

Current trends in research on human milk exchange for infant feeding

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Abstract:

Breastfeeding is critical for the healthy growth and development of infants. A diverse range of infant-feeding methods are used around the world today. Many methods involve feeding infants with expressed human milk obtained through human milk exchange. Human milk exchange includes human milk banking, human milk sharing, and markets in which human milk may be purchased or sold by individuals or commercial entities. In this review, we examine peer-reviewed scholarly literature pertaining to human milk exchange in the social sciences and basic human milk sciences. We also examine current position and policy statements for human milk sharing. Our review highlights areas in need of future research. This review is a valuable resource for healthcare professionals and others who provide evidence-based care to families about infant feeding.

Keywords: human milk | human milk expression | infant-feeding patterns | lactation | milk banking | breastfeeding

Article:

Key Messages

- Breastfeeding is critical for the healthy growth and development of infants, but it is not always possible or desired.
- Human milk exchange provides opportunities for parents to obtain human milk for infant feeding.
- There are relative risks, benefits, and costs of different methods of human milk exchange for infant feeding.
- Social sciences and basic human milk sciences research provide essential evidence for clinical practice and public health education related to human milk exchange.

Breastfeeding is critical for the healthy growth and development of infants (Victora et al., 2016). Global recommendations for infant and young-child feeding are that infants be exclusively breastfed from within an hour of birth to 6 months of age and continue to be breastfed, with the addition of complementary foods, to 2 years of age or beyond (World Health Organization [WHO], 2003). Exclusive breastfeeding in the first 6 months of life provides infants with protection from infectious disease–related morbidity and mortality and confers maternal benefits,

which include reduction of risk for postpartum hemorrhage, invasive breast cancer, cardiovascular disease, ovarian cancer, Type 2 diabetes, and other chronic conditions associated with overweight (Victora et al., 2016). Feeding infants as recommended can be challenging or considered undesirable. In situations where a mother's milk is insufficient or unavailable, WHO and UNICEF recommend the following alternatives: breastfeeding by another healthy lactating woman, expressed human milk obtained through a human milk bank or from another healthy lactating woman, or a breast milk substitute (BMS), such as an infant formula (WHO, 2003). WHO notes that the best alternative depends on the individual circumstances of infants and their caregivers.

Human milk is a substrate containing essential nutrients, immune support, and hormonal signals that are significant to infant health and survival, growth, and development (Hinde & Milligan, 2011; Riskin et al., 2012; Sellen, 2007). The composition of human milk differs from that of other species in the presence and level of many immune factors, including lactoferrin, immunoglobulin A (IgA), and human milk oligosaccharides, with growing evidence that these factors contribute to improved infant health outcomes (Bode, 2012, 2018; Breakey, Hinde, Valeggia, Sinofsky, & Ellison, 2015; Hettinga et al., 2011; Lönnerdal, 2010; Witkowska-Zimny & Kaminska-El-Hassan, 2017). Given the evolutionary and public health significance of breastfeeding and human milk in human development and health throughout the life course, there are relative tradeoffs involved when BMSs are used (Gribble & Hausman, 2012; Sellen, 2007; Sriraman, Evans, Lawrence, & Noble, 2018; WHO, 2003). For these reasons, parents and caregivers increasingly seek human milk options when a parent's own milk is not available or requires supplementation.

The use of expressed human milk for infant feedings, whether through peer-to-peer human milk sharing or commercial markets for human milk and derivative products, is growing globally (Cassidy, Dowling, Mahon, & Dykes, 2018). As a result, healthcare professionals are increasingly called on to provide guidance for informed infant-feeding decisions that involve human milk exchange (HME). The evidence base for HME is important to healthcare professionals who provide infant-feeding support to families. In this review, we examine peer-reviewed literature pertaining specifically to *the exchange of expressed human milk*. Recognizing that a variety of terms are commonly used to describe HME, here we contextualize the exchange of expressed human milk as follows: banked human milk (B-HM), commodified human milk (C-HM), and shared human milk (S-HM). We organize the review by considering trends within the social sciences research on HME, basic human milk sciences and implications for HME, and policies and position statements on HME. The literature reviewed in this article spans roughly the past 30 years. We close with recommendations for future research.

Trends Within Social Sciences Research on Human Milk Exchange

HME has a rich and diverse history in human societies throughout geographic locations and cultures (Hewlett & Winn, 2014; Hrdy, 1992; Konner, 2018). From the commodification of lactating bodies (see Boswell-Penc & Boyer, 2007; Castilho & Barros Filho, 2010; Cowling, Machado, Paton, & West, 2017; Fildes, 1988; Golden, 2001; Harrison, 2018; Jones-Rogers, 2017; Machado, 2017; Sussman, 1982; West & Knight, 2017; Winer, 2017; Wolf, 2001) to the emergence of lactoengineering (Boyer, 2010; Fentiman, 2009; Merlino-Barr & Groh-Wargo,

2019; Swanson, 2009), the methods, scale, and extent to which HME has been integrated into cultural, societal, national, and global institutions and policies vary widely (Cassidy et al., 2018; Palmquist, in press; Shaw & Bartlett, 2010).

In this section, we highlight the following trends in social science research on HME: (a) the growth and challenges of human milk banking (HMB); (b) family knowledge, attitudes, and perceptions about HMB; (c) the promotion and uptake of HME in clinical settings; (d) promoting and sustaining donations to HMB; (e) understanding practices and experiences associated with human milk sharing (HMS); and (f) strategies that families use to navigate the potential risks of HMS.

Growth and Challenges of Human Milk Banking

Human milk banks, which collect expressed human milk and dispense it to preterm, sick, motherless, or abandoned infants, have existed since the early twentieth century (Moro, 2018). Although they have waxed and waned in popularity, the inherent institutional gatekeeping as well as the costs associated with operation have meant that human milk banks have been relatively scarce and not widely accessible (Kent, 2017). Human milk banks are integral to the standard of care for medically fragile preterm neonates (DeMarchis, Israel-Ballard, Mansen, & Engmann, 2017); however, they are not universally available globally, and their presence does not equate with access to B-HM (Boundy, Perrine, Nelson, & Hamner, 2017; Israel-Ballard, 2018; PATH, 2013). Although the supply of B-HM has dramatically increased in the United States in recent years, economic and systemic barriers, such as racism, have been reported in access to B-HM. Not-for-profit models have predominated human milk banks, but there is a growing trend toward the establishment of commercial entities that pay donors for their milk (Boyer, 2010; Fentiman, 2009; Harrison, 2018). Improving the proportion of infants who have access to B-HM remains a global public health priority (WHO, 2014a).

The implementation of evidence-based practice for human milk banks varies widely within and between countries where they are operational (PATH, 2013). Brazil has the world's largest network of human milk banks, with more than 220 that provided B-HM to 170,000 neonates in 2015 (DeMarchis et al., 2017). The success of Brazil's program is attributed, in part, to the integration of human milk bank systems within a national healthcare policy (Arnold, 2006). In contrast, the use of B-HM in U.S. neonatal critical care settings varies by many factors, including geographic region, institutional breastfeeding rates, Baby-Friendly Hospital status, and proximity to a human milk bank (Perrin, 2018; Perrine & Scanlon, 2013). There is still reluctance among healthcare providers in some countries (including the United Kingdom and Ireland) to use B-HM despite having operation guidelines because of perceived limited evidence of benefit and attitudes related to its acceptability (Modi, 2006).

Prioritizing distribution of B-HM can be a challenge during times of constrained supply. A recent study uses an economic model to demonstrate the outcomes in survival and cost-effectiveness of using different prioritization strategies, which may assist in policy development (Taylor, Joolay, Buckle, & Lilford, 2018). It is important to note, however, that B-HM use and supply are often not monitored in infant-feeding surveillance systems, which suggests a systematic lack of prioritization of B-HM as an important feeding resource.

A content analysis of charitable-giving literature has yielded a proposed framework to support promotion of donations to human milk banks that expand and sustain supply (Stevens & Keim, 2015). Ward et al. (2012) used a quality improvement framework to increase the proportion of very small-for-gestational-age (SGA) infants who receive pasteurized B-HM in the first 14 days of life. More recently, Brandstetter et al. (2018) put forth a decision tree to assist healthcare providers in balancing limited supply of B-HM, prioritization, and supporting continued breastfeeding and provision of parents' own milk.

