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Gaps in Microbial Risk Management Guidance for Users of Expressed Breastmilk

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Abstract

Expressed breastmilk (EBM) is used in various use-contexts ranging from home feeding of healthy full term, older infants to neonatal intensive care units (NICUs) administering pasteurized donor EBM to medically fragile premature newborns. In some cases, contaminated EBM has been the source of microbial pathogens that caused infection in vulnerable infants. However, microbial risk management guidance has evolved unevenly across different EBM use-contexts. Recommendations are not often stratified by risk, may be difficult for working parents to implement, or limited in some use-contexts such as peer-to-peer EBM sharing and commercial fee-for-service processing. This review characterizes the various EBM use-contexts and the microbial risk management strategies (e.g., process controls, preventative hygiene and sanitation, microbiological criteria) used to reduce the risk of EBM-mediated infections in infants. We examine microbial safety guidance developed by various organizations and identify gaps in risk stratification, regulatory oversight, and feasibility. In some cases, current guidance is poorly targeted to the infants at greatest risk. While in lower-risk contexts, exacting or inconsistent recommendations can increase caregiver burden without clear clinical benefit. Risk managers and risk communicators should align guidance with infant vulnerability. Guidance on strategies applicable to high-risk settings such as NICUs should be prioritized and the burden in low-risk, parent-managed settings that does not reduce risk should be considered.

Expressed breastmilk use-contexts

Human breastmilk is used across a widening range of clinical, commercial, and parent-managed settings. These expressed breastmilk (EBM) use-contexts differ substantially in recipient infant vulnerability, microbial contamination likelihood, and risk mitigation strategy. Microbial safety guidance has evolved unevenly across these settings, resulting in recommendations that are often not stratified by risk or absent altogether for some use-contexts[1,2].

Healthy full term, older infants receiving their own mother's EBM, a practice common among working parents and during travel, represent a relatively low risk group[1,3]. Premature and medically fragile infants in NICUs receiving unpasteurized mother's own milk, pasteurized donor milk, or human milk-derived fortifiers represent the most vulnerable infants (**Box 1**). There is a spectrum for infant vulnerability, and risk is generally highest among infants who are very young (within the first 2 months of life), born prematurely, or are otherwise immune compromised.

Box 1. Expressed Breast Milk (EBM) Terminology

EBM users: Individuals, organizations, or commercial entities that express, process, distribute, administer, or receive EBM as part of infant feeding. This includes parents and their infants, hospitals, donor milk banks, commercial manufacturers and service providers, and participants in informal milk-sharing networks.

EBM use-contexts: Distinct scenarios in which EBM is expressed, handled, processed, and ultimately consumed by an infant. Each use-context is defined by the infant who consumes the EBM and the processing of the EBM. Examples include parent-managed feeding of healthy term infants, use of mothers' own milk or donor milk in NICUs, pasteurized donor milk banking, commercial human milk–derived products, informal milk sharing, and fee-for-service processing of a parent's own milk.

Parent-Managed EBM: EBM collection with a breast pump, occurring outside the hospital setting, typically at home, work, or while traveling.

Peer-to-Peer Shared EBM: Exchange of unscreened, unprocessed EBM between individuals, which may be facilitated by online platforms (e.g., Only the Breast, Eats on Feets, Human Milk 4 Human Babies) or local social networks, and operating outside institutional oversight.

NICU-Managed EBM (Mother's Own Milk): Use of a mother's EBM for her own infant, particularly in hospital settings for medically fragile infants.

Pasteurized Donor EBM: Non-profit or for-profit milk bank collected, processed, and distributed donated EBM, typically for medically fragile infants in a hospital/NICU setting.

Commercial EBM Processing Services: Fee-for-service processing of a parent's own EBM such as freeze-drying or shipping (e.g., Milkify, Milk Stork), in which the processed EBM is returned to the parent for use by their own infant rather than redistributed.

Commercial EBM–derived Products: Pasteurized EBM and human milk-derived fortifiers (e.g., Prolacta) manufactured and sold by for-profit milk banks for use in NICUs.

Microbial risk management strategies: Practices for reducing the microbial risk associated with EBM: (1) process controls, (2) microbiological criteria, and (3) preventive hygiene and sanitation.

Guidance for microbial risk management strategies:

Recommendations for process controls, microbiological criteria, and hygiene and sanitation practices developed by various institutions (e.g., CDC, ABM, AAP).

