Microbiological Safety of Donor Human Milk for Term Infants - Review Article

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Abstract: Breastfeeding is recognized as the most secure and optimal approach to infant nourishment. In situations where breastfeeding is insufficient or unavailable, donor human milk from reputable human milk banks is a viable alternative to breast milk. The objective of this paper was to conduct a comprehensive review of the microbiological safety associated with the utilization of donated human milk for infant feeding. Donated human milk is prone to contamination during collection, storage or transportation; therefore, all efforts should be taken to render it microbiologically safe as it is fed to infants, who are more prone to infection. Donor human milk collected, processed and stored under hygienic conditions can be safely used for infant feeding in the absence of the mother's own milk.

Keywords*:* Breast milk, mother's milk, donor human milk, human milk bank, microbiological safety.

INTRODUCTION

Breast milk is widely acknowledged as the optimal nutritional source for neonates, attributable to its comprehensive array of macro- and micronutrients, in conjunction with various non-nutritive bioactive constituents, including hormones, immunoglobulins, growth factors, cytokines, microbes, metabolites, and human milk oligosaccharides, all of which significantly influence the health of infants [1-4]. Breastfeeding is the ideal standard for infant nourishment since it naturally supplies infants with essential vitamins, nutrients, and immune-enhancing components necessary for their growth and development [5-7]. WHO [8] has recommended exclusive breastfeeding until the child is 6 months old, followed by continued complementary feeding for the next 2 years. Direct breastfeeding is the safest and optimal method of infant feeding.

Donor human milk [DHM] from several well-established human milk banks [HMB] is the practical alternate for supplying breast milk [9-14] in absence of breast feeding due to separation, sickness, death, abandonment, no lactating capacity, insufficient production [15, 16], perceived insufficient milk supply [17] or HIV infection of mother [18].

HMB is a service provider that eliminates breast milk donors, gathers donated human milk, screens donor DHM for bacteria, processes it to make it microbiologically safe, and stores it until it is given to hospitals or outpatient patients [19]. Mackenzie *et al.* [20] reported the establishment of HMBs in many developed and developing countries, and their numbers are increasing worldwide. The first HMB was established in Vienna, Austria, in 1909, and there are now more than 700 HMBs spread across 60 countries, with the majority in North America, Europe, and Brazil [21]. The Virtual Collaborative Network of Milk Banks and Associations estimated that more than 800 000 infants receive DHM annually worldwide [22, 23]. Kaech*et al.* [24] identified the diverse factors influencing the sustainability of the HMBs. They categorized them into donation duration, donors' infant features [e.g., gestational age, birth weight], donors' features [e.g., socio-demographic characteristics, milk donation history], and factors related to the milk bank and health care systems [e.g., awareness and support].

DHM proved to be advantageous over formula feeds, including lower rates of infection and feeding intolerance [25, 26], but is prone to contamination during collection, storage, or transportation. All efforts should be taken to render it microbiologically safe, as it is fed to infants, who are more prone to infection. In this review, an attempt has been made to highlight the importance and microbiological safety of donor milk for infant feeding.

Significance of Breast Milk

Breast milk is considered the most nutritious food for infants owing to its macro and micronutrients [27], bioactive and immune factors such as antibodies, lysozyme, growth factors, antimicrobial peptides, microRNAs, stem cells and human milk oligosaccharides [5, 28] and presence of beneficial bacteria such as *Bifidobacterium* and *Lactobacillus* [29, 30]. Gut flora of breast-fed infants is constituted by breast milk, as an infant consuming approximately 800 ml/day of breast milk would ingest 1×10^5 to 1×10^7

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E-ISSN: 1929-4247/26

Table 1: Bioactive Components of Breast Milk

Components	Biological Activity	References
Oligosaccharides	Modulate the bacteria-host interactions and exert positively impact the composition of intestinal flora and protects infants against infection and diarrhea	[36]
Bioactive Proteins	Responsible for nutrition absorption, growth stimulation, modulation of immune system and pathogen defence	[37]
Polyunsaturated Fatty Acids	Extend natural resistance by enhancing intestinal epithelial barrier integrity	[38]
Secretory IgA	Either by a direct immune protection	[39]
Lactoferrin	Modulate immune protection	[39]

bacteria [31, 32], which assists in the development and maturation of the immune system of newborns [33]. The development of the infant microbiome with bacteria present in raw [unpasteurized] human milk is confirmed by higher gut microbiome diversity in infants fed pasteurised human milk or formula [34]. Disease transmission through breastfeeding or donor human milk is rare, most likely owing to the complex, intrinsically protective composition of human milk and its protective effects on the infant gut lining [35]. Diverse bioactive components of breast milk and their biological significance are delineated in Table **1**.