Family Knowledge, Attitudes, and Perceptions About Human Milk Banking

Despite support by WHO, HMB is not readily accepted everywhere. A 2014 survey of attitudes to HMB among Turkish women revealed that a majority of the 350 respondents had never heard of HMB, and that religious concerns and social stigma were potential barriers to accessing B-HM (Gürol, Ozkan, & Celebioğlu, 2014). A more recent survey of 240 Turkish women found that although cross-nursing and HMS were considered normative and that 63% had heard of HMB, only 23% considered HMB culturally acceptable (Ergin & Uzun, 2018). Mothers in India reported being willing to both donate milk and accept B-HM, but many expressed concerns about donating milk due to concerns about adequate milk supply or that milk expression may weaken their health (Mondkar et al., 2018). Mothers of infants in India who received B-HM cited several concerns, including access to B-HM post discharge, religious concerns, fathers' and grandmothers' attitudes, and general social stigma (Mondkar et al., 2018). In Nigeria, a survey of 1,235 mothers revealed low awareness of HMB, but high willingness to use B-HM or donate milk, conditional on spousal acceptance (Iloh et al., 2018). A higher awareness of HMB was associated with younger mothers with higher occupational status, whereas non-Christian mothers with lower occupational status were more likely to report requesting payment for donating their milk (Iloh et al., 2018). These emerging studies are significant contributions to a greater understanding of HMB in diverse sociocultural settings.

Islamic milk kinship is an ancient belief and practice that still has cultural currency among Muslim families worldwide (Clarke, 2007; El-Khuffash & Unger, 2012; Ozdemir et al., 2015). According to traditional Islamic belief, kinship ties are created when an infant receives milk from someone other than their own mother (AlHreashy, 2018; Thorley, 2014). Milk kinships are often formed deliberately to forge socially constructed kinship ties to biologically unrelated families (Saari & Mohd Yusof, 2015). Studies have found that sharing breastfeeding or expressed human milk is more culturally acceptable than HMB in the context of milk kinship for several reasons. These reasons include that many banks pool milk from multiple donors prior to pasteurization and dispensing; the anonymity of pooled milk and the lack of information regarding contributions from a single donor introduce a moral and ethical dilemma for parents of babies who might be fed B-HM (al-Naqeeb, Azab, Eliwa, & Mohammed, 2000; Ghaly, 2012; Shah, 1994; Thorley, 2014). Direct HME with a known donor or donors facilitates documentation of the origin of human milk and the relationships created by its consumption (AlHreashy, 2018; El-Khuffash & Unger, 2012; Gribble, 2014a; Hsu et al., 2012; Ozdemir et al., 2015; Thorley, 2012). In the United Kingdom, the HMB community has worked with the Muslim Council of Britain (MCB) to offer advice to healthcare providers, families, and religious leaders (Williams et al., 2016).

Promotion and Uptake of Human Milk Exchange in Clinical Settings

Healthcare providers' knowledge, attitudes, and perceptions of HME in hospital settings have been the focus of several important studies in recent years. Ethnographic research in the United States illustrates how the concept of "safety" of B-HM is culturally constructed and negotiated in the language and institutional culture of neonatal intensive care units (NICUs) (Carroll, 2014). Bacteria are often leveraged to construct particular conceptualizations of the relative risks or benefits of B-HM, as illustrated in a recent critical review of HME in Spain (Romero-Bachiller & Santoro, 2018) and in an ethnographic study of B-HM in South Africa (Waltz & Ross, 2016). Healthcare providers may work in a NICU that promotes B-HM, even while reporting significant gaps in their knowledge of the science behind the recommendations (Carroll & Herrmann, 2012). Conversely, HMB implementation may be strongly supported by healthcare providers, but other barriers to promoting them may exist within some institutions. For example, a study in India found that staffing shortages were a barrier to documenting parents' informed consent for B-HM, and there were other challenges, including inadequate supply of human milk donations, a shortage of trained staff to collect milk, and high volumes of wasted milk due to unhygienic conditions (Mondkar et al., 2018).

Cross-cultural research on HMB indicates that counseling families on the use of B-HM should attend to diverse historical, political, economic, sociocultural, and historical concerns. Social issues, such as racism, poverty, and implicit bias, have been identified as barriers to equitable uptake of B-HM in the United States (Boundy et al., 2017; Brownell, Lussier, Bielecki, et al., 2014; Brownell, Lussier, Hagadorn, et al., 2014; Parker et al., 2013; Profit et al., 2017; Riley et al., 2016; Sigurdson, Morton, Mitchell, & Profit, 2018). An emerging body of research describes the relationship between historical trauma, slavery, and forced wet-nursing among black/African-American mothers, which not only negatively affect attitudes, perceptions, and initiation of breastfeeding within this population but also may influence parents' attitudes about accepting B-HM for infants in the NICU (Asiodu & Flaskerud, 2011; Collins, David, Handler, Wall, & Andes, 2004; DeVane-Johnson, Giscombe, Ii, Fogel, & Thoyre, 2018; DeVane-Johnson, Woods-Giscombe, Thoyre, Fogel, & Williams, 2017; LoVerde, Falck, Donohue, & Hussey-Gardener, 2018; Riley et al., 2016; Street & Lewallen, 2013).

The proportion of infants who receive pasteurized B-HM globally may increase throughout time as healthcare providers become more knowledgeable about evidence-based recommendations, and as the barriers to parents receiving information about B-HM are removed. Family-centered strategies in which a healthcare provider facilitates a culturally sensitive informed consent process between a recipient family and donor family, while also fulfilling institutional requirements for medical screening of donors, hold promise for ensuring that pooling and pasteurizing donor human milk do not present insurmountable barriers to Muslim preterm babies receiving life-saving B-HM (al-Naqeeb et al., 2000; Hsu et al., 2012). The integration of cultural humility, breastfeeding peer-counseling support, and psychosocial support has also been shown to have positive influences on both breastfeeding decisions and mothers' acceptance of B-HM for preterm infants in black/African-American communities in the United States (Asiodu, Waters, Dailey, & Lyndon, 2016; Johnson, Kirk, Rosenblum, & Muzik, 2015; Kozhimannil,

Attanasio, Hardeman, & O'Brien, 2013; Meier, Engstrom, Mingoelli, Miracle, & Kiesling, 2004; Miracle, Meier, & Bennett, 2004).

There have been recent case studies and reports of emergent shifts in healthcare providers' considerations related to use of unpasteurized S-HM in clinical settings. One report from the United States describes two cases in which infants who had complex conditions were not eligible to receive B-HM in the hospital and were being fed with S-HM obtained through peer-to-peer milk-sharing networks (Barbas, Sussman-Karten, Kamin, & Huh, 2017). The authors of the case report note that barriers in access to B-HM in hospital settings often lead parents to bring in S-HM without disclosing it to healthcare providers. This observation is consistent with research that describes how institutional and sociocultural barriers to using B-HM, including stigma and lack of support, lead families to avoid disclosing their milk-sharing practices (Martino & Spatz, 2014; Tomori, Palmquist, & Dowling, 2016). Increased recognition of healthcare providers' ethical responsibility to discuss the relative risks of all infant-feeding alternatives as well as safer HMS practices (see Gribble, 2012) has led some hospitals to develop a legal waiver, which facilitates greater transparency between hospital staff and patients about the use of S-HM within their institution (e.g., Spatz, 2016).

A small qualitative study illustrates the downfalls of attempting to implement a dramatic change in protocols for infant feeding in the NICU without providing a strong evidence base for those changes (Miller, Fenstermacher, & Buchko, 2018). In this case study, sterilized human milk was being implemented in place of pasteurized B-HM in a NICU, and nurses were challenged by the lack of available evidence to support its use. In contrast, Sen et al. (2017) describe increased uptake of Holder-pasteurized (i.e., heated to 62.5 °C for 30 minutes) B-HM for healthy infants in their hospital. A few studies touch on the relationship between partial supplementation with B-HM and parents' own lactation outcomes (Arslanoglu et al., 2013; Cassar-Uhl & Liberatos, 2018; Kair, Flaherman, Newby, & Colaizy, 2015; Kantorowska et al., 2016; Palmquist & Doehler, 2014; Parker, Burnham, Mao, Philipp, & Merewood, 2015) and tensions that may arise in supplementation with B-HM concomitantly with supporting lactation (Esquerra-Zwiers et al., 2016).

