# Human Milk Donation in Aotearoa New Zealand

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## ABSTRACT

**Introduction:** Mother's own milk (MOM) provides optimal nutrition for infants. When MOM is unavailable or insufficient, donor human milk (DHM) is recommended. Feeding DHM instead of infant formula (IF) to low birth weight and very preterm infants is associated with a reduced risk of serious gastrointestinal infection. However, there is limited research investigating DHM use in low-risk populations, including moderate-late preterm (MLP) and early term (ET) infants. Little is known about human milk (HM) donation practices in New Zealand (NZ), where access to HM banks is limited. This thesis aimed to explore mothers' and health professionals' (HP) views and experiences of HM donation in NZ and summarise the available literature regarding the benefits and risks of DHM use in MLP and ET infants.

**Methods**: Key databases were systematically searched for ongoing and completed randomised and observational studies comparing DHM *versus* IF to supplement MOM in MLP and ET infants. Characteristics of identified studies were summarised. In addition, two electronic surveys were circulated via social media to mothers and HP involved with HM donation in NZ. The surveys included questions on mothers' and HP demographics, experiences and perceptions of informal HM donation. Descriptive and thematic analyses were undertaken using SPSS and NVivo, respectively.

**Results:** Seven studies fulfilled the inclusion criteria of the systematic review, of which 2033 infants received DHM as a supplement or substitute to their MOM. Most of these studies were from the United States and investigated neonatal hypoglycaemia and breastfeeding outcomes. Five ongoing randomised controlled trials were identified, exploring a range of biochemical, anthropometric and infant health outcomes. The HP survey (n=283) reported that DHM was available in 86% of workplaces and most frequently used for full-term infants (71.8%). Almost all respondents supported DHM use in hospitals (98.6%) and pasteurisation of DHM was reported by 56.5% of HP. Qualitative analysis demonstrated that HP felt HM donation could improve with better advocacy, access, affordability and guideline development. Most mothers (n=496) donated (51.5%) or sought DHM (25.6%) for their infant and arranged DHM exchanges between individuals (51.9%). Most HM donors were satisfied or extremely satisfied with their HM donation experience (90.8%). Mothers felt informal milk sharing was beneficial to infants' health (e.g., improved immunity) and avoided exposure to IF. However, mothers had concerns regarding the composition of DHM (e.g., contamination) and how this may impact infants' health. Benefits of informal HM donation for the donor were highlighted (e.g., altruism), though negative implications were also identified (e.g., oversupply).

**Conclusion:** Systematic review of the literature demonstrated limited evidence on the clinical effects of using DHM instead of IF to supplement MOM in MLP and ET infants. High-quality research on this practice's potential benefits and risks for this population is required. Furthermore, this thesis provides first insights into HM donation in NZ. Results indicated that HM donation is widely supported and common throughout the country. Future interventions are needed to support safe and equitable access to DHM in NZ.

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## GLOSSARY

ABM = Academy of Breastfeeding Medicine ARA = Arachidonic Acid **BFHI** = Baby Friendly Hospital Initiative DHA = Docosahexaenoic Acid DHM = Donor Human Milk EBF = Exclusive Breastfeeding EHM = Expressed Human Milk EMBA = European Milk Bank Association FAO = Food and Agriculture Organisation FOS = Fructooligosaccharide FT = Full Term GOS = Galactooligosaccharide HM = Human MilkHM bank = Human Milk bank HM donation = Human Milk donation HMBANA = Human Milk Banking Association of North America HMF = Human Milk-based Formula HMO = Human Milk Oligosaccharide HoP = Holder Pasteurisation IF = Infant Formula IgA = Immunoglobulin AIgG = Immunoglobulin GLCPUFA = Long-Chain Polyunsaturated Fatty Acid LP = Late PretermMLP = Moderate-Late Preterm MOM = Mother's Own Milk MP = Moderate Preterm NEC = Necrotising Enterocolitis NH = Neonatal Hypoglycaemia NICU = Neonatal Intensive Care Unit PPMS = Peer-to-Peer Milk Sharing SES = Socioeconomic Status

# 1. INTRODUCTION

# 1.1 MODERATE-LATE PRETERM AND EARLY TERM INFANTS

# 1.1.1 Definition and epidemiology of moderate to late preterm and early term infants

The World Health Organisation (WHO) defines preterm birth as an infant born before 37 completed weeks of gestation or 259 days since the beginning of the mother's last menstrual cycle.<sup>1</sup> Preterm births are often subdivided into extremely preterm (<28 weeks' gestation); very preterm ( $28^{+0}$  to  $31^{+6}$  weeks' gestation); moderate preterm ( $32^{+0}$  to  $33^{+6}$  weeks' gestation) and late preterm ( $34^{+0}$  to  $36^{+6}$  weeks' gestation). Globally, approximately 5-18% of infants are born preterm and this rate continues to increase.<sup>2</sup> In New Zealand, MLP and ET births made up 7.9% and 6.4% of all live births in 2020, with infants born MLP accounting for 81% of births before 37 weeks.<sup>3</sup>

A full term (FT) birth has traditionally been categorised as an infant born between 37 completed weeks to less than 42 completed weeks' of gestation<sup>4</sup> but, more recently, FT births have been considered as occurring between 39<sup>+0</sup> and 41<sup>+6</sup> weeks' gestation<sup>5</sup> as evidence grows concerning substantial decreases in adverse health outcomes for births occurring closer to the expected delivery date.<sup>6</sup> Births occurring between 37<sup>+0</sup> to 38<sup>+6</sup> weeks' gestation are considered early term (ET) to acknowledge their physiological immaturity and vulnerability to adverse health outcomes,<sup>7</sup> while infants who are born at or above 42<sup>+0</sup> weeks' gestation are considered postterm.<sup>8</sup> Moderate to late preterm (MLP) and ET births account for a substantial percentage of all live births globally, constituting 7% and 25%, respectively.<sup>9</sup> The increasing number of MLP and ET births, alongside the poorer outcomes associated with early birth, has become a significant public health concern.<sup>10</sup>

## 1.1.2 Growth and development of moderate-late preterm and early term infants

MLP and ET infants are subject to structural and functional immaturity, placing them at greater risk of clinical complications.<sup>11,12</sup> However, their physiological complexities are often overlooked due to their similar appearance and weight to FT infants.<sup>11,13</sup> Compared to an infant born at term, MLP and ET infants may lack the physiological self-regulatory abilities to appropriately adapt to the postnatal environment.<sup>14</sup> As such, MLP and ET infants are more likely to experience slower growth, developmental delays and clinical complications than an infant born at term.<sup>15</sup>

## 1.1.3. Short-term health outcomes of moderate-late preterm and early term infants

MLP and ET infants have been shown to have lower rates of breastfeeding compared to infants born at term. A US study investigating the breastfeeding prevalence of moderately preterm (MP, n=2,323) and late preterm (LP, n=9,172) infants born between 2003 and 2009 found that MP (60.7%) and LP (62%) infants had lower rates of breastfeeding initiation compared to term infants (70.1%, n=119,502).<sup>16</sup> Furthermore, a 2014 retrospective cohort study of 4,052 ET

infants in the US found that these infants had a 1.5 times higher odds of not initiating breastfeeding compared to infants born at term.<sup>17</sup> Wang et al. therefore found that electronic medical records of LP infants born in the US between 1997 and 2000 were more likely than term infants to experience hypoglycaemia (15.6% vs. 5.3%), require intravenous fluid administration (27% vs. 5%) and have delayed discharge from hospital due to poor feeding (76% vs. 28.6%).<sup>18</sup>

There is substantial evidence demonstrating the greater risk of respiratory disorders in MLP and ET infants. Infants born before term expose their lungs to the extrauterine environment prior to adequate surfactant production, alveolar ventilation and pulmonary blood flow.<sup>19</sup> In the US, respiratory distress has been seen to affect LP infants at a higher rate than FT infants (28.9% vs 5.3%) and increases with every week prior to 39 weeks' gestation.<sup>13</sup> Furthermore, Madar et al. found that ET infants born by elective Caesarean delivery were 120 times more likely to require postnatal ventilation support for surfactant deficiency than those born between 39 and 41 weeks' gestation.<sup>20</sup> LP and ET infants (n=4,672) admitted to Canadian tertiary-care neonatal units have, therefore, been shown to be more likely than their FT equivalents to require assisted ventilation (34.4% and 30.9% vs. 27.1%) and external surfactant use (7.7% and 5.2% vs. 2.9%).<sup>21</sup>

MLP and ET infants are also at an increased risk of hypoglycaemia compared to a term infant due to abrupt cessation of placental glucose supply at birth and having not yet formed adequate glycogen reserves. <sup>12,22</sup> Their ability to effectuate a ketogenic response following low glucose availability is, therefore, limited. <sup>12,22</sup> Studies have shown that MP (15.6%), LP (7.1%) and ET (4.9%) infants experience a higher prevalence of hypoglycaemic events than their FT peers (0.7%), <sup>18,23,24</sup> highlighting the importance of close glucose monitoring in these populations.

Developmental immaturity of the innate immune system predisposes an MLP infant to neonatal infection.<sup>25</sup> Infants born before term receive less immunoglobulin G (IgG) via the placenta as the majority of this antibody is acquired by the infant in the last four weeks of pregnancy.<sup>26</sup> It is, thus, unsurprising that an Italian retrospective study of MLP infants admitted to a neonatal unit between 2008 and 2013 reported these infants were three times more likely to be treated for any infection than their FT counterparts (16.6% vs 5.4%).<sup>27</sup> Studies have shown that MLP and ET infants have higher rates of respiratory infection<sup>19,28</sup> and hospital admissions for gastrointestinal, viral, nonspecific, urinary, skin, soft tissue, invasive bacterial, lower and upper respiratory tract infections than infants born at term.<sup>29–32</sup>

Preterm infants are also at a higher risk of hyperbilirubinaemia. Infants born at 36 weeks' gestation across 11 US hospitals were approximately eight times more likely to develop severe neonatal hyperbilirubinaemia in their first month after birth than infants born at 40 weeks' gestation (>20 mg/100 mL, 5.2% vs 0.7%).<sup>33</sup> Furthermore, an analysis of medical records from 1146 MLP infants born in the UK showed that MLP infants were more likely to require phototherapy treatment for hyperbilirubinaemia than FT infants (59% vs. 0.6%).<sup>34</sup> Hyperbilirubinaemia occurs primarily due to immaturity of the hepatic system and enzymes involved with regulating bilirubin, leading to accumulation of unconjugated bilirubin in the

blood.<sup>35</sup> If left untreated, hyperbilirubinaemia can lead to the deposition of bilirubin in the brain, causing neuropathological conditions such as kernicterus which is known to increase the risk of dystonic or athetoid cerebral palsy and hearing loss.<sup>36,37</sup>

## 1.1.4. Long-term health outcomes of moderate-late preterm and early term infants

The risk of adverse metabolic outcomes increases when considering the long-term effects of MLP and ET birth. Studies have shown that MLP and ET infants have a higher risk of developing childhood obesity.<sup>38,39</sup> A prospective population-based study by Boyle et al. revealed that MLP and ET infants are more susceptible to overweight and obesity by the age of 3 and 5 years than infants born VP.<sup>38</sup> Such outcomes have been shown to carry into adolescence for LP and ET infants.<sup>40,41</sup> Increased adiposity substantially increases the risk of long-term metabolic and endocrine conditions.<sup>42</sup> Correspondingly, Sweden-based studies investigating MLP and ET infants' health outcomes have shown that they are more likely to experience hypertension, hyperlipidaemia, cardiovascular disease and diabetes in adulthood than their FT counterparts.<sup>43–48</sup>

Infants born MLP or ET are also at an increased risk of neurodevelopmental and cognitive impairment. Studies have demonstrated that MLP and ET infants, compared to infants born at term, have poorer long-term outcomes in cognitive, educational, behavioural, developmental and neurological domains.<sup>49,50</sup> A national registry of Norwegian infants found that LPT infants were more likely to develop cerebral palsy (RR 2.7 [2.2-3.3]), schizophrenia (RR 1.3 [1.0-1.7]) and disorders of psychological development, behaviour and emotion (RR 1.5 [1.2-1.8]) in adulthood than infants born at term.<sup>51</sup> Furthermore, a US study showed that infants born MLP had higher need for special education (MP=11.92%, LP=6.27%, FT=4.28%, p <0.05) than their FT equivalents in grade one (as determined by direct child assessment test scores, including reading and math).<sup>52</sup> Poorer academic outcomes and the need for special education continued to increase with decreasing gestational age, suggesting a dose-response effect based on GA.<sup>52</sup> These outcomes indicate the requirement for close neurodevelopmental surveillance and subsequent early intervention in MLP and ET infants, who usually do not qualify for high-risk infant follow-up.

## 1.1.5. Why is human milk important for moderate-late preterm and early term infants

MLP and ET infants present significantly higher healthcare costs than FT infants in their first three years of life (4813€ vs 4047€).<sup>53,54</sup> For both preterm and term infants, human milk (HM) has been shown to reduce the incidence of infection, retinopathy of prematurity, necrotising enterocolitis (NEC), late-onset sepsis and later life non-communicable diseases such as diabetes and obesity.<sup>55–62</sup> Given the increased risk of adverse health outcomes in MLP and ET infants, breastfeeding, rather than feeding HM substitutes such as IF, can potentially mitigate the incidence of such conditions in these populations through exposure to health-promoting components unique to HM.<sup>63</sup>

## 1.1.6. Challenges of breastfeeding moderate-late preterm and early term infants

HM is recommended as the preferred source of nutrition for MLP infants.<sup>64</sup> Despite this, MLP and ET infants in the US have lower breastfeeding rates than infants born at term.<sup>16,17</sup> MLP infants may have difficulty orchestrating their suck, swallow and breathing reflexes due to their immature neurodevelopment and poor muscle tone.<sup>65,66</sup> Furthermore, LP infants are prone to prolonged sleeping periods, low stamina and fatigue during feeding resulting in reduced efficiency in stimulating and emptying the breast, reducing milk production and nutritional intake.<sup>64,67–69</sup> A qualitative study with Canadian mothers reported that challenges in breastfeeding LP infants include perceived reductions in milk supply, latching difficulties, feelings of failure and a lack of healthcare professional support following hospital discharge.<sup>70</sup> The Academy of Breastfeeding Medicine (ABM) and European Society for Paediatric Gastroenterology Hepatology And Nutrition, therefore, recommend supporting breastfeeding in MLT and ET infants through careful observation for latching or suckling difficulties, providing mothers with breastfeeding education and encouraging early milk expression and skin-to-skin contact.<sup>64,71</sup>

#### **1.2. BENEFITS OF HUMAN MILK**

#### 1.2.1. Composition of human milk

HM contains a wide variety of nutritional factors which support immune maturation and organ development and positively alter the gut microbiota.<sup>72</sup> Nutritionally, HM comprises water, carbohydrate, lipid, protein, vitamins and minerals, making it the gold standard of infant nutrition.<sup>73,74</sup> Meta-analyses have shown that the nutritional profile of HM from mothers who gave birth at term (37-42 weeks' gestation) typically provides, per 100 mL milk, 67 kcal of energy, 6.2 g of lactose, 1.3 g of protein, 3.0 g of fat, 28 mg of calcium and 17 mg of phosphorus, though significant variations exist among subjects.<sup>75</sup> In comparison, the milk of a mother who has delivered preterm (<37 weeks' gestation) has a greater quantity of protein (1.5 g/100 mL), fat (3.5 g/100 mL) and energy (71 kcal/100 mL)<sup>75</sup> to accommodate for the increased nutritional requirements of a preterm infant. HM lipids provide the main energy component of HM, with a dominance of monounsaturated fatty acids (45-50%), followed by saturated fatty acids (35-40%) and polyunsaturated fatty acids (~15%).<sup>74</sup> Long-chain polyunsaturated fatty acids (LCPUFA), including docosahexaenoic acid (DHA) and arachidonic acid (ARA), are found in HM and are particularly important for infant neural and visual development and protection from infection.<sup>76</sup>

Many vitamins (K, E, D, A, C, folate, B12, B6, riboflavin, thiamine) and minerals (choline, magnesium, phosphorus, calcium, zinc, iron, iodine, copper) are abundant in HM.<sup>77</sup> The mineral content of HM tends to follow a downward trend throughout lactation, likely due to a concomitant decrease in protein, to which minerals may be bound to, and increased volume of milk with prolongation of lactation.<sup>78</sup> Between-subject variability of vitamins within HM is common.<sup>79</sup> The quantity of many essential vitamins such as vitamin D, thiamine, retinol,

riboflavin, cobalamin, folate and pyridoxine is strongly influenced by the maternal diet and bodily stores.<sup>72,77</sup>

Hormones including erythropoietin, calcitonin, adiponectin, leptin, resistin and ghrelin are all found in significant concentrations in HM.<sup>72</sup> Adiponectin is a key hormone in regulating metabolism by increasing insulin sensitivity and reducing inflammation.<sup>72,80</sup> Newburg et al. observed an inverse correlation between infant adiposity and the level of adiponectin in HM from mothers in the US and Mexico, leading to speculation that adiponectin may protect against obesity in exclusively breastfed infants.<sup>80</sup> Together, adiponectin, leptin, resistin and ghrelin all play a crucial role in regulating metabolism through modulating appetite and body composition.<sup>81</sup> However, the concentration of cortisol in maternal milk of 650 Finish women has been found to be influenced by a range of biological and social factors, including maternal weight, preterm birth and maternal educational status.<sup>82</sup> Higher cortisol concentrations in HM have shown to be protective of rapid body mass gains in term infants born in the US<sup>83</sup> and were correlated with lean mass at hospital discharge among New Zealand MLP infants born between 2017 and 2019.<sup>84</sup> Such findings may indicate that HM cortisol exposure could be associated with early metabolic pathways<sup>83</sup>; however, the effect of HM cortisol on neonatal outcomes requires further investigation.<sup>84</sup>

HM is also rich in whey (lactoferrin, alpha-lactalbumin, immunoglobulins) and casein (betacasein, k-casein) proteins. In early infancy, the protein makeup of HM is predominantly whey (89:11 whey-to-casein ratio) to support immunity and protect against infection.<sup>85</sup> However, as whey proteins begin to decline throughout lactation, casein – proteins that provide bioactive components to support calcium absorption – simultaneously increase to a whey-to-casein ratio of approximately 60:40.<sup>85</sup> Furthermore, HM contains bioactive proteins with immunological properties, including cytokines, immunoglobulins, growth factors and microbiological factors, that support the development of an infant's immune system.<sup>86</sup> Immunoglobulin G, A and M, lysosome and lactoferrin work alongside cytokines to remove harmful foreign antigens from the body.<sup>87</sup> Immunoglobulin A (IgA) is the main immunoglobulin found in HM, making up approximately 90% of antibodies.<sup>88</sup> IgA in HM has been shown to prevent bacterial and viral colonies from forming in an infant's intestine, reducing the risk of translocation of pathogens across the mucosal barrier.<sup>89</sup> This process is critical to a new-born as they do not yet possess their own immunoglobulin reserve.<sup>90</sup>

Growth factors found in HM, namely epidermal growth factor and transforming growth factoralpha and beta, are essential in supporting the functionality of the gastrointestinal mucosa at birth as they promote cell maturation and repair.<sup>86</sup> Such healing mechanisms may be critical to preterm neonates with intestinal damage from conditions such as necrotising enterocolitis (NEC).<sup>86</sup> Additionally, human milk oligosaccharides (HMO) – complex glycan molecules made up of 5 different monosaccharides – are the third most abundant compound in HM after lactose and lipids, and, although not digested by the infant, possess a range of prebiotic and antimicrobial functions to mediate symbiosis within the microbiota.<sup>91,92</sup> Glycoproteins such as lactoferrin and lactadherin are unique to mammalian milk and contribute to a healthy microbiota by inhibiting pathogens adhering to the mucosal surface.<sup>93</sup>

## 1.2.2. Adaptivity of human milk

The composition of HM differs between each mother and infant dyad and adjusts throughout each stage of lactation to meet the infant's needs.<sup>94</sup> Variations in milk composition have been identified between the length of gestation, between individuals, and diurnally.<sup>75</sup> For example, fat and lactose content gradually increase throughout lactation while protein content decreases.<sup>75</sup> Furthermore, as an infant feeds, the composition of the milk gradually changes as the breast empties.<sup>95</sup> At the beginning of a feed, the infant receives foremilk which contains a higher quantity of water.<sup>95</sup> Foremilk is gradually replaced by hindmilk which is richer in fat.<sup>95</sup> However, studies have shown that the composition of fat in HM over 24 hours varies substantially between mothers and can be affected by the stage of lactation, time of day, periods between feeds, degree of breast emptying, milk storage capacity and maternal diet.<sup>96,97</sup>

Colostrum, the first milk produced by the mammary gland, is rich in protein, growth factors and immunological components such as IgA, leukocytes and lactoferrin; however, it contains low quantities of lipid, lactose and energy.<sup>98</sup> Colostrum is typically produced in low quantities for the first few days following parturition until transitional milk begins to form. Transitional milk is similar to colostrum, though it has higher quantities of macronutrients to support the needs of the rapidly growing infant.<sup>72</sup> Transitional milk occurs between approximately seven days to two weeks postpartum, when it is then considered mature milk.<sup>72</sup> The lactose concentration in mature milk remains relatively stable throughout lactation, while the quantity of lipids slightly increases in the early lactation period before it begins to plateau.<sup>75,99</sup> Additionally, the content of protein in mature milk decreases over the first 12 weeks of lactation and stabilises thereafter.<sup>75</sup> It is thought that this may be a result of slowed rates of growth in the later stage of infancy.<sup>100</sup>

# 1.3. INFANT FORMULA

# 1.3.1. What is infant formula?

The Codex Alimentarius Commission - the body responsible for the implementation of the international food standards, guidelines and codes of practice set by the WHO and Food and Agriculture Organisation (FAO) of the United Nations Food Standards - defines infant formula (IF) as "*a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding*".<sup>101</sup> Fundamentally, IF is a HM substitute for the purpose of infant feeding, formulated to meet the nutritional requirements of infants based on their physiological characteristics.<sup>102</sup>

Particular IFs are manufactured to fit under a range of age categories. Most often, IFs can be classified into one of the following categories: preterm and term formula (80 and 67 kcal/100 mL), starter/IF (0-6 months), follow-on formula (6 months-1 years), or growing-up/toddler formula (1-3 years).<sup>103</sup>

The composition of IF can be manipulated to accommodate various medical requirements. There is a variety of specialised IF feeds, including soy formula for infants with congenital lactase deficiency and galactosaemia; hypoallergenic formula containing extensively hydrolysed protein for infants with milk protein allergy; anti-reflux formula to reduce regurgitation and emesis; preterm formula to assist in short-term growth outcomes; or term formula.<sup>104</sup> Amino acid-based IF contains only free amino acids and may be utilised for infants with conditions such as protein maldigestion, malabsorption, gastrointestinal tract impairment, short bowel syndrome, severe food allergy, or eosinophilic gastrointestinal disorders,<sup>105</sup> while carbohydrate-free formulas may be indicated for managing carbohydrate metabolism disorders or malabsorption issues.<sup>106</sup> Fat-modified IF, on the other hand, may be necessary for the dietary management of fat malabsorption, insufficient bile salts, chylothorax, or long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency and low-mineral formulas are helpful in specific nutrient disorders or renal insufficiency.<sup>107</sup> Although only few infants meet the criteria for specialised IF,<sup>108</sup> for infants unable to be breastfed and have medical conditions preventing them from consuming standard varieties of IF, specialised IF may be a life-saving option.

## 1.3.2. Composition of infant formula

The composition of IF generally remains consistent<sup>109</sup> given the strict regulations with which manufacturers must comply. It is crucial for IF to provide adequate quantities of carbohydrate, protein, fat, vitamins and minerals to best support infant growth and development.<sup>109,110</sup> Most standard IFs are comprised of purified bovine milk, whey and casein-based protein, a blend of vegetable oils, lactose, vitamins and minerals.<sup>109</sup> The standard formula typically provides 68 kcal/100 mL and 1.4-1.7 g/100 mL of protein.<sup>111</sup> In comparison, preterm varieties of IF contain greater quantities of macro- and micro-nutrients, including energy (80 kcal/100 mL), protein (2.0-2.4 g/100 mL), calcium and phosphorus, specific to the increased nutritional requirements of preterm infants.<sup>112</sup>

With the known protective effects of HM beyond nutrition, manufacturers have made modifications to IF, attempting to resemble the composition and functionality of HM more closely.<sup>113</sup> One such change is the adjustment in the size and composition of fat globules. The structure of milk fat globules within HM are approximately 3–5  $\mu$ m and are organised into a tri-layered milk fat globule membrane composed of mostly phospholipids, cholesterol, enzymes and protein. <sup>114,115</sup> In contrast, the fat droplets within IF are smaller (0.3-0.5  $\mu$ m) and are primarily coated with only proteins. <sup>114,115</sup> Breij et al. investigated the effect of providing IF with large, phospholipid–coated lipid droplets to 91 infants born between 37 and 42 weeks' gestation. The study found that the intervention group had a higher incidence of diarrhoea and stool frequency, and found no significant difference in weight, length or head circumference compared to the standard IF group (n=83).<sup>114</sup> Other studies investigating the effect of adding modified lipid droplets to IF for healthy, term infants have also found no significant differences in anthropometric measures compared to infants consuming standard IF.<sup>116,117</sup>

Similarly, recent trials have examined the effect of adding DHA and ARA to IF. However, a 2020 systematic review and meta-analysis investigating the effect of DHA- and ARA-supplemented IF on long-term cognitive function showed no evidence of any benefit to support the addition of LCPUFA to IF in preterm and term infants.<sup>118</sup> Additionally, the content of LCPUFA in HM differs depending on the stage of lactation, maternal diet and between each feeding,<sup>119</sup> presenting ongoing complexities in matching IF with the composition of LCPUFA in HM.

Investigations into adding human milk oligosaccharide (HMO) to IF have also received considerable interest. HMOs are absent from IF, leading to the development of HMO substitutes, galactooligosaccharides (GOS) and fructooligosaccharides (FOS) which act to mimic the functionality of HMO within IF.<sup>120</sup> Around 200 HMOs have been isolated from HM, each with various proposed functions;<sup>121</sup> however, IF companies can currently only synthetically produce two (GOS and FOS). Very little evidence exists regarding the effects of GOS and FOS in IF.<sup>120</sup> However, small-scale studies have reported no significant difference in anthropometric indices (weight, length and head circumference), feeding tolerance, stool frequency, vomiting or spit-up events, gastric emptying, upper respiratory tract infections or gastrointestinal issues between FT infants consuming standard IF compared to GOS- and FOSadded IF.<sup>122-124</sup> One study based in Thailand reported softer stools in infants consuming IF containing GOS and FOS.<sup>122</sup> However, this may be explained by a larger load of oligosaccharides requiring fermentation which subsequently increases the content of faecal water.<sup>122</sup> Although adding GOS and FOS to IF may have no reported harmful effects, they may also provide no additional benefits. This, however, has not prevented IF with added HMO substitutes from becoming commercially available and highly marketed.<sup>125</sup>

## 1.3.3. Why is infant formula used?

For infants with no access to their mother's milk or milk from a donating mother, IF is the recommended source of nutrition for the first six months after birth.<sup>126</sup> For such infants, IF is a crucial option to support healthy growth and development during a time when they are most susceptible to adverse consequences of inadequate nutritional intake.<sup>109</sup> A mother's milk may be supplemented with IF for a variety of reasons; however, may subsequently give rise to harmful side effects, including adverse outcomes on the infant's gut microbiome, reductions in the maternal milk supply, decreases in the duration of breastfeeding and poorer metabolic outcomes.<sup>127</sup> Despite this, many maternal and neonatal complications can prevent successful breastfeeding. Common factors associated with early cessation of breastfeeding are lactational (latching and suckling; sore, cracked or bleeding nipples; pain when breastfeeding; engorged breasts; infected or abscessed breasts), psychosocial (prolonged periods of separation from the infant, perceived milk insufficiency, burden of milk pumping), nutritional (insufficient milk supply; inadequate infant weight gain; ineffective milk transfer), medical (maternal illness; infant illness; medication use), or lifestyle (returning to work/education) factors.128-131 Additionally, maternal choice, low maternal education and lack of family and health professional support are among the influencing factors in low breastfeeding initiation,<sup>132</sup> which may subsequently influence the use of alternative infant feeds such as IF.