The vulnerability of the infant to infection is one factor to consider. A second factor is the likelihood that the EBM could be contaminated. For example, pooled, donor EBM that undergoes a pasteurization step has a lower likelihood of being contaminated with a vegetative pathogen than pooled, donor EBM that is unpasteurized. Other use-contexts include informal peer-to-peer milk sharing and commercial fee-for-service processing of a mother's own EBM, including freeze-drying or shipping services that fall outside milk-banking, manufacturing, or parent-managed EBM. Safety and regulatory oversight differ among these use-contexts (**Figure 1 & 2**). However, it should be noted

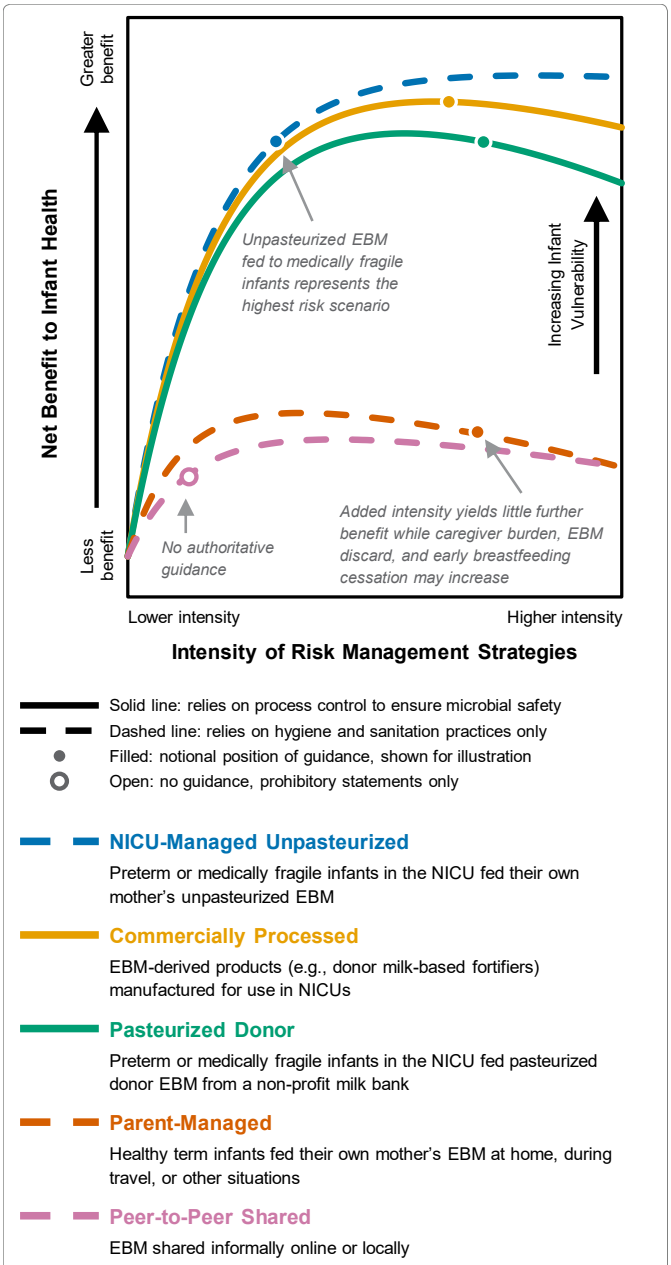

Figure 1. Conceptual relationship between the intensity of risk management strategies and net benefit to infant health in different expressed breastmilk (EBM) use-contexts. Higher curves indicate greater net benefit from risk reduction strategies. Curves show diminishing returns at very high intensity risk reduction strategies. Dashed lines represent EBM use-channels that rely primarily on preventative hygiene and sanitation practices, which are subject to variability in individual human performance. Solid lines represent EBM use-channels where process control help ensure microbial safety.

that the incidence of illness from microbial contamination of EBM is low among all infants receiving EBM[4].

Here, we describe EBM use-contexts that considers both infant vulnerability and methods for expression and storage of EBM. EBM use-contexts represent distinct pathways through which EBM moves from expression to infant feeding. Parent-managed EBM generally follows a short, decentralized pathway from expression to home storage and feeding. NICU-managed own mother's milk still reflects a single mother-infant dyad but the EBM may pass through hospital transport, storage, preparation, and administration systems. Pasteurized donor EBM and commercially processed human milk-derived products follow more institutionalized pathways involving donor screening, pooling, processing, testing, and redistributing to medically vulnerable infants. Peer-to-peer shared EBM follows decentralized exchange pathway, often without screening, testing, or formal oversight[5]. These differences should inform microbial risk management strategies across settings (**Figure 1**).