A recent report presents several case studies of using pasteurized B-HM for feeding orphaned or abandoned term infants in South Africa, many of whom were at risk for or had acquired HIV perinatally (Reimers, Shenker, Weaver, & Coutsooudis, 2018). This report adds important insights to the literature on the clinical outcomes of feeding term infants with B-HM. As HMB expands globally, new research that investigates structural and institutional barriers to donor human milk in international settings will provide an opportunity to conduct more robust comparative sociocultural analyses.

Promoting and Sustaining Donations to Human Milk Banks

Several studies have explored the experiences and motivations of HMB donors. In a small study of U.S. donors who had infants in the NICU, becoming a donor was a way of providing hope to other babies and families and was often facilitated by nurses (Candelaria, Spatz, & Giordano, 2018). HMB donors in France, the United States, and Brazil reported being motivated by the desire to help others, and having excess milk (Alencar & Seidl, 2009; Azema & Callahan,

2003; Osbaldiston & Mingle, 2007). Brazilian donors were motivated by the encouragement of healthcare providers and knowing the importance of B-HM for infants (Pimenteira Thomaz et al., 2008). Hospitals are an important referral for donors in Guatemala, where all NICU mothers are asked to donate milk and approximately 70% do (Paynter & Celis-Hecht Mendoza, 2018). A study of donors in Spain reported that higher milk volumes were donated by women who had a SGA child, started donating at an earlier stage of lactation, and were a prior donor (Sierra-Colomina et al., 2014). Some mothers come to HMB donation on the death of their infant, and one study provides guidance for healthcare workers in hospital settings to support human milk donation in the context of bereavement (Carroll et al., 2014). Studies that have explored perceptions of HMB among individuals who have shared their milk with a peer shed light on the complexity of factors that weigh into decisions about what to do with a surplus of human milk (Gribble, 2013; Perrin et al., 2016).

Understanding Practices and Experiences Associated With Human Milk Sharing

HMS, also often referred to as *peer-to-peer*, *informal*, *casual*, and *private-arrangement milk sharing* (PAMS), is another method of HME that has increased during the past decade (Akre, Gribble, & Minchin, 2011; O'Sullivan, Geraghty, & Rasmussen, 2018). In HMS, individuals are responsible for negotiating the specific terms of the exchange, and S-HM is exchanged without payment, although nonmonetary forms of remuneration for donors' time and efforts are sometimes provided (Palmquist & Doehler, 2015). HMS is commonly facilitated by Internet-based social-networking platforms, but it is also widely facilitated offline via interpersonal relationships among family members, friends, and members of local communities. Although there are no population-based studies that estimate the prevalence of HMS for infant feeding, two recent surveys from the United States indicate that awareness and participation in the practice are growing (Keim et al., 2014; O'Sullivan et al., 2018), and a 2018 study of mothers with self-reported low milk supply found that nearly one third of respondents had used S-HM, not B-HM (Cassar-Uhl & Liberatos, 2018).

A majority of studies of HMS have been conducted in populations of Western, educated, industrialized, rich, and democratic (WEIRD) societies (Henrich, Heine, & Norenzayan, 2010). Several new studies of the knowledge, attitudes, and perceptions of B-HM in non-WEIRD societies, however, touch on attitudes about S-HM as well (Clarke, 2007; Ergin & Uzun, 2018; Mondkar et al., 2018). In WEIRD societies where HMS has been studied, mothers rely heavily on expressing milk to feed their own infants (Boswell-Penc & Boyer, 2007; Boyer, 2010; Johns, Amir, McLachlan, & Forster, 2016; Labiner-Wolfe & Fein, 2013; Ryan, Team, & Alexander, 2013). Milk-sharing donors are typically mothers who were breastfeeding and/or expressing milk for their own infants, resulting in a surplus they were able to share (Gribble, 2014b; Palmquist & Doehler, 2014; Perrin et al., 2016; Reyes-Foster & Carter, 2018; Reyes-Foster, Carter, & Hinojosa, 2015; Thorley, 2012). S-HM donors in the United States (Palmquist & Doehler, 2014; Perrin et al., 2016; Reyes-Foster et al., 2015) are demographically similar to Human Milk Banking Association of North America (HMBANA) milk donors in the United States (Osbaldiston & Mingle, 2007).

Unresolved breastfeeding challenges and lactation insufficiency are common threads among all recent studies of HMS in WEIRD societies (Cassar-Uhl & Liberatos, 2018; Gribble,

2014a; McCloskey & Karandikar, 2019; O'Sullivan et al., 2018; Palmquist & Doehler, 2014, 2015; Perrin et al. 2014; Reyes-Foster et al., 2015; Tomori et al., 2016). One cross-sectional study based on self-reported survey data of parents who used S-HM to feed their infants found that rates of preterm birth; C-section births; lower levels of spousal/partner, family, and employer support for breastfeeding; and lower levels of pediatrician support for breastfeeding were significantly higher among parents seeking milk than those who were sharing their milk (Palmquist & Doehler, 2014). Parents whose infants have experienced extreme difficulty gaining weight or tolerating infant formula feedings may also be drawn to HMS in the absence of other alternatives, such as being able to access or afford B-HM (Cassar-Uhl & Liberatos, 2018; Gribble, 2014a; McCloskey & Karandikar, 2019; O'Sullivan et al., 2018; Palmquist & Doehler, 2015). Mothers seeking S-HM for their infants may rely on one or two long-term donors or several different donors (Gribble, 2014a; Palmquist & Doehler, 2014; Reyes-Foster et al., 2015; Thorley, 2012).

Others who report seeking S-HM include nongestational parents and caregivers (i.e., adoptive parents, foster parents, parents by surrogacy, and grandparents), parents of chronically ill infants and older children, parents of babies born through surrogacy, and LGBTQ+ parents (Gribble, 2014a, 2014b; MacDonald et al., 2016; Zizzo, 2009). Lactation insufficiency may be the most common factor associated with HMS (Cassar-Uhl & Liberatos, 2018). Mothers, however, report sharing expressed milk and cross-nursing as part of shared childcare arrangements with other family members or friends, which may have nothing to do with low milk supply or lactation difficulties, and more to do with the value and meaning of interpersonal relationships and convenience (Gribble, 2018; McCloskey & Karandikar, 2019; Thorley, 2008; Tomori et al., 2016).

Parents who give and receive S-HM may be exceptional in the ways that they value breastfeeding and human milk, and in the ways that they view formula feeding as detrimental to infants' health (Carter, Reyes-Foster, & Carter, 2018; Cassar-Uhl & Liberatos, 2018; Gribble, 2014a; McCloskey & Karandikar, 2019; O'Sullivan, Geraghty, & Rasmussen, 2016; Perrin et al., 2016; Tomori et al., 2016). Milk-sharing donors often choose to give their milk directly to a recipient family rather than a human milk bank for philosophical or logistical reasons, or because they did not meet the eligibility criteria of some human milk banks (Cassidy, 2012b; Gribble, 2013; Perrin et al., 2016). HMS is not, however, mutually exclusive with donating milk to a human milk bank (see Palmquist & Doehler, 2015). A study in which in-depth interviews were conducted with milk-sharing donors in the United States found that many individuals were not aware that giving milk to a human milk bank was an option because they did not receive information about milk bank donation from their healthcare providers (Perrin et al., 2016). Similar gaps in awareness about donations to human milk banks have been reported in India (Mondkar et al., 2018), Turkey (Ergin & Uzun, 2018; Gürol et al., 2014), and Nigeria (Iloh et al., 2018).

The practice of anonymously purchasing human milk with no context about the recipient infant (see Geraghty et al., 2015; Keim et al., 2013, 2015) has not been described in the social sciences literature of HMS for infant feeding (Reyes-Foster & Carter, 2018). In fact, many online HMS networks actively monitor their sites for commercial activities, prohibit private purchase and sale of human milk within their communities, and operate on social media platforms with registered

users to avoid anonymous exchange (Cassidy, 2012a; Gribble & Hausman, 2012; Reyes-Foster & Carter, 2018). Although individuals who exchange S-HM may be initially unknown to one another, it appears common for meaningful relationships to develop, enhancing trust (Carter et al., 2018; Gribble, 2018; McCloskey & Karandikar, 2019; O’Sullivan et al., 2016; Reyes-Foster et al., 2015; Tomori et al., 2016).