#### 1.3.4. How is infant formula used?

IF is often produced and sold in powder form as manufacturers have strived to extend preservation and provide a product with a long shelf-life.<sup>133</sup> Currently, the manufacturing process used to produce powdered IF cannot guarantee a sterile product,<sup>134</sup> increasing the risk of intrinsic contamination and subsequent foodborne illnesses.<sup>135</sup> Bacteria of the Enterobacteriaceae family, including Enterbacter sakazakii and Salmonella, have, therefore, been attributed to causing life-threatening conditions such as neonatal meningitis, bacteraemia. NEC and necrotising meningoencephalitis.<sup>136</sup> Enterbacter Sakazakii has been estimated to infect 1/100,000 infants aged under 12 months and 8.7/100,000 low birth-weight infants and has been reported to carry a neonatal mortality rate of up to 33%.<sup>137,138</sup> The WHO and FAO estimate that 50-80% of neonatal Cronobacter sakazakii cases are attributable to powdered IF usage.<sup>137</sup> As such, two infants in the US died of *Enterbacter sakazakii* infection in 2022 after consuming contaminated powdered IF,<sup>139,140</sup> leading to international IF recalls due to the potential presence of harmful bacteria.<sup>139,140</sup> Alongside the intrinsic microbial risk of powdered IF, reconstituting powdered IF with unsterile water can provide a gateway for microbiological contaminants.<sup>141</sup> For these reasons, the WHO and FAO recommend that infants - especially those at the greatest risk of illness - should ideally be fed sterile liquid IF as these feeds are free from pathogenic microorganisms.<sup>142</sup> However, liquid IF often comes at a higher cost, shorter shelf-life and are not widely available outside hospital settings.<sup>134,142</sup>

There are limited studies investigating the adequacy of IF preparation, handling and storage in home settings. However, a US-based pilot study of 15 mothers investigating in-home IF preparation and feeding practices found that 73% did not wash their hands prior to IF preparation and 20% of mothers did not wash equipment prior to use. The study also showed that 47% of mothers did not bring the water to a boil before use; 60% did not check the temperature of the feed before infant consumption, and 66% did not keep the bottle cool during transport.<sup>143</sup> To ensure that microbial contamination of IF is kept to a minimum, vigilant temperature and sterilisation control are crucial - especially for preterm or low birthweight infants who are at increased immunological risk.<sup>144</sup>

Mothers of infants who require IF should be provided adequate education surrounding the use of IF.<sup>145</sup> However, Cheng et al. found that the comprehensiveness of IF and bottle-feeding resources in Australia were lacking and were often hard to understand, limiting their effectiveness.<sup>145</sup> The study showed that the overall comprehensiveness of 74 formula-feeding resources was moderate, with a mean comprehensiveness score of 54.4%.<sup>145</sup> In particular, the amount of formula to feed infants (35%), the use of bottle teats (31%), special IF (30%), the composition of IF (23%), and the risk of bacterial contamination (20%) were among the most poorly addressed topics within the resources.<sup>145</sup> A similar study based in the US reported that the directions for preparation, use and storage of IF were consistent with a reading level appropriate for college.<sup>146</sup>

Furthermore, a systematic review investigating the behaviours of bottle-feeding mothers found that 11 studies reported over- or under-concentration of feeds by up to 30% and 23%, respectively, as a result of reconstitution errors.<sup>147</sup> The associated risks of providing an incorrect ratio of IF with water or other liquids can lead to an infant gaining excess weight, failing to thrive or experiencing electrolyte imbalances.<sup>148,149</sup> Receiving support and education from a health care professional on how to prepare and use IF correctly has been shown to positively influence the reconstitution of IF feeds.<sup>150</sup> However, a systematic review found that mothers who are formula-feeding reported receiving a lack of sufficient education from their health care provider.<sup>147</sup>

## 1.3.5. The International Code of Marketing of Breast-milk Substitutes

Any product that is being used to replace HM is a termed a breast-milk substitute<sup>151</sup>; however, for marketing purposes, IF is often referred to as formula or milk. Considering that HM is the optimal source of nutrition for infants, the International Code of Marketing of Breast-milk Substitutes outlines a health policy framework and recommendations for regulating the marketing of breast-milk substitutes, feeding bottles and teats.<sup>151</sup> The code – adopted and effectuated in New Zealand through legislated food standards and three voluntary codes<sup>152</sup> - aims to protect, promote and support breastfeeding by preventing member countries' governments, healthcare professionals and infant food manufacturers from advocating HM substitutes. Despite such international agreements, globally, IF purchase and use has continued to increase throughout recent years, with the volume of IF sales from 2008 to 2013 increasing by 40.8%.<sup>153</sup> Furthermore, estimates have suggested that the IF industry was worth US\$44.8 billion in 2014 and was projected to reach US\$70.6 billion by 2019.<sup>154</sup> Although the global rate of exclusive breastfeeding (EBF) is slowly increasing,<sup>155</sup> IF marketing and use remains high, undermining the establishment and continuation of breastfeeding.<sup>151,156</sup>

## 1.3.6. Benefits and risks of using infant formula

IF is a nutritionally safe and convenient option for mothers unable or unwilling to breastfeed their infants. For example, a mother may need to return to work or study. IF is, therefore, a suitable option to facilitate this transition - especially if the workplace does not provide facilities for hygienic collection and storage of expressed milk, flexible hours or breaks to breastfeed.<sup>157,158</sup> Barnes et al. investigated the reasons for exclusive IF use among 102 mothers in a tertiary maternity hospital in Australia.<sup>159</sup> The study found that one of the most common reasons for choosing to use IF exclusively was 'convenience and coping' as IF supported their lifestyle and allowed mothers to receive more support from partners and wider family.<sup>159</sup> Such findings demonstrate the convenience of having IF when mothers are not easily able or may choose not to breastfeed.

In high income countries, IF is more commonly used in families of low socioeconomic status (SES) than in families of high socioeconomic status. Gibbs & Forste conducted a study of 8,030 American mothers examining infant feeding practices and SES.<sup>160</sup> The study found that mothers from low SES were 1.76 times more likely to feed their infant predominantly IF than

mothers from moderate-high SES (47.9% vs. 27.2%, p <0.05). Despite assumptions that families of low SES are more likely to rely on the more affordable option of breastfeeding,<sup>161</sup> short parental leave, targeted marketing and the high cost of IF may exacerbate socioeconomic inequalities and neonatal health risks associated with IF use.<sup>162</sup>

Lastly, preterm infants fed IF have been shown to have advanced and more rapid weight gain at term than their breastfed peers. A meta-analysis found that preterm infants (born  $\leq 37$  weeks of gestation and/or under 2500 g at birth) fed IF had a higher fat mass across 32 and 36 weeks' and at term than their breastfed peers,<sup>163</sup> possibly as a result of a protein intake excessive to requirements.<sup>164</sup> Such findings led to the "Early Protein Hypothesis," whereby excessive protein intake beyond the infant's metabolic requirements may increase insulin secretion and insulin-like growth factor, ultimately causing rapid growth, early adiposity rebound and a higher BMI in childhood.<sup>165</sup> Testing this theory, studies across Europe have shown that IF with a lower quantity of protein is associated with a reduced weight gain velocity and body mass in infancy and childhood, with growth trajectories similar to breastfed infants.<sup>166–169</sup> For example, a study by Koletzko et al. found that of 636 participants, infants assigned to the higher protein group (n = 323) had a significantly higher weight (12.42 kg vs. 12.60 kg), weight-for-length z score  $(0.18 \pm 0.86 \text{ vs}, 0.37 \pm 0.93)$  and body mass index  $(16.1 \pm 1.2 \text{ vs}, 16.4 \pm 1.3)$  at 24 months of age than the lower protein group, for which growth parameters did not differ from the control group of exclusively breastfed infants.<sup>168</sup> The infants' length across both intervention groups was unaffected, indicating that the differences in weight were likely due to increases in fat mass.<sup>168</sup> Clearly, the protein content of IF is associated with accelerated weight gain beyond expected growth, which may increase the risk of later-life obesity.<sup>170,171</sup>

## 1.4. HUMAN MILK DONATION

## 1.4.1. What is human milk donation?

Human milk donation (HM donation) is the gifting of expressed milk to a human milk bank (HM bank), registered facility or informally shared with another mother for consumption by an infant unrelated to the donor.<sup>172</sup> In circumstances where mothers cannot breastfeed or lack sufficient milk supply, HM banks and informal milk sharing play a crucial role in providing HM to vulnerable infants.<sup>173</sup>

In hospitals with the support of a HM bank, donor human milk (DHM) is most often reserved for VP infants, infants with gastrointestinal anomalies, metabolic disorders or infants who are born weighing <1500 g with a heightened risk of infection.<sup>173</sup> DHM is a beneficial option for such infants as, even after pasteurisation, it retains many growth and immune factors<sup>174</sup> which help protect the immature gut mucosa from pathogen invasion, reduces the risk of NEC and prevents unnecessary exposure to IF.<sup>175</sup> With increasing recognition of the benefits of DHM, interest in creating DHM facilities has proliferated globally.<sup>176</sup> This interest has been especially apparent amidst international shortages of IF as a result of supply chain issues, IF recalls and major IF facilities ceasing production.<sup>177</sup> Estimates from 2021 suggest that upward of 756 HM

banks were operational across 66 countries,<sup>178</sup> a substantial increase from the approximate 500 HM banks in 2018.<sup>179</sup>

## 1.4.2. Why is donated human milk used?

Feeding DHM to low birth weight and VP infants instead of IF is associated with a multitude of benefits to neonatal health. Such benefits include a reduced risk of NEC, improved feeding tolerance, decreased length of hospital stay and increased rates of breastfeeding.<sup>180–184</sup> For these reasons, DHM is the preferred alternative when mother's milk is not available or insufficient.<sup>185</sup>

Studies across various countries have investigated the motivations behind mothers donating milk to an HM bank. Qualitative studies of HM donors in Brazil, France and the United States reported that one of the most common reasons for mothers to donate their milk was due to excess milk production.<sup>186–188</sup> An equally popular reason to donate milk to HM banks was altruism - to help another mother/infant in need.<sup>187,188</sup> For mothers who have sought or chosen to feed their infant DHM over IF during the post-partum hospitalisation period, motivations are related to a perception that DHM is a more nutritious<sup>189,190</sup>, natural<sup>189,190</sup> and healthy<sup>190,191</sup> option compared to the artificial nature of IF<sup>189,190</sup> and because DHM provided a short-term bridge toward EBF.<sup>190</sup> However, hesitation to use pasteurised DHM was reported to be due to preference not to feed their infant another mother's milk, unknown donors, fear that DHM is unsafe and may transmit diseases, religious and cultural reasons, uncertainty surrounding the process of HM banks and paternal reluctance.<sup>189,191–194</sup>

## 1.4.3. How is donated human milk used?

As there is limited research investigating the clinical benefits of DHM use in a term or lowrisk population (>32 weeks' gestation, weighing >1500 g at birth), DHM is more often allocated to infants with a greater risk of adverse health outcomes.<sup>176,195</sup> An online questionnaire circulated across 142 German, Austrian and Swiss neonatal units showed that 77% of units providing the highest level of neonatal care (level three) used DHM in their standard feeding regime. In comparison, only 26% of level two units used DHM for the care of their infants.<sup>196</sup> A neonatal nutritional practice survey across 33 Australian and New Zealand neonatal facilities showed similar limitations in utilising DHM, with 15 units reporting having no access to DHM.<sup>197</sup> However, a 2020 study investigating the prevalence of DHM use in 214 US nurseries found that 17.6% of nurseries routinely used DHM for well newborns born between 35-40 weeks' gestation.<sup>198,199</sup> Of these nurseries, 85% of donor milk programs were  $\leq$ 5 years old, indicating that inpatient DHM use for low risk infants is a novel and emerging practice. With rapid growth in DHM utilisation, a recent shift in its use to include more lowrisk infants is evident; however, unpasteurised informal milk sharing is simultaneously increasing among mothers of healthy infants.<sup>198,200</sup>

A recent advancement in the HM industry is the use of DHM to produce a ready-to-feed human milk-based formula (HMF). This concept involves the addition of human cream (derived from the separation and centrifugation of HM) and HM protein (isolated by dialysis and freeze-

drying of HM) to whole HM donated by lactating donors.<sup>201</sup> DHM provided to a very low birth weight infant often requires fortification to meet their increased nutritional demands.<sup>202</sup> HMF is therefore designed to address these increased caloric and protein needs by providing a product enriched with protein and fat of human origin.<sup>201,203</sup> One HMF company, Prolacta, produces commercially available HMF designed for premature and critically ill infants.<sup>203</sup> However, very little evidence exists regarding HMF use and further research is needed to validate the efficacy of HMF, especially in premature and critically-ill infants.

Similarly, HM-based fortifier has gained significant attention for very low birth weight infants.<sup>204</sup> HM-based fortifier is designed to be added to mothers' or donor HM in place of a bovine milk-based fortifier. Canadian studies have shown that fortifying HM with HM-based fortifier compared to bovine milk-based fortifier in very low birth weight infants had no difference in the risk of NEC, feeding intolerance, infection and mortality and no improvement in growth,<sup>204</sup> and no difference to neurodevelopmental outcomes at 18 months corrected age.<sup>205</sup> At present, there is insufficient evidence to support using HM-based fortifier in place of bovine milk-based fortifier for very low birth weight infants.

## 1.4.4. Regulation, facilitation and screening of human milk donors

Operational safety and quality are fundamental to the safe facilitation of HM banks.<sup>206</sup> However, internationally, operational procedures of individual HM banks vary depending on the legal regulations of their respective governing body.<sup>176</sup> International HM bank guidelines endorse screening potential donors for similar serological, microbiological, medical and lifestyle parameters.<sup>206–209</sup> One such guideline published by the Human Milk Banking Association of North America (HMBANA) outlines the screening procedures that a mother must undergo to determine whether they are fit for milk donation.<sup>210</sup> Similar to the guidelines for donor screening created by the United Kingdom Association for Milk Banking,<sup>211</sup> the HMBANA guideline suggests that potential donors be serologically screened for the human immunodeficiency virus 1 and 2, human T-lymphotropic virus 1 and 2, hepatitis virus B and C, syphilis and tuberculosis.<sup>210</sup> Additionally, the HMBANA advises that donors who have had a blood transfusion or an organ or tissue transplant within the past 12 months be temporarily denied eligibility to donate milk.<sup>210</sup> Donors will also be screened via written questionnaires examining tobacco, alcohol and illegal drug use; medication intake; piercings or tattoos within the last 12 months; or previous travel that may place one at higher risk of transmitting Creutzfeldt-Jakob disease.<sup>210</sup> Mothers who do not meet the criteria for HM donation are not eligible to donate their milk.

## 1.4.5. Expression and storage of human milk for donation

To ensure the safe exchange of DHM, some HM banks provide donors with instructions on how to best express, store and transport their milk to the HM bank facility. The temperature and amount of time spent in storage and transport can significantly impact the safety and quality of expressed milk due to the increased risk of bacterial contamination and changes in the macronutrient content of the milk.<sup>212</sup> To reduce the risk of such hazards, the European Milk Bank Association (EMBA) and National Institute for Health and Clinical Excellence have each developed a set of guidelines for expressing, handling, and storing DHM.<sup>208,209</sup> Both guidelines encourage eligible donors to collect expressed milk rather than drip milk (milk that spontaneously drips from the contralateral breast during breastfeeding); ensure that breast pump equipment is thoroughly cleaned and sterilised prior to use; ensure appropriate hand washing and hygiene protocols; use containers provided by the HM bank or hospital (labelled with date and time), and freeze milk at or below -18°C as soon as possible to maintain the nutritional and microbial content.

## 1.4.6. Pasteurisation of donor human milk

DHM often undergoes pasteurisation to inactivate various bacterial and viral pathogens, which could otherwise be transferred through ingestion of raw HM.<sup>213,214</sup> With ongoing advancements in technology, new milk processing techniques are being developed to reduce the risk of milkborne illnesses and preserve bioactive components found in HM.<sup>185</sup> Various methods are used to pasteurise HM, including high-temperature short-time, high-pressure processing, microwave irradiation, thermo-ultrasonic treatment and ohmic heat treatment or flash-heating.<sup>185,215</sup> However, as Holder Pasteurisation (HoP) is internationally endorsed by Milk Bank Associations,<sup>210,216</sup> it is the most commonly used pasteurisation technique.<sup>217</sup> HoP involves heating milk in a water bath to 62.5°C, ensuring it is held at this temperature for 30 minutes to reduce or destroy heat-liable pathogens.<sup>217</sup> It is then rapidly cooled and frozen at -20°C until required. Although HoP destroys a significant amount of IgA in DHM, the remaining immunoglobulin content, in combination with the bactericidal effects of HoP, has been shown to effectively destroy and inhibit adhesion and growth of harmful pathogens such as *Escherichia coli*.<sup>185,218,219</sup>

Many naturally present components of HM, including immunological and growth factors, may remain in pasteurised DHM;<sup>220</sup> however, this is significantly dependent on the degree of processing of DHM prior to infant ingestion. The inadvertent degradation of some of the components within DHM is inevitable following heat treatment, with reported reductions in lipase, amylase and some immune factors and hormones, which consequently may affect the digestibility and nutrient availability for the ingesting infant.<sup>217</sup> However, a review of 44 studies showed that DHM retains many beneficial nutritional and biologically functional properties following HoP treatment, including a range of cytokines, growth factors, amino acids, vitamins, lipids and saccharides (**Table 1**).<sup>174</sup> Studies investigating the effect of pasteurisation on the concentration and activity of lysozyme, IgA, sIgA, IgM, IgG, lactoferrin, TNF-a, IL-10, IL-8, IL-6, IL-1b, INF-g and white blood cell count have reported reductions with varying degrees of significance.<sup>174</sup> This is likely a result of various methodologies and experimental designs used to quantify such measures.<sup>174</sup>

<u>Table 1. Compositional Changes to Donor Human Milk Following Holder Pasteurisation</u> (adapted from <sup>174,221</sup>)

Component	<b>Retained with HoP</b>	Reduced or complete loss with HoP
Immunoglobulins		IgG-4

Engumos		Lingga
Enzymes		Lipase
		Alkaline phosphatase
		Amylase
Cytokines	IL-2	MIP-1β
	IL-4	MCAF/MCP-1
	IL-5	
	П -13	
	II = 13 II = 12p70	
	п. 17	
Growth Factors	EGF	IGF-1
	TGF-βI	IGF-2
	TGF-β2	IGFBP-2
	MCP-1	IGFBP-3
		EPO
		HB-EGF
		HGF
Hormones		Ingulin
Hormones		
		Adiponectin
		Leptin
		Cortisol
		Progesterone
Amino Acids	Free amino acids	Aspartate
	Taurine	Glutamine
	Methionine	
	Cystine	
	Glutamate	
Vitamina	D	Agorhia   Dahydroggoorhia
v italiilis		Ascorbic + Denydroascorbic
		Ascorbic Acid
	B2	Вб
	B5	
	Biotin	
	B3	
	B12	
	Zinc	
Oxidative Stress	Malondialdehyde	Glutathione
Markers	OPAC and Heyanal	Glutathione perovidase activity
Warkers	ORAC and Hexanar	Total antiovident consoity
T to the	Del	
Lipids	Polyunsaturated fatty acid $n3$ (20:5, 22:5,	
	22:6)	
	Polyunsaturated fatty acid <i>n</i> 6 (18:2, 18:3,	
	20:2, 20:3, 20:4, 22:4, 22:5)	
	Monounsaturated fatty acid (14:1, 15:1,	
	16:1, 17:1, 22:1, 20:1, 24:1)	
	Saturated fatty acid (10:0, 16:0, 15:0,	
	17:0, 20:0, 21:0, 22:0, 24:0)	
Nitrogen Content	Total nitrogen content	
Saccharides	Oligosaccharides	
Sacchanues	Chaosaminoglucans	
	Grycosanninogrycans Maeireettel	
	INIYOINOSITOI	
1	Lactose	

Empty cells = no data available.

IgG=immunoglobulin G, IL=interleukin, MIP-1 $\beta$ =macrophage inflammatory protein-1-beta, MCAF=monocyte chemotactic and activating factor, MCP-1=monocyte chemotatractant protein-1, EGF=epidermal growth factor, TGF- $\beta$ 1=transforming growth factor beta 1 and 2, IGF=insulin-like growth factor 1 and 2, insulin-like growth factor binding protein 2 and 3, EPO=erythropoietin, HB-EGF=heparin-binding epidermal growth factor, NGAC=oxygen radical absorbance capacity.

#### 1.4.7. Donor human milk handling and storage recommendations

Following pasteurisation, DHM is refrigerated or frozen and stored before it is later thawed for use.<sup>222</sup> The HMBANA recommends storing DHM in a refrigerator at 4°C and using the product within 24 hours.<sup>210</sup> If stored frozen, international guidelines suggest that DHM be stored for no longer than three to six months and should be kept at a temperature of -20°C to maintain safety and quality.<sup>209,210,216,223,224</sup> Any DHM stored frozen for over one year should be discarded.<sup>210</sup> Due to the various processing steps that DHM undergoes, beneficial components found naturally in HM may further deteriorate.<sup>222</sup> Schlotterer and Perrin conducted a systematic review of 14 peer-reviewed studies investigating the effect of short- and long-term refrigeration and freezing on the quality and composition of HoP DHM.<sup>225</sup> The review found that under refrigerated conditions, no significant changes were observed in microbial growth throughout various periods ranging from 24 hours to 9 days. However, the combined effect associated with storing DHM in frozen conditions was unclear. The content of fat and subsequent energy was reported to decrease by 3-8% between 24 hours and eight months of frozen storage (-20°C), while the carbohydrate composition remained stable throughout extended frozen storage.<sup>225</sup> The change in protein content was inconsistent, with both significant increases (13.4%)<sup>226</sup> and decreases (3.9%)<sup>227</sup> reported. Microbial growth, antimicrobial activity and antioxidative capacity under frozen conditions were investigated, and no significant changes were reported for the first 8 months<sup>225</sup>; however, one study reported an increase in bacterial growth at six months.<sup>228</sup> The effect of refrigeration and freezing DHM seems to have mixed effects dependent on the length and temperature of storage; however, prolonged storage and freezing tend to have a more significant deteriorative effect on the composition of DHM than short-term storage.

## 1.4.8. Benefits and risks of donor human milk

Although there is a lack of evidence supporting the use of DHM in MLP and ET infants, various studies have shown the health benefits attributable to the use of DHM compared to IF in infants born  $\leq$ 37 weeks and/or  $\leq$ 2500 g. Three systematic reviews have investigated the effect of DHM on the clinical outcomes for premature infants and collectively found that DHM was protective against NEC compared to IF.<sup>184,229,230</sup> Two of these reviews also found a significant decrease in the incidence of feeding intolerance with DHM use,<sup>229,230</sup> while Schultz et al. also reported fewer episodes of diarrhoea in infants receiving DHM over IF.<sup>231</sup>

DHM has also been shown to be associated with slower growth rates than IF in the early postnatal period. A systematic review by Boyd et al showed that of infants aged <37 weeks' gestation or with low birthweight (<2500 g), those consuming IF regained their birthweight earlier and had a greater increase in weight in the first two months of life than infants consuming solely DHM.<sup>229</sup> This study also found that parameters of growth, including length and head circumference, tended to be in favour of IF. The benefits to an infant's short-term growth are clear; however, further investigation on the effect of consuming DHM rather than IF on an infant's long-term growth and health is warranted.

DHM has also been reported to create a bridge toward breastfeeding, with studies from Italy and the US showing that DHM use in neonatal units can increase the rate of breastfeeding by

up to 22%.<sup>182,232,233</sup> However, more recently, concerns have been raised about the negative impact that DHM can have on the initiation and duration of breastfeeding. Williams et al. conducted a systematic review of DHM use and rates of maternal breastfeeding to investigate such speculations.<sup>234</sup> The review found a significant increase in the number of infants receiving any of their mother's milk on discharge from the hospital after introducing DHM (RR 1.19, p = <0.01); however, no differences in EBF on discharge or for the first 28 days of life after introducing DHM were found. It has been suggested that DHM use may cause mothers to undervalue their own milk and subsequently rely on DHM.<sup>235</sup>

Furthermore, according to cost analyses, HM banks are more costly to operate compared to utilising IF. A 2017 study from a German milk bank found that the cost of providing DHM to infants with birth weights <1500 g was €82.88 per litre, compared to IFs €10.28 per litre.<sup>236</sup> The majority of the additional DHM costs were attributable to personnel (51%), materials (27%) and overheads (22%). Trang et al. found similar findings, with the unit cost of providing DHM to 363 very low birth weight infants in 2012 costing CAD \$4.95 per ounce, whereas providing preterm formula was 38-fold cheaper, averaging at CAD \$0.13 per ounce.<sup>237</sup>

Although the cost associated with DHM use is higher than IF, the potential cost saving attributable to health benefits cannot be underestimated. A systematic review exploring the economic benefit of DHM use versus HM substitutes in low birth weight, very low birth weight and extremely preterm infants found that cost-saving benefits with DHM use ranged from USD \$8167 to \$238,000 per infant.<sup>238</sup> The review measured a variety of outcomes, including duration of hospital stay, incidence and severity of NEC (medical and surgical), sepsis, viral infection, incidence of feeding intolerance, duration of enteral gavage feeding, time to full feed, weight gain and hospitalisation costs. However, of the seven studies included in the review, six were from high-income countries and the majority were based in North America (5/7 studies), limiting the extrapolation potential of the systematic review findings. Furthermore, four studies were model-based analyses, indicating a need for further high-quality trial-based investigations to determine the cost of DHM use in premature and low birth weight infants.

The reduction in cases of NEC associated with DHM feeding is of particular significance. A 2019 systematic review of predominantly VP infants found that feeding with DHM compared to preterm or term IF, either as supplementation to maternal milk or as a sole diet, decreases the likelihood of developing NEC by 87%.<sup>184</sup> According to the 2012 National Institute of Child Health and Human Development, up to 9,000 US infants are affected by NEC per year,<sup>239</sup> and each case of confirmed NEC are estimated to incur health costs upward of USD \$30,681.<sup>240</sup> Thus, depending on the baseline incidence of NEC, DHM feeding in preterm infants may significantly reduce healthcare expenditure as a result of a decreased prevalence of NEC.