Microbiology of Breast Milk

Initially, breast milk was considered sterile, but recent studies have established that it harbours bacteria, viruses, fungi, yeasts, and minor genera, collectively known as the human milk microbiome [40]. The retrograde flow governs Microflora of human milk [contamination of the mammary duct with microbes from the infant's oral cavity during suckling] and the entero-mammary pathway [contamination of the mammary gland with maternal gut bacteria via the lymphatic circulation] or transfer from maternal skin [7, 41, 42]. Microflora of human milk is also influenced by diverse factors such as the stage of lactation, maternal body mass index, age, diet [41], geographical location, socio-economic status, use of antibiotics or probiotics during pregnancy, mode of delivery [41], host immunity [43], composition of breast milk, HIV infection and method of collection [44] and mode of breastfeeding [45]. However, other investigators reported no effect of delivery mode, infant sex, or maternal body mass index on the breast milk microbiome [46, 47].

Microflora in human milk is diverse and varies significantly between individuals [48, 49]. Diversity in the microbial flora of breast milk differed between term- and preterm-delivered mothers and was also influenced by perinatal antibiotic use. Khodayar-Pardo *et al.* [50] noted lower counts of Enterococcus spp. in colostrum and higher counts of Bifidobacterium spp. in breast milk from term-delivered mothers. Antibiotic therapy in lactating mothers also affects the prevalence of Lactobacillus, Bifidobacterium, and Staphylococcus spp. in human milk [51, 52] and results in a decline in the abundance of Bifidobacterium, Staphylococcus, and Eubacterium spp. [53]. Raw human milk generally contains a viable bacterial count [cfu/ml] of 10^2-10^3 [48, 54] and may reach a level of 10^6 due to bacterial growth [55]. Human milk is dominated by Gram-positive bacteria, including Staphylococci, Streptococci, Corynebacteria, Propionibacteria, Lactobacillus spp., and Bifidobacteria [31, 56]. The "core" bacteriome of Human Milk Microbiota is composed of nine genera, including *Staphylococcus*, *Streptococcus*, *Serratia*, *Pseudomonas*, *Corynebacterium*, *Ralstonia*, *Propionibacterium, Sphingomonas, and* Bradyrhizobium, representing approximately 50% of the microbial milk community [48, 57]. Later, Zimmermann and Curtis [44] reported that *Staphylococcus*, *Streptococcus*, *Lactobacillus*, *Pseudomonas*, *Bifidobacterium*, *Corynebacterium,* and *Enterococcus* were the predominant genera in breast milk. Other identified bacteria in breast milk are Lactobacillus*salivarius*, *Lactobacillus fermentum, Bacteroides, Blautia*, *Clostridium*, *Collinsella*, *Coprococcus*, *Eubacterium*, Acinetobacter*, Bradyrhizobium* [31,58,59], *Lactococcus*, *Leuconostoc*, and Enterobacteriaceae [60]. Breast milk has been reported as a possible source of Group B streptococcus [61] and is a leading cause of neonatal infections in developed countries [62].

Donor Human Milk [DHM]

In the absence of breast milk, formulated milk may be offered to infants, but diversity in gut flora of formula-fed infants and breastfed infants has been noted [63-65]. Therefore, infant formulas may contain components similar to human breast milk, but are not considered perfect substitutes [43]. Diverse human milk- based fortifiers are added to human milk or DHM to meet the nutritional needs of infants. All human milk-based nutritional products available on the market are not created equally due to differences in manufacturing processes, which influence their composition (immunoglobulins, lysozyme, lactoferrin) and, thereby, their efficacy [66-68]. Probiotic bacteria and prebiotics, alone or in combination (synbiotics), are also incorporated into commercial milk formula to mimic the natural prebiotic and probiotic effects present in human milk [69, 70]. Recent research found no significant increase in iron absorption in Thai children after a single serving of probiotics, synbiotics, or an iron-fortified follow-up formula [71].