Strategies That Families Use to Navigate the Potential Risks of Human Milk Sharing

Social scientists have been interested in the ways that parents conceptualize the risks and benefits of HMS as well as the strategies they use to mitigate potential risks. Studies indicate that parents typically weigh the potential risks of S-HM against the risks of feeding their infant with formula (Carter et al., 2018) and may actually cite a belief that S-HM is safer than infant formula in their decision to use milk acquired from a peer (Cassar-Uhl & Liberatos, 2018). Parents’ risk mitigation practices are highly contextual and reflect the nature of their relationship with a prospective donor or recipient family (Carter et al., 2018; Gribble, 2014c; O’Sullivan et al., 2018; Palmquist & Doehler, 2015; Reyes-Foster et al., 2015). Milk-sharing recipients report receiving milk primarily via face-to-face deliveries from individuals they have screened, or less commonly through shipments from people they know or have screened; both parents giving and receiving S-HM use screening practices. In-person exchanges ostensibly mitigate the risks of anonymous sharing (Gribble, 2014c; McCloskey & Karandikar, 2018, 2019; O’Sullivan et al., 2016; Palmquist & Doehler, 2015; Reyes-Foster & Carter, 2018; Reyes-Foster et al., 2015; Reyes-Foster, Carter, & Hinojosa, 2017).

The extent to which healthcare providers are consulted about HMS activities varies (McCloskey & Karandikar, 2019; O’Sullivan et al., 2016; Tomori et al., 2016). Several studies found that HMS decisions are made by triangulation of numerous sources of information that does not come from healthcare providers. Notably, only 16.7% of users of S-HM in the United States cited “pediatrician suggested” as a major contributor to their supplementation choice, whereas individuals not participating in milk sharing more frequently relied on pediatrician advice (48.3%, $p < .001$) as an important factor in making supplementation choices (Cassar-Uhl & Liberatos, 2018). These findings point to variations in the degree to which HMS is considered a practice that requires medical surveillance and oversight.

Parents who are unfamiliar with HMB or HMS have expressed concern about the safety of both practices prior to receiving education or counseling about the relative risks and benefits (Ergin & Uzun, 2018; Esquerra-Zwiers et al., 2016; Pal, Soontarapornchai, Noble, & Hand, 2019; Rabinowitz, Kair, Sipsma, Phillipi, & Larson, 2018). Social stigma and proscriptions that prevent healthcare providers from providing information about HMS may have unintended consequences, including exacerbating mothers’ experiences with stress associated with lactation difficulties and parents circumventing disclosure of using S-HM (Barbas et al., 2017; Schafer, Ashida, & Palmquist, 2018; Spatz, 2016; Tomori et al., 2016).

Basic Human Milk Science and Implications for Human Milk Exchange

Basic laboratory studies of human milk composition and bioactivity, as well as clinical studies of maternal-to-child transmission of disease (MTCT), provide insights into HME. In this section of

the review, we consider the current state of human milk science and trends in research related to (a) potentially harmful microbes and other substances in expressed human milk; (b) characteristics of B-HM; (c) characteristics of C-HM; and (d) characteristics of S-HM, including HME that is facilitated by healthcare providers.

Potential Pathogenicity of Expressed Human Milk

Viruses. The literature regarding viruses in human milk ranges from reports that have documented vertical transmission (i.e., MTCT through breastfeeding); to evidence of viruses passing into the milk of an infected individual, with or without evidence of MTCT; and to case reports of infants (typically preterm infants) acquiring infection through their mothers' own expressed milk. Those viruses for which MTCT through expressed human milk has been confirmed include the human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV) I and II (Ando et al., 2004; Biggar et al., 2006; Li et al., 2004; Moriuchi, Masuzaki, Doi, & Katamine, 2013; Rigourd, Meyer, Kieffer, Aubry, & Magny, 2011), cytomegalovirus (CMV) (Bardanzellu, Fanos, & Reali, 2018; Capretti et al., 2009; Chiavarini et al., 2011; Dworsky, Yow, Stagno, Pass, & Alford, 1983; Josephson et al., 2014; Lanzieri, Dollard, Josephson, Schmid, & Bialek, 2013; Maschmann et al., 2006; Novakova et al., 2014; Picaud et al., 2018; Ross, Shimamura, & Boppana, 2012), and brucellosis (Al-Eissa, 2012; Arroyo Carrera, López Rodríguez, Sapiña, López Lafuente, & Sacristán, 2006; Ceylan, Köstü, Tuncer, Peker, & Kırımı, 2012). WHO provides guidance on maternal infections that may be contraindicated while breastfeeding, as well as guidance regarding minimizing or eliminating the transmission of viral infections (WHO, 2003, 2009, 2015a, 2015b).

Pathogenic bacteria. Human milk, once considered sterile, is now understood to contain a complex microbiome featuring innate commensal bacteria, viruses, archaea, fungi, and protozoa (Jiménez et al., 2015), with considerable diversity in bacterial phylotypes among lactating individuals (Fernández et al., 2013; Hunt et al., 2011). There is growing evidence of a relationship between the human milk microbiome, human milk oligosaccharides (HMOs), and the development of the infant gut microbiome, indicating a critical role for the innate bacteria in human milk in normal neonatal immunological development and passive immunity (Cabrera-Rubio et al., 2018; Gregory et al., 2016; Pannaraj et al., 2017). *Staphylococcus aureus* has been reported to dominate the milk of women with acute mastitis compared to healthy controls (Jiménez et al., 2015), but no clear link among mastitis, breastfeeding, and adverse infant outcomes has been established.

Beyond the innate commensal microflora found in human milk, exogenous bacteria may be introduced during collection and proliferate to levels that may be unsafe for consumption when not stored according to recommended guidelines (Academy of Breastfeeding Medicine [ABM], 2010). There are case reports of bacterial infections in infants resulting from the consumption of expressed human milk, which may have been contaminated during collection and handling, or due to high bacterial loads associated with mastitis (Table 1). It is important to note that most of these reports involved mothers' own milk given to preterm infants, who are at greater risk for infection due to an underdeveloped immune system (Dutta et al., 2015; Kumar et al., 2017).

Table 1. Adverse Outcomes Related to Bacteria Transmitted Through Expressed Human Milk.

Year	Setting	Infant Characteristics	Type(s) of Milk	Pathogen	Source	Outcomes	Reference
1986	Special care nursery	n/a	Maternal and donor	<i>Serratia marcescens</i>	Improperly disinfected breast pumps in hospital	30 infants colonized, 0 deaths	(Gransden, Webster, French, & Phillips, 1986)
1989	Hospital	Preterm ($n = 98$) during first 2 weeks of life	Maternal and donor	Coagulase-negative (CoN) staphylococci; <i>Staphylococcus aureus</i> ; gram-negative bacilli	Maternal and donor milk	100% of infants exposed to CoN staph; 64% exposed to gram-negative bacilli; 41% exposed to <i>S. aureus</i> . No adverse events attributed to ingestion of bacteria from milk.	(Law, Urias, Lertzman, Robson, & Romance, 1989)
2000	Hospital	Triplets born at 26 weeks of gestation	Maternal	Group B streptococcus	Maternal milk	Infants treated and recovered	(Olver, Bond, Boswell, & Watkin, 2000)
2003	Hospital	1 term; 3 preterm	Maternal	Group B streptococcus	Maternal milk (with and without apparent mastitis)	1 death	(Kotiw et al., 2003)
2003	NICU	31 NICU infants (various gestational stages)	Donor	<i>Pseudomonas aeruginosa</i>	Hospital equipment used to thaw and warm bottles	31 infants exposed, 14 infected, and 4 deaths (all very low birth weight)	(Gras-Le Guen et al., 2003)
2004	NICU	Triplets born at 26 weeks of gestation	Maternal	Methicillin-resistant <i>Staphylococcus aureus</i>	Maternal milk	2 infants exposed, 2 infants infected	(Behari, Englund, Alcasid, Garcia-Houchins, & Weber, 2004)
2005	NICU	Preterm infants ≤ 30 weeks of gestation ($n = 3$)	Maternal	Group B streptococcus; <i>Klebsiella pneumoniae</i>	Maternal milk	3 infants developed sepsis	(Godambe, Shah, & Shah, 2005)
2005	NICU	Quadruplets born at 29 weeks of gestation	Maternal	Methicillin-resistant <i>Staphylococcus aureus</i>	Maternal milk	4 infants exposed, 1 infant died	(Gastelum, Dassey, Mascola, & Yasuda, 2005)
2006	Special care nursery	Preterm infant at 31 weeks of gestation	Maternal	Group B streptococcus; methicillin-resistant <i>Staphylococcus aureus</i>	Maternal milk	Recurrent bacteremia	(Byrne, Miller, & Justus, 2006)
2007	Hospital	Healthy term infant	Maternal	Group B streptococcus	Maternal milk	Meningitis and recurrent sepsis	(Wang, Chen, Liu, & Wang, 2007)
2010	Hospital	Preterm ($n = 3$)	Maternal	<i>Klebsiella pneumoniae</i> ; <i>Escherichia coli</i>	Maternal milk	3 infections, 1 death	(Widger, O'Connell, & Stack, 2010)
2011	NICU	< 30 weeks of gestation ($n = 209$)	Maternal	Variety	Maternal milk	Cultures in milk were not predictive of infection in infants	(Schanler et al., 2011)
2012	NICU	n/a	Maternal	<i>Klebsiella pneumoniae</i>	Maternal milk	58 infants colonized, 1 infected	(Rettedal et al., 2012)