## **1.5. PEER-TO-PEER MILK SHARING**

## 1.5.1. What is peer-to-peer milk sharing?

Some mothers who cannot breastfeed or lack adequate milk supply to fulfil their infant's needs may seek expressed HM from another lactating mother through informal means.<sup>241</sup> This practice is known as peer-to-peer milk sharing (PPMS), informal milk donation or milk sharing.<sup>242,243</sup> PPMS is not facilitated by a HM bank; instead, it involves using social networks, including friends, family, local community members or online acquaintances, to exchange expressed HM for the purpose of infant feeding.<sup>242,243</sup> The act of PPMS is a common and growing industry, yet little evidence exists regarding the prevalence of its practice.<sup>244</sup> Small-scale studies have investigated the awareness of PPMS in the US. One study of 813 mothers who gave birth to an infant >24 weeks' gestation investigated their HM sharing awareness and prevalence. The study drew attention to the high awareness of PPMS among mothers, with 75% and 73% of participants being aware of an infant receiving peer-donated milk or a mother sharing her milk, respectively.<sup>245</sup> Among those who have heard of PPMS, the most common sources of information regarding the practice come from friends, family, books, media, online websites, blog entries, radio or magazines.<sup>245–247</sup>

#### 1.5.2. Why is peer-to-peer milk sharing used?

With an extensive array of evidence supporting the benefits of HM,<sup>73,110</sup> mothers may feel inclined to opt for HM provided by a peer rather than using IF.<sup>242</sup> As such, Thornley<sup>248</sup> reported that of 43 Australian survey respondents involved with PPMS, the main reason for seeking shared milk between 1978 and 2008 was to "meet the mother's desire for her baby to have HM, rather than milk deriving from an animal." Perrin et al. reported various causes for seeking HM via Facebook communities, with the foremost reason being infant (colds, general immunity, necrotising enterocolitis or terminal illness) or maternal (medication use, food poisoning or breast cancer) health concerns.<sup>249</sup> Seeking HM from peers to supplement a mother's milk has also become increasingly popular due to limited supply and access to banked milk, which is most often prioritised for hospitalised or critically ill infants.<sup>250</sup> On the other hand, milk donors are motivated to share their excess milk for altruistic and practical reasons. Gribble et al. summarised such reasons as wanting to help another mother/infant in need, having surplus milk that they did not want to go to waste, believing that HM is important and/or superior to IF, or beliefs that donating to a HM bank was not accessible, practical or acceptable.<sup>251</sup>

#### 1.5.3. How is peer-to-peer milk sharing facilitated?

Social media has become the mainstay for connecting mothers who require HM for their infant with mothers who have excess HM to share.<sup>251</sup> There are several not-for-profit online websites to enable the safe exchange of HM from donor to the receiver, such as Eats on Feets, Human Milk for Human Babies (HM4HB), MilkShare and Only the Breast.<sup>252–255</sup> Most PPMS platforms have protocols and agreements to protect both parties involved in the transaction.<sup>256</sup> For example, MilkShare guidelines forbid selling HM; donors are to be refunded for the cost of basic supplies, and the recipient is to pay shipping costs.<sup>255</sup> Furthermore, the ABM encourages families to make informed nutritional decisions and reduce the risks involved with PPMS by following safe milk handling practices and performing medical screening of the donor.<sup>200</sup> However, ABM advises against internet-based milk sharing as the donor and recipient

are previously unknown to each other; the donor cannot be medically screened, and the milk is often not fit for infant consumption upon exchange due to thawing, spoilage or bacterial contamination.<sup>200</sup> Despite these recommendations, PPMS continues to become ever more popular.<sup>243</sup>

PPMS is often commenced for selfless purposes;<sup>242</sup> however, certain HM exchanges may be for profit.<sup>256</sup> Research has shown that over half (57%) of posts on milk-sharing platforms in the US were advertising their milk for profit, with mothers with an abundance of excess HM being more likely to sell than donate.<sup>257</sup> The commercialised reality of HM sharing introduces the risk of HM adulteration, whereby HM is mixed with water or cow's milk to increase total volume.<sup>258,259</sup> As such, Keim et al. found that of 102 samples of HM purchased from internet-based platforms in the US, 10% were contaminated with bovine-DNA, indicating the presence of cow's milk within the HM sample.<sup>259</sup> Ingestion of cow's milk during infancy can adversely affect an infant's health due to insufficient iron content and an excessive quantity of protein and minerals.<sup>260</sup> An inadequate nutrient composition as such can cause irritation of the gastric lining leading to intestinal blood loss; iron deficiency; and can increase the renal load, placing additional pressure on the infant's kidneys and increasing the risk of dehydration.<sup>260</sup>

## 1.5.4. How does informal milk sharing differ from formal human milk donation?

Unlike formal HM donation, the screening of donors in PPMS tends to be low. As such, one study reviewing postings made on US milk-sharing websites in 2011 found that of 174 donors, only 2% mentioned that they had been screened for infectious diseases and 20% self-reported being "disease-free".<sup>257</sup> This was likely compounded by the fact that only 3% (n=2) of mothers seeking HM requested proof of blood screening results or a disease-free status in their postings.<sup>257</sup> Furthermore, Palmquist et al. described the HM-sharing practices of 867 donors and recipient mothers in the US. The study found that among mothers who had serious concerns about the disease status of the donor (81.9%), the majority did not request information on the donor's blood tests (65%), prenatal records (79%) and medical history (62%).<sup>243</sup> Without sufficient medical screening, donating mothers may be transferring infectious diseases through their milk and exposing the infant to severe illnesses, including Human Immunodeficiency Virus and Cytomegalovirus, which may go unrecognised without specific testing.<sup>214</sup>

Additionally, PPMS does not have formally established operating procedures as seen in HM banks. HM donated to HM banks often undergoes pasteurisation and microbiological testing prior to ingestion by the recipient infant.<sup>173</sup> However, PPMS is open to a myriad of collection, storage and transportation techniques that can create conditions for pathogenic bacteria to thrive.<sup>261</sup> It is important to acknowledge that although PPMS bears a significant risk of microbiological contamination, research has shown that many milk-sharing mothers follow safe handling and storage practices as recommended by the ABM.<sup>262</sup> As such, a 2017 survey conducted by Reyes-Foster and colleagues explored the extent to which mothers involved in PPMS adhered to the ABM clinical handling and storage recommendations. The study's outcomes were promising, with 78.9% of participants regularly sanitising pumping equipment, 82.3% washing their hands before handling expressed milk and 54.4% using ice when

transporting milk.<sup>263</sup> Additionally, unsafe practices were seldomly reported, with 8.5% of participants reporting freezing milk for more than six months before feeding to an infant and 1.5% of participants leaving received milk at room temperature for over eight hours before being given to an infant.<sup>263</sup> Despite positive milk handling and storage practices, Keim et al. found that of 101 HM samples purchased from internet-based platforms, 74% were contaminated with gram-negative bacteria.<sup>261</sup> This may infer that regardless of following the correct milk handling etiquette, meticulous cleaning and sanitary processes are required to eliminate the bacterial risk of PPMS effectively.

## 1.5.5. Compositional differences between shared milk and formally donated milk

HM donation differs from PPMS because donor selection, quality assurance, transportation and pasteurisation are precisely controlled due to HM banks' extensive guidelines and practices.<sup>264</sup> As discussed in section four, pasteurised DHM is subject to the degradation of the bioactive components found in HM, including immunological factors, lipase and hormones.<sup>217</sup> However, less than 10% of milk shared between peers in the US is flash-heated (an at-home pasteurisation method involving heating milk in water to 100°C, then cooling the milk to 37°C to kill potentially harmful microbes<sup>265</sup>).<sup>243</sup> Subsequently, the aforementioned biologically active and nutritional components are likely to remain as the extensive process of pasteurisation, freezing, long-term storage and thawing is omitted.<sup>266</sup> However, this also means that harmful bacterial and viral contaminants that can be found in HM, such as Cytomegalovirus, Hepatitis or Human Immunodeficiency Virus,<sup>267</sup> remain undestroyed. Indeed, one study found that 21% of HM samples anonymously purchased from a popular US PPMS website were positive for Cytomegalovirus DNA.<sup>261</sup> In the general population, studies have shown that 84-100% of mothers are positive for Cytomegalovirus but remain asymptomatic,<sup>268</sup> highlighting the importance of adequate donor and milk screening. The United States Food and Drug Administration, the American Academy of Pediatrics, the HMBANA, the New Zealand College of Midwives, the Australian Breastfeeding Association, the ABM and the EMBA all, therefore, discourage feeding infants raw milk from unscreened donors or the internet due to the potential risk that PPMS carries.<sup>200,269–273</sup> Rather, each of these societies encourages mothers who wish to partake in milk sharing to understand the potential risks and strategies to mitigate PPMS risks to support informed decision-making.<sup>200,269–273</sup>

## 1.5.6. Benefits and risks of peer-to-peer milk sharing

Infants and mothers may face complications that make EBF unsuitable or not possible.<sup>242,250</sup> A mother may prefer HM over formula, be diagnosed with infectious disease, be sick or unwell, present with breast hypoplasia, or die during childbirth.<sup>250</sup> Or, an infant may be adopted or born in a same-sex couples' family<sup>242,250</sup>. In such circumstances, many mothers or caregivers unable to provide a sufficient supply of milk may seek another mother's milk to avoid the risks associated with formula feeding.<sup>274</sup> For example, a case of an adopted US infant who failed to thrive due to IF intolerance was soon rectified by being fed DHM.<sup>275</sup> However, with limited supply and access to DHM from HM banks,<sup>244</sup> PPMS may be the only viable option to provide an infant with milk of human origin.

The perceived risk of PPMS tends to be overridden by the strength of the relationship between milk-sharing mothers.<sup>243</sup> An online questionnaire found that among 54 PPMS donors in the US, most chose to share their milk with a friend/someone known to them (49%).<sup>247</sup> Similarly, among mothers who had received shared milk (n=31), 13% was acquired from a family member, and 59% was from a friend/someone known to them.<sup>247</sup> Interestingly, one respondent expressed that screening donors were more important for those unknown to the recipient.<sup>247</sup> An online survey administered by Kuznetsova et al. further demonstrated such themes. Of the 422 US respondents participating in PPMS, 56% had no concern about the safety of the milk they received and 78% chose not to carry out medical screening of the donor as they "trusted" them.<sup>276</sup> Rather, as DHM is available for purchase from HM banks in the US, these mothers chose to be involved with PPMS over HM donation due to the cost associated with purchasing milk from a HM bank (53.3%).<sup>276</sup> Furthermore, some respondents had concerns about the compositional quality of banked milk following pasteurisation (26.5%) and the inability to access prescriptions for DHM from a HM bank (23%).<sup>276</sup> In the face of such adversity, PPMS can undoubtedly stimulate friendship and unity between mothers experiencing similar circumstances.<sup>277</sup> Perhaps, these perceived benefits, in the face of barriers to accessing DHM, lead to the minimisation of potential health risks for mothers engaging in PPMS.

#### 1.6. BREASTFEEDING IN NEW ZEALAND

#### 1.6.1. New Zealand rates of breastfeeding

In New Zealand, the Ministry of Health recommends that an infant be exclusively breastfed until around six months of age and are continued to be breastfed up to two years of age or beyond.<sup>278</sup> All accredited maternity services in New Zealand are required to achieve and maintain the Baby Friendly Hospital Initiative (BFHI) standards set by the WHO and United Nations Children's Fund.<sup>279</sup> The overall aim of BFHI is to improve the rates of EBF initiation and ensure culturally safe, evidence-based care for mothers and infants.<sup>280</sup> Since the establishment of BFHI in 1991, there has been a substantial increase in the percentage of infants who are EBF at six months of age. The rate of EBF in infants aged six months in 1991 was 2.5%.<sup>281</sup> This has since increased to 9.5% in 2021-2022 period.<sup>282</sup> Nevertheless, **Figure 1** shows that the rate of EBF in New Zealand has not improved since 2012, steadily decreasing by 0.2-2% annually from 2011 to 2021. Compared globally, 18% of infants are EBF for six months,<sup>283</sup> highlighting the disproportionately low EBF rates in New Zealand. In 2021, 77.5% of New Zealand infants consumed HM as their sole nutrition source at hospital discharge.<sup>284</sup> Yet, by six months of age, the percentage of EBF infants dropped to 8.7%.<sup>282</sup> Despite a higher EBF initiation rate, the maintenance of this practice is in New Zealand is substandard.



<u>Figure 1.</u> Rate of exclusive breastfeeding in New Zealand infants aged six months, 2011-2022 (adapted from  $^{282}$ ). Data are %.

With decreases in EBF in the last decade, the use of IF in New Zealand has simultaneously increased. From 2016 to 2021, the rate of infants who were solely fed IF at discharge from the hospital remained relatively stable, averaging 3.5% (**Figure 2**). However, the increasing rate of partially breastfed infants (infants fed a combination of HM and IF) is of more concern. **Figure 2** exhibits the steady rise in New Zealand infants partially breastfed at discharge from the hospital, increasing from 12.1% in 2016 to 16.4% in 2021. Furthermore, of 5570 infants from mainly Auckland and Waikato, 40% are being introduced to solid food before four months of age.<sup>285</sup> Findings as such are suboptimal as studies have shown that replacing HM and introducing HM substitutes have adverse effects on the rate and duration of EBF and total breastfeeding.<sup>156,286,287</sup>



<u>Figure 2.</u> New Zealand rates of artificial feeding and partial breastfeeding at discharge from hospital, 2016 to 2021 (adapted from  $^{284,288}$ ). Data are %.

Breastfeeding rates among Māori and Pacific peoples have remained lower than New Zealand/European peoples for the past ten years.<sup>289</sup> When examining the rate of EBF at two weeks post-partum by ethnicity, absolute and relative differences exist between New Zealand/European, Maori and Pacific infants. From 2011 to 2020, the rate of EBF at two weeks for New Zealand/European infants decreased by 1% (73.3% to 72.3%).<sup>290</sup> In comparison, for infants of Maori and Pacific ethnicity, the rate of EBF decreased by 2.7% (68.9% to 66.2%) and 8.4% (68% to 59.6%), respectively.<sup>290</sup> A study by Bennett et al. identified the determinants of EBF in Māori women.<sup>291</sup> The study found that almost all Māori women initiated breastfeeding (96%); however, only 12% EBF their infant for the recommended six months. Factors associated with longer EBF duration were feeling it was best to breastfeed for longer than six months; connection to Te Ao Māori; feeling that breastfeeding would not impede their return to work; being undecided about immunisation status, and being an experienced mother.<sup>291</sup> Furthermore, Maori are more likely to be of lower socioeconomic classes<sup>292</sup> which has previously been shown to affect breastfeeding outcomes.<sup>293</sup> Future interventions aimed at integrating cultural principles of whanau ora (family) and reducing socioeconomic disparities may help to enable successful breastfeeding among Māori.

## 1.6.2. Milk banks in New Zealand

In February 2014, New Zealand saw the establishment of its first formal HM bank, the Christchurch Women's Hospital's Neonatal Unit Human Milk Bank.<sup>294</sup> Since its formation, the Christchurch milk bank has assisted many infants in need. In 2019 alone, 40% of the 919 infants admitted to the Neonatal Unit were nutritionally supported with pasteurised DHM provided by the Christchurch milk bank.<sup>294</sup> Three additional HM banks, Whangai Ora Milk Bank of Midcentral, Rotary Community Breast Milk Bank of Christchurch and Pataka Miraka

Milk Bank of Wellington, have since been formed.<sup>295–297</sup> Of note, no facilities have been established in Auckland, the largest and most populated city of New Zealand. With only four formal HM bank facilities in New Zealand, most mothers who wish to be involved with HM donation may not be presented with the opportunity to either provide donor HM for their infant when their milk is unavailable or donate their excess HM to help a struggling mother. Without an adequate HM donation facilitation system in place, vulnerable infants may have limited access to the benefits of DHM.<sup>298</sup>

## 1.6.3. Informal milk sharing in New Zealand

Little is known about the current processes in which New Zealand mothers and/or health professionals facilitate informal HM sharing. The New Zealand College of Midwives reports that informal milk sharing in New Zealand often occurs via social media platforms, websites or community-based groups whereby women seeking DHM are connected with women who can gift their milk to those in need.<sup>273</sup> The Ministry of Health, established HM banks, organisations and District Health Boards of New Zealand all support and recommend comprehensive serological, microbiological and lifestyle screening prior to any HM donation arrangement.<sup>294,295,299–302</sup> However, the rate, operations and facilitation of informal milk sharing in New Zealand remains largely unknown and requires further exploration.

# 2. METHODS

## 2.1. SYSTEMATIC REVIEW METHODS

## Types of Studies

Both randomised and observational studies, including randomised controlled trials, quasirandomised trials, non-randomised controlled trials, cohort, case-control, cross-sectional studies and before-and-after studies were considered for inclusion in the review. Studies must have been published prior to April 2022.

## Types of Participants

Participants included MLP infants (born between  $32^{+0}$  and  $36^{+6}$  weeks' gestation) and ET infants (born between  $37^{+0}$  and  $38^{+6}$  weeks' gestation), and/or with a birth weight of >1500 g, requiring supplementation of mother's milk with an alternative feed (either DHM or IF). Studies involving infants with congenital abnormalities or genetic/metabolic disorders which may otherwise affect health outcomes were excluded.

## Intervention/Exposure

The intervention consisted of exposing infants to DHM as supplement or substitute to mother's milk.

DHM consisted of expressed HM by a donating mother for the purpose of consumption by an infant with no- or limited- supply of their mother's milk. DHM may have been pasteurised or unpasteurised, facilitated by a HM bank or via individual arrangements (through family, friends, social media or internet groups, lactation consultants or midwives). Feeding mode may have been enteral feeding (either oral, gastric or transpyloric feeding tubes) or bottle feeding.

## Comparator

The comparison consisted of exposing infants to IF as supplement or substitute to mother's milk. Both preterm and term varieties of IF were considered for inclusion in the review.

Types of Outcome Measures

## Primary Outcome:

Rate of EBF at discharge or beyond (as defined by investigators).

## Secondary Outcomes:

- 1. Growth (changes in weight, length, head circumference and z-scores, growth velocity, body composition, body mass index at any time point, as defined by investigators).
- 2. Feed intolerance during hospitalisation (resulting in cessation or reduction of feeds, or as defined by investigators).

- 3. Duration of nutritional support (parenteral nutrition and/or enteral feeding), measured in days.
- 4. Incidence of infection during hospital stay (positive culture in a normally sterile bodily fluid, or as defined by investigators).
- 5. Incidence of NEC Bell's Stage 2 or more.<sup>303</sup>
- 6. Incidence of gastroenteritis during hospitalisation (gastrointestinal infection with diarrhoea and/or dehydration).
- 7. Incidence of hypoglycaemia (blood glucose <2.6 mmol/L, or as defined by investigators).
- 8. Incidence of neonatal morbidity (incidence of re-hospitalisation, respiratory or gastrointestinal infection in the first month of life).
- 9. Incidence of childhood morbidity (incidence of re-hospitalisation, overweight and obesity, respiratory or gastrointestinal infection, otitis or allergy).
- 10. Neurodevelopmental outcome during childhood (Total score at Age and Stages questionnaire ASQ, Bayley Scales of Infant and Toddler Development, or as defined by investigators).
- 11. Health economic analysis (any cost analysis associated with supplementation of mother's milk, or as defined by investigators).

# Search Methods for Identification of Studies

The Cochrane and Cochrane Neonatal criteria and standard methods formed the basis of the search method for this review. We used MEDLINE via Ovid, EMBASE, CINAHL, Scopus and Cochrane Central Register of Controlled Trials (CENTRAL) to search for published, full-text studies. The search was limited to studies published prior to April 2022. All geographic regions were considered. Searches were conducted from May 2022 to June 2022.

# Electronic Searches

Search terms pertinent to the research topic were used in combination with database-specific limiters (see **appendix 1** for full search strategy) for neonates and randomised controlled trials; quasi-randomised trials; non-randomised controlled trials; cohort studies; case-control studies; cross-sectional studies; and before-and-after studies. Protocols available on clinical trial registries (ClinicalTrials.gov, WHO's International Trials Registry and Platform and the Australian New Zealand Clinical Trials Registry) of ongoing or recently completed trials were searched. Studies published in English, Mandarin, Portuguese or Spanish were considered for inclusion in the review.

# Searching Other Resources

Reference lists in included studies were examined to identify relevant studies which were not identified in the primary search. Furthermore, known researchers in this area were consulted to determine whether any unpublished or ongoing research was available for review.
## Selection of Studies

Two investigators independently evaluated and appraised the retrieved studies, following the steps below.

- 1. Use reference management software, Covidence,<sup>304</sup> to combine search results and remove duplicate records of the same report.
- 2. Screen titles and abstracts to select relevant reports and exclude studies irrelevant to this review.
- 3. Screen the full text of potentially relevant reports.
- 4. Examine full-text studies for compliance with the eligibility criteria and combine multiple reports of the same study if eligibility criteria are met. Exclude studies not meeting the criteria for inclusion and record the reason for exclusion.
- 5. Finalise studies for inclusion and proceed to data extraction.

Any disagreements were resolved through discussion until consensus was reached. The selection process was documented in sufficient detail illustrated in a PRISMA flow diagram,<sup>305</sup> and a 'Characteristics of excluded studies' table.

## Data Collection and Analysis

The standard data collection methods as indicated by the Cochrane Neonatal Group were followed.

## Data Extraction and Management

Data extraction forms were developed for the purpose of data collection. Two review investigators independently extracted data from each eligible study. Information extracted from each controlled trial included but were not limited to source details, eligibility assessment, methodological details, characteristics of participants, details of intervention and control, and outcomes reported. Data extracted from observational studies included but were not limited to source details, eligibility assessment, methodological details, eligibility assessment, methodological details, eligibility assessment, methodological details, characteristics of participants, details of exposure and control, outcomes reported, confounder adjustments and types of analyses used. In the case of insufficient data or the requirement for further information, the primary study investigators were contacted for further information.

Data extraction, contacting authors for additional information, risk of bias assessment and analysis were beyond the scope of this thesis and therefore are not presented.

## Assessment of the Risk of Bias in Included Studies

The Quality Assessment Tool for Quantitative Studies<sup>306</sup> was used to assess the risk of bias in included studies. The strength of each study was rated as strong (1 point), moderate (2 points) or weak (3 points) against each of the six pre-specified criterion where bias may be introduced (selection bias, design, confounders, blinding, data collection and attrition). An overall rating

of strong (no weak ratings), moderate (one weak rating) or weak (two or more weak ratings) was assigned to each study on which to base a judgement about the risk of bias. Studies with the least amount of points were considered as having the lowest risk of bias.

## Measure of Treatment Effect

This systematic review directly compared DHM to IF either as supplementation of mother's milk or as sole diets when mother's milk is unavailable.

## Controlled Trials

For dichotomous data, the number of events in each study's control and intervention groups were calculated to determine risk ratios (RRs). For continuous data, mean differences (MDs) between the control and intervention groups were calculated. Where outcomes were not measured equivalently, we reported standardised mean differences (SMDs). Risk differences (RDs) were reported, and where a significant effect was identified, we calculated the numbers needed to treat to benefit (NNTB) or the numbers needed to treat to harm (NNTH). We reported 95% confidence intervals (CIs) for all outcomes.

## **Observational Studies**

For dichotomous data, the prevalence/incidence of events from each study's control and exposure groups was calculated to determine the adjusted risk ratios (aRRs) or odds ratios (aORs). For continuous data, adjusted mean differences (aMDs) were calculated between the prevalence/incidence of events from the study's control and exposure groups. Adjusted outcomes were prioritised over unadjusted outcomes, where possible.

### Unit of Analysis Issues

The unit of analysis was the individual infant participating in the study. Infants were only considered once for analysis. For clustered randomised studies, the neonatal unit or hospital was the unit of analysis. Clustered randomised studies were analysed using an estimate of the intra-cluster correlation coefficient (ICC) obtained from the trial, where possible. Otherwise, an ICC from a similar study or study population was used.<sup>307</sup> Where an ICC from a similar study or study population was reported within the review and a sensitivity analysis was conducted to examine the effect of variation in the ICC. The ICC was then used to calculate the reduced effect size.

Cluster-randomised and individually randomised studies were only combined if little heterogeneity was identified between the study designs and the relationship between the effect of the intervention and choice of randomisation unit was considered unlikely. In the event that heterogeneity in the randomisation unit was identified, a sensitivity analysis was performed to investigate the possible effects of the randomisation unit.

#### Dealing with Missing Data

Outcomes were analysed on an intention-to-treat basis, where possible. We therefore analysed outcomes based on the initial intervention/exposure allocated to the participating infant, regardless of what intervention/exposure they received. In circumstances where pertinent data was missing, or reported data was unclear, we contacted the original investigators of that study to request further information. Any assumptions of the methods used to deal with the missing data was explicitly reported. Where necessary, sensitivity analyses were conducted to assess how sensitive outcomes were to assumptions that were formed. The potential impact of missing data on the review findings was addressed in the 'Discussion' section.

#### Assessment of Heterogeneity

To provide clinically significant outcomes, the clinical and methodological characteristics of each included study was analysed to determine whether they were sufficiently homogenous to initiate meta-analysis. To do this, we examined the forest plot of each study and assessed for heterogeneity using the Chi<sup>2</sup> test and I<sup>2</sup> statistic. The I<sup>2</sup> statistic of each analysis was calculated to determine inconsistencies across the studies and the variability of effect estimates resulting from heterogeneity. The I<sup>2</sup> results was interpreted as below:

- 25% or below was considered as no heterogeneity
- 25%-49% was considered as low heterogeneity
- 50%-74% was considered as moderate heterogeneity
- 75% or greater was considered as high heterogeneity

Substantial heterogeneity was identified as having an I<sup>2</sup> above 50% with a low Chi<sup>2</sup> result (P-value <0.10).<sup>308</sup> In circumstances where substantial heterogeneity was detected, we investigated the potential causes via sensitivity and sub-group analyses. Where statistical heterogeneity was identified, this was considered when interpreting the meta-analysis results.

### Assessment of Reporting Biases

We performed an extensive search for eligible studies and excluded studies where data were duplicated. In instances where ten or more studies were identified for meta-analysis, we assessed for the possibility of publication bias by evaluation of a funnel plot. Where significant reporting bias was identified, a sensitivity analysis was conducted to establish and compare the effect of including and excluding such studies in the analysis.

### Data Synthesis

Meta-analyses was undertaken using R Studio.<sup>309</sup> We examined all included studies for potential clinical diversity, and meta-analysis was only used in situations where clinical consistency was certain. Fixed-effect models were only used for meta-analysis of randomised or quasi-randomised studies that were reasonably assumed to have the same underlying

treatment effect. Random effect models were used for meta-analysis of non-randomised and observational studies. Random effect models were also used for meta-analysis of randomised studies in instances where the included studies underlying treatment effects were assumed to be different. In instances where moderate or high clinical heterogeneity was detected, sensitivity and subgroup analyses were conducted to identify potential causes.

# Quality of Evidence

The quality of the evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach<sup>310</sup> for the following clinically relevant outcomes:

- 1. EBF at discharge or beyond (as defined by study investigators).
- 2. Growth (changes in weight, length, head circumference and z-scores, growth velocity, body composition, body mass index at any time point, as defined by investigators).
- 3. Duration of hospital stay, measured in days.
- 4. Feed intolerance during hospitalisation (resulting in cessation or reduction of feeds or as defined by investigators).
- 5. Incidence of infection during hospitalisation.
- 6. Gastroenteritis (gastrointestinal infection with diarrhoea and/or dehydration).
- 7. Hypoglycaemia (blood glucose <2.6 mmol/L, or as defined by investigators).

Two investigators independently assessed the quality of the evidence for each of the study outcomes listed above. Each study's evidence quality was ranked as high, moderate, low or very low.