When mothers' own milk is not available, donor human milk [DHM] has been recommended by organizations such as the WHO, AAP, ESPGHAN as a suitable and practical alternative [11, 72]. A recent investigation in North Carolina on the composition of breast milk from 11 to 17 months postpartum found a significant increase in the concentrations of total protein, lactoferrin, lysozyme, Immunoglobulin A, oligosaccharides, and sodium. In contrast, zinc and calcium concentrations declined, with no alteration in concentrations of lactose, fat, iron and potassium. Results indicated that donor milk collected after 1 year postpartum might not be nutritionally adequate and may require mineral fortification [73].

Microbiology of Donor Human Milk

Mothers should be encouraged to donate breast milk to human milk banks [HMB] to serve infants deprived of their mother's own milk [74] in case of insufficient breast milk secretion from mothers [75] due to illness, severe medical conditions or those undergoing tremendous stress [76], breast milk from several well-established HMB is the practical alternate for supplying breast milk but donor human milk [DHM] can be contaminated during collection, storage, or processing [77, 78]. Jones [79] pointed out that the method of expression of breast milk, environmental, hygienic and storage conditions at home, shipping, processing at HMBs and handling in neonatal intensive care units [NICUs] are the primary sources of pathogenic microorganisms in human milk.

Usually, human milk has a lower [< 3 log cfu/ml] bacterial concentration [31, 56] but microbiological analysis of raw DHM collected in Vietnam, revealed presence of bacteria count at a level of $<10^3$cfu/ml in 15.4% samples, 10^3-$<10^5$cfu/ml in 63.0% samples and $>10^5$cfu/ml in 21.6% samples constituted of *Staphylococcus epidermidis*, *Acinetobacter* sp., gram-positive bacillus, Staphylococcus coagulase-negative and *Staphylococcus aureus* [80]. Recently, microbiological analysis of DHM in the UK [2017-2023] revealed a total viable count of 10^3-10^5 cfu/ml in 70.1% of samples, no growth in 18.3% of samples, and $>10^5$ cfu/ml in 11.5% of samples. Staphylococcus *epidermidis* was found in 61.5% of samples [81].

No globally accepted microbiological standards for expressed milk exist [82]; however, a total bacterial count < 10^6cfu/ml has been reported as the physiological threshold for bacterial load in human milk [83, 84]. The United Kingdom's National Institute for Health and Care Excellence have declared that donor milk with < 1 x 10^5cfu/ml bacterial counts, < 1 x 10^4cfu/ml Enterobacteriaceae or 10^4cfu/ml *S. aureus* is acceptable for further processing [85]. Other investigators considered raw donor milk containing $\geq 10^4$cfu/ml of coagulase-negative Staphylococcus [86] and a bacterial count of ≥ 10^5cfu/ml as indicators of poor quality [87]. Recently, Serra *et al.* [88] considered expressed breast milk to be bacteriologically acceptable if mesophilic aerobic bacteria and total enterobacteria counts are < 10^5cfu/ml and < 10 cfu/ml, respectively. Presence of *Escherichia coli*, enterobacteria, *Staphylococcus aureus*, *Streptococcus faecalis*, Pseudomonas, Salmonella or fungi in expressed milk was considered a contaminant. Contamination of expressed breast milk with Listeria species [89], methicillin-resistant *Staphylococcus aureus* [90], Salmonella species [91] and *Mycobacterium tuberculosis* [92] has been reported. A schematic diagram of the HDM flow is shown in Figure **1**. Various factors may influence the safety of DHM, including donor selection criteria, DHM expression methods, DHM processing, and hygienic conditions during storage and transportation.

Selection Criteria for Breast Milk Donors

Total bacterial counts in human milk are also associated with the type of milk donor. Miura *et al.* [93] reported lower bacterial counts [cfu/ml] in human milk collected from the term group [3,930cfu/ml] in contrast to those from the preterm group [26,700cfu/ml]. Donor women willing to give their milk are carefully screened for HIV-1, HIV-2, human T-cell leukaemia virus 1 and 2, hepatitis B, hepatitis C and syphilis [94]. Breast milk donors are screened based on the following criteria to ensure the safety of donor milk for infants [85].