Year	Setting	Infant Characteristics	Type(s) of Milk	Pathogen	Source	Outcomes	Reference
2013	NICU	Very low birth weight (<i>n</i> = 2)	Donor	<i>Bacillus cereus</i>	Gastric feeding tube residuals (after 4 hours of incubation)	Infection	(Decousser et al., 2013)
2013	NICU	≤ 28 weeks of gestation (<i>n</i> = 2)	Maternal	Group B streptococcus	Maternal milk	Sepsis	(Davanzo et al., 2013)
2014	NICU	32 weeks of gestation	Maternal	<i>Staphylococcus aureus</i>	Maternal milk (without apparent mastitis)	Sepsis	(Kayıran, Can, Kayıran, Ergonul, & Gürakan, 2014)
2016	NICU	Preterm infants (<i>n</i> = 5)	Shared (healthcare provider facilitated)	<i>Escherichia coli</i>	Shared raw breast milk from Mom A	5 infants colonized in respiratory tract; clinical course not affected by colonization	(Nakamura et al., 2016)
2016	Home	Healthy term (26 to 65 days old)	Maternal	<i>Staphylococcus aureus</i>	Maternal milk (without apparent mastitis)	Diarrhea	(Chen et al., 2016)
2017	NICU	29 weeks of gestation (<i>n</i> = 1)	Maternal and donor	<i>Cronobacter sakazakii</i>	Maternal breast pump	Spastic cerebral palsy	(Bowen, Wiesenfeld, & Kloesz, 2017)
2018	NICU	27 weeks of gestation (<i>n</i> = 1)	Maternal	<i>Cronobacter sakazakii</i>	Maternal milk attributed to home breast pump	Infant death	(McMullan et al., 2018)
2018	Hospital	Term infant	Maternal	Group B streptococcus	Maternal milk (without apparent mastitis)	Meningitis and recurrent bacteremia	(Ueda et al., 2018)

Note: NICU = Neonatal intensive care unit.

A U.S. population-based survey of breastfeeding mothers who also expressed their milk at home found that almost all engaged in recommended practices for milk expression and storage (Labiner-Wolfe & Fein, 2013). Although there is a risk of bacterial contamination of milk due to storage and handling practices, human milk contains bioactive factors that inhibit bacterial growth during storage (Marín et al., 2009; Sosa & Barness, 1987). Studies conducted in NICU settings have found no relationship between bacteria levels in mothers' own milk or presence of common pathogens and adverse preterm infant outcomes (Law, Urias, Lertzman, Robson, & Romance, 1989; Schanler et al., 2011); therefore, screening and pasteurizing this milk is not a typical NICU practice. Until recently, neonatal units in France routinely pasteurized mothers' own milk; however, a 2018 review recommended pasteurization only after cultures indicate the presence of pathogenic bacteria, due to evidence of improved growth rates in preterm infants receiving raw mothers' milk (Masson et al., 2018; Montjoux-Régis et al., 2011; Picaud et al., 2018). Nonetheless, a recent report from the CDC's *Mortality and Morbidity Weekly Report* traced a *Cronobacter sakazakii* infection in a preterm infant to a breast pump and home sink, indicating that infections from poor hygiene are possible and underscoring the importance of proper hygiene for milk expression (Bowen, Wiesenfeld, & Kloesz, 2017).

Exposure to medications and other substances. The accumulation of medications and other substances in human milk, and their potential to affect infant health, is influenced by frequency of use, molecular weight, dosage, half-life, the volume of milk consumed by the infant, and the age of the child (Hale, 2019). Only those bioactive chemical constituents of prescription and recreational drugs that are able to pass into the mammary gland may be transmitted through human milk. For these reasons, few drugs pose a clinically significant risk to infants during breastfeeding or through HME.

WHO identifies the following drugs as possible contraindications to breastfeeding or providing expressed milk: sedating psychotherapeutic drugs, opioids, anti-epileptic drugs, radioactive iodine-131, excessive use of topical iodine or iodophors, and cytotoxic chemotherapy (WHO, 2009). It is important to note that opioid medications are commonly prescribed during labor and after birth, and in this circumstance, breastfeeding and providing expressed human milk are not contraindicated (Martin, Vickers, Landau, & Reece-Stremtan, 2018). Opioid antagonist medications (i.e., naltrexone) pass into human milk, and animal studies suggest they may cause tumors; however, therapeutic use of methadone and buprenorphine is not contraindicated for breastfeeding (WHO, 2014b). Recreational drugs, including nicotine, alcohol, ecstasy, amphetamines, cocaine, and other stimulants, are not considered a contraindication to breastfeeding one's own infant (WHO, 2009, 2014b). In most circumstances, WHO recommends that mothers with substance use disorders be encouraged to breastfeed (while also being supported to cease their substance use) unless the risks clearly outweigh the benefits (WHO, 2014b). These recommendations were designed for mothers who are breastfeeding their own infants, and the risk-to-benefit ratios may differ when considering the uses of human milk within different contexts of human milk exchange. Information regarding the safety of maternal drug use during lactation is available from a variety of government and nongovernment services (Table 2). Research in this area is intensifying, and new information about transmission rates and infant outcomes associated with maternal drug use is updated frequently.

Table 2. Online Resources for Information Regarding the Safety of Maternal Drug Use During Lactation.

Source	URL
e-lactancia	http://www.e-lactancia.org/
SickKids MOTHERISK	http://www.motherisk.org/
The Breastfeeding Network	https://www.breastfeedingnetwork.org.uk/detailed-information/drugs-in-breastmilk/
TOXNET Toxicology Data Network	http://toxnet.nlm.nih.gov/

Exposure to environmental contaminants. Environmental contaminants, including heavy metals and persistent organic pollutants (POPs) in the soil, air, water supply, and food supply, may be measured in human milk. There is limited information, however, regarding both the short-term and long-term impact of these exposures on infants' health (LaKind, Berlin, & Mattison, 2008; Nickerson, 2006). Fetal exposures *in utero* and infants' direct exposures to environmental contaminants pose a greater risk as compared with indirect exposure via breastfeeding or human milk (Weisstaub & Uauy, 2012); breastfeeding protects against these exposures, and human milk contains components that counteract the potential negative effects of environmental exposures (Díaz-Gómez et al., 2013; Hausman, 2006; Nickerson, 2006).