Evidence derived from randomised trials was considered as high quality; however, the quality assessment was downgraded one level where serious (or two levels if very serious) limitations were identified, based on the five domains below<sup>311,312</sup>:

- Design (risk of bias)
- Consistency across studies
- Directness of the evidence
- Precision of estimates
- Presence of publication bias

Evidence from observational studies was considered as low quality, and downgraded to very low quality if any of the above factors, critical problems or unsystematic clinical observations were identified (e.g. case series or case reports).<sup>311,312</sup> In cases where an observational study was graded as very low, it was excluded from the review. However, an observational study was upgraded to moderate if one (or high if two) of the following criteria were met<sup>311,312</sup>:

- Displayed a large magnitude of effect
- All plausible confounding was shown to reduce the demonstrated treatment effect

- Exhibited a dose-response gradient

The Guideline Development Tool<sup>313</sup> was used to form a 'Summary of findings' table to report the quality of evidence for each outcome. In using the GRADE approach, evidence was assessed and categorised into one of the four domains below.

- 1. High: we are very confident that the true effect lies close to the estimate of the effect.
- 2. Moderate: we are moderately confident that the true effect is likely to be close to the estimate of the effect.
- 3. Low: we have low confidence that the true effect is close to the estimate of the effect.
- 4. Very low: We have very low confidence that the true effect is close to the estimate of the effect.

## Subgroup Analysis Investigation of Heterogeneity and Sensitivity Analysis

Where sufficient data was available, we planned to investigate the following subgroup analyses:

- a) DHM that is pasteurised versus unpasteurised to supplement mother's milk.
- b) IF that is preterm versus term to supplement mother's milk.
- c) Effects of supplementation of mother's milk for MLP versus ET infants.

However, data available were insufficient to undertake subgroup analysis and assessment of heterogeneity. If we had identified significant heterogeneity, we planned to undertake sensitivity analysis to determine if the review findings regarding the primary outcome were affected by the inclusion of only studies considered to have an adequate methodology (risk of selection and performance bias).

## 2.2. SURVEY METHODS

#### Aim

This research project used electronic survey methodology to investigate mothers' and health professionals' perceptions and experiences of informal HM donation in Aotearoa New Zealand.

### Research Questions

- 1. What are the current informal HM donation practices among healthcare organisations and communities in New Zealand?
- 2. What are the views and perspectives of New Zealand mothers and health professionals on informal HM donation?

## Study Design

This research was a mixed-method survey and contained both open- (free text) and closed-(multiple choice) questions, providing both quantitative and qualitative data. Two electronic surveys were created – one for the mothers and one for the health professionals. The platform used for the development of the surveys was Qualtrics. The surveys included a range of questions regarding mothers' and health professionals' demographic information, experiences and perceptions regarding informal HM donation. Display logic functionality was used to customise the survey to the respondent, showing only relevant questions based on their previous answers. The mothers' and health professionals' survey questions are available in **appendices 2** and **3**, respectively.

### Eligibility criteria

### Health Professionals

Health professionals were invited to participate in the survey if they, in the last five years, were involved in the facilitation of informal HM donation in Aotearoa New Zealand. Involvement with HM donation was defined as being a neonatologist, dietitian, lactation consultant, midwife, neonatal nurse, or other qualified health professional who facilitated the donation and/or receipt of HM, or who has been directly involved in the neonatal care of an infant receiving DHM.

### Mothers

Mothers who have been directly involved with informal HM donation were invited to participate in the survey. Direct involvement constituted mothers donating their own milk for another mother's infant; mothers receiving donated HM for their infant; or both. Those who were not directly involved but wished they could have been, or were not presented with the opportunity, were also invited to participate in the survey. The target population was mothers who gave birth to an infant after 01/01/2018.

#### Sampling and Recruitment

A snowball sampling method was used to recruit participants. The research team engaged with key stakeholders, clinicians and health professional organisations via email and requested that they consider taking part in the survey and/or identify potential participants who may be willing to contribute to the study and disperse the survey accordingly. The research team simultaneously circulated the surveys via advertisements on social media platforms (Facebook, Twitter and LinkedIn) to target mothers and health professionals involved with HM donation. Social media targeting strategies were used to reach Māori, health professionals and mothers with young infants. Tangible rewards were used to motivate participation in each survey by offering the opportunity to partake in a draw to win a gift voucher at survey cessation.

Survey responses were anonymous and participants were not directly contacted at any stage. However, key contact information for the principal investigator (telephone, email, affiliation) was provided in the participant information located on the survey's cover page. Mothers were encouraged to discuss the study information with their whānau/family, friends, colleagues and/or healthcare providers for support in deciding whether they wish to take part.

## Data Collection

The survey was circulated throughout New Zealand from 1<sup>st</sup> of April to 1<sup>st</sup> of July 2022. As there was no estimation of how many health professionals and mothers had been involved with milk donation in New Zealand, no formal sample size calculation was undertaken. We aimed to reach as many respondents as possible using targeted social media advertisements and key health professional organisations to circulate the survey. Survey responses were securely stored within the browser-based software and only accessed via a password-protected University of Auckland server. All responses provided in the survey were confidential and all data were stored anonymously for a period of 12 months before being permanently deleted.

### Informed Consent Process

Informed consent was obtained from all study participants. The survey's landing page contained information about the purpose of the survey and eligibility criteria. Before survey initiation, participants granted consent upon selecting the "I agree" option and initiating to respond to the survey's questions.

If participants wished to withdraw from the survey, they were able to stop the survey at any point by closing the browser window. Incomplete answers were, therefore, not included in the data analysis.

### Data Management

Survey responses were securely stored within the browser-based software, Qualtrics. All responses provided in the survey were confidential and anonymised. Upon completion of the survey, participant data was auto-saved within the Qualtrics software for a period of 12 months before permanent deletion.

The survey was open from 1<sup>st</sup> April 2022 to 1<sup>st</sup> July 2022. Any attempted responses after this time were denied access and relocated to a closed survey page.

## Statistical Analysis

Data were exported from Qualtrics into Microsoft Excel 2016 software for descriptive analysis. Descriptive analyses are presented as frequencies of the total number of responses to each question (%). IBM SPSS Statistics 28 was used for statistical analysis. Chi-squared test and Fisher Freeman Halton exact test were used to investigate associations between categorical variables. A p-value below 0.05 was considered statistically significant.

Qualitative information was analysed using thematic analysis within NVivo. The qualitative analysis process consisted of automatic identification of common phrases and recurring words by NVivo software that the Lead Investigator validated. Related words and phrases of text were then grouped into relevant thematic groups. Next, identified thematic groups were categorised into relevant overarching themes related to the answers provided by mothers and health professionals, respectively. Finally, collaborative discussions within the research team were initiated to validate the identified themes.

### Ethical Considerations

Ethical approval was granted by the Auckland Health Research Ethics Committee (AHREC application #AH23817) on 21 March 2022.

### 3. RESULTS

#### 3.1. SYSTEMATIC REVIEW RESULTS

The scale of this review is too large for a 90-point thesis; therefore, the findings of this review will be completed and published at a later date. My contribution is as follows: protocol development, registration and finalisation (PROSPERO registration ID: <u>CRD42022329890</u>); literature search; screening of abstracts; full-text review for eligibility, and finalisation of the studies to be included. Data extraction, contacting authors for additional information, risk of bias assessment and analysis are beyond the scope of this thesis.

#### Included Studies

An overview of the search and study selection process is shown in **Figure 3**. A total of 3944 studies were identified in the initial search. After 2247 study titles and abstracts were reviewed, fifty-one studies were identified as relevant to the research question and assessed for eligibility. Thirty-six studies were excluded during the full-text review due to not matching at least one of the criteria prespecified for inclusion in this review, leaving seven studies that fulfilled the review eligibility criteria and were therefore included in the review.

Five studies were identified as ongoing and, therefore, could not be included in the final analyses. A further three studies were marked as abstracts and author was contacted for further information.

#### Characteristics of Included Studies

From the studies identified through database searching up to June 2022, a total of seven studies were included in the systematic review. Across the seven studies (**Table 2**), 2033 infants received DHM as supplement or substitution to their mother's milk, with 91% of participants originating from one study. Five of the seven studies were based in the US and the majority were retrospective studies from 2017 onwards. Most of the studies investigated neonatal hypoglycaemia and rates of EBF in infants with a gestational age above 35 weeks and no funding or conflicts of interest were disclosed. Furthermore, the majority of studies compared DHM to IF as supplementation to mother' milk in infants admitted to neonatal intensive care units (NICU) or postnatal wards.

#### Characteristics of Ongoing Studies

As shown in **Table 3**, five ongoing trials were identified as investigating the use of DHM versus IF as supplementation or substitute to mother's milk in MLP and ET infants. All of the studies were registered within the last six years and are randomised controlled trials. The majority of the studies are based in the US, funded by universities and explore a range of biochemical, anthropometric, morbidity and infant feeding outcomes.



Figure 3. Study flow diagram.

## Table 2. Characteristics of Included Studies

#	Title	Author and Year	Study Design	Population	Setting	Intervention/ Comparison (n)	Funding/ Sponsor	Outcome Measures
1	Milk protein quantity and quality in low-birthweight infants: Metabolic responses and effects on growth. <sup>314</sup>	Räihä N, Heinonen K, Rassin D et al. Year: 1976	Randomised controlled trial.	GA between 28 and 36 weeks; and birthweight of < 2,100 g.	Premature Unit of Children's Hospital in Helsinki, Finland.	DHM (22) compared to IF (84).	Nil.	Feeding difficulties, oedema, NH, hyperbilirubinaemia, initial weight loss, rate of weight gain, weight regain from birth, length, blood urea nitrogen, ammonia, urine osmolarity, pH, serum protein, albumin and globulin.
2	Supplementary feeding in maternity hospitals and the risk of cow's milk allergy: A prospective study of 6209 infants. <sup>315</sup>	Saarinen KM, Juntunen- Backman K, Jarvenp AL et al. Year: 1999	Randomised controlled trial.	Healthy, full-term infants (GA strata pending author's response).	Three maternity hospitals in Helsinki, Finland.	DHM (1859) compared to IF (1789).	Helsinki University Central and Jorvi Hospitals.	Incidence of cow's milk allergy.
3	Outcomes associated with type of milk supplementation among late preterm infants. <sup>316</sup>	Mannel, R & Peck J. Year: 2017	Retrospective cohort.	LP infants (35 <sup>+0</sup> to 36 <sup>+6</sup> weeks GA).	Tertiary hospital in Oklahoma, US.	BF and EHM or pasteurised DHM (20) compared to BF and any IF (93).	Nil.	Length of hospital stay, feeding status at hospital discharge, NH, hyperbilirubinemia, difficulty breastfeeding.
4	The impact on the exclusive breastfeeding rate at 6 months of life of introducing supplementary donor milk into the level 1 newborn nursery. <sup>183</sup>	Merjaneh N, Williams P, Inman S et al. Year: 2020	Retrospective cohort.	Infants admitted to level 1 nursery; mother intends to EBF; supplementation indicated.	Level 1 newborn nursery at the University of Florida, US.	MM and DHM (49) compared to MM and IF (73).	Nil.	EBF at six months of life and timing of introduction to solid food
5	Type of feeding provided with dextrose gel impacts hypoglycemia outcomes: comparing donor milk, formula, and breastfeeding. <sup>317</sup>	Sen S, Andrews C, Anderson E et al. Year: 2020	Retrospective cohort.	Infants $\geq$ 35 weeks GA who received dextrose gel in the first 48h of life for NH.	Medical Center and Women's Hospital, Boston, US.	Dextrose gel and DHM (33) compared to dextrose gel and IF (33).	Nil.	Incidence of NH.
6	Supplementation-based hypoglycemia guidelines including donor breast milk reduce NICU admission. <sup>318</sup>	Ponnapakkam A, Rees D, Gallup MC. Year: 2021	Before and after study.	Infants > 35 weeks GA with risk factors for NH (LPI, SGA, LGA, and IDM).	Level 3 NICU in Texas, US.	MM and DHM (35) compared to MM and term IF (47).	Nil.	NICU admission for NH and rates of exclusive breastfeeding at discharge.
7	Clinical characteristics and breastfeeding outcomes in term dyads following in-hospital supplementation with pasteurized donor human milk or formula. <sup>319</sup>	Riley J, Cherkerzian S, Benjamin C et al. Year: 2021	Prospective cohort.	Infants > 36 weeks GA requiring nutritional supplementation.	Tertiary care hospital in north-eastern US.	MM and DHM (15) compared to MM and IF (24).	Brigham and Women's Hospital.	Rates of direct breastfeeding at one month post-partum.

DHM=donor human milk, EBF=exclusively breastfeed NH=neonatal hypoglycaemia, MM=mother's milk, EHM=expressed human milk, NICU=neonatal intensive care unit.

#### Table 3. Characteristics of Ongoing Studies

ſ	#	Title	Trial ID	Registration Year	Study Design	Population	Intervention/ Comparison	Setting	Target sample size	Funding/ Sponsor	Outcome Measures
	1	Giving donor milk instead of formula in moderate-late preterm infants: the GIFT trial.	ACTR N1262 10005 29842	2021	Pilot RCT.	Infants admitted to NICU with GA of $32^{+0}$ to $36^{+6}$ weeks with birth weight >1500g.	Pasteurised DHM compared to standard term IF.	South Australia.	100	Charities, societies and foundations.	Time to full enteral feeds, feeding tolerance, time to full suck feeds, duration of IV glucose, time to regain birthweight, weight z-score, length, head circumference, % free fat mass, % fed HM, length of hospitalisation, episodes and length of hospital readmittance, sepsis, NEC, method of feeding.
	2	Study of outcomes in preterm babies who are fed with mothers' own milk and pasteurised donor human milk against babies who are fed with mothers' own milk with preterm formula.	CTRI/ 2018/ 11/01 6480	2018	RCT.	Infants admitted to nursery with GA between 28 to 34 weeks.	MOM and pasteurised DHM compared to MOM and preterm IF.	New Delhi, India.	428	Kalawati Saran Children's Hospital, Lady Hardinge Medical College, New Delhi, India.	Feeding intolerance, NEC, sepsis, mortality, weight, length, anaemia of prematurity, osteopenia of prematurity, retinopathy of prematurity, rehospitalisation.
	3	The Milk, Growth and Microbiota study (MGM).	NCT0 32202 82	2017	RCT.	Late preterm newborns between 34 and 37 weeks' gestation and birth weight <2100 g.	Pasteurised DHM compared to preterm IF.	California, US.	48	University of California, US.	Weight change, abundance of bifidobacteria, lactobacillus and clostridium.
	4	Effectiveness of donor human milk supplementation for the treatment of hypoglycaemia in the breastfed infant.	NCT0 40303 12	2022	RCT.	$\geq$ 36 weeks' GA with blood glucose of <40mg/dl after birth.	Commercially sterilised DHM compared to standard term IF.	Omaha, Nebraska, US.	62	University of Nebraska, US.	Neonatal hypoglycaemia, duration of EBF, parental satisfaction of infant feeding.
	5	Donor breast milk and breastfeeding rates.	NCT0 45725 81	2020	RCT.	GA >34 weeks admitted to NICU.	MOM and DHM compared to MOM and IF.	California, US.	32	University of California, US.	% HM consumption at discharge, % HM consumption after discharge, BF duration, intention to BF, weight, height, head circumference, intestinal microbiome (microbial profiling), intestinal microbiome (alpha diversity).

RCT=randomised controlled trial, NICU=neonatal intensive care unit, GA=gestational age, DHM=donor human milk, MOM=mother's own milk, IF=infant formula, HM=human milk, NEC=necrotising enterocolitis, IV=intravenous, EBF=exclusive breastfeeding, BF=breastfeeding.

## 3.2. HEALTH PROFESSIONAL SURVEY RESULTS

## 3.2.1. QUANTITATIVE RESULTS

A total of 283 health professionals responded to the survey. Thirty-nine responses were left unsubmitted and were therefore excluded from the analysis. A further three participants consented to partake in the survey; however, they did not answer any of the questions. One respondent did not consent to the survey and eight participants did not answer any questions past the first eight demographic questions. Therefore, 232 survey responses were included in the final analysis. Respondents could skip questions, and some questions allowed participants to select multiple answers. The final number of responses (response count) for each question is shown in each table.

### Study Population

Demographic details of the respondents are shown in **Table 4.** Of the health professionals who responded to the survey (n=232), almost all (97.8%) were female and were of New Zealand/European descent (69.5%). Fifty-two health professionals (20%) selected 'other', indicating they identified as an ethnicity unlisted in the survey options. Of those who selected 'other', English (n=18), European (n=5), South African (n=3) and American (n=3) were among the most frequently reported ethnicities. There were no respondents of Pacific Islands' descent. The majority of health professionals were midwives (43.7%) working under district health boards (57.8%) and were from Auckland (12.3%), Waikato (11.4%) or Canterbury (10.5%). Respondents were equally distributed across primary (32.3%), secondary (21.2%) and tertiary (26.1%) care. Most health professionals (64.7%) were aged 40 or above and over half (50.9%) had 15 or more years of experience working in neonatal health.

Health Professional Demographics	Response Count, n (%)
Gender (n=230) <sup>†</sup>	
Female	225 (97.8)
Male	3 (1.3)
Non-binary	-
Undisclosed	2 (0.9)
Age (n=229) <sup>†</sup>	
18-29	19 (8.3)
30-39	62 (27)
40-49	52 (22.7)
≥50	91 (39.7)
Undisclosed	5 (2.3)
Ethnicity (n=232) <sup>†</sup> *	
New Zealand European	178 (69.5)
Māori	14 (5.5)
Chinese	2 (0.8)
Indian	3 (1.2)
Other	52 (20.3)
Undisclosed	7 (2.7)

#### Table 4. Health Professional Demographics

Organisation (n=232) <sup>†</sup>	
District Health Board	134 (57.8)
Non-governmental Organisation	10 (4.3)
Plunket	5 (2.2)
Private Care	8 (3.4)
Self-employed	62 (26.7)
Other	13 (5.6)
District Health Board (n=114) <sup>†</sup>	• • •
Auckland	14 (12.3)
Bay of Plenty	3 (2.6)
Canterbury	12 (10.5)
Capital & Coast	6 (5.3)
Counties Manukau	11 (9.6)
Hawke's Bay	8 (7)
Hutt	4 (3.5)
Lakes	2 (1.8)
Midcentral	9 (7.9)
Nelson Marlborough	2 (1.8)
Northland	5 (4.4)
South Canterbury	-
Southern	5 (4.4)
Tairāwhiti	5 (4.4)
Taranaki	3 (2.6)
Waikato	13 (11.4)
Wairarapa	4 (3.5)
Waitematā	7 (6.1)
West Coast	-
Whanganui	1 (0.9)
Health Profession (n=232) <sup>†</sup> *	
Neonatologist	6 (1.9)
Dietitian	6 (1.9)
Lactation Consultant	46 (14.6)
Midwife	138 (43.7)
Nurse	56 (17.7)
Lead Maternity Carer	26 (8.2)
Paediatrician	6 (1.9)
Other	32 (10.1)
Years of Experience in Neonatal Health $(n=230)^{\dagger}$	
0-5	40 (17.4)
6-10	40 (17.4)
11-15	33 (14.3)
≥15	117 (50.9)
Level of Healthcare (n=229) <sup>†</sup> *	
Primary	94 (32.3)
Secondary	82 (28.2)
Tertiary	76 (26.1)
Other (e.g., community-based work)	39 (13.4)

<sup>†</sup>Response count. \*Participants could select multiple answers.

### Donor Human Milk Availability

Questions related to DHM availability are shown in **Table 5**. DHM was reported to be available across 86% of facilities and was most often (38.7%) organised via individual arrangements (family/friends/internet/social media). The availability of DHM did not significantly differ across North- and South-Island district health boards (Chi squared  $[X^2]$  (1, n=131) = 0.2, p =

.66). Furthermore, no significant association was found between the availability of DHM and the type of organisation that the respondent worked (test statistic = 5.2, p = .13). Highest rate of formal HM donation via HM banks were reported for district health boards in Canterbury (91.7%), Midcentral (77.8%) and Capital & Coast (66.7%) since there are established HM banks among these regions. In contrast, HM donation across Waikato (76.9%), Hawke's Bay (87.5%) and Hutt (75%) were most reliant on hospital staff facilitation via informal arrangements. Respondents from Auckland reported most frequently facilitating HM donation through hospital staff (50%) or individual arrangements (42.9%, **Figure 4**).

Donor Human Milk Utilisation	<b>Response Count, n (%)</b>
Availability of DHM (n=232) <sup>†</sup> *	
Yes – Facilitated through the hospital staff	90 (27.4)
Yes – Via a human milk bank	65 (19.8)
Yes – Organised between individuals	127 (38.7)
No	46 (14)
Formal maternal consent requirements (n=180) <sup>†</sup>	
Yes	168 (93.3)
No	7 (3.9)
Unsure	5 (2.8)
Frequency of DHM use (n=182) <sup>†</sup>	
Often (e.g., daily/weekly)	69 (37.9)
Sometimes (e.g., fortnightly/monthly)	52 (28.6)
Rarely (e.g., quarterly/annually)	51 (28)
Never	-
Unsure	10 (5.5)
Limited availability of DHM restricting use $(n=182)^{\dagger}$	
Often (e.g., daily/weekly)	87 (47.8)
Sometimes (e.g., fortnightly/monthly)	41 (22.5)
Rarely (e.g., quarterly/annually)	32 (17.6)
Never	4 (2.2)
Unsure	18 (9.9)
Availability of Guidelines/Procedures relating to the us	e of DHM (n=182) <sup>†</sup>
Yes	129 (70.9)
No	26 (14.3)
Unsure	27 (14.8)

#### Table 5. Donor Human Milk Utilisation

<sup>†</sup>Response count. \*Participants could select multiple answers.

DHM=donor human milk



<u>Figure 4.</u> Proportion of respondents reporting donor human milk availability in their district health board (DHB). \*Participants could select multiple answers. No responses available for West Coast and South Canterbury DHBs. Number of responses for each DHB presented as (n).

### Donor Human Milk Usage

Details of DHM utilisation are shown in **Table 5**. Health professionals were asked which infants usually received DHM and could select multiple answers. Of the 177 respondents, most (53%) selected four or fewer criteria to determine which infants received DHM and most frequently reported utilising DHM for FT (71.8%), ET (65%), LP (58.2%) and MLP (54.2%) infants (**Figure 5**). There was a significant association between the level of care for which the respondent worked and the criteria used to allocate DHM (**Table 6**). Term infants more frequently received DHM when being cared at primary, secondary or other (i.e., private practice) health care sector (test statistic = 20.5, p = <.01), preterm infants more frequently received DHM under secondary level of care (test statistic = 34.1 p = <.01), while low-birthweight infants more frequently received DHM if being cared for under tertiary and secondary levels of care (test statistic = 11.5, p = .02, respectively). Health professionals working across multiple levels of care used DHM more frequently for low birthweight infants (75.7%).



Figure 5. Gestational age and weight of infants reported to be receiving donor human milk. Data are n (%). Participants could select multiple answers; therefore, the percentages do not equal 100 percent.

Table 6. Pro	portion o	f Rest	ondents	Reporting	Which	Categories	of	Infants	Receive	Donor
Human Milk	under the	eir Lev	vel of Car	re		•				

Criteria	Primary	Secondary	Tertiary	Other	Mix*	P value**
	( <b>n=46</b> )	( <b>n=38</b> )	( <b>n=40</b> )	(n=13)	(n=37)	
Preterm Infants	19 (41.3%)	30 (78.9%)	30 (32.5%)	5 (38.5%)	27 (73%)	<.001
Term Infants	39 (84.8%)	32 (84.2%)	18 (45%)	11 (84.6%)	26 (70.3%)	<.001
<u>&lt;</u> 1500 g	21 (45.7%)	25 (65.8%)	27 (67.5%)	5 (38.5%)	28 (75.7%)	.02

Respondents could select more than 1 criteria.

\*Respondents working across multiple levels of care. \*\*Fisher-Freeman-Halton Exact Test.

The frequency of DHM usage was similarly distributed, with 37.9% of participants reporting using DHM within their workplace often (e.g., daily/weekly), sometimes (25.5%, e.g., fortnightly/monthly) or rarely (28%, e.g., quarterly/annually). DHM utilisation differed depending on the location of the health professional. Respondents working in District Health Boards located in the South Island reported using DHM 2.3 times more frequently (daily/weekly) than those in the North Island (86.7% vs. 37%, respectively, p = <.01, **Table 7**). Respondents who reported most frequently using DHM daily or weekly were from Canterbury (83.3%), Midcentral (88.9%) or Nelson/Marlborough (100%). In contrast, respondents from Taranaki (100%), Whanganui (100%), Waitematā (50%) and Northland (40%) were among those who reported rarely using DHM within their workplace. Almost half (47.8%) of all health professionals stated that they often would like to use DHM to feed their neonatal patients; however, they are unable to due to limited availability. Furthermore, primary healthcare was

most frequently using DHM sometimes (45.2%), while tertiary care most frequently used DHM often (57.4%, **Figure 6**).

<u>Table 7. Proportion of Respondents Reporting Frequency of Donor Human Milk Use in Their</u> <u>Geographical Region</u>

Frequency of DHM Use	North Island (n = 73)	South Island (n = 15)	P value*
Often	27 (37%)	13 (86.7%)	.002
Sometimes	23 (31.5%)	1 (6.7%)	
Rarely	23 (31.5%)	1 (6.7%)	
· _ · · · · · · · · · · · · · · · · · ·			

\*Fisher-Freeman-Halton Exact Test.



<u>Figure 6.</u> Reported frequency of donor human milk use for each level of healthcare. Values are percentages of the frequency of donor human milk use for level of health care. Number of respondents for each level of healthcare indicated as (n). Primary=community-level health care. Secondary=health care services provided by specialists. Tertiary=specialist care for inpatients. Bars represent frequency of DHM use: often (blue), sometimes (orange), and rarely (grey).

### Donor Human Milk Guidelines and Processing

Guidelines were available within 70.9% of workplaces. However, **Figure 7** shows that only in six out of twenty district health boards (30%) all respondents agreed that guidelines were available. Responses were inconsistent in 5 DHBs (25%), with respondents indicating that guidelines were both available and unavailable at their respective district health board. Guidelines or protocols were not available in only one DHB.



<u>Figure 7.</u> Proportion of respondents reporting guideline/protocol availability in their district health board. Bars indicate the availably of guidelines/protocol: guideline/protocol is available (blue), no protocol/guideline is available (orange) or respondent did not know the answer (grey). No responses available for West Coast and South Canterbury DHBs. Number of respondents for each DHB indicated as (n).

Among health professionals who indicated undertaking screening of the DHM or donor, the majority reported that serological (e.g., blood testing for antibodies against HIV, Hepatitis C or B and syphilis, 45.8%) and lifestyle (e.g., smoking status, medication, drug and alcohol intake, 43%) testing were the most common screening procedures undertaken prior to the distribution of DHM. A limited number (11.2%) of respondents reported testing for microbiological contamination (Figure 8). The type of screening processes undertaken was significantly associated with the type of organisation for which the respondent worked (test statistic = 15.5, p = .04, **Table 8**). Health professionals from district health boards or Plunket were more frequently undertaking all three screening processes (26.7%) than those who worked for non-governmental organisations/charities/trusts (14.3%) and private care/self-employed (6.5%). Furthermore, geographical region was significantly associated with the number of screening processes undertaken (test statistic = 11.3, p = <.01), with the majority of North Island district health boards conducting two out of three types of screening processes (61.4%), while the majority of South Island district health boards reported more frequently undertaking all three screening processes (60%). Donors and/or DHM were reported not to be screened across 8.4% of district health boards.



<u>Figure 8.</u> Screening processes reported to be undertaken on donor and/or donor human milk. Figures are presented as n (%). Lifestyle screening=e.g., smoking status, medication, drug and alcohol intake. Serological=e.g., blood testing for antibodies against HIV, Hepatitis C or B and syphilis. Microbiological=e.g., bacterial contamination testing.