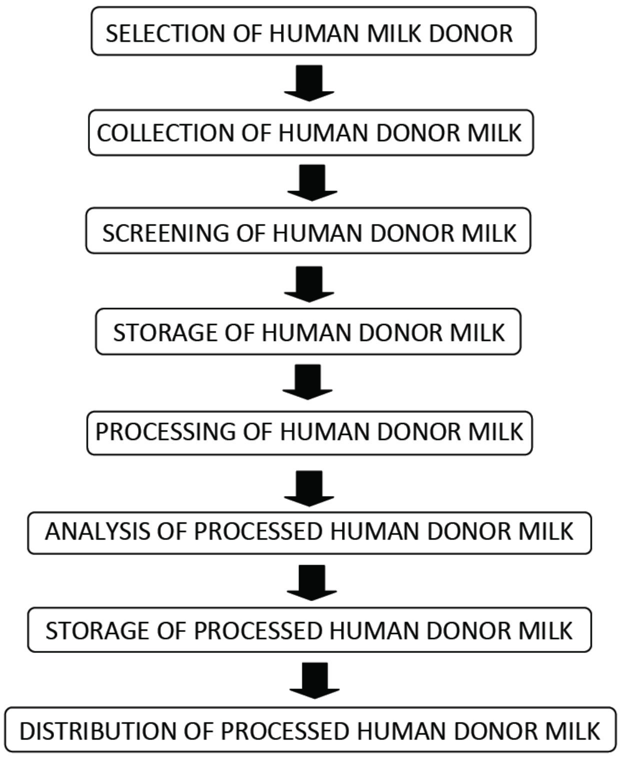

Figure 1: Schematic diagram for flow of Human Milk.

- Must have good general health
- Must undergo the mandatory serological testing [HIV 1 or 2, hepatitis B or C, human T-lymphotropic virus [HTLV] type I or II or syphilis] for reducing the risk of passing on infections
- Should not smoke, be exposed to high or sustained levels of passive smoke or use nicotine replacement therapy
- Should not consume alcohol regularly exceeding recommended alcohol levels forbreastfeeding mothers [1 to 2 units, once or twice a week]
- Should not be using or have recently used recreational drugs
- Should not have previously tested positive results for HIV-1 or -2, hepatitis B or C, HTLV type I or II or syphilis
- Should not be at an increased risk of Creutzfeldt-Jakob disease
- Should not be currently taking any medication or undergoing any other medical therapy
- Should not be exposed to high or sustained levels of environmental or chemical contaminants

Method of Milk Expression

DHM can be obtained from the breast either by employing manual expression or a breast pump. The advantages of hand expression over breast pump expression include lower cost, no equipment required, and greater comfort [95]. Borges *et al.* [96] reported that the quality of human milk expressed at home is as safe as that expressed at a human milk bank, provided hygienic conditions are maintained during conservation, storage, and transportation. Primary sources or factors contributing to bacterial contamination of expressed breast milk [EBM] are collection containers and pumps at NICU [97], and reuse of collection equipment at home [84].

The methods of expression also influence the microbiology of EBM. Breast milk expressed by breast pumps had a significantly higher rate of bacterial contamination by staphylococci and Gram-negative bacilli than milk expressed by the manual method [98]. Milk pumps may contribute higher bacterial concentration [> 6 log cfu/ml], consisting of Gram-negative bacteria such as enterobacteria, Pseudomonas, Stenotrophomonas, etc., and yeasts may be added from rinsing water and/or poor hygienic practices [98 - 105]. Liu *et al.* [106] reported illness in infants [bloody stools] offered with donor breast milk contaminated with *Clostridium perfringens* from a breast milk pump. Reasons for higher bacterial counts and greater risks include ineffective cleaning and decontamination of breast pump systems, inadequate maintenance of collection and storage equipment, and non-compliance with the recommended milk storage conditions [98, 107].

Effective Processing of DHM

AAP [10] announced that unpasteurized donor milk is unsafe and is not recommended for feeding infants due to higher bacterial or viral contamination or possible presence of drugs or other substances like cow milk protein. Pasteurization of human donor milk is necessary to ensure its microbiological safety [108], and diverse temperature-time combinations recommended for processing HDM are shown in Table **2**. Moro *et al.* [111] denoted diverse methods such as Holder pasteurization [62.5°C/30 min], high-temperature short-time pasteurization [72°C/15 sec],

Table 2: Recommended Heat-Treatment for Human Donor Milk

Temperaure-Time Combination	References
72°C/15 sec	[109, 110]
62.58°C/30 min	[94, 109]
62.5°C/30 min	[111]
62.5°C/20 min	[112]
62.5°C/ 5 min	[113]
60ºC/30 min	[86]
57°/30 min	[112]
56.0°C/15 min	[114]
40°C/30 min	[86]

high-pressure treatment [300-800 MPa/< 5-10 min] and ultraviolet-C treatment [200-280 nm] to render donor milk safe for infants.

