Kim. Executive Director, Mothers Milk Bank, Austin. Personal communication in April 2015. Interviewed by Kara Preas Huertas.
- Utah Dept of Health Medicaid. (2015). *Utah.gov*. Retrieved from Utah.gov: <https://medicaid.utah.gov/Documents/files/January2015-MIB.pdf>
- Wight, N. E. (2001). Donor human milk for preterm infants. *Journal of Perinatology*, *21*(4), 249. Retrieved from <http://search.ebscohost.com.proxy.seattleu.edu/login.aspx?direct=true&db=a9h&AN=8882383&site=ehost-live>