Table 8	<u>. Proportion of</u>	t Respondents	Reporting	<u>the Numbe</u>	r of Screening	<u>g Processes</u>	<u>Undertaken</u>
<u>in Their</u>	<u>Organisation</u>	-	1 0			-	

Number of Screening	N <sup>†</sup>	DHB/	NGO, charities,	Private care/	Other	P value*
Processes		Plunket	trusts	self-employed		
1 screening process	19	8.1%	14.3%	19.6%	18.2%	.042
2 screening processes	77	52.3%	71.4%	47.8%	45.5%	
3 screening processes	28	26.7%	0%	6.5%	18.2%	
Not screened	26	12.8%	14.3%	26%	18.2%	

<sup>†</sup>Number of respondents. \*Fisher-Freeman-Halton Exact Test. Screening process=lifestyle, microbiological or serological screening. DHB=District Health Board. NGO=Non-governmental organisations.

Pasteurisation (defined as heating HM to  $62.5^{\circ}$ C for 30 minutes prior to infant ingestion to kill potentially harmful microbes) was reported to be undertaken by 27.7% of respondents. Pasteurisation was more frequently reported in the South Island compared to North Island (73.3% vs. 27.4%, respectively,  $X^2$  (1, n=77) = 11, p = <.01), but did not differ among organisations (test statistic = 4.7, p = .19). Additionally, the majority (69.3%) of respondents reported that the nutritional composition of DHM is not analysed, and 28.5% were unsure whether nutritional analysis was performed. Three (2.6%) district health boards, including Hawke's Bay, Midcentral and Tairawhiti, reported that DHM was nutritionally analysed.

#### Donor Human Milk Practices

Health professionals reported that the associated expenses of HM donation (e.g., screening, pasteurisation, nutritional composition assessment) are most frequently covered by the

healthcare system (38.6%). Health professionals working under a district health board or Plunket most frequently reported that expenses were covered by the healthcare system (44%), while those working privately or self-employed reported costs are covered by the individuals (32%, donor and/or mother of the receiving infant, **Figure 9**). Over one quarter (26.7%) of respondents were unsure of how the associated expenses of HM donation were paid. Clinical documentation of DHM use (e.g., observation charts, fluid balance charts) was reported by the majority (88.9%) of health professionals.



<u>Figure 9.</u> Coverage of human milk donation-associated expenses reported by health professionals working under District Health Boards (blue); Non-governmental organisations, charities and trusts (orange); private care (grey); or other workplace (yellow). Figures are %. Number of respondents for each organisation indicated in brackets.

In circumstances where DHM has not been completely used, over half of the health professionals reported that excess DHM is frequently frozen and stored for later use (28.2%) or disposed of (27.8%). Almost one-quarter of participants (23.4%) did not know what was done with leftover DHM, and only 6.6% and 1.8% of respondents reported excess DHM being offered to a lower-priority infant or being used for research purposes, respectively (**Table 9**).

Donor Human Milk Procedures	Response Count, n (%)
DHM documentation within clinical notes $(n=180)^{\dagger}$	
Yes	160 (88.9)
No	8 (4.4)
Unsure	12 (6.7)
DHM screening procedures (n=179) <sup>†</sup> *	
Serological	130 (38.6)
Microbiological	32 (9.4)
Lifestyle	122 (36)
DHM and/or the donor are not screened	26 (7.7)
Unsure	29 (8.6)

### Table 9. Donor Human Milk Procedures

Analysis of DHM nutritional composition $(n=179)^{\dagger}$					
Yes	4 (2.2)				
No	124 (69.3)				
Unsure	51 (28.5)				
Pasteurisation of DHM prior to infant consumption (na	=177) <sup>†</sup>				
Yes	49 (27.7)				
No	100 (56.5)				
Unsure	28 (15.8)				
What is done with excess DHM $(n=176)^{\dagger*}$					
Disposed of	63 (27.8)				
Stored frozen and used later	64 (28.2)				
Offered to a lower priority infant	15 (6.6)				
Used for research	4 (1.8)				
Unsure	53 (23.4)				
Other	28 (12.3)				

<sup>†</sup>Response count. \*Participants could select multiple answers. DHM=donor human milk.

#### Health professionals' Viewpoints on Donor Human Milk Use

Health professional opinions regarding the practice of HM donation are shown in **Table 10**. Of the 205 health professionals who responded regarding how DHM should be prescribed, respondents most frequently felt that DHM should be prescribed by the medical team as a nutritional product equal to IF (80.5%), followed by 11.7% of respondents who felt that DHM should be prescribed as a nutritional supplement (equal to vitamins and minerals). The majority of health professionals were in support of DHM use in hospitals and community settings, though it was more common for respondents to support the use of DHM in the hospital (98.6%) compared to the use of DHM in the community (86.7%).

Table 10. Heal	th Professional	Viewpoints	on Human	Milk Donation

Viewpoints on Human Milk Donation	Number of Participants (n), %							
How should DHM be prescribed $(n=205)^{\dagger}$								
As a nutritional product (equal to infant formula)	165 (80.5)							
As a nutritional supplement (equal to vitamins and	24 (11.7)							
minerals)								
As a medicine (equal to pharmacological drugs)	16 (7.8)							
Support of DHM use in hospitals (n=218) <sup>†</sup>								
Yes	215 (98.6)							
No	2 (0.9)							
Unsure	1 (0.5)							
Support of DHM use in the community $(n=218)^{\dagger}$								
Yes	189 (86.7)							
No	9 (4.1)							
Unsure	20 (9.2)							

<sup>†</sup>Response count. DHM=donor human milk.

## 3.2.2. QUALITATIVE RESULTS

The survey had five free-text questions relating to views about informal HM donation. Health professionals were asked about how current informal HM donation practices could be improved and the potential risks and benefits of informal HM donation for both the infant and the donor. Identified codes and themes are presented in **Figure 10**.



Figure 10. Coding tree of health professional perceptions on how current informal human milk donation practices could be improved and the potential risks and benefits of informal human milk donation for both infant and donor.

### Improvements to Current Informal Human Milk Donation Practices

Out of the 240 respondents, 173 (72%) participants answered the question "*How could current practices regarding informal milk/waiū donation be improved?*". Four main themes emerged from the responses provided. Themes included: a) advocacy, b) reduce cost, c) better access, and d) guidelines. Example quotes are displayed in **Table 11**.

### Advocacy

Health professionals felt that education, promotion, and championing for informal HM donation would normalise and improve support for the practice. Health professionals discussed how informing mothers, other health professionals and the public about informal HM donation would allow mothers to have an informed decision regarding all of the potential feeding options available for her infant. Respondents commonly felt that "*education*", "*information*" and "*understanding*" was needed to improve informal HM donation practices. Additionally, health professionals felt that with improved advocacy, informal HM donation would become more mainstream and may support HM rather than IF feeding as being the primary alternative option when mothers' milk is unavailable.

#### Reduce costs

By using words such as "*available*" or "*accessible*", health professionals identified that mitigation of costs would inevitably make DHM use more attainable. Health professionals agreed that reducing costs through funding for screening and pasteurisation required for informal HM donation may increase the safety and accessibility for families seeking DHM. Additionally, it was noted that having free milk screening available would mean that health professionals could "*safely advocate for this option*" and that offering free, cheap processing and/or resources for informal HM donation would improve the safety of the practice.

#### Better access

Health professionals frequently felt that providing equitable access to informal HM donation services may improve safety and participation in the practice. Some health professionals stated that they wished a milk bank was available in their workplace, with some health professionals elaborating that access to DHM would subsequently increase with a greater number of community- and hospital-based milk banks. Additionally, some health professionals felt that having access to screening, pasteurisation and/or equipment, including bottles, breast milk pumps or storage containers at a low cost could improve the current informal HM donation scene.

### Guidelines

Health professionals identified that the lack of standardised pathways for informal HM donation has influenced their ability to facilitate the use of donor HM. Some respondents felt

that a standardised, nationwide set of HM donation guidelines would be beneficial for "*safe*" and "*easy*" exchange of DHM from donor to recipient. Health professionals felt that creating a reference point for further information for both health professionals and parents involved in informal HM donation may improve the trust in and the efficiency of DHM exchange. Furthermore, few respondents felt that an easier and faster consent process would be beneficial to the current informal HM donation process. The responses in **Table 11** highlight the need for a time-effective consent process to ensure that infants who may benefit most from DHM have prompt access to the milk without delay, which may in turn reduce IF initiation.

Table 11.	Codes	and th	hemes	pertaining	to	"How	could	current	practices	<i>regarding</i>	informa	<u> 1</u>
<u>milk/waiū</u>	donati	on be	improv	ved?"					-		, i i i i i i i i i i i i i i i i i i i	

	<b>Identified</b> Codes	Theme		Example Quotes
•	Inform about		a)	"Readily available information on appropriate guidelines /
	practice			screening for donors / what to look for when arranging
•	Normalise practice	A decasa	<b>b</b> )	informal milk donation."
•	Human milk	Auvocacy	0)	dongto and use donor milk and that this should be
	prioritised			aonale and use aonor milk and indi inis should be
				is inadequate"
			c)	"Being able to quickly access milk for new-borns needing
				milk with donated milk rather than first accessing AF
				[artificial formula]."
٠	Free/cheap		a)	"Free milk screening available so that we can safely
	screening and			advocate this option. Also, an option for milk to be
	pasteurisation	Reduce Cost		pasteurised or treated safely and cheaply in the community."
٠	Government or		b)	"Centralised funding to support
	health district			screening/testing/pasteurisation/storage and distribution."
-	funding			
•	Access to DHM		a)	"Have DHM more available for those who want to donate
•	Access to screening,	-		and/or receive."
	pasteurisation, and	Better	b)	"Access to a milk bank would provide more safety and
	resources (e.g.,	Access	\ \	consistency to whanau seeking milk donation."
	bottles)		c)	"Mothers could be given breast pumps and bags/bottlesto
•	More milk banks			neip facultate pumping mik for aonation.
•	Create guidelines		a)	"Currently we do not allow the informal sharing of mother-
•	Easier consent		1.5	to-mother breast milk."
	process	Cuidalinas	b)	"Clear, current, evidence-based guidance for practical risk
		Guidelines		reduction, risks, and benefits. "If a mother knows someone she trusts that can give her
			()	If a moment knows someone she trusts that can give her
				stating she takes full responsibility and start using the milk
				maybe as auickly as an hour timeframe."

DHM=donor human milk.

### Benefits of Informal Milk Sharing for the Infant

Three main themes were identified following thematic analysis of the responses provided for *"What do you think are the benefits of informal milk/waiū sharing for the baby/pēpi?"*. Of the 240 survey participants, 193 responses were provided (80%). Identified themes included a)

health benefits, b) prioritise human milk feeding, and c) species-specific nutrition. Codes, themes and example quotes are displayed in **Table 12**.

## Health benefits

Health professionals felt that a major benefit of informal milk sharing was the benefits to the infant's health. Respondents felt that many of the health benefits that come from breastfeeding an infant are also seen in infants fed HM through informal milk sharing routes. Many felt that informal milk sharing would have a positive effect on infants' microbiome/gut, immune system, and would reduce the risk of non-communicable disease. Additionally, some respondents linked the benefits of informal milk sharing with the reduction in IF use and how this may reduce the chance of short- and long-term morbidities for the infant. Some health professionals further described how this avoidance of IF may in turn increase the health benefits for the infant and expose the infant to biomolecules only available in HM.

## Prioritise human milk feeding

Health professionals felt that informal milk sharing benefits infants as it provided a gateway to HM feeding. Responses highlighted that an increased access to HM could in turn reduce the reliance on the use of IF. Health professionals emphasised that informal milk sharing will help "avoid" and reduce the "use" of and "exposure" to IF. Of those who felt that informal milk sharing may sharing provides a bridge to breastfeeding, some described how informal milk sharing may "help", "support", "encourage" or "promote" mothers in their journey of breastfeeding establishment and continuation to ensure that infants receive HM and the associated benefits.

## Species-specific nutrition

Health professionals also discussed the benefit of providing infants with a feeding option that is uniquely suited to human infants, some respondents quoting "*human milk for human infants*". Additionally, some respondents felt that providing a HM product to infants was more physiologically normal and provides infants with "*optimal*" or "*perfect*" species-specific nutrition.

Table	12.	Codes	and	themes	pertaining	to	"What	do	you	think	are	the	benefits	of	informal
<u>milk/w</u>	vaiū	sharing	<u>g for</u>	the bab	<u>v/pēpi?"</u>								Ū.	Ū	Ū.

Identified	Theme	Example Quotes
Codes		
<ul> <li>Benefits of HM</li> <li>Immunity</li> <li>Microbiome/Gut</li> <li>Less morbidity</li> </ul>	Health Benefits	<ul> <li>a) "Provides optimal nutrition for infant including all the benefits of breast milk."</li> <li>b) "[Infants receive] antibodies such as IgA [immunoglobulin A] that aren't present in artificial milk."</li> <li>c) "Improved gut microbiome cultivation."</li> <li>d) "Reduced SUDI [sudden unexpected death in infants] risk, reduced gastro and respiratory viruses, reduced long term health issues."</li> </ul>

•	HM not IF Reduced IF use Bridge to breastfeeding Access to HM	Prioritising Human Milk Feeding	a) b) c)	"Babies get breastmilkhelps mums to continue to breastfeed without using formula top ups." "The potential of keeping the baby on exclusive breastmilk- feeding while a mother solves a short-term breastfeeding challenge." "Enhanced equity for those who otherwise may not have access (e.g., lower socioeconomic status)."
•	Nutrition	Species-	a)	"Provides optimal nutrition for infant including all the
•	Natural	Nutrition	b)	"Human milk for human babies. Biologically normal."

HM=human milk, IF=infant formula.

#### Risks of Informal Milk Sharing for the Infant

Of the 240 survey participants, 194 (80.8%) responded to "*What do you think are the risks of informal milk/waiū sharing for the baby/pēpi?*". Three main themes emerged following thematic analysis. These themes included a) infant illness, b) contaminated milk, and c) undisclosed factors. Identified codes, themes and example quotes are displayed in **Table 13**.

#### Infant illness

Many health professionals identified bacterial or viral transmission from the donor to the ingesting infant as a risk of informal milk sharing. Some participants used words such as "*low*", "*potential*", "*possible*" or "*minimal*" alongside "*risk*" to emphasise that although there is a risk of microbiological transmission, the risk is not considerable. The commonly identified transmissible diseases were hepatitis, human immunodeficiency virus and cytomegalovirus. One participant noted that the risk of these viruses is especially higher for the premature population. Health professionals also tied the risk of infant illness to the screening of the donating mother. Of the participants who highlighted a lack of screening and pasteurisation as a risk for the infant, some referred to an increased risk if the donor was not screened for lifestyle or serological indicators; while others referred to unscreened milk; and one referred to milk remaining unpasteurised.

### Contaminated milk

Respondents also frequently identified milk contamination being a potential risk to the infant as a result of informal milk sharing. Health professionals felt that the donated milk being ingested by the infant may be tainted by products (drugs, medications, alcohol), poor handling processes (collection, storage, transit), or general lack of hygiene, all of which have the potential to cause harm to the infant. Some respondents identified that ineffective handling processes may be compounded by poor health literacy and a lack of safety information/guidelines which could ultimately lead to, for example, unsafe attempts to pasteurise milk at home.

#### Undisclosed factors

Some health professionals voiced concern regarding the composition of the donated milk and felt that some donors may not disclose their full medical, lifestyle or serological background. Phrases such as "*undisclosed*" or "*not honest*" were used in combination with lifestyle and medical factors such as pharmaceuticals, recreational drugs, alcohol, or smoking. Mistrust of the donor was also evident regarding the composition of the shared HM. For example, one respondent stated there was "*no control over the…contents*" and another felt that you cannot be sure of the "*honesty of the content*" within the donated milk. However, some of the health professionals concerned regarding the content of the donated milk felt that this was related to the lack of donor and milk screening as opposed to a mistrust or non-disclosure of the donor. These respondents used words such as "*not screened*" or "*unknown*" to refer to the unascertained content of the donated milk.

Table 13. Codes and themes pertaining to "What do you think are the risks of informal milk/waiū sharing for the baby/pēpi?"

	Identified Codes	Theme	Example Quotes
•	Unscreened Microbe transmission	Infant Illness	<ul> <li>a) "With no screening, serology and lifestyle there is potential risk to [the] receiving pepi."</li> <li>b) "Sharing of harmful bacteria and/or viruses through the milk."</li> </ul>
•	Contamination Incorrect procedures	Contaminated Milk	<ul> <li>a) "Milk being contaminated with drugs/alcohol/medicine. Microbes growing during transit."</li> <li>b) "Lack of hygienic practices in expressing, storage, transport."</li> </ul>
•	Adulteration Donor non- disclosure	Undisclosed Factors	<ul> <li>a) "Potentially non-EBM [expressed breastmilk] products being given."</li> <li>b) "Non-disclosure of lifestyle practices/medications/dietary that would otherwise deter mother receiving the breastmilk/waiū."</li> </ul>

### Benefits of Informal Milk Sharing for the Donor

Of the 240 survey respondents, a total of 190 (79.2%) health professionals responded to "*What do you think are the benefits of informal milk/waiū sharing for the donor*?". Following thematic analysis, four main themes emerged. Themes included a) altruism, b) using excess human milk, c) benefits to total wellbeing, and d) building community. Identified codes, themes and example quotes are displayed in **Table 14**.

### Altruism

The majority of respondents felt that the biggest benefit of informal milk sharing for the donor is to be able to assist another mother and infant dyad. Health professionals recognised the altruistic feeling of helping and supporting another family who are unable to provide their own breastmilk to their infant but wish to feed their infant HM. Health professionals described positivity, satisfaction, contribution, value and pride as feelings associated with informal milk sharing.

#### Using excess human milk

Health professionals felt that a benefit for the donor is that their excess milk does not go to waste and is instead given to another infant in need. Respondents felt that the labour of expressing their milk would be worthwhile if their overflow or excess milk could then be valuable to other mothers wanting to feed their infant HM. Some respondents also noted that donation may in turn reduce space required to store their excess milk.

## Benefits to total wellbeing

Health professionals identified a range of health benefits across mental, emotional, and physical parameters. Respondents felt that sharing HM places importance on the value of HM and the positive impact that women can have on each other and for the benefit of other infants in need. One participant highlighted the reduced risk of post-natal depression. Respondents also acknowledged the physical benefits of continuing to express milk and others recognised the potential for an increase in breastfeeding initiation and duration, which ultimately may reduce the risk of morbidity, including diabetes, lactational amenorrhoea, cancer and cardiovascular disease. Health professionals also reflected on the benefit that informal milk sharing can have for mothers who have lost their infant and the impact it can have in their grieving process. One respondent described how it can give the donor a sense that "*at least something positive can come from their loss*".

## Building community

The final theme identified by respondents was the development of community, friendships, and sisterhood. Health professionals discussed the enhanced feeling of connectedness through building community and sharing positive experiences between mothers. Support was frequently mentioned by those who identified community as a benefit of informal HM donation for the donor. Health professionals discussed the potential for mutual benefit for the donor and recipient mother of being able to support or be supported during times of hardship.

Identified Codes	Theme	Example Quotes
<ul> <li>Helping</li> <li>Supporting mother/infant in need</li> <li>Giving back</li> </ul>	Altruism	<ul> <li>a) "Being able to help another pēpi/māmā/whānau."</li> <li>b) "Feeling that they have been able to support another mama and pepi with their breastfeeding goals."</li> <li>c) "A rewarding sense of giving back to others."</li> </ul>
• No/less human milk wastage	Using excess human milk	a) "Provides donor with a way to use excess milk that may otherwise be discarded."
<ul> <li>Empowerment</li> <li>Improved wellbeing</li> <li>Reduced morbidity</li> <li>Heal infant loss</li> </ul>	Benefits to total wellbeing	<ul> <li>a) "Empowering women and lactating people to support each other"</li> <li>b) "Emotional/mental benefits of being able to provide breastmilk to another baby."</li> <li>c) "Reduced risk of cancer, CVD [cardiovascular disease], diabetes."</li> </ul>

Table 14. Codes and themes pertaining to "What do you think are the benefits of informal milk/waiū sharing for the donor?"

٠	Breastfeeding		d)	"Could help with grieving process in the case of infant loss."
	longevity		e)	"Increased BF [breastfeeding] rates and time frames."
٠	Community	Building	a)	"The feeling of aroha and helping community. Gaining of
	-	community		friendships and support."

### Risks of Informal Milk Sharing for the Donor

Of the 240 survey participants, 184 (76.7%) responded to "*What do you think are the risks of informal milk/waiū sharing for the donor?*". Three main themes emerged following thematic analysis, including a) feelings of guilt, b) feelings of obligation and c) negative impact on donor wellbeing. Identified codes, themes and example quotes are displayed in **Table 15**.

## Feeling of guilt

Health professionals felt that donors may be vulnerable to blame or feelings of responsibility if the recipient infant were to become sick after consuming their donated milk. Some respondents discussed the possible inadvertent passing on of bacterial or viral illnesses and how this may subsequently result in blame being projected on to the donor who provided the milk, despite benevolent intentions. With this blame, donors may carry guilt for their part in the infant's illness. One recipient stated how this may have further ramifications to the relationships that have been formed through informal milk sharing.

### Feelings of obligation

Some health professionals also felt that donors may be at risk of receiving pressure from the recipient family to continue donating their milk. Respondents felt that donors may feel obliged to continue supplying milk beyond what they are comfortable supplying due to the increased pressure (self-inflicted or otherwise). Some health professionals discussed the burden that milk expression can carry and how it can be difficult to say no to family or friends in need. Furthermore, respondents reflected on the impact that frequent and ongoing milk donation would have on their own infant's milk supply. With more milk being donated to recipient infants, health professionals discussed how the donor may run out of milk for her own infant, which may impact the amount of feed her infant receives. One participant also reflected on the impact that this may have on the donor's spare milk for her own infant in the case of unforeseen emergencies.

### Negative impact on donor wellbeing

Health professionals voiced potential risks to physical and mental health. Respondents felt that with ongoing milk expression, some donors may be at risk of nutritional deficiencies or dehydration. For example, one respondent stated that donors could be at risk of *"iron and mineral deficits"* related to post-partum nutrient depletion. Health professionals identified oversupply and mastitis as another physical risk to donors involved in informal milk sharing. Respondents felt that donors who increase their supply to meet recipient family demands may be at risk of oversupply, especially if the donations are suddenly no longer needed.

Respondents then discussed how this may increase the donor's risk of engorgement, blocked milk ducts or mastitis. Lastly, health professionals felt that the task of milk expression is labour-intensive. Some respondents felt that informal milk sharing was time-consuming; tiring and required a lot of effort; and came at a financial cost attributable to travel and resources with no reimbursement. Some respondents elaborated to explain that this may then take time away that could be spent with the donor's own family or other important commitments.

Table 15. Codes and themes pertaining to "What do you think are the risks of informal milk/waiū sharing for the donor?"

	<b>Identified Codes</b>	Theme		Example Quotes
•	Blame/ feelings of responsibility for infant illness	Feeling of guilt	<ul><li>a)</li><li>b)</li><li>c)</li></ul>	"If the baby got sick or contracted something, the family may blame the donor." "They may inadvertently pass something onto pēpi through their milk." "If something did go wrong, they would feel guilty."
•	Pressure to continue donating Impact on own infants' intake	Feelings of obligation	a) b) c)	"Pressure to maintain a supply and to continue donations." "The donor may feel too needed such that they prioritise expression of milk over other important family needs." "Less milk available for her own infant."
•	Reduced donor nutrition status Labour intensive Oversupply/mastitis	Negative impact on donor wellbeing	a) b) c) d)	"Could deplete their own nutrient stores." "It's tiring and takes time to pump milk." "Time consumption, petrol expenses dropping off milk." "Increased risk of mastitis from oversupply."

## 3.3. MOTHERS' SURVEY RESULTS

### 3.3.1. QUANTITATIVE RESULTS

A total of 566 mothers responded to the survey. However, given the snowball sampling methodology utilised for dissemination, it is not possible to know how many people the survey invitation has reached. Seventy responses were incomplete and therefore were excluded from the analysis for the following reasons: declined consent (n=1), no questions answered (n=6) and incomplete responses (n=63). Therefore, a total of 496 responses were included in the final analysis. Respondents were not required to answer all survey questions, and some questions allowed for multiple answers. The final number of responses for each question is shown in each table.

#### Study Population

Demographic details of the respondents are shown in **Table 16**. Of the mothers who responded to the survey (n=496), the majority were aged between 30 and 39 years (63.9%) and were of New Zealand/European descent (75.6%), 7.6% were of Māori descent and 1 participant was of Pacific Island descent. Sixty-eight respondents (12.3%) selected 'other', indicating they identified as an ethnicity unlisted in the survey options - mostly English (n=22), European (n=20), Asian (n=7) and American (n=5). The majority of respondents were from Auckland (31.1%), Canterbury (17.4%), Wellington (13.3%) and Waikato (11.3%), had one (41.9%) or two (38.3%) children and had breastfed one (43.3%) or two (35.1%) infants.

Participants were asked to provide responses relating to their most recent child (**Table 16**). The respondent's infants were well distributed across the ages of 0-6 months (31.7%), 7-12 months (14.3%), 1-2 years (24.6%) and  $\geq$ 2 years (29.4%) and were most frequently girls (55.1%). The majority of the respondent's infants were born in hospital (81.7%) and did not require post-natal care of any form (36.7%), however mothers also reported infants' admission to postnatal ward (30.2%) and NICU (22.8%).

Maternal and Infant Demographics	Number of Participants, n (%)
Age (n=496) <sup>†</sup>	•         •   •   • • • • • • • • • • •
<18	2 (0.4)
18-29	106 (21.4)
30-39	317 (63.9)
>40	70 (14.1)
Undisclosed	1 (0.2)
Ethnicity (n=552) <sup>†</sup> *	
New Zealand European	418 (75.6)
Māori	42 (7.6)
Samoan	3 (0.5)
Cook Islands Māori	1 (0.2)
Chinese	12 (2.2)
Indian	8 (1.3)
Other	68 (12.3)
Infant Place of Birth $(n=495)^{\dagger}$	
Auckland	154 (31.1)
Bay of Plenty	19 (3.8)
Canterbury	86 (17.4)

#### Table 16. Maternal and Infant Demographics

Gisborne	4 (0.8)					
Hawke's Bay	8 (1.6)					
Marlborough	6 (1.2)					
Nelson-Tasman	6 (1.2)					
Northland	9 (1.8)					
Otago	31 (6.3)					
Southland	4 (0.8)					
Taranaki	8 (1.6)					
Tasman	1 (0.2)					
Waikato	56 (11.3)					
Wellington	66 (13.3)					
West Coast	5 (1.1)					
Whanganui-Manawatū	32 (6.5)					
Facility of Birth (n=493) <sup>†</sup>						
Hospital	403 (81.7)					
Birthing centre/maternity unit	29 (5.9)					
Home birth	54 (11)					
Other	7 (1.4)					
Infant Level of Postnatal Care (n=496) <sup>†</sup>	Infant Level of Postnatal Care $(n=496)^{\dagger}$					
Postnatal ward	150 (30.2)					
Special Care Baby Unit	32 (6.5)					
Neonatal Intensive Care Unit	113 (22.8)					
No postnatal care was required	182 (36.7)					
Other	19 (3.8)					
Number of Children (n=496) <sup>†</sup>	•					
1	208 (41.9)					
2	190 (38.3)					
3	65 (13.1)					
<u>≥4</u>	33 (6.7)					
Number of Children Breastfed (past and present) (n=49	96) <sup>†</sup>					
0	11 (2.2)					
1	215 (43.3)					
2	174 (35.1)					
3	61 (12.3)					
<u>&gt;</u> 4	35 (7.1)					
Age of Youngest Child (n=496) <sup>†</sup>						
0-6 months	157 (31.7)					
7-12 months	71 (14.3)					
1-2 years	122 (24.6)					
$\geq 2$ years	146 (29.4)					
Sex of Youngest Infant (n=496) <sup>†</sup>	• • •					
Boy	216 (43.5)					
Girl	273 (55.1)					
Twins of different sex	4 (0.8)					
Undisclosed	3 (0.6)					

<sup>†</sup>Response count. \*Participants could select multiple answers.