Microbial risk management strategies for EBM

Microbial risk management strategies vary among EBM use-contexts and can be summarized into three approaches: (1) process controls, (2) microbiological criteria, and (3) preventive hygiene and sanitation.

Process controls are validated interventions, such as holder pasteurization, embedded within documented food safety systems like HACCP (Hazard Analysis Critical Control Points)[6,7]. Pasteurization parameters (time, temperature) are based on pathogen reduction in bovine milk which are described in the FDA's Pasteurized Milk Ordinance. The most common parameters used are referred to as holder pasteurization, in which milk is heated to 62.5°C (145°F) for 30 min then cooled. This process inactivates HIV, cytomegalovirus (CMV), HTLV, hepatitis, and vegetative bacterial pathogens (e.g. Group B *Streptococcus*, among others), but not bacterial spores such as those of *Bacillus cereus*.

Process controls such as holder pasteurization are applied in use-contexts where EBM is pooled and redistributed for high-risk infants, as in non-profit milk banks and the manufacture of EBM-based fortifiers. Process controls are not recommended for individual parent-managed EBM. Holder pasteurization remains the dominant approach in donor milk banking, while alternative processing approaches, such as high-temperature short-time processing and ultra-high temperature systems like retort processing, are used by some commercial manufacturers[8]. While research studies have evaluated alternative non-thermal methods, novel processing techniques are not widely used. Pasteurization requires both equipment and human resources to implement and reduces bioactive components of EBM, including immunoglobulins, enzymes, and antimicrobial proteins[8,9], but these negative tradeoffs are outweighed in many cases by the benefit of enhanced microbial risk reduction. Pasteurization provides greater control of potential vegetative microbial hazards in EBM than does testing or hygiene and sanitation alone. Consequently, process controls are key risk reduction steps for milk banks and companies that manufacture EBM-based fortifiers who serve the highest risk, medically fragile infants.

A second approach to risk management involves testing EBM for microorganisms and comparing results to standard criteria. Microbial testing is widely applied in donor EBM banking and human milk-derived product manufacturing, but its utility is constrained by sampling limitations and its retrospective nature[9]. Application of this approach requires the development of a testing strategy and pre-defined thresholds (i.e., microbiological criteria) against which test results can be compared. Tests can be performed to quantify indicator organisms or to detect the presence of specific pathogens. Indicator testing provides indirect information on microbial quality and hygiene. Notably, pathogen-specific testing is not completely effective at identifying pathogens, even when present, because of low pathogen prevalence and small sample sizes used in testing[10].

Microbiological criteria are typically presented as either presence/absence (e.g., no detectable bacteria on standard plate count) or as quantitative limits (e.g., $<10^4$ CFU/mL total plate count)[11]. These thresholds are used to screen donor milk, and in some cases, to support recommendations for hygiene, sanitation, and storage practices. It is worth noting that other frameworks (such as those used in the FDA Model Food Code), although not utilized in any existing EBM microbiological criteria, define acceptable safe handling conditions which limit pathogen *growth* (not absolute levels) below a defined threshold under different time-temperature scenarios. For example, some storage recommendations are based on time-temperature combinations that prevent *Listeria monocytogenes* growth from exceeding 1 log, and are not specific to the starting level.

Regardless of the metric, overreliance on microbiological criteria as a risk management strategy has several tradeoffs. Testing is expensive. Negative microbial results do not exclude the presence of pathogens. Furthermore, conservative testing thresholds, particularly those for indicator organisms, can result in rejection of donor EBM without clear evidence of increased risk. Microbiological criteria and testing should be used in support of a broader risk management strategy that accounts for the role of subsequent processing steps, to avoid unnecessary EBM discard.