Characteristics of Donor Human Milk Obtained Through Human Milk Banks

HMB provides cost-effective means of provisioning safe B-HM for vulnerable preterm infants globally (Arslanoglu, Ziegler, Moro, & WAPM Working Group on Nutrition, 2010). In recent years, WHO (2008) has issued calls to expand the use of pasteurized B-HM for medically fragile infants, because feeding infant formula greatly increases the risk of severe medical complications and death in SGA and preterm infants (Quigley, Embleton, & McGuire, 2018; WHO, 2015c). Methods of donor selection and screening, and of processing human milk, vary among countries that have milk banks (Grøvslien & Grønn, 2009; Omarsdottir, Casper, Akerman, Polberger, & Vanpée, 2008; PATH, 2013; Tully, Jones, & Tully, 2001). Human milk banks across the world screen and/or conduct serological testing for some or all of the following communicable diseases: HIV, hepatitis B and C, syphilis, HTLV I and II, and Creutzfeldt–Jakob disease (PATH, 2013). Prospective donors are commonly screened for drug use and recreational substance use through behavioral screening only; in other words, B-HM is not routinely tested for contamination with pharmaceutical and other drug substances (PATH, 2013). One recent study validated the use of a behavioral screening survey to assess donors' eligibility based on self-reported use of caffeine, nicotine, and illegal substances in Spain (Escuder-Vieco et al., 2014).

There are few scientific reports related to the prevalence of substances in milk that is donated to HMB. A small study that analyzed B-HM in Spain found no evidence of illegal drug use, but did find evidence of caffeine use and occasional exposure to tobacco smoke (Escuder-Vieco et al., 2016). Some human milk banks use donor screening that replicates screening of blood donors—including having had recent tattoos and piercings, a history of incarceration, and living in the United Kingdom during the 1980s—despite weak evidence to support the relevance of these behaviors to risk reduction in human milk donation.

Pasteurization techniques are regularly used in HMB to reduce the risk of pathogen transmission (Israel-Ballard et al., 2007; Naicker et al., 2015); however, heat treatment also compromises the

nutritional and immunological properties of the milk (Akinbi et al., 2010; Chang et al., 2013; Marx et al., 2014; O'Connor, Burkle, & Olness, 2001; Peila et al., 2016; Vieira, Soares, Pimenta, Abranches, & Moreira, 2011). An emergent line of research examines how different types of heat treatment affect human milk composition and bioactivity, with important implications for understanding the relationship between B-HM processing and infant outcomes.

Milk that has been pasteurized via the Holder technique has been shown to retain some antimicrobial capability (Meng et al., 2016). Flash pasteurization eliminates the bacteria in human milk (Naicker et al., 2015), albeit reducing the concentration of milk immunoglobulins (Chantry et al., 2009). Heat treating human milk that contains spore-forming bacteria (e.g., *Bacillus cereus*) exacerbates the risk of spore and enterotoxin formation and increases the risk of gastrointestinal distress among immunocompromised infants (de Segura et al., 2012). Other innovations in pathogen elimination for B-HM, including high-pressure processing, microwave pasteurization, and ultraviolet-C irradiation, are currently being studied as methods to improve nutrient retention in heat-treated B-HM (Peila et al., 2017). A recent study has explored the possibility of introducing a personal microbiome into B-HM using small quantiles of mothers' own milk to offset the reduction of immunologically significant commensal bacteria through heat treatment (Cacho et al., 2017).

There are currently no universal HMB standards regarding milk pooling and setting cutoffs for acceptable bacteria levels in pre-pasteurized B-HM. For example, (HMBANA (2018) pools milk from multiple donors prior to pasteurization, does not define a bacteria threshold for milk to be acceptable for donation, but does define standards for dispensing raw donated human milk as follows: "Only milk from pools with $< 10^4$ CFU/mL of normal skin flora (e.g. coagulase negative *Staphylococcus diptheroids*, *Staphylococcus epidermis*, *Streptococcus viridans*) is acceptable to dispense raw. The presence of any pathogens is unacceptable" (p. 41). In the United Kingdom (National Institute for Health and Care Excellence [NICE], 2010), there are pre-pasteurization acceptability thresholds of $< 10^5$ CFU/mL, and milk is only pooled from single donors. Other HMB networks, including those in India and Australia, also report pre-pasteurization thresholds for accepting milk at $< 10^5$ CFU/mL (Bharadva et al., 2014; Hartmann et al., 2007).

Preterm infants fed with Holder-pasteurized B-HM have reduced risk for necrotizing enterocolitis (NEC) and improved bronchopulmonary dysplasia compared to those fed infant formula but also slower rates of growth (Quigley et al., 2018; Villamor-Martínez et al., 2018). Not all human milk banks routinely pasteurize donor milk, particularly when rigorous serological and behavioral screening are used. High levels of bacteria, even those thought or known to be of potential pathogenicity, have not been correlated with infection in infants (Jiménez et al., 2015). A 2004 report from a human milk bank in Oslo, Norway, reported pasteurizing only 10.5% of the milk from screened donors, due to either bacteria loads (threshold for pasteurization is defined as $> 10^4$ CFU/mL) or the presence of specific pathogens (Lindemann, Foshaugen, & Lindemann, 2004). Although 62% of the donors in this study were CMV-positive (CMV+), raw milk from CMV+ donors only went to infants > 32 weeks gestational age (GA) or > 1500 grams. CMV transmission remains clinically contentious, particularly for fragile infants, and a surge of recent research aims to provide greater clarity regarding the relative risks and management of CMV+ milk for preterm infants (Bardanzellu et al., 2018).

The macronutrient content of milk from individual donors varies significantly (John et al., 2019; Wojcik, Rechtman, Lee, Montoya, & Medo, 2009). Some factors contributing to this variability are well documented, such as changes that occur in the early weeks postpartum as lactation is established. In mature milk, the subject effect explains a larger source of variability than a time effect for many nutrients and bioactive factors, suggesting the existence of unique individualized “milk-prints” that are independent of time (Perrin, Fogleman, Newburg, & Allen, 2017). This variability among donors may translate into large macronutrient variations in B-HM. Smith et al. (1984) studied 22 samples of pooled B-HM in the United Kingdom and found a fourfold difference in creatinocrit values. Others have reported wide variability in the fat and calorie composition of B-HM (de Halleux & Rigo, 2013; Meredith-Dennis et al., 2018; Stoltz Sjöström, Ohlund, Tornevi, & Domellöf, 2014). A simulation study of random donors revealed that almost one third of pools with four to five donors would not meet expected fat targets of 3.5 g/dL, indicating the need for more rigorous research into the composition of B-HM and how HMB processes may affect the nutrient content (John et al., 2019). Calorie and protein variations are of greatest concern to preterm and SGA infants, who face the greatest risks of growth faltering and who are fed at prescribed rates instead of *ad libitum* (Stolzer, 2010).

Characteristics of Commodified Human Milk

There are scant scientific studies that elucidate whether financial compensation affects the quality and safety during HME. The few studies that are available, however, draw attention to important scientific, clinical, and bioethical issues that pertain to all methods of HME. In one study that assessed safety using drug screening, nonhuman protein sources, and milk dilution rates, the quality of C-HM procured during a 5-year period by a U.S.-based commercial entity differed by dilution rates (14/2060, 0.7% vs. 57/2875, 2.0%) after the introduction of a donor remuneration program (Bloom, 2016). It is important to note that the incidence of nonhuman protein sources was very low (2/4935, 0.04%) during the entire study period, which may be related to the fact that it was communicated to milk suppliers that their milk would be tested. Differences in the retention of nutrients in C-HM that may be processed differently than B-HM have not been well studied. Some emerging evidence suggests that “shelf-stable” human milk, which is processed with retort methods, results in greater reduction in microbial proteins, essential amino acids, and vitamins as compared with Holder-pasteurized milk (Lima et al., 2018; Lima, Wagner-Gillespie, Perrin, & Fogleman, 2017; Meredith-Dennis et al., 2018).

A number of Internet sites host private marketplaces for C-HM. A study of anonymously C-HM from the Internet, screened only to *exclude* sellers who asked about recipient infants, found the presence of viruses and pathogenic levels of bacteria; this C-HM was also shipped to a U.S. post office box, and lack of care in packaging was evident (Keim et al., 2013, 2015). Discrepancies in individuals’ reports of personal tobacco and caffeine use, and the presence of tobacco and caffeine metabolites in the samples of anonymously C-HM, were also noted (Geraghty et al., 2015). Around 10% of the C-HM was found to be adulterated with bovine milk, a rate 250 times greater than where milk screening and testing are instituted (Bloom, 2016; Keim et al., 2015). Balancing remuneration with potential increased risks of adulteration or dilutions remains a significant consideration for commodified and commerce-free HMEs.