#### Involvement with Human Milk Donation

Details of respondents' experience with HM donation are shown in **Table 17**. Over half (51.6%) of respondents had donated HM, or had received DHM during their hospital stay (12.3%) or following discharge from the hospital (13.1%). Sixty nine respondents (13.9%) wished they had been involved with HM donation but it was not available. Of those who had been involved with HM donation, most donations were organised between individuals (family/friends, 51.8%) or facilitated through hospital staff (21.8%). Those who selected

'other' (n=3) reported being introduced to HM donation through their private health care professional.

#### Infant Feeding Experiences

Most of the respondents' infants were exclusively fed mother's milk (59.3%) or partially fed mother's milk and DHM (17.3%) in their first six months of life (**Table 17**). Forty-six respondents (9.3%) selected 'other' and indicated they fed their infant a combination of mother's milk, DHM and IF (n=45); or had mother's milk, DHM and total parenteral nutrition in the infants' early days of life (n=1). **Table 18** shows that infants of respondents born across almost all regions of New Zealand were most frequently fed exclusively with their mother's milk. Mothers from Gisborne (100%), Taranaki (100%) and Northland (88.9%) were among those most frequently feeding their infants their own milk exclusively. Respondents from Canterbury (51.5%), Hawke's Bay (50%) and Marlborough (50%) were most frequently using any DHM to support feeding their infants.

Table 17.	Infant Feedin	ng Ex	periences

Infant Feeding Experiences	Number of Participants, n (%)					
Involvement with HM Donation $(n=496)^{\dagger}$						
HM donor	256 (51.6)					
Recipient of DHM during hospital admission	61 (12.3)					
Recipient of DHM after discharge from hospital	65 (13.1)					
Both donated and received DHM	39 (7.9)					
Wished to be involved but it was not available	69 (13.9)					
Directly breastfed another mother's infant	6 (1.2)					
Facilitation of HM donation arrangement (n=550) <sup>†</sup> *						
Facilitated through the hospital	120 (21.8)					
Facilitated through a milk bank	88 (16)					
Organised between individuals	285 (51.8)					
Facilitated through charities/organisations	54 (9.8)					
Other	3 (0.6)					
Infant Mode of Feeding (n=496) <sup>†</sup>						
Exclusively fed mother's milk	294 (59.3)					
Partially fed mother's milk and infant formula	56 (11.3)					
Partially fed mother's milk and DHM	86 (17.3)					
Partially fed DHM and infant formula	10 (2)					
Exclusively fed infant formula	3 (0.6)					
Exclusively fed DHM	1 (0.2)					
Other	46 (9.3)					
Health Professional Support with Breastfeeding (n=494	4) <sup>†</sup>					
Yes	419 (84.8)					
No	75 (15.2)					
Satisfaction with Breastfeeding Experience (n=494) <sup>†</sup>						
Extremely satisfied	195 (39.5)					
Satisfied	173 (35.0)					
Neither satisfied nor dissatisfied	49 (10)					
Dissatisfied	52 (10.5)					
Extremely dissatisfied	25 (5)					
Reasons for Dissatisfied/Extremely Dissatisfied with B	reastfeeding Experience (n=125) <sup>†</sup> *					
Infant had difficulty breastfeeding	77 (30.8)					
Did not feel emotionally/physically supported to	34 (13.6)					
breastfeed						
Infant was not gaining enough weight	31 (12.4)					
Mother had difficulty breastfeeding	73 (29.2)					

No longer wished to breastfeed	6 (2.4)
Other	29 (11.6)
Satisfaction with HM donation experience $(n=291)^{\dagger}$	
Extremely satisfied	170 (58.4)
Satisfied	94 (32.4)
Neither satisfied nor dissatisfied	19 (6.5)
Dissatisfied	8 (2.7)
Extremely dissatisfied	-

<sup>†</sup>Response count. \*Participants could select multiple answers.

HM=human milk, DHM=donor human milk.

#### Table 18. Proportion of Respondents Reporting Infant Feeding Mode by Birth Region

Infant Birthplace	Number of Respon- dents	Exclusiv e MOM	MOM + IF	MOM + DHM	DHM + IF	Exclusiv e IF	Exclusiv e DHM	MOM, IF + DHM	Other
Auckland	154	64.9%	11.7%	9.8%	3.2%	0.7%	-	9%	0.7%
Bay of Plenty	19	73.7%	-	21%	-	-	-	5.3%	-
Canterbury	86	38.4%	10.5%	31.3%	1.2%	-	-	18.6%	-
Gisborne	4	100%	-	-	-	-	-	-	-
Hawke's Bay	8	37.5%	12.5%	25%	-	-	-	25%	-
Marlborough	6	50%	-	33.3%	-	-	-	16.7%	-
Nelson- Tasman	6	83.3%	16.7%	-	-	-	-	-	-
Northland	9	88.9%	11.1%	-	-	-	-	-	-
Otago	31	61.3%	16.1%	16.1%	-	-	-	6.5%	-
Southland	4	75%	-	25%	-	-	-	-	-
Taranaki	8	100%	-	-	-	-	-	-	-
Tasman	1	-	-	-	-	-	-	100%	-
Waikato	56	58.9%	12.5%	12.5%	1.8%	-	1.8%	12.5%	-
Wellington	66	57.5%	9%	16.7%	1.5%	1.5%	-	13.6%	-
West Coast	5	80%	-	20%	-	-	-	-	-
Whanganui- Manawatū	32	53.1%	9.4%	28.1%	6.3%	-	-	3.1%	-

MOM=mother's own milk, IF=infant formula, DHM=donor human milk.

#### Breastfeeding Experiences

Most (84.8%) respondents received some level of support with initiating or maintaining breastfeeding from a health professional (e.g., lactation consultant, midwife, or lead maternity carer, **Table 17**). The majority of respondents felt extremely satisfied (39.5%) or satisfied (35%) with their breastfeeding experience. Of those who reported being neither satisfied nor dissatisfied (10%), dissatisfied (10.5%) or extremely dissatisfied (5%) with their breastfeeding experience, most (60%) reported it being a result of their infant or themselves having difficulties breastfeeding. However, 29 respondents (11.6%) selected 'other' and indicated that their breastfeeding experience was impaired for reasons including their infant being premature (n=2) or tube-fed (n=4), maternal medical complications (n=7), previous breast surgeries (n=4) and over- (n=2) or under-supply of milk (n=17). Mothers more frequently reported being dissatisfied or extremely dissatisfied with their breastfeeding experience were those who had received DHM for their infant (33.6%) or had directly breastfeed another mother's infant (33%),
compared to mothers who had donated their milk (7.5%), both donated and received DHM (7.7%) or had wished to be involved with HM donation (15.9%, **Table 19**).

Involvement with HM	Number of Respondents	Extremely Dissatisfied	Dissatisfied	Neither Satisfied nor	Satisfied	Extremely Satisfied
donation				Dissatisfied		
HM Donor	255	3.2%	4.3%	5.1%	32.9%	54.5%
DHM Recipient	125	10.4%	23.2%	17.6%	32%	16.8%
HM Donor and	39	-	7.7%	17.9%	30.7%	43.6%
Recipient						
Directly BF	6	-	33.3%	-	16.7%	50%
Another Mother's						
Infant						
Wished to be	69	5.8%	10.1%	10.1%	52.2%	21.7%
Involved with						
HM Donation						

Table 19. Proportion of Respondents from Each Level of Involvement with HM Donation Reporting Their Satisfaction with Breastfeeding Experience

HM=human milk, DHM=donor human milk, BF=breastfed.

#### HM Donation Experiences

Most mothers who donated their milk (n=255) were either satisfied or extremely satisfied with their HM donation experience (90.8%, **Figure 11**). HM donors aged below 30 were more frequently dissatisfied or extremely dissatisfied (19.5%) with their HM donation experience compared to those aged 30 years or above (14.5%, **Table 20**). However, no significant association was found between maternal age and satisfaction with HM donation experience (test statistic = 5.6, p = .33). Of HM donors who were dissatisfied or neither satisfied nor dissatisfied with their HM donation experience (n=27), some reported that a lack of structure made donating milk cumbersome (n=6) and time-consuming (n=4). A few HM donors also reported feeling they did not receive adequate information or support to donate their milk effectively (n=6). Furthermore, some respondents reported having poor experiences due to feeling pressured to continue donating (n=2), having their milk rejected by milk banks (n=4) and the burden of obtaining and paying for resources (n=2).



<u>Figure 11.</u> Satisfaction with human milk donation experience reported by human milk donors and those who have both donated and received donated human milk. Figures are presented as n (%).

Table 20. Proportion of Human Milk Donors Reporting Satisfaction with Human Milk Donation Experience in Each Age Group

Maternal Age	Number of Respondents	Extremely Dissatisfied	Dissatisfied	Neither Satisfied	Satisfied	Extremely Satisfied	P value*
				nor Dissatisfied			
<30 years	64	6.5%	13%	7.5%	39.3%	33.7%	.33
>30 years	227	4.7%	9.8%	10.7%	33.9%	40.9%	

\*Fisher-Freeman-Halton Exact Test.

#### Management of Donated Human Milk

Of HM donors and mothers who used DHM for their infant, lifestyle (e.g., smoking status, medication, drug and alcohol intake, 43.6%) and serological (e.g., blood testing for antibodies against HIV, Hepatitis C or B and syphilis, 29.9%) screening were the most frequently reported screening processes undertaken prior to DHM exchanges (**Table 21**). Most of the respondents reported undertaking one (47.4%) or two (39%) screening processes, however 14.7% of respondents did not perform any type of screening prior to HM exchange (**Table 21**).

Management of Donor Human Milk and Support for its Use	Number of Participants, n (%)
Screening processes undertaken prior to DHM exchan	ge (n=675) <sup>†</sup> *
Serological	202 (29.9)
Microbiological	52 (7.7)
Lifestyle	294 (43.6)
None	99 (14.7)
Unsure	28 (4.1)
Number of screening processes undertaken (n=405) <sup>†</sup>	
1 screening	192 (47.4)
2 screenings	158 (39)
3 screenings	51 (12.6)
4 screenings	4(1)
Was the Milk Pasteurised/Flash-heated? (n=414) <sup>†</sup>	
Yes – through donor or recipient mother	14 (3.4)
Yes – through milk bank or hospital facility	63 (15.2)
No	250 (60.4)
Unsure	87 (21)
Were there any associated costs? $(n=412)^{\dagger}$	
Yes	144 (35)
No	268 (65)
Who paid the associated costs? $(n=144)^{\dagger}$	
Healthcare system	11 (7.6)
Donor	54 (37.5)
Recipient mother	42 (29.2)
Health Insurance	-
Other	30 (20.8)
Unsure	7 (4.9)
Support for DHM use in hospitals $(n=484)^{\dagger}$	
Yes	477 (98.6)
No	5(1)
Unsure	2 (0.4)
Support for informal DHM arrangements between mo	thers (n=484) <sup>†</sup>
Yes	445 (92)
No	17 (3.5)
Unsure	22 (4.5)

Table 21. Management of Donor Human Milk and Support for its Use

<sup>†</sup>Response count. \*Participants could select multiple answers.

DHM=donor human milk.

While 21% of HM donors and mothers who used DHM for their infant were unsure if DHM was pasteurised prior to infant ingestion, most (60.4%) reported that pasteurisation was not undertaken prior to the DHM exchange. Of those who reported home-pasteurisation by the donor or recipient mother (n=14, 3.4%), the majority reported scalding the milk (n=3) or using a water bath for various periods of time (n=3). The geographical region in which the infant was born was significantly associated with whether DHM was pasteurised (test statistic = 37.1, p = <.01, **Table 22**), with infants born in the South Island more frequently receiving pasteurised milk (37.2%) than infants born in the North Island (11%).

Table 22. Proportion of Human Milk Donors and Mothers who Used Donor Human Milk for their Infant Reporting Undertaking Donor Human Milk Pasteurisation in their Infant's Island of Birth

Infant Birthplace	Number of Respondents	Yes – via donor or mother of recipient infant	Yes – via a human milk bank	No	I don't know	P value*
North Island	292	3.1%	7.9%	67.1%	21.9%	<.001
South Island	121	7.4%	29.8%	44.6%	18.2%	

\*Fisher-Freeman-Halton Exact Test.

Costs associated with the HM donation arrangement (e.g., screening, pasteurisation, transport) was reported by 144 (35%) HM donors and mothers who had used DHM for their infant. Such costs were frequently covered by the donor (37.5%) or recipient mother (29.2%). Of those who selected 'other' (n=30, 20.8%), the majority of costs were reported to be shared between the donor and recipient mother (n=15), or the costs were partially covered with support from charities (n=9), the healthcare system (n=2) or a milk bank (n=2).

#### Support for Donor Human Milk Use

Overall, almost all (98.6%) respondents support the use of DHM in hospitals (**Table 21**). In contrast, a total of 446 respondents (92%) supported informal DHM arrangements between mothers, while 39 respondents (8%) were either unsure or did not support DHM use between mothers (**Figure 12**).



Figure 12. Overall maternal support for donor human milk use in hospital and community/informal milk sharing. Figures are presented as n (%).

#### Behaviours of Human Milk Donors

HM donors were asked about how many infants had received their DHM. Of the 295 mothers who had donated their milk (59.5%), the majority had donated to one (29.8%) or two (17.1%) infants; however, sixty-two respondents (21.2%) did not know how many infants had received their donated milk (**Table 23**). The majority (42.8%) of the donations were a one-off donation; however, almost half of the respondents reported donating their milk weekly (23.6%) or monthly (21.2%). Furthermore, the duration of donations was most often less than one month (30.8%) or over six months (23.5%). Neither the frequency nor duration of donations (test statistic = 2.1, p = .59; and test statistic = 5.8, p = .20, respectively) was associated with whether the infant was born in the North- or South Island.

The majority (97.6%) of HM donors reported sticking to their normal diet and not making any dietary changes when donating their milk (**Table 23**). However, some of these mothers reported following the same diet that was required for their own infant (n=15), e.g., dairy-, gluten-, egg-, nut-, soy-free. Of those that did make dietary changes in order to donate (n=7), majority removed dairy (n=5), egg (n=2), alcohol (n=2) or caffeine (n=2).

#### Behaviours of Mothers of Recipient Infants

One-hundred-sixty-five mothers reported using DHM multiple times daily to feed their infant (76.2%). The duration of DHM use varied among recipient mothers. Most (42.9%) recipient mothers used DHM for their infant for four weeks or longer. However, 28.9% of recipient mothers used DHM for under one week. The duration of DHM use was significantly associated with the geographical region in which the infant was born (test statistic = 8.6, p = .03), with infants born in the North Island more frequently receiving DHM for four weeks or longer (52%) compared to infants born in the South Island (29.2%, **Table 24**).

Human Milk Donation Behaviours	Number of Participants, n (%)
HUMAN N	IILK DONORS
Number of infants who have received donors' DHM	(n=292) <sup>†</sup>
1 infant	87 (29.8)
2 infants	50 (17.1)
3 infants	33 (11.3)
4+ infants	60 (20.6)
Unsure	62 (21.2)
Frequency of Donations (n=292) <sup>†</sup>	
Daily	36 (12.3)
Weekly	69 (23.6)
Monthly	62 (21.2)
One-off donation	125 (42.8)
Duration of Donation (n=289) <sup>†</sup>	
<1 month	89 (30.8)
1-2 months	43 (14.9)
3-4 months	51 (17.7)
5-6 months	38 (13.2)
6+ months	68 (23.5)
Diet Changes to Donate DHM (n=290) <sup>†</sup>	
Yes	7 (2.4)
No	283 (97.6)
MOTHERS OF DHM	A RECIPIENT INFANTS
Frequency of DHM use $(n=164)^{\dagger}$	
Multiple times per day	125 (76.2)
Once daily	24 (14.7)
Weekly	3 (1.8)
Fortnightly	-
Less than fortnightly	12 (7.3)
Duration of DHM Use (n=163) <sup>†</sup>	
<1 week	47 (28.9)
1-2 weeks	24 (14.7)
3-4 weeks	22 (13.5)
4+ weeks	70 (42.9)

Table 23. Human Milk Donation Behaviours of Human Milk Donors and Mothers of Donor Human Milk Recipient Infants

<sup>†</sup>Response count. DHM=donor human milk.

# Table 24. Proportion of Respondents Reporting Duration of Donor Human Milk Use for Their Infant's Island of Birth

Infant Birthplace	Number of Respondents	<1 week	1-2 weeks	3-4 weeks	4+ weeks	P value*
North Island	98	23.6%	12.2%	12.2%	52%	.03
South Island	65	36.9%	18.5%	15.4%	29.2%	

\*Fisher-Freeman-Halton Exact Test.

#### 3.3.2. QUALITATIVE RESULTS

The survey contained a range of open-text questions regarding the respondents' opinions of HM donation. The respondents were asked about their motivations to engage with HM donation, how they felt HM donation in New Zealand could be improved and what risks and benefits they perceived the practice might have for the donor and the infant. Identified codes and themes pertaining to respondents' motivations and experiences are presented in **Figure 13**. Codes and themes regarding respondents' perceptions on how current informal HM donation practices could be improved and what risks and benefits the practice might have for the donor and the infant. HM donation practices could be improved and what risks and benefits the practice might have for the donor and the infant are shown in **Figure 14**.



Figure 12. Coding tree of mothers' motivations to engage- or experiences with informal human milk donation.



Figure 13. Coding tree of mothers' perceptions on how current informal human milk donation practices could be improved and the potential risks and benefits of informal human milk donation for both infant and donor.

## Motivations to Engage with Human Milk Donation

#### Donors

Of the 295 mothers who donated their own milk, a total of 291 (98.6%) answered the question "*What were your reasons/motivations to donate your milk/waiū*?". Four main themes were identified: a) altruism; b) utilise excess milk; c) enable human milk use, and d) reciprocity. Example quotes are displayed in **Table 25**.

#### Altruism

The majority of HM donors felt that their primary motive to engage with HM donation was to support other mothers and infants in need. Mothers reported feeling "good" and "helpful" after sharing their excess milk with families facing hardship and preferred not to feed their infant formula. One mother reported donating her milk as a "*random act of kindness/love*".

#### Utilise excess milk

HM donors also reported engaging with HM donation as a way of using their excess milk supply. Mothers felt that they would rather an infant in need use their milk than "*tip milk down the sink*" or "*let such precious milk go to waste*". In some cases, mothers pointed to a mutual benefit between themselves and the recipient infant in that the infant could benefit from their milk while they reduced the amount of milk stored in their freezers.

#### Enable human milk use

Mothers felt that donating their milk provided infants with the opportunity for HM feeding. Respondents highlighted their understanding of the importance and benefits of HM and felt that DHM was equally valuable. Some donors further discussed how every mother should be provided the option of providing their infant with HM instead of IF when they otherwise may not have had the option.

## Reciprocity

Reciprocity was identified as a theme for those who had both donated and received DHM. Mothers felt that donating milk once their milk supply was established was a way to give back to those who had supported them in their infant feeding journey. Furthermore, some respondents felt they were supporting mothers facing similar breastfeeding difficulties that they once shared.

# Recipients

A total of 165 DHM recipients were invited to answer the question, "*What were your reasons/motivations to seek donated breast milk/waiū to supplement your own milk/waiū*" of which all responded (100%). Three themes were identified: a) prioritise human milk feeding; b) medically indicated, and c) low milk supply. Example quotes are displayed in **Table 25**.

#### Prioritise human milk feeding

DHM recipients felt motivated to seek DHM to provide their infant HM in preference to IF. Mothers commonly discussed the "*importance*", "*benefits*" and "*value*" of HM and wanted to avoid the "*risks*" associated with IF use. Many mothers felt DHM incurred the same benefits as HM and was the next best alternative to their own milk.

#### Medically indicated

Mothers of infants receiving DHM reported various medical complications of the infant that motivated them to seek DHM, including insufficient weight gain, illness, inability to breastfeed and contraindications for IF feeding. In such circumstances, some mothers decided to feed with DHM to potentially enhance their infant's health outcomes over supplementing with IF. For example, one mother shared that she wanted her adopted child to receive optimal nutrition to support brain and gut healing following in utero drug and alcohol exposure. Furthermore, mothers also reported seeking DHM as they were facing medical complications or medication use that prevented them from successfully or safely breastfeeding their infant.

#### Low milk supply

Respondents discussed how their milk supply was "*lacking*", "*minimal*", "*delayed*', "*low*", or "*had not come in*", which led to them seeking DHM to feed their infant. Some respondents discussed how their supply was delayed for the first few days or weeks of their infant's life, and DHM enabled them to continue to provide their infant exclusively HM. These mothers spoke of how DHM was a temporary measure to bridge the gap until they were able to breastfeed themselves - especially if their infant was born prematurely.

## Mothers' who Directly Breastfed another Mother's Infant

A total of six respondents reported directly breastfeeding another mother's infant. All six (100%) respondents answered the question, "*How was your shared breastfeeding/whāngai*  $\bar{u}$  *experience?*". One main theme emerged following analysis of the answers provided: to nurture. Example quotes are displayed in **Table 25**.

#### To nurture

Respondents reflected on their reasoning for directly breastfeeding another mother's infant. All respondents had directly breastfed another infant on a short-term basis to support another mother/infant dyad. Most mothers discussed their altruistic intent of helping friends or family in need and how it felt like a naturally intuitive solution when they had a sufficient milk supply to share. Furthermore, mothers felt that sharing their milk via the breast was "*totally normal*" and "*seemed natural*" when another mother was unable to breastfeed her own infant.

Table 22. Codes and themes relating to the Motivations and Experiences of Those Involved in Human Milk Donation

<b>Participant Group</b>	<b>Identified Codes</b>	Theme	Example Quotes
HM Donors	<ul> <li>Helping another infant/mother dyad</li> <li>Providing support</li> </ul>	Altruism	<ul> <li>a) "To help pēpi &amp; māmā in need."</li> <li>b) "I wanted to support other mums and babies who might be struggling."</li> </ul>
	• Less milk wastage	Using Excess Milk	a) "I had an oversupply and didn't want it to go to waste!"
	<ul> <li>Prioritise HM</li> <li>Providing access to HM</li> </ul>	Enable HM Use	<ul> <li>a) "I know how much other mothers value being able to provide breastmilk instead of using formula."</li> <li>b) "[I wanted] other babies to have access to breastmilk when they otherwise might not have."</li> </ul>
	• Give back	Reciprocity	a) "My twin boys spend 4 months in NICU [neonatal intensive care unit] and it was a way for me to feel like I was giving back."
Mothers of DHM Recipients	<ul> <li>HM not IF</li> <li>Benefits of HM</li> <li>Best start to life</li> </ul>	Prioritise HM Feeding	<ul> <li>a) "I preferred that my baby have donated breastmilk rather than formula."</li> <li>b) "I wanted to give my baby the best start for their health, immunity, gut development."</li> <li>c) "I wanted bubs to have exposure to all the goodies of breast milk, especially in her first few days of life."</li> </ul>
	<ul> <li>Low infant weight</li> <li>Infant illness</li> <li>Infant unable to breastfeed</li> <li>Infant unable to consume IF</li> <li>Maternal medical complications</li> </ul>	Medically Indicated	<ul> <li>a) "My baby had lost too much weight."</li> <li>b) "My daughter had low blood sugars in special care unit."</li> <li>c) "Due to severe tongue, lip and cheek ties which were left untreated my baby was unable to latch correctly."</li> <li>d) "Baby reacted to all formulas and got really sick."</li> <li>e) "Mother unable to breastfeed due to brain injury."</li> <li>f) "I had to stop breastfeeding to take medication but wanted my pēpi to have breastmilk for a bit longer."</li> </ul>
	<ul> <li>Delayed lactation</li> <li>Limited milk supply</li> </ul>	Low Milk Supply	<ul> <li>a) "My milk supply was delayed due to extreme blood losspost-birth."</li> <li>b) "I had low milk supply."</li> </ul>
Mothers who Directly Breastfed Another Mother's Infant	<ul><li>To support others</li><li>Felt normal</li></ul>	To Nurture	<ul> <li>a) "I offered [to directly breastfeed] as the mother needed support."</li> <li>a) "It was a given and totally normal to share what we had."</li> </ul>

DHM=donor human milk, IF=infant formula, HM=human milk.

#### Improvements to Current Informal HM Donation Practices

A total of 428 respondents (86.1%) answered the question, "*How could current practices regarding informal milk/waiū donation be improved*?". Three themes were identified: a) improve access; b) wider knowledge, and c) easier process. Example quotes are displayed in **Table 26**.

#### Improve access

Respondents frequently felt that implementing strategies to widen access to DHM would improve the current informal HM donation practices. Many respondents felt that having local milk banks would provide a "more structured arrangement", which would enable a "quick" and "efficient" exchange of HM. Additionally, HM donors, recipients or those who had both donated and received DHM discussed how reducing the cost of transport, resources, and screening through government or district health board funding would reduce the burden of exchanging HM and facilitate greater involvement in HM donation. For some mothers, increasing the number of people involved with HM donation seemed an important outcome as they wished for DHM to be available to all infants – irrespective of age and health status. Furthermore, some mothers shared their experiences of feeling "cut off" from accessing DHM due to limited milk bank supply, leaving them with no choice but to feed with IF.

## Wider knowledge

Many respondents highlighted the need for more health professional, hospital and community "awareness", "information", "education", "advice", "advertising" and "encouragement" for donating and receiving DHM. Some respondents reported discovering HM donation by chance through social media pages or conversations with their peers. Others stated they wished they had known of HM donation earlier to avoid feeding with IF. Antenatal classes or during the inhospital postpartum period were commonly suggested as places where mothers could be made aware and informed of HM donation. Additionally, those who have – or wished to have – been involved in HM donation expressed their desire to see DHM use normalised and made commonplace, with one mother stating that people were often "disgusted" that she shared her milk with another mother's infant. Respondents felt DHM should be offered as a first-line option to supplement mothers' milk, taking priority over IF.

## Easier process

Many mothers voiced the need for an easier and more systematic process to donate and/or receive DHM. Respondents felt that the current system of informal HM donation feels "*haphazard*" and "*clandestine*," making for a "*long and drawn-out process*" to exchange HM. Some mothers felt that HM donation being difficult made sharing milk via social media more attractive. Many respondents discussed how arranging delivery/pick-up of the milk was stressful, with one mother stating that she had to "*arrange a local restaurant to [keep the milk] in their freezer for the courier to collect*". Mothers felt this issue might be reduced with a funded transport system or more local drop-off/pick-up hubs. Similarly, respondents felt that the screening and pasteurisation process could be easier if there were dedicated locations for such matters at a low price.

Furthermore, respondents who have – or wished to have – been involved in HM donation felt that a centralised system would be beneficial for providing mothers with the necessary resources and information on the safe facilitation of HM donation. Here, donors felt

they could connect with mothers of infants in need and have a point of reference/contact for further guidance regarding HM donation.

Table 23. Codes and themes regarding	"How could current	practices regarding informal
milk/waiū donation be improved?"		