The effects of the diverse methods used to process DHM to render it microbiologically safe for infants are inconsistent. Holder pasteurization [HP] of DHM resulted in the loss of bioactive compounds, water-soluble vitamins, and immunoglobulins, and lowered the activity of signalling proteins and enzymes [115]. However, human milk oligosaccharides are found resistant to HP and remain unaltered in DHM [116]. Eradicated the beneficial bacterial flora and antimicrobial peptides, thereby reducing the bacteriostatic mechanisms, rendering the milk more prone to post-pasteurization bacterial contamination [111]. Vass *et al.* [117] noted a decline in 14 amino acids and an increase in the other 6 in holder pasteurized DHM.

On the other hand, High-Temperature Short-Time [HTST] pasteurization was better at preserving water-soluble vitamins, lactoferrin, and some cytokines in pasteurized HDM [118]. Picaud and Buffin [119] reported that, despite heat-induced alterations in the bioactive components of breast milk, pasteurized breast milk retains significant bacteriostatic, maturation, and immune-stimulating properties. Pasteurization has been reported to reduce lipolysis and increase proteolysis of lactoferrin and caseins, whereas protein hydrolysis remains unaltered [120].

Other processing methods, such as high-pressure processing, induced less damage to exosomes and their miRNA content [115]. In contrast, ultraviolet-C irradiation reduced the microbial load and inactivated cytomegalovirus, while retaining the bioactive components, fatty acid profile, and levels of immunological proteins in fresh human milk [111].

Pasteurization of human donor milk reduced bacterial counts to 1-9 cfu/ml in 17.9% of samples and ≥10 in 72% of samples, and the commonly reported microorganisms in pasteurized human donor milk were gram-positive bacilli, *Staphylococcus epidermidis,* and *Acinetobacter* sp. [80]. It has been reported that pasteurization failed to eradicate anaerobic, fastidious bacteria such as *C. perfringens, which* are highly heat-resistant and resistant to contamination in breast milk [106]. Under these conditions, commercial sterilisation, also called retort pasteurization, can be employed to preserve donor human milk, in which the milk is heated to 115-145°C for several minutes under pressure. Retort pasteurization is advantageous over holder pasteurization, as the former method can inactivate heat-stable toxins and spores, rendering human milk more microbiologically safe while causing significant losses of bioactive proteins [66, 67]. Adoption of high hydrostatic pressure technique at pressures < 600 MPa without heat-treatment induced better retention of the bioactive components in human milk, including lactoferrin, lysozyme and bile salt simulated lipase [121, 122] and when employed in conjunction with low heat-treatment, inactivated spores [123].

Good Hygienic Practices during Handling of DHM

It has been reported that the method employed for collecting DHM, the probability of milk shortage for feeding their own child due to milk donation, and the likelihood of HIV transmission or quality deviation due to pasteurization and transportation are accountable for lower acceptance of HDM from HMBs [124]. Microbiological quality of raw DHM determines its suitability for further processing, the efficacy of

Table 3: Identified Critical Control Points during Processing of DHM have been Identification

Processing Steps	CCP (Hazard Type)	Critical Limits for CCP	Monitoring Procedure	Corrective Actions
SELECTION OF HUMAN MILK DONOR	CCP 1 (CHEMICAL)	Human milk donors should not be infected (HMBANA, 2015), [94]	Screened for HIV-1, HIV-2, human T-cell leukemia virus 1 and 2, hepatitis B, hepatitis C and syphilis	Not considered as Human Milk Donors
PASTEURIZATION	CCP 2 (BIOLOGICAL)	Aerobic bacteria ≤ 10 CFU/ml (Arslanoglu *et al*., 2023), [127]	Ensuring heating of HDM to 62.5°C/30 min	Discarding Pasteurized Donor Milk and not to be used as HDM

processing treatments, and the adoption of Good Hygiene Practices [GHP]. Finally, this ascertains the competence of processed DHM for infant feeding. Critical Control Points during DHM processing have been identified (Table **3**), and strict monitoring of hygiene and adherence to the critical limits will ensure DHM is safe for infant feeding.