Human Milk Obtained Through Sharing and Healthcare Provider–Facilitated Exchanges

In this nascent area of scientific inquiry, there is limited research that describes the characteristics of S-HM. Two cross-sectional, survey-based studies relying on self-report of milk sharers' storage and handling practices revealed mixed results on the extent to which individuals who are providing S-HM may follow the recommended hygiene practices in the expression of milk (Gribble, 2014c; Reyes-Foster et al., 2017). A 2016 case study documented provision of raw S-HM in a Japanese hospital where donors were serologically screened for hepatitis B, hepatitis C, HTLV I, and HIV. The report noted that five preterm infants had respiratory tract colonization of *E. coli* that was identified during standard weekly surveillance cultures, and it was attributed to S-HM from a single donor; however, the infants' clinical course was not affected by this colonization, supporting other findings that the presence of pathogenic bacteria in milk is not predictive of outcomes (Law et al., 1989; Nakamura et al., 2016; Schanler et al., 2011). A study of S-HM and B-HM obtained through commerce-free models found no difference in the rates of total aerobic bacterial or coliform growth as compared to raw milk donated to human milk banks (Perrin et al., 2018). There were also no observed differences in the macronutrient or water content between samples. The contrast between these findings and those of Keim et al. (2013, 2015) suggests that when there is an absence of donor screening and testing, payment for human milk vastly increases the risk of milk contamination. Whether S-HM is subject to intentional adulteration has not yet been studied.

Policy and Position Statements on Human Milk Exchange

Although there is established and widely accepted guidance from health authorities regarding HMB and the use of B-HM in clinical settings, particularly in the NICU, the situation for S-HM is very different. Since the initiation of Internet-mediated HMS in 2010, at least 21 statements regarding the practice of S-HM feeding have been issued by lactation support organizations, health ministries and agencies, religious entities, and professional organizations (Table 3). Position statements communicate an organization's commitment to providing a product or service that meets a client or patient need in a specific circumstance, and may vary from a brief declarative statement of internal policy, to a more ideal evidence-based definition of the circumstance, impact on stakeholders relevant to the organization, and description of actions appropriate to addressing the circumstance. Policy statements are more formal, comprehensive justifications of a position and are intended to guide the target audience and provide operational directives in specific circumstances (e.g., American Academy of Family Physicians, 1995; Ontario Medical Students Association, 2019). Although the impact and audience of position and policy statements are often different, each can be analyzed for efficacy on the basis of how well they define the problem, are based in evidence, contain solutions, provide action and decision guidance, and describe the impact of the position or policy (Weiner, 2005).

Table 3. Summary of Position Statements and Policy Statements for Human Milk Exchange.

Organization	Organization type	Current version published (originally published)	Infant population*	Audience	Basis for recommendation	Nature of problem**
Academy of Breastfeeding Medicine (ABM)	Professional organization—medicine	2018	Hospital and home	Doctors	Evidence based	Insufficient access to human milk
Agence Nationale de sécurité du médicament et des produits de santé (AFSSAPS; France)	National public health ministry	2011	Hospital and home	General public	Professional opinion	Milk sharing is a high-risk behavior
American Academy of Nursing (AAN)	Professional organization—nursing	2015	Home	Nurses	Evidence based	Insufficient access to human milk
American Academy of Pediatrics (AAP2)	Professional organization—medicine	2018 (2017)	Hospital and home	Doctors	Professional opinion	Problem not defined
American Academy of Pediatrics (AAP1)	Professional organization—medicine	2018 (2012)	Hospital and home	Doctors	Professional opinion	Milk sharing is a high-risk behavior
Auckland District Health Board (ADHB)	Regional public health ministry	2015 (2012)	Home	General public	Evidence based	Insufficient access to human milk
Australian Breastfeeding Association (ABA)	Infant-feeding peer support organization	2018 (2014)	Home	Families and infant-feeding support	Limited evidence	Insufficient access to human milk
Australian College of Midwives (ACM)	Professional organization—midwifery	2017 (2014)	Hospital and home	Midwives	Evidence based	Insufficient access to human milk
Breastfeeding USA (BFUSA)	Infant-feeding peer support	2017 (2012)	Hospital and home	Families and infant-feeding support providers	Evidence based	Insufficient access to human milk
British Association of Perinatal Medicine (BAPM)	Professional organization—medicine	2016	Hospital and home	Doctors	Limited evidence	Problem not defined
Canadian Paediatric Society (CPS)	Professional organization—medicine	2010	Hospital	Doctors	Professional opinion	Problem not defined
Committee on Nutrition of the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)	Professional organization—medicine	2013	Hospital	Doctors	Evidence based	Problem not defined
Food Safety Authority of Ireland (FSAI)	National nutrition ministry	2017	Hospital—preterm	General public	Evidence based	Milk sharing is a high-risk behavior
Health Canada (HC)	National health ministry	2010	Hospital and home	General public	Professional opinion	Problem not defined
Health Canada (HC-IU)	National health ministry	2014	Home	General public	Professional opinion	Milk sharing is a high-risk behavior

Organization	Organization type	Current version published (originally published)	Infant population*	Audience	Basis for recommendation	Nature of problem**
Human Milk Banking Association of North America and European Milk Banking Association (HMBANA/EMBA)	Nonprofit organization	2015	Hospital and home	General public	Professional opinion	Insufficient access to human milk
La Leche League International (LLLI)	Infant-feeding peer support	2015 (2011)	Home	Families and infant-feeding support providers	Limited evidence	Insufficient access to human milk
Ministry of Health New Zealand (HMNZ)	National public health ministry	2016	Hospital and home	General public	Evidence based	Insufficient access to human milk
Perinatal Services British Columbia (PSBC; Canada)	Regional public health ministry	2016	Home	Care providers and families	Evidence based	Insufficient access to human milk
United Kingdom Association for Milk Banking (UKAMB)	Nonprofit organization	2016	Home	General public	Professional opinion	Problem not defined
United States Food and Drug Administration (FDA)	National public health ministry	2018 (2010)	Hospital and home	General public	Professional opinion	Milk sharing is a high-risk behavior
Waitemata District Health Board (New Zealand)	Regional public health ministry	2017	Hospital	General public	Limited evidence	Insufficient access to human milk

*Note: *Hospital* refers to infants who are being cared for in a hospital. *Home* refers to infants who are living outside of the hospital, in most cases presumed to be otherwise healthy. ****Organization** defined the problems associated with milk sharing as predominantly insufficient access to human milk via a parent or milk bank (insufficient access to human milk), and milk sharing as inherently a high-risk behavior with respect to the potential harm that can come to the infant receiving milk through milk sharing (milk sharing is a high-risk behavior); or it did not define a problem in their statement regarding milk sharing.

Of the 21 statements considered here, more than half independently cite evidence in various fields for their recommendations, although the relevance of the cited sources and quality of evidence vary highly. Some statements rely on support for their position based on food marketing and sales regulation, restrictions on the sale of human tissue, and evidence from clinically regulated distribution of human milk in highly controlled trials, all of which are not applicable to S-HM in community settings. The remainder rely on consensus statements from their own or other organizations or call for prohibition of HMS without context or explanation. Four statements do not address HMS but are nonetheless cited by other organizations as the foundation of their own position.

Of the statements that defined a problem specific to milk sharing, the problem was framed or defined in three ways: (a) barriers in access to human milk; (b) HMS as a high-risk behavior; or (c) HMS as a liability for the organization. The statements that framed the central problem as a lack of access to human milk (ABM, AAN, ABA, ACM, BFUSA, LLLI, MHNZ, PSBC, ADHB, and WDHB) were most likely to be evidence based, to provide perspectives from multiple sources, and to include relevant information and resources for risk mitigation. Statements that framed milk sharing as an inherently high-risk practice (AFSSAPS, AAP1, HC-IU, HMBANA/EMBA, FDA, and FSAI) were more likely to rely on non-peer-reviewed evidence, such as professional opinion or non-infant-feeding-related food regulations, and to cite sources that were not pertinent to milk sharing. Three statements cited no evidence (HC-IU, HMBANA/EMBA, and FDA). Four statements did not define a problem in their statements (AAP2, HC, ANSM, and UKAMB did not define a problem). A lack of problem clarity and balanced evidence base would limit the efficacy of these policies or position statements to communicate solutions and useful perspectives regarding HMS.