Finally, risk management approaches that emphasize preventive hygiene and sanitation are fundamental across all EBM use-contexts. Preventive sanitation and hygiene addresses cross-contaminaton that could come from the mother, feeding equipment, and the surrounding environment[4]. Strategies include hygienic expression, cleaning and sanitation of equipment, and storage and handling practices. Their effectiveness depends on consistent execution by caregivers, and the consequences of poor execution varies across infant populations. For preterm and medically fragile infants receiving unpasteurized EBM, stringent hygiene practices are the only barrier ensuring microbial safety for this high risk group. For healthy full term, older infants, the relative risk of infection from microbial contamination in EBM is lower[4]. Consequently, the benefit of intensive sanitizing beyond effective cleaning and cold storage is also less. Additionally, in pasteurized EBM, vegetative microbial pathogens are controlled via processing, therefore the EBM handling steps post-pasteurization should receive greater emphasis on hygienic practices (i.e., during prepration of feeds). Direct evidence during EBM collection is limited, and studies often struggle to link specific practices to outcomes[12]. Risk management guidance should consider feasibility, particularly among strategies directed at individual caregivers who are managing EBM for a lower risk infant.

Guidance for microbial risk management strategies and the organizations that develop them

Guidance for microbial risk management in EBM is developed by multiple organizations targeting overlapping EBM users including parents, healthcare providers, milk banks, and commercial manufacturers. Although these recommendations often address similar practices (**Figure 1**), they differ considerably in intensity, implementation burden, and risk stratification[13–15].

Parent-facing guidance in the U.S. for EBM fed to one's own infant is disseminated primarily by the Centers for Disease Control and Prevention (CDC), with additional clinical protocols translated for parent and provider use by the Academy of Breastfeeding Medicine (ABM) and the American Academy of Pediatrics (AAP) [16–18]. These recommendations emphasize hand hygiene, cleaning of breast pump kits, and time-and-temperature limits for refrigerated and frozen EBM storage. However, important differences exist among organizations. For example, ABM's guidance permits storage for 6–8 hours at room temperature and 5–8 days of refrigeration when EBM is expressed under "very clean conditions", whereas CDC recommends more conservative limits of 4 hours at room temperature and 4 days under refrigeration. CDC guidance also stratifies sanitation recommendations according to infant vulnerability, recommending daily sanitization of pump parts for infants under two months, preterm, or immunocompromised infants, while allowing less intensive approaches (washing only) for healthy older infants. This guidance is based on infant risk for *Cronobacter* spp. infection which declines precipitously after 2 months of age for healthy infants[19].

Additional guidance exists for healthcare providers caring for hospitalized and medically fragile infants. Organizations such as ABM, the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), and the National Association of Neonatal Nurses (NANN) recommend additional safeguards specific to inpatient handling of EBM, including labeling systems, traceability protocols, dedicated EBM feed preparation areas, and procedures intended to prevent misadministration[20–22].

Donor milk banking is governed primarily through professional guidelines, including those issued by the Human Milk Banking Association of North America (HMBANA) and the European Milk Bank Association (EMBA)[23]. These frameworks add several risk management layers absent from parent-facing guidance including donor screening, microbiological testing, and pastuerization. However, regulatory oversight differs by organizational structure and is subject to change. In the US, for-profit human milk banks are regulated by the FDA as food under current Good Manufacturing Practices and the Food Safety Modernization Act's Preventive Controls for Human Food Rule (ref 24). The FDA inspects donor milk banks against the applicable requirements of 21 CFR part 117 , although non-profit banks have historically been exempt from FDA food-facility registration because they are considered charitable food establishments ; separately, three states (California, New York, and Maryland) classify EBM as tissue and require milk banks operating there, regardless of profit status, to hold a tissue bank license. Commercial manufacturers of EBM-based products operate under the FDA Preventive Controls for Human Food Rule that incorporate hazard analysis and validated process controls. The HACCP framework for managing processing controls like pasteurization is also recommended by major non-profit milk banking organizations to ensure reproducible application of the treatment Products modified to function as fortifiers may additionally meet the definition of an exempt infant formula and be regulated as such under 21 CFR parts 106 and 107[6,25]. Across these organizations, broad strategies and approaches are similar, but vary considerably in specfics particularly for parent-facing guidance[26].

Gaps in current guidance and associated consequences

Current microbial risk guidance for EBM is often applied broadly across use-contexts despite substantial differences in recipient infant vulnerability. In lower-risk contexts, exacting or impractical recommendations may reduce adherence, increase caregiver burden, and

contribute to unnecessary EBM discard. Carré et al. (2018) reported that 55% of mothers in a French cohort had at least three deviations from recommended practices, including deviations related to breast pump cleaning and decontamination [27]. Some deviations reflected the impracticality of the guidance itself. For example, mothers noted that recommendations to store dried pump parts in an airtight container before the next use were difficult to follow because the pump parts were often not dry before the next pumping session.