Arslanoglu*et al.* [125] suggested that raw DHM intended for infant feeding should qualify the microbiological standards of ≤10^5cfu/ml total viable microorganisms, ≤10^4cfu/ml, Enterobacteriaceae and ≤10^4cfu/ml *Staphylococcus aureus*, whereas pasteurised DHM should have a total viable microbial count of <10 cfu/ml. GHPs must be implemented at every step of DHM handling to minimize the risk of microbiological contamination and ensure that DHM remains microbiologically safe for infant consumption. Currently, the Human Milk Banking Association of North America [HMBANA] discards thawed pasteurised DHM after 24 h; no abatement in bacterial growth was noted during storage of thawed DHM up to 9 days at 4°C [126]. HMBANA [127] declared that expressed DHM is acceptable for donation up to 3 months when stored in a fridge freezer or up to 6 months in a freezer at −20°C. Standard Operating Procedures outlining guidelines for DHM safety are delineated below.

- Hygienic practices like proper hand washing, donning gowns, masks, gloves, trimming nails, and locking long hair should be maintained
- Gloves should be worn and changed between handling raw and heat-treated milk.
- Staff should undergo regular health checks and be immunized against Hepatitis B
- Regular training of the staff [87]
- Validate, calibrate and maintain all equipment used in donor milk handling and processing as per the manufacturer's instructions:
- Clean and store all donor milk containers and equipment properly
- Pasteurized and unpasteurized donor milk should be stored in separate freezers and refrigerators
- All containers used for keeping donor milk should be made of food-grade material
- All donated milk should be immediately transferred to the freezer
- Donor milk awaiting pasteurization should be stored in the freezer [-20°C] for not more than 3months from the date of expression
- Donor milk should be adequately thawed [allowed maximum temperature rise 8°C] before pasteurization and may be kept in the refrigerator for not more than 24 h
- Pasteurized [62.5°C/30 min] donor milk should be rapidly cooled to ≤ 4°C
- Lid of bottles of pasteurized donor milk should be opened just after use, and the opened bottle [128]
- Container to be frozen should never be filled [125]
- Cold chain should be maintained during transportation of DHM to the HMB to retain its nutritional and microbiological quality [16].

A review of evidence on the impact of WASH (Water, Sanitation and Hygiene) on child health and nutrition indicated that poor WASH contributes significantly to the incidence of diarrhoea and that this can be substantially reduced with effective handwashing, sanitation, and water treatment. Proper WASH and Good Hygienic Practices can reduce the incidence of microbial contamination, thus protecting child health from disease burden arising from poor WASH. However, the effect of WASH on child growth, especially on undernutrition, is unclear [129]. During the collection, storage, and processing of DHM, WASH is a critical factor in ensuring microbiological safety for child health.

Training for Breast Milk Donors

A descriptive cross-sectional study conducted in India revealed that 71.29% of mothers donated human milk, and only 27.08% were regular donors [130]. Encouragement from healthcare professionals, relatives, or friends, gathering information on breast milk expression from the primary health care unit, and receiving help from the unit's professionals to breastfeed were associated with a higher prevalence of donation [131]. Many breastfeeding mothers willingly donate their expressed milk to HMB [132, 133]. Still, donor milk is less acceptable due to a lack of awareness and education regarding the importance of breast milk, coupled with a lack of transparency about the processes involved in sourcing and preparing donor milk [134]. Doshmangir *et al.* [135] suggested the mother’s education during pregnancy and nursing regarding the importance of breastfeeding, reasons for donating milk and the method of donating breast milk to encourage mothers to donate their excess breast milk. Training given to all new donors must cover the following [85].

- Hand washing and the importance of milk donation
- Good personal hygiene practices
- Collecting and expressing milk, including cleaning and using breast pumps and containers
- Storing of donated milk [including cooling and freezing]
- Labelling of donated milk and documenting storage conditions
- Transportation of donated milk

CONCLUSION

Mother’s own milk is the most promising food for infants, but in case of its unavailability, donor human milk is a practical substitute. Microbiological safety of donor milk at Human Milk Banks depends on the appropriate selection of donor mothers, hygienic conditions during collection and handling, and proper processing and storage of donated human milk. Pasteurization is a heat treatment that kills microorganisms, and the extent of microbial reduction (% reduction) is directly related to the initial microbial content of the raw milk. Adequate implementation of WASH during the collection and processing of raw mother’s milk (before processing) is the key factor in determining the final microbiological quality of processed DHM. Mothers should be encouraged to donate their excess breast milk to Human Milk Banks for feeding infants deprived of their own mother’s milk.

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