Solutions developed within statements fell into three broad philosophical perspectives: (a) individual autonomy in decision making; (b) recommendation that individuals should defer to the advice of a medical professional; or (c) proscription of HMS under all circumstances. Autonomy-focused statements provided pragmatic suggestions for screening donors and handling milk safely, and encouraged engagement with a health or lactation professional as a consultant (AAN, ABA, BFUSA, MHNZ, PSBC, WDHB, and ADHB). Statements recommending deference to medical professionals presumed that individuals would not have the knowledge, means, or desire to screen potential donors, handle milk safely, and participate in an active discussion of specific benefits and risks for their circumstances. Such statements contained fewer overall resources for families and professionals as compared to autonomy-focused statements, but rather urged deference to medical professional advice (ABM and LLLI). Statements among the three solution types describe the common limitations of professional knowledge about milk-sharing practices, creating a paradox wherein families are expected to defer to professional judgment that is described as lacking from within the professions themselves. Proscriptive statements provided no discussion of resources or autonomy, instead advising against any form of sharing human milk or endorsing only milk obtained from a formal milk bank (AAP1, AAP2, ANSM, FDA, FSAI, HC, HC-IU, HMBANA/EMBA, and UKAMB).

The impact of a policy or position statement is, by design, to influence behavior. Statements that addressed intended or potential impact did so to varying degrees of detail and specified three potential infant populations: (a) health-fragile or hospitalized infants, (b) otherwise healthy

infants based in the community, and (c) both health-fragile and otherwise healthy infants. Statements regarding health impacts exclusively to health-fragile and hospitalized infants were AAP1, AAP2, HMBANA/EMBA, and UKAMB. Otherwise healthy infants' impacts were discussed by statements from ABM, ACM, MHNZ, PSBC, ADHB, and WDHB. Mention of both health-fragile and otherwise healthy infants addressed superficially the general need for additional consideration for health-fragile infants compared to otherwise healthy infants (AAN, LLLI, and ABA). Seven statements provided no distinction between or discussion of differential impacts to health-fragile or otherwise healthy infants (ANSM, FDA, HC, HC-IU, HMBANA/EMBA, and UKAMB). Overall, there is a lack of consistency in aligning policy and position statements to existing evidence to provide practical and immediately accessible risk abatement for families participating in HMS.

Future Research Directions

HME is an important research area for the social sciences, basic biological and nutritional sciences, clinical sciences, and public health, making it ideal for transdisciplinary collaborations. There are several key areas in need of improved evidence that will push the field forward. We provide some of our own suggestions, based on our careful reading of the literature and the research trends we have described above.

Surveillance Systems

Diverse methods of HME are relevant to how parents feed their infants in societies throughout the world. There is a need for improved measures of infant-feeding practices at the population level to facilitate more powerful estimates of the prevalence of HME and its association with various infant-feeding outcomes. Prospective clinical and epidemiological studies of HME are needed to generate high-quality data on infant outcomes. The existing science supports that the risks, costs, and benefits of HME for infant feeding are highly context-specific; for example, evaluating the tradeoffs between various kinds of infant-feeding methods requires consideration of an infant's age and health status as well as the source(s) of nutrition (whether it is a parent's own milk, infant formula, B-HM, or S-HM). There is growing consensus among studies of HME that one means to ensure infant safety is healthcare provider support in informed decision making for HME and infant feeding.

Effects of Human Milk Exchange on Infants

Studies are needed that examine the effect of supplementation of breastfed or exclusively human milk-fed infants with B-HM, S-HM, or formula on infant outcomes. Moreover, there is a need for ways to capture the quality of lactation support in NICU settings that take into account the importance of human relationships in individuals' lactation outcomes and infant-feeding decisions during NICU stay and post NICU discharge.

Long-Term Effects of Human Milk Exchange on Milk Donors

Arguably, the effects of HME on infant health, growth, and development are of the highest priority; however, milk donation may also have a measurable impact on donors' own health,

lactation trajectories, and lactation outcomes. We did not find any studies that have prospectively studied the physiological effects of HME on short- and long-term health outcomes of donors. Population-based data on the effects of milk expression on lactation outcomes, more generally, are needed to begin to map the differential effects of various lactation practices that are used in the context of infant feeding.

Improving Human Milk Banking

Rigorous comparative research on HMB practices and infant outcomes is strongly indicated. Different human milk banks may use significantly different methods for screening donors, compensating donors, processing milk, feeding infants, and providing micro- and macronutrient supplementation. Understanding what works in which situations may lead to breakthroughs in HMB. New research exploring ways of processing human milk to retain bioactivity and optimize nutrient composition has potential to drive new innovations in HMB.

Researchers have begun to examine knowledge and attitudes about HMB and infant feeding, including in non-WEIRD contexts. Within many of the new research reports are insights to the ways that human milk is valued and diverse sociocultural contexts of HME. In the future, implementation studies of HMB are needed to better document and understand the factors that shape the acceptability, feasibility, appropriateness, cost-effectiveness, uptake, and fidelity to recommended best practices of HMB, particularly in low- and middle-income countries. A social ecological perspective to HMB implementation may provide key insight for how to remove structural barriers that prevent equitable access to B-HM. Moreover, more ethnographic and careful sociocultural study of all forms of HME are needed to better understand contemporary practices and inform more robust comparative analyses.

Emerging Models of Human Milk Exchange

We found only a few studies that investigated methods of HME that involved C-HM. This is an area of research, particularly within the social sciences, that may provide important insights into other economies of human milk that intersect with HMB and HMS but have not yet been elucidated. Emergent models of healthcare provider-facilitated milk sharing in community and clinical settings are pushing the boundaries of possibility in expanding accessibility to S-HM while also using evidence-based practice for donor screening. Future research that evaluates these practices by linking them to safety and lactation and infant-feeding outcomes will advance the quality of these practices.

Human Milk Exchange in Emergencies

The updated operational guidance for infant feeding in emergencies notes that there is limited evidence to inform implementation of HME in emergency response (Angood, 2017). There is a significant need to improve the quality of evidence for infant feeding in emergency situations to inform coordination and mobilization of donated human milk and S-HM in emergencies. There may also be potential for HME to address critical issues for infant feeding in situations where there is a high prevalence of infant malnutrition, particularly in the first 6 months of life. Innovations in HMB may be complementary to other solutions that are being considered, such as

new kinds of therapeutic milks, more effective feeding protocols (see Angood et al., 2015), and integrated maternal lactation and infant-feeding support in cases of acute malnutrition.

Evidence-Based Policies and Resources

Finally, there is a need for stronger evidence-based guidance related to HME for peer and professional lactation supporters. Adherence to infant-feeding advice from lactation and health professionals often depends on the family's perception of applicability to their unique circumstances. In circumstances in which advice is not provided in a way that the family feels meets their needs, adherence to advice is low, and likelihood of nondisclosure of infant-feeding practices is high, potentially complicating or hindering infant and young child care (Heinig et al., 2006; Weiner, 2005). When a policy statement does not specifically describe the likely outcomes of the recommendations within, there is limited potential for addressing potential outcomes or generating meaningful practice changes to affect a desired behavior change (Weiner, 2005). Effective policies for HME will be strengthened by advances in the social sciences and basic biological sciences and high-quality evidence.

Conclusions

Diverse methods of HME are found around the world today. These practices potentially have a significant impact on the immediate and long-term health of infants as well as individuals who provide their milk. Effects likely vary based on the health of the recipient infant and should be considered when making decisions about HME. Emerging information is available to assist parents in making informed decisions regarding the relative risks, benefits, and costs of different kinds of HME for individual families' infant-feeding decisions; however, this information is not regularly reflected in policies and position statements. There are many areas for new research that hold potential for advancing our understanding of HME globally, and for advancing the science of human milk, clinical lactation support, and public health. Policies and other official guidance for HME will be stronger by integrating insights from the basic sciences and the social sciences.

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