Ide	ntified Codes	Theme	Example Quotes
<ul> <li>Mo</li> <li>Rec</li> <li>DH</li> </ul>	ore milk banks duced cost IM for all infants	Improve Access	<ul> <li>a) "Milk banks all across NZ [New Zealand] for all families to donate to and access."</li> <li>b) "If it could be subsidised for mothers to provide their milk to others and have no costs associated with it would help encourage more mothers to do it."</li> <li>c) "Discount on pumps or milk bags for donors."</li> <li>d) "I wish all babies in special care could have donor milk as first option."</li> <li>e) "If supply allows it should be available to all babies in hospital."</li> </ul>
<ul> <li>Inc</li> <li>Mo</li> <li>No</li> </ul>	reased awareness ore information rmalise DHM use	Wider Knowledge	<ul> <li>a) "More awareness, mothers could be told about it in antenatal/by midwives."</li> <li>b) "Better knowledge of what is available. There is almost no information unless you go hunting and/or know that milk banks are a thing."</li> <li>c) "Information on pros/cons/risks."</li> <li>d) "Normalise it! I donated to our local NICU[neonatal intensive care unit] and people find this weird."</li> </ul>
<ul> <li>Sta pro</li> <li>Mo</li> </ul>	ndardise ocesses ore facilitation	Easier Process	<ul> <li>a) "National system[there are] minimal standards/guidelines for collection, screening and distribution."</li> <li>b) "Every hospital that aids birthing women should have a system for connecting lactating parents and/or dispensing donor milk."</li> <li>c) "Milk banks should have access to courier servicesto reduce costs and increase ability to share &amp; receive milk."</li> </ul>

DHM=donor human milk.

## Benefits of Informal Milk Sharing for the Infant

Of the 497 respondents invited to answer the question, "What do you think are the benefits of using donor milk/waiū for the baby/pēpi?", 450 (90.5%) responded. Three themes were identified from the answers provided, including: a) prioritise human milk feeding, b) health benefits, and c) species-specific nutrition. Example quotes are displayed in **Table 27**.

## Prioritise human milk feeding

Respondents who had donated or received DHM for their infant highlighted that DHM provided an infant with the opportunity to feed with HM instead of formula. These mothers felt DHM was a "better alternative than formula" and contained a wide range of components that formula "will never be able to imitate". Many respondents, especially those who had donated DHM, emphasised their belief that all infants should be provided with HM, where possible, reducing the need for HM alternatives such as IF. By using words such as "choice", "chance", "opportunity", "option", "alternative" and "preference", mothers demonstrated their viewpoint that DHM widens the potential feeding option for infants and can help some mothers attain their goal of feeding with human-derived milk.

#### Health benefits

Respondents commonly felt that informal milk sharing was beneficial to an infant's health. Mothers supported feeding with DHM due to the antibodies and immune properties unique to HM. Similarly, mothers felt DHM positively affected an infant's gut health by introducing a range of bacteria that support healthy microbiome development. Donors and/or mothers of recipient infants and those who wished to be involved with informal HM donation discussed how DHM, compared to IF, would be better tolerated by the ingesting infant and may reduce the risk of short- (NEC, infection) and long- (diabetes, neurodevelopment, asthma, obesity, eczema) term morbidity.

#### Species-specific nutrition

Respondents also felt that DHM was a physiologically suitable feeding choice for human infants. Mothers agreed that DHM was more "*natural*" than providing a manufactured HM substitute, with one respondent stating, "*it's literally what nature has evolved for our babies*". Some mothers also used the phrase "*human milk for human babies*" and indicated that the composition and nutritional profile of HM were the most appropriate for human infants.

Table 24. Codes and themes regarding	"What do	you think	are the b	penefits o	<u>f informal</u>
milk/waiū sharing for the baby/pēpi?"					

Identified Codes	Theme	Example Quotes
<ul> <li>Avoid infant formula</li> <li>Opportunity for human milk</li> </ul>	Prioritise Human Milk Feeding	<ul> <li>a) "Donated milk is the next best option to avoid the risks of introducing a non-human milk food option."</li> <li>b) "Gives mothers an option for an alternative way of feeding baby instead of formula."</li> <li>c) "More babies get breast milk."</li> </ul>
<ul> <li>Benefits of huma milk</li> <li>Immunity</li> <li>Gut/microbiome</li> <li>Reduced morbid</li> <li>Improved tolerar</li> </ul>	n Health Benefits ity ice	<ul> <li>a) "All the benefits of breast milk."</li> <li>b) "[Donor human milk] is full of antibodies for several diseases, and helps build immunity."</li> <li>c) "For me a huge one was microbiome and gut health."</li> <li>d) "Long term health benefits e.g. T2DM [type two diabetes mellitus] in adulthoodreduced allergies."</li> <li>e) "Less risk of intolerance/allergy/tummy upsets."</li> </ul>
<ul> <li>Natural</li> <li>Human food for human infants</li> <li>Suitable nutrition profile</li> </ul>	Species- al specific Nutrition	<ul> <li>a) "Natural, nothing synthetic about it."</li> <li>b) "Breast milk from humans is the best way to nourish a human baby."</li> <li>c) "It's the biological norm for human babies and contains a multitude of components that cannot be reproduced in formulas."</li> <li>d) "Perfect composition of macronutrients."</li> </ul>

#### Risks of Informal Milk Sharing for the Infant

A total of 441 respondents (88.7%) answered the question, "What do you think are the risks of using donor milk/waiū for the baby/pēpi?". Three main themes emerged following the analysis of the answers provided. Identified themes include: a) contamination; b) infant illness, and c) unknown composition. Example quotes are displayed in **Table 28**.

#### Contamination

Respondents felt that informal milk sharing carries a risk of contamination. Many mothers identified that DHM may cause harm to an ingesting infant as a result of poor hygiene and improper handling, storage and transport. Mothers often reflected on informal milk donation being a trust-based system which can make it challenging to ensure donors maintain hygienic and safe practices. Some mothers also acknowledged the risk of bacterial contamination from incorrect storage, thawing and reheating practices of the recipient mother. As a result of poor handling practices, these mothers highlighted the potential risk of infectious agents being introduced to the milk.

## Infant illness

Respondents commonly identified transmission of pathogenic microbes from the donor to the ingesting infant as a risk of informal milk sharing. Most often, mothers discussed infection or disease transfer from the donor as an unintentional consequence of using DHM. However, some mothers used words such as "*low*", "*theoretical*", "*potential*", "*small*", "*hypothetical*", "*some*" or "*possible*" as precursors to "*risk*" to highlight their belief that the chance of viral or bacterial illness was minor. Mothers felt that the risk of illness from pathogenic contamination was significantly lower if the milk and donor were adequately screened and the donated milk was pasteurised. Furthermore, those who had been – or wished to be – involved in informal milk sharing discussed the potential for infant reactions following DHM ingestion. Traces of allergens or unknown components of the donor's milk were identified as having the potential to cause a harmful reaction for the ingesting infant.

## Unknown composition

Mothers frequently felt disconcerted regarding the composition of the DHM. Those who had been – or wished to be – involved in informal HM donation felt that they could not be certain of the donor's dietary choices and discussed the risk of exposure to dietary habits avoided by the family of the infant (e.g., pork, non-vegan products, caffeine). Furthermore, some mothers of recipient infants felt that the donated milk may not contain an appropriate composition. Some mothers reported that the DHM may contain antibodies inferior to those of the mother, change diurnally, or have a nutritional profile incompatible with their infant's age and nutritional needs. Lastly, many mothers voiced concern regarding undisclosed factors within the donated milk, including harmful substances such as pharmaceutical drugs (prescription or recreational), cigarettes, or alcohol, which have the potential to harm an infant.

Table 25. Identified codes and themes regarding "What do you think are the risks of informal milk/waiū sharing for the baby/pēpi?"

	<b>Identified Codes</b>	Theme	Example Quotes
•	Contaminated milk Unsafe practices	Contamination	<ul> <li>a) "Risk of medications or drugs being passed into the donor breast milk."</li> <li>b) "Potential contamination of bad bacteria due to improper storage and transportation."</li> </ul>
•	Microbe transmission Reaction/allergies	Infant Illness	<ul> <li>a) "Diseases/illnesses being passed on to baby."</li> <li>b) "Risk of passing on infections."</li> <li>c) "Some babies may reacts to some contents (e.g allergies and intolerances)."</li> </ul>
•	Donors dietary choices Untailored milk Undisclosed factors	Unknown Composition	<ul> <li>a) "You don't know what the donor mother has consumed."</li> <li>b) "Different milk composition depending on the age of baby may not be totally suitable."</li> <li>c) "If the donor has failed to disclose any medications or lifestyle risks that could impact [the baby]."</li> </ul>

## Benefits of Informal Milk Sharing for the Donor

Of the 295 HM donors invited to answer the question, "*What do you think are the benefits of informal milk/waiū sharing for the donor?*", 267 (90.5%) responded. Three themes were identified: a) altruism; b) use excess human milk, and c) benefits to wellbeing. Example quotes are displayed in **Table 29**.

#### Altruism

Many mothers discussed the positive feelings associated with donating their milk to another mother and infant in need. By using words such as "*satisfying*", "*soul-warming*", "*pride*", "*helpful*", "*supporting*", "*fulfilment*" or "*amazing*", mothers emphasised the altruistic sentiments that came from donating their milk. Some mothers - especially those who had both donated and received DHM for their infant - also felt that informal HM donation was a way to give back to those who had previously supported them, be it staff within the hospital neonatal unit or donors from the wider community.

## Use excess human milk

Those who had donated their milk felt that informal HM donation prevented their excess milk from going to waste. Many mothers discussed their preference for their milk to be offered to another mother/infant in need as opposed to being disposed of, with some mothers noting feelings of guilt and reluctance when throwing out their "*liquid gold*". Some donors also felt they regained their storage space after donating some of their milk supply.

## Benefits to wellbeing

Many mothers identified various physical, emotional, mental and social factors that would positively affect the donor's wellbeing following informal HM donation. Respondents highlighted that with prolonged pumping, the donor's physical health may improve by decreasing the risk of breast cancer, stimulating weight loss and relieving the donor from engorgement. Those who had donated their milk also recognised that regular milk donations may increase or maintain their milk supply for their and other infants in need. Mothers also acknowledged the mental and emotional benefits of donating their milk through an increased sense of purpose, self-achievement, empowerment, happiness and altruism. Furthermore, through supporting friends/family, forming connections and feeling a sense of community, mothers discussed how a donor's social wellbeing would be positively affected following informal HM donation.

Table 26. Codes and themes regarding "What do you think are the benefits of informal milk/waiū sharing for the donor?"

	<b>Identified Codes</b>	Theme	Example Quotes
•	Help another mother/infant Pay it forward	Altruism	<ul> <li>a) "That feeling of giving and knowing you helping grow another human and helping a fellow mum."</li> <li>b) "It felt wonderful knowing that I could make a difference and support another family who is probably having a hard time."</li> <li>c) "Being able to give back to the NICU [neonatal intensive care unit] and people who gave me and my whanau so much love and care."</li> </ul>
•	Less human milk wastage Increased storage space	Use Excess HM	<ul> <li>a) "Avoiding having to throw away milk."</li> <li>b) "Milk that might have been otherwise wasted gets used."</li> <li>c) "It frees up freezer space."</li> </ul>
•	Community Maintain supply Health benefits	Benefits to Wellbeing	<ul> <li>a) "That feeling of community and love and kindness and knowing no matter what you are not alone."</li> <li>b) "Donating breastmilk can help the donor have a steady and abundant supply of breastmilk for the babies."</li> <li>c) "Donating milk was important for my mental and physical wellbeing during a very difficult time."</li> </ul>

#### Risks of Informal Milk Sharing for the Donor

A total of 257 (86.5%) respondents answered the question, "*What do you think are the risks of informal milk/waiū sharing for the donor?*". Eighty-two respondents (31.9%) felt there were no or minimal risks for the donor; however, three main themes emerged following the analysis of the answers provided. These were: a) risks to donor wellbeing; b) vulnerability to harm, and c) cost. Example quotes are displayed in **Table 30**.

#### Risks to wellbeing

Mothers felt that informal HM donation may present risks to a donor's mental and physical health. Mothers discussed the potential for nutrition-related morbidities, including excessive weight loss and nutritional deficits. One mother shared her experience of being diagnosed with pregnancy and lactation-associated osteoporosis attributable to hyperlactation, culminating in fractures. Mothers also highlighted the effort and time required to pump extra milk. Stress, fatigue and exhaustion were words commonly used to express the feelings associated with the labour of pumping and donating extra milk. Furthermore, many mothers felt that HM donors were at risk of oversupply, mastitis, blocked milk ducts and nipple trauma as a result of increasing their milk supply to provide for another infant. Mothers highlighted that such issues may subsequently affect the donor's ability to breastfeed their own infant.

## Vulnerability to harm

Respondents often discussed how donors may be at risk of being exploited by the mother of the recipient infant. Mothers felt that donors may face pressure to continue donating or to donate more milk than they are comfortable supplying. Furthermore, mothers who had donated HM felt that donors may be subject to blame if the recipient infant were to become ill after ingesting DHM and discussed how this blame may precipitate guilt. Some respondents also voiced concern regarding the donor's safety if conflict were to arise between donor and recipient. These mothers felt that donors could be at risk of "*abuse*" or "*unsafe situations*" and discussed their discomfort sharing their address with strangers for private DHM collections.

#### Cost

Some respondents also highlighted the potential financial implications that informal HM donation may have for the donor. Mothers discussed the cost attributable to serological screening, travel and resources such as a pump and milk bags. One respondent stated that costs as such can be "difficult to budget when you're a family with a new baby." Furthermore, some donors noted the additional financial risk if the mother of the recipient infant does not reimburse the donor for any associated costs.

Table 27. Codes and themes regarding "What do you think are the risks of informal milk/waiū sharing for the donor?"

Identified Codes	Theme	Example Quotes
• Health		a) "Increased fatigue and stress."
• Labour	Risks to	b) "[The donor's] health could suffer i.e. nutritional deficits."
Oversupply/mastitis	Wellbeing	c) <i>"It's quite time consuming and involved when you're trying</i>
		to get by with your own baby."
		d) "Creating an oversupply which could result in mastitis."
Pressure		a) <i>"The donor could feel pressured to donate more than they</i>
• Safety		can sustain."
• Blame/guilt	Vulnerability	b) "The people I donated to knew where I lived. Had the
C C	to Harm	relationship gone bad, this could have been dangerous."
		c) "If something were to happen because of the donated milk,
		[the donor] could be held liable."
Cost of resources	Cost	a) "Cost of equipment and consumables."
Travel expenses		b) "Cost of petrol."

#### 4.1. Summary of Findings

This thesis explored mothers' and health professionals' perceptions and experiences of informal human milk donation in New Zealand. It also investigated the benefits and risks of feeding DHM compared to IF as supplementation or substitute of mother's milk for MLP and ET infants. The survey findings demonstrated that informal milk sharing in New Zealand's hospitals and communities is prevalent and mothers and health professionals highly support the practice. However, the results also indicated that informal milk sharing practices vary widely nationwide. Furthermore, the very few studies eligible for inclusion in the systematic review highlight the limited evidence available investigating benefits and risks of supplementing a mother's milk with DHM compared to IF for infants at low risk of serious morbidities associated with exposure to IF, such as those born MLP and ET.

#### 4.2. Systematic Review

The health effects of using DHM instead of IF to supplement mother's milk for VP (<32 completed gestational weeks) and low-birth weight infants (born weighing <1500 g) have been thoroughly investigated. Evidence suggests that DHM use in these populations reduces the risk of NEC and feeding intolerance, improves breastfeeding outcomes and decreases the length of hospital stay.<sup>180–184</sup> Existing nutritional guidelines for the use of DHM in clinical settings are, therefore, designed specifically for these populations. In contrast, limited high-quality research exists regarding the nutritional management of MLP and ET infants, despite making up a substantial proportion of preterm births and having greater nutritional needs than FT infants.<sup>9,12</sup> We therefore undertook a systematic review with the aim of synthesising the current body of evidence regarding the benefits and risks of DHM use in MLP and ET infants and highlighting potential gaps in knowledge that require further investigation.

Only seven studies met the inclusion criteria of the systematic review, demonstrating the paucity of evidence related to outcomes of using DHM versus IF in MLP and ET infants as a supplement or substitute to mother's milk. We did, however, identify five ongoing trials, indicating active interest in the potential benefits that feeding DHM instead of IF may confer for the MLP and ET population. Both the included and ongoing studies contained a degree of geographical bias, with most based in Finland or the US; thus, generalisability outside these countries is limited. Despite limited evidence to date, the studies currently available report that DHM may reduce the number of NICU admissions;<sup>318</sup> improve exclusive breastfeeding rates at discharge,<sup>316,318</sup> one month<sup>319</sup> and six months<sup>183</sup>; reduce the prevalence of solid food introduction before six months<sup>183</sup>; reduce the prevalence of cow's milk allergy<sup>315</sup>; reduce the concentration of blood urea nitrogen, urine osmolarity, serum total protein and serum albumin<sup>314</sup>; and improve blood glucose concentrations<sup>317,318</sup> and recurrent episodes of neonatal hypoglycaemia.<sup>317</sup>

Only two studies, from 1976 and 1999, investigating metabolic responses, effects on growth and incidence of cow's milk allergy were randomised controlled trials which are considered the preferred method to examine the true effect of an intervention.<sup>320</sup> The remaining studies were mostly observational in design and are subsequently at a higher risk of confounding and selection, information and reporting biases,<sup>321</sup> thus, providing limited robust evidence. However, with ethical concerns in mind, the random allocation of infants with access to their mother's milk to IF or DHM as a sole diet in the present day is impermissible. This systematic review, therefore, focused on studies comparing feeding infants DHM versus IF to supplement a mother's milk when it is not available or insufficient to meet an infant's nutritional needs. It is clear that with a surge in the establishment of HM banks in recent years, more extensive, high-quality research into the outcomes associated with DHM use for MLP and ET infants is required to inform future practice.

In addition, most of the included studies focused on outcomes related to neonatal hypoglycaemia and exclusive breastfeeding. Moreover, the majority of the infants included in the systematic review originated from one study conducted in 1999 investigating cow's milk allergy. The effect of feeding DHM instead of IF on various health conditions is, therefore, less extensively studied. Thus, short-term (growth, feeding tolerance, duration of nutritional support, incidence of infection, incidence of NEC, neonatal morbidity) and long-term (growth, childhood morbidity, neurodevelopment) health outcomes of MLP and ET infants and health economic analyses should be investigated in future research. Nevertheless, the ongoing studies are investigating a range of health outcomes that may provide higher quality evidence for- or against- the use of DHM compared to IF to supplement a mother's milk in MLP and ET infants.

#### 4.3. Health Professional and Maternal Surveys

#### 4.3.1. Donor human milk availability

Our survey revealed a high prevalence of DHM use in New Zealand. This finding is unsurprising as data from the Christchurch HM bank suggest that, from 2014-2017, the number of HM donors and infants receiving DHM has continued to increase by 240% and 130%, respectively.<sup>214</sup> Furthermore, a survey of New Zealand and Australian NICU nutrition practices from 2018 indicated that unpasteurised DHM was available within 39% of facilities that reported using DHM, a 47% lower availability than in this survey.<sup>197</sup> Compared to practices elsewhere, studies in the US also suggest a high prevalence of mothers engaging in HM donation as donors (12-69%) or recipients (7-44%).<sup>247,322</sup> As reported by health professionals, our survey identified a high proportion of informal milk sharing in clinical settings, possibly due to the limited HM banks available in the country. However, a study based in Australia found that up to 75% of mothers of infants born MLP would have considered giving their infant pasteurised DHM from a HM bank during their infants' hospitalisation, but it was unavailable to them.<sup>323</sup> Likewise, this study also found a proportion of mothers who wished that they had the option of DHM for their infants but HM donation was not available or unknown to the respondent. Despite evident disparities in access to DHM, these findings highlight the high maternal interest in HM donation and the potential for future growth.

Although the practice of HM donation was common among the survey respondents, the health professional survey identified that there was a lack of consistent responses regarding the availability of DHM within the same district health board. This finding may indicate an absence of central HM donation co-ordination, unequal access to and availability of informally shared HM, mixed understanding and inconsistent practices between health professionals. As the study surveyed a range of health professionals across primary, secondary and tertiary care, the inconsistency in DHM availability reported in this survey may be a result of variation in standard practice dependant on the level of care that the respondent worked within or a lack of regular DHM availability. Respondents working under primary level of care mostly used DHM for low birth weight infants. Correspondingly, DHM is reported to be more commonly available and used in the highest levels of neonatal care in the US compared to facilities caring for infants aged >32 weeks' gestation and weighing more than 1500 g at birth.<sup>324</sup>

#### 4.3.2. Coverage of donor human milk-associated expenses

Given that informal HM donation in New Zealand is most often organised between peers,<sup>273</sup> any associated costs are assumed to be covered by those involved in the HM exchange. However, the surveys found that health professionals most frequently reported that the associated costs of informal HM donation are covered by the healthcare system, whereas mothers most frequently stated that costs were paid by the donor, recipient mother or shared between donor and recipient. This inconsistency may be explained partially by the fact that most health professionals reported working under district health boards where they are more likely to have access to serological screening in the hospital setting. In contrast, respondent mothers may represent more HM exchanges organised between individuals outside of the healthcare system, whereby costs are borne by those involved in informal HM exchange.

This research investigated informal DHM-associated expenses with regard to processing (e.g., screening, pasteurisation, nutritional composition assessment), transport (e.g., petrol, courier services) and resources (e.g., milk bags, milk pumps, bottles). Although mothers in this survey voiced concern regarding the coverage of such expenses, the specific costs were not investigated, so it is not possible to determine the financial impact the practice may have on a family's budget. In the US, however, HM donors can sell their HM to other mothers in compensation for their time.<sup>247</sup> Although this option may recognise the time and effort spent by donors and provide a source of income for some mothers, other HM sharers have expressed discomfort around this practice as it restricts DHM access to only affluent parents who can afford to purchase DHM.<sup>247</sup> Furthermore, apparent disparities in DHM allocation have been reported within the literature, with infants of white, young and insured mothers being the most likely demographic to receive DHM during their hospital stay. With an uncoordinated system for HM donation in New Zealand, those not aware of informal HM sharing and marginalised populations may not be presented with the opportunity or may not be able to afford the costs related to informal HM donation, thus, aggravating health disparities. It is, therefore, crucial to

ensure that the costs associated with HM donation remain equitable to enable all infants with no or limited access to their mother's milk have equal access to DHM.<sup>325</sup>

#### 4.3.3. Human milk donation guidelines

The New Zealand infant feeding guidelines for babies and toddlers encourages and promotes exclusive breastfeeding as the ideal mode of infant feeding until six months or beyond<sup>326</sup> yet little guidance exists regarding informal HM sharing in New Zealand. The Ministry of Health offers some information on the practice of informal HM donation,<sup>299</sup> such as routes of procurement (e.g., individual arrangements, social media), potential contaminants of informally shared HM (bacteria, viruses, nicotine, medicines) and recommendations to "*check the health status of the donor and ensure the milk is collected in a safe and hygienic way*". However, no official guidelines or recommendations have been established, except for few individual district health boards, HM banks and organisations that have developed brief recommendations on undertaking informal HM donation.<sup>295,300–302,327</sup>

Guidelines for informal milk sharing were reported to be available within most workplaces of the health professionals responding the survey. However, when analysed by district health board, responses from large North Island districts reported that guidelines regarding the use of DHM were both available and unavailable in their district. This finding indicates a lack of standard operational procedures and inconsistent instruction on HM donation practices across health care facilities. A possible explanation for this finding may be that South Island district health boards have had more exposure to HM banks. The Christchurch Women's Hospital's Neonatal Unit Human Milk Bank and Christchurch Rotary Community Breast Milk Bank were the first HM banks established in New Zealand in 2014 and 2018, respectively. In contrast, the first HM bank in the North Island (Whangai Ora Milk Bank) was established only recently in 2021. Thus, health professionals from the North Island may not yet be aware of, or familiar with, HM donation guidelines within their workplace. With inconsistent knowledge of whether HM donation guidelines exist, some health professionals may be unaware of informal milk sharing practices and fail to offer the option of DHM for infants who may benefit from its use, which may also reduce involvement with HM donation and subsequent availability of DHM.

Establishing a framework for the safe and effective facilitation of DHM was identified as a necessary step to improve HM donation in New Zealand by both health professionals and mothers participating in the survey. Data from an audit of IF use in the Christchurch NICU found that prior to the establishment of the HM bank, the majority of MLP infants were the largest consumers of IF for the first seven days after birth until their mother's milk supply was established.<sup>214</sup> With DHM being recommended as the next best alternative to HM,<sup>328</sup> this population in particular may benefit from DHM to avoid unnecessary exposure to IF while their mother's milk supply establishes. Correspondingly, compared to their standard practice of providing IF when mothers' milk is insufficient or unavailable, a US NICU found that the introduction and integration of DHM into their neonatal supplementation algorithm reduced NICU admissions for asymptomatic neonatal hypoglycaemia, caused a greater mean increase in blood glucose values and increased the rate of exclusive breastfeeding at discharge.<sup>318</sup>

However, currently, there is a lack of comparable studies of DHM use in MLP and ET infants to support the development of evidence-based guidelines for these populations.

#### 4.3.4. Donor human milk use and allocation

The trends in DHM use reported by mothers of this survey showed that most infants were fed DHM multiple times per day for either under one week or over four weeks. In corroboration with the literature, this may indicate that some New Zealand mothers are using DHM as a short-term bridge until their breastmilk supply is established,<sup>189,190</sup> while others may utilise DHM as a nongoing supplement or substitute for their milk.<sup>322,329</sup> Due to limited supply, DHM from HM banks is most often available for short-term periods to support mothers until they are able to breastfeed.<sup>250</sup> Concurrent with the duration of DHM use found in our study, an audit of the Christchurch HM bank found that DHM was most often used for one week until the mother's milk supply was sufficient to meet her infant's nutritional requirements.<sup>214</sup> However, mothers of our survey from the North Island frequently used DHM for four weeks or longer. These mothers are likely not receiving the support they need to breastfeed and are, therefore, using DHM as supplement to avoid IF.

An important survey finding of health professionals' experiences with informal HM donation in New Zealand is that DHM is most often used for MLP and ET infants. Our findings mirror those reported by the Christchurch HM bank, whereby MLP infants represent a significant proportion of those who required supplementation of mothers' milk.<sup>214</sup> Furthermore, the survey findings corroborate trends in the literature investigating the demographic of infants who receive DHM. Studies of NICUs and postnatal wards across the United States,<sup>330</sup> Poland,<sup>331</sup> China,<sup>332</sup> Vietnam<sup>333</sup> and Taiwan<sup>334</sup> have reported that DHM is most often allocated to infants born between 32-38 weeks' gestation or with a birthweight above 1500 g. Such findings may be because this population represents most infants requiring neonatal care.<sup>184,229,335-337</sup> In contrast, some studies of NICUs in Japan and Ireland<sup>338,339</sup> indicate that DHM is most often utilised for very premature infants (<32 weeks' gestation) or infants with a birthweight below 1500 g. These findings are similar to those found in our survey, whereby health professionals working under tertiary level care (specialist care for hospitalised patients, e.g., NICU) reported most frequently using DHM for infants with a birthweight below 1500 g. Thus, current clinical practice, scientific evidence and the recommendation by the World Health Organisation<sup>328</sup> may indicate that birthweight is a more effective criterion for highlighting the most vulnerable infants in need of DHM, such as those at risk of NEC and other morbidities related to prematurity.