Time burden is also a well-documented barrier to breastmilk expression[28,29]. Guidance perceived as unrealistic may therefore reduce confidence in EBM handling, increase mental stress, and contribute to disposal of EBM that does not reduce risk. Inconsistency across major guidance may further reduce comprehension and adherence. Differences between CDC and ABM recommendations for storage duration and cleaning practices provide an example[30]. A study found that only 54% of Australian mothers correctly identified refrigerated storage times for EBM, and participants emphasized the need for concise written instructions and consistency across the guidance they received. These findings suggest that risk management guidance must be scientifically sound as well as feasible, understandable, and appropriately tailored to the intended user.

Donor milk banks appropriately employ multiple risk reduction layers, including donor screening, hygiene protocols, microbiological testing, and pasteurization because their products are often used for medically vulnerable infants. However, infections linked to pasteurized donor milk appear to be rare, and some microbiological testing requirements may impose costs on milk banks, hospitals, and families without clear evidence of proportional clinical benefit. Because donor EBM cost remains a barrier for both hospitals and individuals[31], microbial risk management strategies in this pathway should be evaluated not only for their relative benefit to reducing contamination, but also their relative cost in direct expenses and EBM availability.

At the same time, insufficient or poorly targeted guidance in higher-risk contexts may have serious consequences. Most reported EBM-associated microbial infections occur in very preterm (28 week to < 32 weeks), and very low birthweight infants (<1500 g) in NICUs[4]. In these settings, infants are highly susceptible to infection, and lapses in hygiene during expression, handling, storage, or preparation may facilitate pathogen cross-contamination. Strengthening guidance for these high-risk contexts may improve EBM safety without extending the same level of burden to caregivers of healthy term infants, for whom the potential benefit of intensive sanitation are lower.

Gaps in risk management guidance create additional challenges in several EBM use-contexts. Informal peer-to-peer milk sharing groups are online platforms and local networks facilitate the exchange of unscreened, unprocessed EBM at scale. Yet, major authoring bodies generally provide only cautionary statements discouraging the practice rather than guidance to reduce risk among families who share EBM despite these warnings[32]. The online platforms that facilitate peer-to-peer EBM sharing offer a limited framework for risk reduction. For example, the group *eats on feets* recommends four pillars for safe breastmilk sharing: informed choice, donor screening (in this instance, donor screening means self-exclusion and communication between peers), safe handling, and home pasteurization. These approaches have significant limitations or downsides, but the online platforms themselves are important venues for communicating risk mitigation strategies to this community.

A voluntary professional association is responsible for safety oversight of U.S. non-profit milk banks, rather than a regulatory agency. Commercial fee-for-service processors of a mother's own milk, including those offering freeze-drying or shipping, occupy an undefined regulatory space. The EBM is neither donated nor sold as a product and existing milk banking and manufacturing frameworks do not clearly apply. Commercial human milk–derived products occupy an evolving regulatory environment in which parent and provider-facing guidance has not kept pace with product development.

Together, these gaps and inconsistencies suggest that current EBM guidance could be better stratified among EBM users. Guidance that is difficult to implement, particularly when evidence for clinical benefit is limited, may warrant modification. For example, recommendations to wash breast pump parts after each use can be difficult for working parents to follow, and these constraints have been associated with reduced adherence and earlier cessation of breastfeeding[33,34]. In lower-risk settings, particularly for older healthy infants, the potential benefit of more intensive sanitation practices should therefore be considered alongside caregiver burden, feasibility, EBM discard, and breastfeeding continuation. This contrasts with NICU settings, where most reported cases of infection linked to EBM have occurred linked to unpasteurized EBM or re-contamination of pasteurized donor EBM during feed preparation. In this use-context, the primary barriers to contamination are hygiene and sanitation, and this may justify more stringency specific to this group (**Figure 2**).