## 4.3.5. Pasteurisation and screening of donated human milk

International HM bank guidelines emphasise the importance of adequate screening and pasteurisation of the donor and DHM prior to consumption to ensure the safety of DHM for hospitalised infants.<sup>206–209</sup> In particular, serological, medical and lifestyle screening of the donor and microbiological testing of DHM are endorsed as prerequisite screening procedures prior to the DHM exchange.<sup>206–209</sup> Pasteurisation is often undertaken by HM banks with

specialised staff and equipment; however, informal HM donation places the choice of screening and pasteurisation with the donor and recipient mother.<sup>200</sup>

The majority of health professionals and mothers who responded to the surveys reported screening the donor only for lifestyle and serological parameters. Compared to literature based in the US where lifestyle and serological screening is undertaken by 5-72% and 3-27% of mothers,<sup>243,257</sup> respectively, New Zealand mothers engaging in informal HM donation tended to report higher rates of serological screening of the donor. This may be because some New Zealand charities, such as Mother's Milk NZ, provide partial funding for serological screening<sup>302</sup> and informal milk sharing facilitated by a health professional may be more likely to have the donor and DHM screened prior to the exchange. Microbiological testing reported in our survey, however, was low - likely because this type of screening is more commonly performed by HM banks and the majority of informal HM exchanges were facilitated between individuals.

Limited studies have investigated informal HM donation practices among mothers and health professionals; however, similar to the results of this survey, where only 3.4% of mothers reported at-home pasteurisation, a US study demonstrated that milk informally shared between mothers seldom undergoes heat treatment (8.7%).<sup>243</sup> Feeding an infant unpasteurised HM risks transmitting harmful microbes, such as cytomegalovirus.<sup>340,341</sup> However, as MLP and ET have a more mature immune system than that of low birth weight and VP infants, MLP and ET infants fed mother's milk supplemented with unpasteurised DHM may be at a lower risk of infection.

Despite low rates of pasteurisation and inconsistent screening practices, most mothers and health professionals who responded to the surveys had concerns regarding the composition of DHM. Respondents highlighted a lack of screening and pasteurisation as key factors leading to their uncertainty of the milk's composition and safety for the infant. However, pasteurisation and donor/milk screening are recommended to mitigate the potential microbiological risks associated with milk sharing.<sup>216</sup> Furthermore, pasteurisation has little effect on the macronutrient composition of HM.<sup>174</sup> This deviation from recommended practice may be explained by mothers and health professionals within these surveys and the wider literature<sup>342–344</sup> identifying that informal HM donation lacks standardised procedures and guidance. Furthermore, mothers and health professionals may have inaccurate knowledge about the effects of pasteurisation and be deterred by the cost associated with serological screening. Such factors may prevent adequate HM donation processes from being undertaken prior to informal DHM exchange.

## 4.3.6. Identified enablers, barriers and improvements

The majority of health professionals and mothers who answered the survey supported DHM use. This finding is unsurprising as similar studies based in South Africa, the US, Zimbabwe, Singapore and Australia have shown that most health professionals and mothers support HM donation and the establishment of HM banks.<sup>189,344–349</sup> Similar to the benefits of DHM

identified in this research, health professionals and mothers from the literature noted that DHM enhances elements of infant (growth, development, immunity, nutrition, reduced risk of morbidity, providing human milk) and maternal (mental health, reduced mastitis, community, altruism, bridge to breastfeeding) health and wellbeing.<sup>189,190,242,329,344,345,347,349</sup> The considerable number of mothers and health professionals supporting HM donation found in the surveys is likely a result of the perceived benefits of DHM also identified by survey respondents.

However, our findings highlighted the need for greater access to and knowledge of DHM to feed hospitalised infants and those in the community. Health professionals and mothers felt that improving the accessibility of DHM and increasing the understanding and awareness of HM donation would improve current HM donation practices. These findings concur with qualitative studies of health professionals' and mothers' opinions on the barriers to DHM use and areas that HM donation practices could improve. Respondents within the wider literature have acknowledged difficulty in procuring DHM, logistical and facilitation issues and a lack of HM donation awareness as major barriers to using DHM.<sup>189,190,242,345,346,348–350</sup> Some mothers from Australia suggested educating expecting mothers on the option for DHM in antenatal classes,<sup>345</sup> which mothers of this study also put forward. Furthermore, the limited access and knowledge of informal HM donation in New Zealand was highlighted by the high percentage of respondent mothers who reported wishing they had the option to be involved with HM donation but it was not available or unknown to them. Without efficient access to and knowledge of DHM, the growth of HM donation in New Zealand may be limited, preventing equitable access to DHM for less vulnerable infants. Improving the awareness of HM donation through health professional training and incorporation of HM donation information in antenatal care may increase the pool of donors available to meet DHM demand, thereby increasing DHM availability for New Zealand infants.

## 4.4. Strengths and Limitations

This research is the first to investigate mothers' and health professionals' practices and perceptions of informal HM donation in New Zealand. The findings of the surveys provide insight into the current processes in which mothers and health professionals from most regions of New Zealand facilitate human milk sharing and the perceived risks and benefits of HM donation. This research can support our understanding of the strengths and weaknesses of current practices and inform the development of future guidelines regarding HM donation in New Zealand.

Furthermore, previous research has focused on the benefits and risks of DHM compared to IF for a high-risk population (<32 weeks' gestation, <1500 g birthweight).<sup>184,229,230</sup> In contrast, this systematic review is exploring the effects of DHM as supplementation or as a sole diet when a mother's milk is unavailable or insufficient for the MLP and ET infant. As limited studies investigating DHM use in MLP and ET infants were identified, this systematic review is the first to consolidate the available evidence for the benefits and risks of DHM use for these populations and identify areas for future research.

A limitation of this research is that the ethnic makeup of the survey respondent pool was not representative of the New Zealand population. Despite high response rate, the maternal and health professional surveys were disproportionately biased in favour of NZ/European participants. Māori, the indigenous peoples of New Zealand, currently represent 17.4% of the New Zealand population.<sup>351</sup> Yet, only 5.5% and 7.6% of health professionals and mothers who answered the survey, respectively, identified as Māori. With a lack of ethnic diversity, the survey findings may disproportionately reflect the viewpoints and practices of NZ/European peoples engaging in HM donation, limiting the generalisability of the survey findings to the wider New Zealand population.

Furthermore, the surveys were distributed and circulated via online platforms, providing wide reach but also restricting the participation to only those with access to social media. Therefore, those who are engaging in informal HM donation but do not have social media or internet access may be less likely to take part in the survey and could have different perspectives. As limited access to internet is associated with lower economic status and/or residing in remote areas in New Zealand,<sup>352</sup> the survey population may over-represent the experiences and opinions of those with higher socioeconomic status and urban settings; we did not collect data on socioeconomic status and level of education and therefore cannot assess whether this is an issue. Furthermore, as the participants could select whether they wished to participate in the study, the survey was limited to a convenience sample and was susceptible to selection bias which may compromise the external validity of the survey findings.

Lastly, the HM donation surveys aimed to reach a broad range of HM donation experiences, including mothers who have directly breastfed an infant unrelated to them, mothers donating their own milk for another mother's baby or mothers receiving DHM for their infant. However, the surveys were not inclusive of experiences of parents who have adopted infants or parents of LGBTQIA+ communities. Parents of these groups may be more likely to benefit from using DHM as they may be less likely or unable to breastfeed their infants. Studies have investigated the effects of induced lactation and have found that milk from non-puerperal mothers has a similar composition to that of milk from puerperal mothers.<sup>353,354</sup> Research suggests that mothers feel inducing lactation enhances the mother-infant bond, increases maternal instinct and heals grief associated with infertility.<sup>355</sup> However, induced lactation and HM donation practices of same-sex or foster parents was out of the scope of the current research and remains a challenge for some parents due to physical difficulties, lack of information, little health professional support and potential stigma.<sup>356</sup> Thus, DHM may be a potentially suitable infant feeding option for these populations.

#### 4.5. Future directions and recommendations

Given the very few studies included in the systematic review, there is an evident gap in the current literature regarding the benefits and risks of DHM use compared to IF in MLP and ET infants. To address this gap in knowledge, future randomised controlled trials should be conducted to investigate the effect of supplementing mother's milk with DHM versus IF on breastfeeding, respiratory, immune, growth, metabolic and neurodevelopmental outcomes, in which MLP and ET tend to fare worse compared to FT counterparts.<sup>16–19,21,28,34,38,46–48,51</sup> Investigating such outcomes will improve the current understanding of the potential benefits and risks that DHM may confer for infants at low risk of developing serious gastrointestinal complications related to bovine milk-based IF and help inform the development of clinical guidelines.

Developing and implementing standardised guidelines on the process and operation of HM donation applicable for all New Zealand healthcare facilities may mitigate health professional uncertainty and variation in practice across different district health boards, alongside ensuring safe and equitable informal HM donation. In 2022, district health boards across New Zealand merged into one entity, Te Whatu Ora, with the aim to provide consistent and equitable care across the nation.<sup>357</sup> With a less fragmented and more streamlined approach to healthcare in New Zealand, an opportunity to gradually role out national HM donation guidelines may be present. National HM donation guidelines should aim to address, among others, the following points:

- Whether a HM donation representative should be assigned to provide information and support facilitation in all accredited maternity services in New Zealand.
- Whether all mothers should be made aware during the post-partum hospitalisation period of the option of HM supplementation, including benefits and potential risks of HM donation and IF.
- Which eligibility criteria should be used for donation and receipt of DHM.
- Whether pasteurisation is recommended and if so, suggested techniques for hospital and informal HM donations.
- Clear and evidence-based contraindications to DHM use.

With standardised national guidelines in effect, health professionals will be more likely to have a shared understanding of HM donation processes and deliver equitable care to infants in need. However, the potential risks and benefits of DHM use in MLP and ET are largely unknown. Further research into DHM use is warranted to provide insight into the role DHM may have in short- and long-term clinical outcomes in infants born MLP and ET.

## **5. CONCLUSION**

Findings presented in this thesis reveal there is an evident gap in the literature comparing the effects of feeding MLP and ET infants with DHM compared to IF as a supplement or substitution of mother's milk. Our surveys identified that these infants represent the largest proportion of those receiving DHM in New Zealand; thus, research on short- and long-term outcomes of feeding DHM compared to IF as supplement or substitution to mother's milk in this population is required. Additionally, this research demonstrates that informal milk sharing in New Zealand is highly prevalent and supported across communities and various levels of healthcare; however, inconsistencies remain with limited structure, guidance and standardised operations. Establishing national and standardised guidelines for informal HM donation is required to minimise the potential risks associated with informal HM donation and ensure equitable access to DHM for New Zealand infants. This thesis begins to address the paucity of knowledge regarding informal HM donation opinions, experiences and practices in a New Zealand context and has identified strengths and weaknesses of current practices to inform future guidelines. Moreover, summarising the current and emerging evidence on the potential benefits and risks that DHM may confer for MLP and ET infants provides an opportunity to improve the nutritional management and health outcomes of this population in future.

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## APPENDICES

## **Appendix 1. Full Search Strategy**

	Query
1	infant, newborn/
2	infant, low birth weight/
3	infant, premature/
4	Intensive Care Units, Neonatal/
5	Intensive Care, Neonatal/
6	Gestational Age/
7	Postnatal Care/
8	(early term or near term or neonat* or neo-nat* or baby* or babies or newborn* or new born or new borns or newly born or premature* or prematurity or pre term or preterm or pre-maturity or low birth weight or LBW or low birthweight or infant or infants or infantile or infancy or NICU or pre-mature* or NICUs or babe or babes or gestational age? or LBWI or preemie or preemies or premie or premies).ti,ab,kw,kf.
9	Milk Banks/
10	(((donor* or donat* or shar* or bank* or supplement*) adj3 (breastmilk or milk)) or DHM or DBM).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11	Infant Formula/
12	(((infant or baby or babies or p?ediatric or milk or feed or artificial or preterm) adj3 formula*) or supplement* feed or formula).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
14	9 or 10
15	11 or 12
16	13 and 14 and 15
17	limit 16 to humans

# Appendix 2. Maternal Survey Questions

<u>Q1. Please select your age group.</u>
<10
18-29
30-39
>40
Preter not to disclose
Q2. Which ethnic group do you belong to? (Select all which apply to you)
New Zealand European
Māori
Samoan
Cook Islands Māori
Tongan
Niuean
Chinese
Indian
Other (Please state, eg, Dutch, Japanese, Tokelauan):
Q3. Where was your baby/pēpi born?
Northland
Auckland
Waikato
Bay of Plenty
Gisborne
Hawke's Bay
Taranaki
Whanganui-Manawatū
Wellington
Tasman
Nelson-Tasman
Marlborough
West Coast
Canterbury
Otago
Southland
Q4. In which type of facility did you give birth?
Hospital
Birthing centre/maternity unit
Home birth
Other:
O5. Did vour baby/pēpi receive postnatal care?
Yes - in the postnatal ward
Yes - under the Special Care Baby Unit
Yes - under the Neonatal Intensive Care Unit
No - my haby/pēni did not require postnatal hospital care
Other
Outor

#### Q6. How many children/tamariki do you have?

#### Q7. How many babies/pēpi have you breastfed/whāngote (past and present)?

Q8. What is the age of your youngest child/pōtiki? 0-6 months old 7-12 months old 1-2 years old ≥2 years old

Q9. What is the sex of your youngest child/pōtiki? Boy Girl Twins of different sex Prefer not to disclose

Q10. How have you been involved with breast milk/waiū donation?

I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi) My baby/pēpi received donated breast milk/waiū <u>during their hospital stay</u> My baby/pēpi received donated breast milk/waiū <u>after discharge from hospital</u> I have <u>both</u> donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū I have directly breastfed/whāngote someone else's baby/pēpi <u>or</u> my baby/pēpi was directly breastfed/whāngote by another mother/māmā

I wish I had the option to be involved with breast milk/waiū donation but it was not available to me

<u>Q11. What mode of feeding did your baby/pēpi receive in their first six months of life?</u> My baby/pēpi was exclusively fed my own milk/waiū (from the breast or expressed milk) My baby/pēpi was partially fed my own milk/waiū and infant formula My baby/pēpi was partially fed my own milk/waiū and donated breast milk My baby/pēpi was partially fed donated breast milk/waiū and infant formula My baby/pēpi was exclusively fed infant formula

My baby/pēpi was exclusively fed donated breast milk/waiū Other:

Q12. Did you receive any support from a health professional to initiate or maintain breastfeeding/whāngai ū? (e.g. lactation consultant, midwife, lead maternity carer) Yes No

Q13. How satisfied were you with your breastfeeding/whāngai ū experience? Extremely satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Extremely dissatisfied

Display Q14:

If Q13. How satisfied were you with your breastfeeding/whāngai ū experience? = Neither satisfied nor dissatisfied

- Or Q13. How satisfied were you with your breastfeeding/whāngai ū experience? = Dissatisfied
- Or Q13. How satisfied were you with your breastfeeding/whāngai ū experience? = Extremely dissatisfied
- Q14. For what reason(s) did you select your answer to the above question? Select all that apply.

My baby/pēpi had difficulty breastfeeding/whāngai ū

I did not feel emotionally/physically supported enough to continue breastfeeding/whāngai ū My baby/pēpi did not gain enough weight

I had difficulty breastfeeding/whāngai ū (e.g. pain, mastitis, cracked and/or bleeding nipples) I no longer wished to breastfeed/whāngote

Other: \_\_\_\_\_

Display Q15:

- If Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Q15. What were your reasons/motivations to seek donated breast milk/waiū to supplement your own milk/waiū?

Display Q16:

If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)

Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q16. What were your reasons/motivations to donate your milk/waiū?

Display Q17:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q17. How was the breast milk/waiū donation arrangement facilitated? Select all that apply.

Facilitated through the hospital health professionals (e.g. lactation consultant, midwife, lead maternity carer)

Facilitated through a breast milk bank

Organised between individuals (family/friends/internet/social media)

Facilitated through charities/organisations (e.g. Plunket, La Leche League)

Other: \_\_\_\_\_

### Display Q18:

- If Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

#### Q18. For how long did you use donated breast milk/waiū?

<1 week

1-2 weeks

3-4 weeks

4+ weeks

Display Q19:

- If Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q19. How often was donated breast milk/waiū used to feed your baby/pēpi?

I used donated breast milk/waiū multiple times per day

I used donated breast milk/waiū once daily

I used donated breast milk/waiū weekly

I used donated breast milk/waiū fortnightly

I infrequently used donated breast milk/waiū (less than fortnightly)

Display Q20:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū
- Q20. I have donated my milk/waiū to:

1 baby/pēpi 2 babies/pēpi 3 babies/pēpi 4 babies/pēpi 4+ babies/pēpi I am unsure how many babies/pēpi have received my donated milk/waiū

Display Q21:

If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)

Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q21. How frequent were your milk/waiū donations? Daily Weekly Monthly One-off donation

Display Q22:

If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)

Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated

my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q22. For how long did you donate your milk/waiū?

<1 month

1-2 months

3-4 months

5-6 months

6+ months

Display Q23:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q23. How satisfied were you with your milk/waiū donation experience?

Extremely satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Extremely dissatisfied

Display Q24:

If Q23. How satisfied were you with your milk/waiū donation experience? = Neither satisfied nor dissatisfied

Or Q23. How satisfied were you with your milk/waiū donation experience? = Dissatisfied

Or Q23. How satisfied were you with your milk/waiū donation experience? = Extremely dissatisfied

Q24. For what reason(s) did you select your answer to the above question? (e.g. timeconsuming, too much responsibility)

Display Q25:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital

- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū
- Q25. Which of the following screening processes occurred prior to the donated breast milk/waiū arrangement? Select all that apply.

Serological (e.g. blood testing for antibodies against HIV, Hepatitis C or B and syphilis) Microbiological (e.g. bacterial contamination testing)

Lifestyle (e.g. smoking status, medication, drug and alcohol intake)

No screening arrangements were undertaken prior to my donated breast milk/waiū experience

I am unsure whether screening arrangements were undertaken prior to my donated breast milk/waiū experience

Display Q26:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū during their hospital stay
- Or Q10. How have you been involved with breast milk/waiū donation? = My baby/pēpi received donated breast milk/waiū after discharge from hospital
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q26. Was the donated breast milk/waiū pasteurised (flash-heated) before being given to the baby/pēpi? (pasteurisation: the process of heating breast milk/waiū to 62.5 °C for 30 minutes prior to being fed to the baby/pēpi to kill potentially harmful microbes).

Yes - the donated milk/waiū was pasteurised by the donor or receiving mother/māmā Yes - the donated milk/waiū was pasteurised through the milk bank/hospital facilities No - the donated milk/waiū remained unpasteurised

I don't know

Display Q27:

If Q26. Was the donated breast milk/waiū pasteurised (flash-heated) before being given to the baby/p... = Yes - the donated milk/waiū was pasteurised by the donor or receiving mother/māmā

Q27. Please describe the pasteurisation process undertaken, if known.

Display Q28:

- If Q10. How have you been involved with breast milk/waiū donation? = I have donated/shared my own milk/waiū to help someone else's mother/baby (māmā/pēpi)
- Or Q10. How have you been involved with breast milk/waiū donation? = I have both donated my own milk/waiū and my baby/pēpi received donated breast milk/waiū

Q28. Did you make any dietary changes in order to donate your milk/waiū?

No, I followed my normal diet

Yes, I changed some components of my diet, including:

<u>Q29. Were there any expenses associated with the breast milk/waiū donation arrangement?</u> (e.g. screening, pasteurisation, transport)

Yes

No

Display Q30:

If Q29. Were there any expenses associated with the breast milk/waiū donation arrangement? (e.g. scr... = Yes

Q30. Who covered the costs associated with the breast milk/waiū donation arrangement? Associated costs were covered by the healthcare system (e.g. serological screening) Associated costs were covered by the breast milk/waiū donor Associated costs were covered by the mother/māmā of the receiving baby/pēpi Associated costs were covered by health insurance I don't know Other:

Display Q31:

If Q10. How have you been involved with breast milk/waiū donation? = I have directly breastfed/whāngote someone else's baby/pēpi or my baby/pēpi was directly breastfed/whāngote by another mother/māmā

Q31. How was your shared breastfeeding/whāngai ū experience? (e.g. your reasons or motivations)

Q32. Do you support the use of donor breast milk/waiū banks in hospitals? Yes No I don't know

Q33. Do you support the use of informal breast milk/waiū donation arrangements between mothers/whāea?

Yes No I don't know

Q34. How could current breast milk/waiū donation arrangements be improved?

Q35. What do you think are the benefits of using donor milk/waiū for the baby/pēpi?

Q36. What do you think are the risks of using donor milk/waiū for the baby/pēpi?

Q37. What do you think are the benefits of donating milk/waiū for the donor?

Q38. What do you think are the risks of donating milk/waiū for the donor?

#### **Appendix 3. Health Professional Survey Questions**

Q1. What is your profession? Select all that apply. Neonatologist Dietitian Lactation Consultant Midwife Nurse Lead Maternity Carer Paediatrician Other: Q2. Which organisation do you work for? **District Health Board** Plunket Private Care Self-employed Non-governmental Organisations/Charities/Trusts (e.g. La Leche League, Mothers Milk NZ Charitable Trust, Human Milk 4 Human Babies) Other:

Display Q3:

If Q2. Which organisation do you work for? = District Health Board

Q3. Which District Health Board do you work for? Auckland District Health Board Bay of Plenty District Health Board Canterbury District Health Board Capital & Coast District Health Board Counties Manukau District Health Board Hawke's Bay District Health Board Hutt District Health Board Lakes District Health Board Midcentral District Health Board Nelson Marlborough District Health Board Northland District Health Board South Canterbury District Health Board Southern District Health Board Tairāwhiti District Health Board Taranaki District Health Board Waikato District Health Board Wairarapa District Health Board Waitematā District Health Board West Coast District Health Board Whanganui District Health Board

Q4. Which level of healthcare do you operate under? Select all that apply. Primary (professional health care provider in the community, e.g. practice nurse, GP, LMC) Secondary (specialist level care) Tertiary (specialist care for hospitalised patients) Other (i.e. community based):

Q5. How many years have you worked with newborns/pepi in neonatal health?

0-5

6-10 11-15

>15

Q6. What gender do you identify as? Male Female Non-binary Prefer not to disclose

Q7.Which ethnic group do you belong to? (Select all which apply to you) New Zealand European Māori Samoan Cook Islands Māori Tongan Niuean Chinese Indian Other (Please state, eg, Dutch, Japanese, Tokelauan): \_\_\_\_\_ Prefer not to disclose

<u>Q8. Please select your age group.</u> 18-29

30-39 40-49  $\geq 50$ Prefer not to disclose

<u>Q9. Is donated human milk/waiū available within your workplace? Select all that apply.</u>
Yes - Facilitated through the hospital staff (e.g. lactation consultants, midwifes, nurses)
Yes - Facilitated through a human milk/waiū bank
Yes - Organised between individuals (whānau/friends/internet/social media)
No

Skip to Q23: If Q9. Is donated human milk/waiū available within your workplace? Select all that apply. = No

<u>Q10. Which babies/pēpi usually receive donated human milk/waiū in your workplace? Select all that apply.</u>

Extremely preterm (less than 28 weeks) Very preterm (28 to 32 weeks) Moderate to late preterm (32 to 37 weeks) Early term (37 to 38 weeks) Full term (39 to 40 weeks) Late term (41 to 42 weeks) Post term (After 42 weeks) Extremely low birth weight (<1000g) Very low birth weight (<1500g) Low birth weight (<2500g)

Q11. How often is donated human milk/waiū used within your workplace? Often (e.g. daily/weekly) Sometimes (e.g. fortnightly/monthly) Rarely (e.g. quarterly/annually) Never I don't know

<u>Q12. How often would your workplace like to use donated human milk/waiū but cannot due to limited availability?</u> Often (e.g. daily/weekly) Sometimes (e.g. fortnightly/monthly) Rarely (e.g. quarterly/annually) Never I don't know

Q13. Are there any guidelines, protocols and/or policies available at your workplace related to informal milk/waiū donation and/or use of donor milk/waiū?

Yes No

I don't know

Display Q14a:

If Q13. Are there any guidelines, protocols and/or policies available at your workplace related to i... = Yes

Q14a. Are you able to share these guidelines with us? Yes No

Display 14b:

If Q14a. Are you able to share these guidelines with us? = Yes

Q14b. Please upload any guidelines, protocols and/or policies available at your workplace related to informal human milk donation and/or use of donor milk:

Q15. Is the use of donated human milk/waiū documented within the clinical notes (e.g. observation charts, fluid balance charts)?

Yes No

I don't know

Display Q16:

If Q9. Is donated human milk/waiū available within your workplace? Select all that apply. = Yes - Facilitated through the hospital staff (e.g. lactation consultants, midwifes, nurses)

- Or Q9. Is donated human milk/waiū available within your workplace? Select all that apply. = Yes Facilitated through a human milk/waiū bank
- Or Q9. Is donated human milk/waiū available within your workplace? Select all that apply. = Yes Organised between individuals (whānau/friends/internet/social media)

Q16. Is informed consent from the mother/māmā required in order to use donor human milk/waiū to feed the baby/pēpi?

Yes No

I don't know

Q17. What type of screening process is usually undertaken on the donor and/or their donated human milk/waiū? Select all that apply.

Serological (e.g. blood testing for antibodies against HIV, Hepatitis C or B and syphilis) Microbiological (e.g. bacterial contamination testing)

Lifestyle (e.g. smoking status, medication, drug and alcohol intake)

The donor and/or the donated human milk/wai $\bar{\rm u}$  are not screened I don't know

Q18. Is the nutritional composition of the donated human milk/waiū assessed? Yes No

I don't know

Q19. Is the donated human milk/waiū pasteurised prior to the baby's/pēpi

consumption? (pasteurisation: the process of heating human milk/waiū to 62.5 °C for 30 minutes prior to being fed to the baby/pēpi to kill potentially harmful microbes) Yes

No

I don't know

Display Q20:

If Q19. Is the donated human milk/waiū pasteurised prior to the baby's/pēpi consumption? (pasteurisa... = Yes

Q20. Please describe the milk/waiū pasteurisation process used within your workplace.

Q21. How are the associated expenses (e.g. screening, pasteurisation, nutritional composition assessment) of donated human milk/waiū paid?

Associated costs are covered by the health care system

Associated costs are covered by the individual (donor and/or mother/māmā of the receiving baby/pēpi)

Associated costs are covered by charitable organisations

Other:\_\_\_\_

I don't know

<u>Q22. In instances where donated human milk/waiū has not been completely used, what is</u> <u>done with the excess milk/waiū? Select all that apply.</u>

The excess milk/waiū is disposed of

The excess milk/waiū is stored frozen and used at a later date

The excess milk/waiū is offered to a low priority baby/pēpi (e.g. stable or healthy baby/pēpi) The excess milk/waiū is used for research I don't know Other: \_\_\_\_\_

Q23. Which category do you think donated human milk/waiū should fall under? As a nutritional product prescribed by the medical team (equal to infant formula) As a nutritional supplement prescribed by the medical team (equal to vitamins and minerals) As medicine prescribed by the medical team (equal to pharmacological drugs)

Q24. Do you support the use of human donor milk/waiū banks in hospitals? Yes No I don't know

Q25. Do you support the use of informal milk/waiū sharing in the community? Yes No I don't know

Q26. How could current practices regarding informal milk/waiū donation be improved?

Q27. What do you think are the benefits of informal milk/waiū sharing for the baby/pēpi?

Q28. What do you think are the risks of informal milk/waiū sharing for the baby/pēpi?

Q29. What do you think are the benefits of informal milk/waiū sharing for the donor?

Q30. What do you think are the risks of informal milk/waiū sharing for the donor?