Conclusion

EBM use-contexts differ substantially, yet current microbial risk-management guidance is not always stratified to reflect these differences. Future recommendations

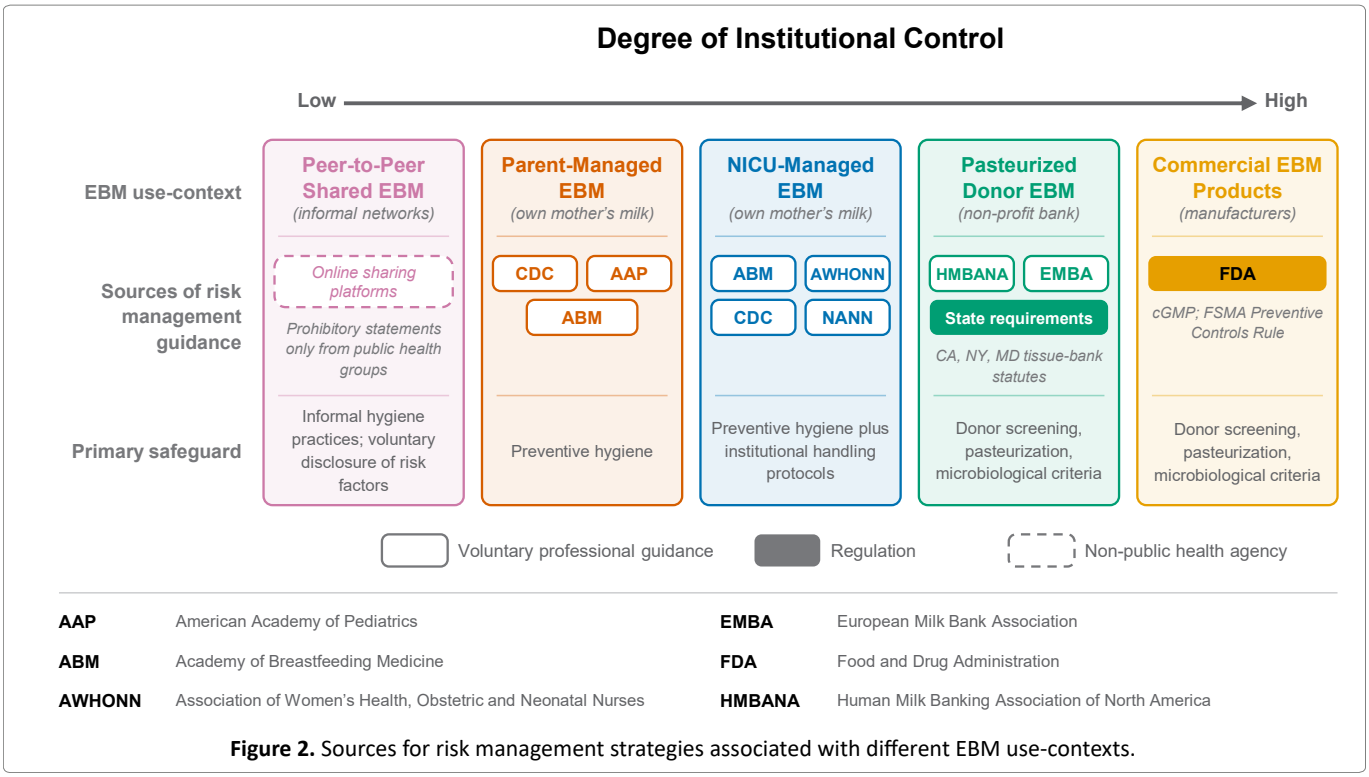

Figure 2. Sources for risk management strategies associated with different EBM use-contexts.

should better align hygiene and handling practices with both the level of microbial risk and the feasibility of implementation. In high-risk settings, particularly NICUs, guidance should prioritize rigorous controls for breast milk expression, feed preparation, and the administration of unpasteurized milk to medically fragile infants. For lower-risk, parent-managed settings, recommendations should promote hygiene while accounting for the practical realities of expressing and handling milk at work and during travel, particularly for healthy, full-term, and older infants. This will require closer collaboration among food safety microbiologists, clinicians, lactation specialists, milk-bank professionals, and caregivers.

Limitations

The literature search and selection process were non-systematic, and the included references were weighted toward guidance and evidence from the United States. Formal quality assessments were not conducted and many of the included publications consisted of guidelines, protocols, descriptive comparisons, and other evidence types that are not readily evaluated using conventional study-quality tools. The conclusions should therefore be interpreted as a synthesis of current recommendations and identified gaps rather than as the findings of a systematic evidence review.

Conflict of Interest

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